Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Albumin IgA

Test Information

Test Name: Corn Albumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Albumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Albumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Albumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Albumin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Albumin IgG

Test Information

Test Name: Corn Albumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Albumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Albumin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Corn Zoomer : Corn Cry Protein IgA

VibrantWellness

Test Information

Test Name: Corn Cry Protein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Cry Protein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Cry Protein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Cry Protein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Cry Protein IgG

Test Information

Test Name: Corn Cry Protein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Cry Protein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Cry Protein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Cry Protein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Cry Protein IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Endochitinase IgA

Test Information

Test Name: Corn Endochitinase IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Endochitinase IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Endochitinase IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Endochitinase IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Endochitinase IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Endochitinase IgG

Test Information

Test Name: Corn Endochitinase IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Endochitinase IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Endochitinase IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Endochitinase IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Exopolygalacturonase IgA

Test Information

Test Name: Corn Exopolygalacturonase IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Exopolygalacturonase IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Exopolygalacturonase IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Exopolygalacturonase IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Exopolygalacturonase IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Exopolygalacturonase IgG

Test Information

Test Name: Corn Exopolygalacturonase IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Exopolygalacturonase IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Exopolygalacturonase IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Exopolygalacturonase IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Expansin IgA

Test Information

Test Name: Corn Expansin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Expansin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Expansin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Expansin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Expansin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Expansin IgG

Test Information

Test Name: Corn Expansin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Expansin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Expansin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Expansin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Expansin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Globulin IgA

Test Information

Test Name: Corn Globulin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Globulin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Globulin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Globulin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Globulin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Globulin IgG

Test Information

Test Name: Corn Globulin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Globulin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Globulin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Globulin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Globulin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Glutelin IgA

Test Information

Test Name: Corn Glutelin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Glutelin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Glutelin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Glutelin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Glutelin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Glutenin IgG

Test Information

Test Name: Corn Glutenin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Glutenin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Glutenin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Glutenin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Glutenin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn IgE

Test Information

Test Name: Corn IgE

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn IgE.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn IgE as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn IgE on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn IgE

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 0.35	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Lipid transfer protein IgA

Test Information

Test Name: Corn Lipid transfer protein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Lipid transfer protein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Lipid transfer protein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Lipid transfer protein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Lipid transfer protein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Lipid transfer protein IgG

Test Information

Test Name: Corn Lipid transfer protein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Lipid transfer protein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Lipid transfer protein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Lipid transfer protein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Lipid transfer protein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Pollen Allergen IgA

Test Information

Test Name: Corn Pollen Allergen IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Pollen Allergen IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Pollen Allergen IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Pollen Allergen IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Pollen Allergen IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Pollen Allergen IgG

Test Information

Test Name: Corn Pollen Allergen IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Pollen Allergen IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Pollen Allergen IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Pollen Allergen IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Pollen Allergen IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Profilin IgA

Test Information

Test Name: Corn Profilin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Profilin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Profilin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Profilin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Profilin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Profilin IgG

Test Information

Test Name: Corn Profilin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Profilin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Profilin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Profilin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Profilin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Corn Zoomer : Corn Thioredoxin IgA

Test Information

Test Name: Corn Thioredoxin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Thioredoxin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Thioredoxin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Thioredoxin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Thioredoxin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Corn Zoomer : Corn Thioredoxin IgG

VibrantWellness

Test Information

Test Name: Corn Thioredoxin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Thioredoxin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Thioredoxin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Thioredoxin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Thioredoxin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Zein IgA

Test Information

Test Name: Corn Zein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Zein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Zein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Zein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Zein IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Zein IgG

Test Information

Test Name: Corn Zein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Zein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Zein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Zein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Zein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Zoomer

Test Information

Test Name: Corn Zoomer

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Zoomer.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Zoomer as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Zoomer on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn Zoomer

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn-Wheat overlap epitope IgA

Test Information

Test Name: Corn-Wheat overlap epitope IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn-Wheat overlap epitope IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn-Wheat overlap epitope IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn-Wheat overlap epitope IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn-Wheat overlap epitope IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Corn ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Corn Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Corn Zoomer : Corn-Wheat overlap epitope IgG

Test Information

Test Name: Corn-Wheat overlap epitope IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn-Wheat overlap epitope IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Corn Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn-Wheat overlap epitope IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Corn Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn-Wheat overlap epitope IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Corn Zoomer : Corn-Wheat overlap epitope IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : A1 β-casein and Islet cell overlap IgA

Test Information

Test Name: A1 β-casein and Islet cell overlap IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for A1 β-casein and Islet cell overlap IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for A1 β-casein and Islet cell overlap IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for A1 β-casein and Islet cell overlap IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : A1 β-casein and Islet cell overlap IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : A1 β-casein and Islet cell overlap IgG

Test Information

Test Name: A1 β-casein and Islet cell overlap IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for A1 β-casein and Islet cell overlap IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for A1 β-casein and Islet cell overlap IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for A1 β-casein and Islet cell overlap IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : A1 β-casein and Islet cell overlap IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : α-lactalbumin IgA

Test Information

Test Name: α-lactalbumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for α-lactalbumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for α-lactalbumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for α-lactalbumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : α-lactalbumin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : α-lactalbumin IgG

Test Information

Test Name: α-lactalbumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for α-lactalbumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for α-lactalbumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for α-lactalbumin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : α-lactalbumin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : αs1-casein and αs2-casein IgA

Test Information

Test Name: αs1-casein and αs2-casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for αs1-casein and αs2-casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for αs1-casein and αs2-casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for αs1-casein and αs2-casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Dairy Zoomer : αs1-casein and αs2-casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : αs1-casein and αs2-casein IgG

Test Information

Test Name: αs1-casein and αs2-casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for αs1-casein and αs2-casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for αs1-casein and αs2-casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for αs1-casein and αs2-casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Dairy Zoomer : αs1-casein and αs2-casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : αS2-casein and Retinal S-antigen overlap IgA

Test Information

Test Name: αS2-casein and Retinal S-antigen overlap IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for αS2-casein and Retinal S-antigen overlap IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for αS2-casein and Retinal S-antigen overlap IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for αS2-casein and Retinal S-antigen overlap IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : αS2-casein and Retinal S-antigen overlap IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : αS2-casein and Retinal S-antigen overlap IgG

Test Information

Test Name: αS2-casein and Retinal S-antigen overlap IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for αS2-casein and Retinal S-antigen overlap IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for αS2-casein and Retinal S-antigen overlap IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Dairy Zoomer : αS2-casein and Retinal S-antigen overlap IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : Beta-casomorphins (BCM) IgA

Test Information

Test Name: Beta-casomorphins (BCM) IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Beta-casomorphins (BCM) IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Beta-casomorphins (BCM) IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Beta-casomorphins (BCM) IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Dairy Zoomer : Beta-casomorphins (BCM) IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : Beta-casomorphins (BCM) IgG

Test Information

Test Name: Beta-casomorphins (BCM) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Beta-casomorphins (BCM) IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Beta-casomorphins (BCM) IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : Beta-casomorphins (BCM) IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : Butyrophilin IgA

Test Information

Test Name: Butyrophilin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Butyrophilin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Butyrophilin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Butyrophilin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Dairy Zoomer : Butyrophilin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : Butyrophilin IgG

Test Information

Test Name: Butyrophilin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Butyrophilin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Butyrophilin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Butyrophilin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
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Certificate of Quality

VibrantWellness

Dairy Zoomer : Butyrophilin IgG

Analyte Reference Range

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For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : Cow's Milk IgE

Test Information

Test Name: Cow's Milk IgE

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Cow's Milk IgE.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Cow's Milk IgE as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Cow's Milk IgE on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Dairy Zoomer : Cow's Milk IgE

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 0.35	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : Dairy Zoomer

Test Information

Test Name: Dairy Zoomer

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Dairy Zoomer.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Dairy Zoomer as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Dairy Zoomer on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : Dairy Zoomer

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : kappa casein IgA

Test Information

Test Name: kappa casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for kappa casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for kappa casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for kappa casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : kappa casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : kappa casein IgG

Test Information

Test Name: kappa casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for kappa casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for kappa casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for kappa casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : kappa casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : Lactoferrin IgA

Test Information

Test Name: Lactoferrin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lactoferrin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lactoferrin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lactoferrin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : Lactoferrin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : Lactoferrin IgG

Test Information

Test Name: Lactoferrin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lactoferrin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lactoferrin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lactoferrin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : Lactoferrin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : serum albumin IgA

Test Information

Test Name: serum albumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for serum albumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for serum albumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for serum albumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : serum albumin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : serum albumin IgG

Test Information

Test Name: serum albumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for serum albumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for serum albumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for serum albumin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : serum albumin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : β casein IgA

Test Information

Test Name: β casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for β casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for β casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for β casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Dairy Zoomer : β casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : β casein IgG

Test Information

Test Name: β casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for β casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for β casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for β casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : β casein IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : β- lactoglobulin IgA

Test Information

Test Name: β- lactoglobulin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for β- lactoglobulin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for β- lactoglobulin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for β- lactoglobulin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : β- lactoglobulin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Dairy Zoomer : β- lactoglobulin IgG

Test Information

Test Name: β- lactoglobulin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for β- lactoglobulin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Dairy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for β- lactoglobulin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Dairy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for β- lactoglobulin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Dairy Zoomer : β- lactoglobulin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Dairy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Dairy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Alpha Livetin IgA

Test Information

Test Name: Alpha Livetin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Alpha Livetin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Alpha Livetin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Alpha Livetin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Alpha Livetin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Alpha Livetin IgG

Test Information

Test Name: Alpha Livetin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Alpha Livetin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Alpha Livetin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Alpha Livetin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Apovitellenin IgA

Test Information

Test Name: Apovitellenin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Apovitellenin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Apovitellenin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Apovitellenin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Apovitellenin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Apovitellenin IgG

Test Information

Test Name: Apovitellenin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Apovitellenin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Apovitellenin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Apovitellenin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Apovitellenin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Avidin IgA

Test Information

Test Name: Avidin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Avidin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Avidin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Avidin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Avidin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Avidin IgG

Test Information

Test Name: Avidin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Avidin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Avidin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Avidin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Egg Zoomer : Avidin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Egg White IgE

Test Information

Test Name: Egg White IgE

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Egg White IgE.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Egg White IgE as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Egg White IgE

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 0.35	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Egg Yolk IgE

Test Information

Test Name: Egg Yolk IgE

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Egg Yolk IgE.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Egg Yolk IgE as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Egg Yolk IgE

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 0.35	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Egg Zoomer (Egg White)

Test Information

Test Name: Egg Zoomer (Egg White)

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Egg Zoomer (Egg White).

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Egg Zoomer (Egg White) as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Egg Zoomer (Egg White) on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Egg Zoomer : Egg Zoomer (Egg White)

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Egg Zoomer (Egg Yolk)

Test Information

Test Name: Egg Zoomer (Egg Yolk)

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Egg Zoomer (Egg Yolk).

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Egg Zoomer (Egg Yolk) as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Egg Zoomer (Egg Yolk) on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Egg Zoomer : Egg Zoomer (Egg Yolk)

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Lipovitellin IgA

Test Information

Test Name: Lipovitellin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lipovitellin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lipovitellin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lipovitellin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Egg Zoomer : Lipovitellin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Lipovitellin IgG

Test Information

Test Name: Lipovitellin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lipovitellin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lipovitellin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lipovitellin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Egg Zoomer : Lipovitellin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Lysozyme IgA

Test Information

Test Name: Lysozyme IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lysozyme IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lysozyme IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lysozyme IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Egg Zoomer : Lysozyme IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Lysozyme IgG

Test Information

Test Name: Lysozyme IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lysozyme IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lysozyme IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lysozyme IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Egg Zoomer : Lysozyme IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Ovalbumin IgA

Test Information

Test Name: Ovalbumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ovalbumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ovalbumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Ovalbumin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Ovalbumin IgG

Test Information

Test Name: Ovalbumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ovalbumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ovalbumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Ovalbumin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Ovomucin IgA

Test Information

Test Name: Ovomucin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ovomucin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ovomucin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ovomucin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Egg Zoomer : Ovomucin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Egg Zoomer : Ovomucin IgG

Test Information

Test Name: Ovomucin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ovomucin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ovomucin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ovomucin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Ovomucin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Ovomucoid IgA

Test Information

Test Name: Ovomucoid IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ovomucoid IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ovomucoid IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Ovomucoid IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Ovomucoid IgG

Test Information

Test Name: Ovomucoid IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ovomucoid IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ovomucoid IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Egg Zoomer : Ovomucoid IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Ovotransferrin IgA

Test Information

Test Name: Ovotransferrin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ovotransferrin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ovotransferrin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ovotransferrin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Egg Zoomer : Ovotransferrin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Certificate of Quality

VibrantWellness

Egg Zoomer : Ovotransferrin IgG

Test Information

Test Name: Ovotransferrin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ovotransferrin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ovotransferrin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ovotransferrin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Ovotransferrin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Vitellogenin-1 IgA

Test Information

Test Name: Vitellogenin-1 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Vitellogenin-1 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Vitellogenin-1 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Vitellogenin-1 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : Vitellogenin-1 IgG

Test Information

Test Name: Vitellogenin-1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Vitellogenin-1 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Vitellogenin-1 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : Vitellogenin-1 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : YGP42 IgA

Test Information

Test Name: YGP42 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for YGP42 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for YGP42 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for YGP42 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Egg Zoomer : YGP42 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Egg Zoomer : YGP42 IgG

Test Information

Test Name: YGP42 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for YGP42 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Egg Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for YGP42 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Egg Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for YGP42 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-08-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Egg Zoomer : YGP42 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Egg ZoomerTM IgG and IgA kit.The reference ranges have been established for all tests in Egg Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : 2s Albumin IgA

Test Information

Test Name: 2s Albumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 2s Albumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 2s Albumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 2s Albumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : 2s Albumin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : 2s Albumin IgG

Test Information

Test Name: 2s Albumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 2s Albumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 2s Albumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 2s Albumin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : 2s Albumin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : 13s Globulin IgA

Test Information

Test Name: 13s Globulin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 13s Globulin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 13s Globulin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 13s Globulin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : 13s Globulin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : 13s Globulin IgG

Test Information

Test Name: 13s Globulin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 13s Globulin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 13s Globulin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 13s Globulin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Grain Zoomer : 13s Globulin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Albumin IgA

Test Information

Test Name: Albumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Albumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Albumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Albumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Albumin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Albumin IgG

Test Information

Test Name: Albumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Albumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Albumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Albumin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Albumin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Alpha globulin IgA

Test Information

Test Name: Alpha globulin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Alpha globulin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Alpha globulin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Alpha globulin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : Alpha globulin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Alpha globulin IgG

Test Information

Test Name: Alpha globulin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Alpha globulin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Alpha globulin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Alpha globulin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Alpha globulin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : B hordein IgA

Test Information

Test Name: B hordein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for B hordein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for B hordein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for B hordein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : B hordein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : B hordein IgG

Test Information

Test Name: B hordein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for B hordein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for B hordein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for B hordein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : B hordein IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Barley Score

Test Information

Test Name: Barley Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Barley Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Barley Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Barley Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Barley Score

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Buckwheat Score

Test Information

Test Name: Buckwheat Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Buckwheat Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Buckwheat Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Buckwheat Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Grain Zoomer : Buckwheat Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : BW10KD IgA

Test Information

Test Name: BW10KD IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for BW10KD IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for BW10KD IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : BW10KD IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : BW10KD IgG

Test Information

Test Name: BW10KD IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for BW10KD IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : BW10KD IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : BWp16 epitope IgA

Test Information

Test Name: BWp16 epitope IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for BWp16 epitope IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for BWp16 epitope IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for BWp16 epitope IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : BWp16 epitope IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : BWp16 epitope IgG

Test Information

Test Name: BWp16 epitope IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for BWp16 epitope IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for BWp16 epitope IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for BWp16 epitope IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : BWp16 epitope IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : C hordein - Omega gliadin overlap IgA

Test Information

Test Name: C hordein - Omega gliadin overlap IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for C hordein - Omega gliadin overlap IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for C hordein - Omega gliadin overlap IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for C hordein - Omega gliadin overlap IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : C hordein - Omega gliadin overlap IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : C hordein - Omega gliadin overlap IgG

Test Information

Test Name: C hordein - Omega gliadin overlap IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for C hordein - Omega gliadin overlap IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for C hordein - Omega gliadin overlap IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : C hordein - Omega gliadin overlap IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : C hordein IgA

Test Information

Test Name: C hordein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for C hordein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for C hordein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for C hordein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : C hordein IgA

Analyte Reference Range

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For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : C hordein IgG

Test Information

Test Name: C hordein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for C hordein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for C hordein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for C hordein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Grain Zoomer : C hordein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : D hordein IgA

Test Information

Test Name: D hordein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for D hordein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for D hordein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : D hordein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : D hordein IgG

Test Information

Test Name: D hordein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for D hordein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for D hordein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : D hordein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Expansin IgA

Test Information

Test Name: Expansin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Expansin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Expansin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Expansin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Expansin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Expansin IgG

Test Information

Test Name: Expansin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Expansin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Expansin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Expansin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Expansin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Fag e 1 IgA

Test Information

Test Name: Fag e 1 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Fag e 1 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Fag e 1 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Fag e 1 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Fag e 1 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Fag e 1 IgG

Test Information

Test Name: Fag e 1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Fag e 1 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Fag e 1 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Fag e 1 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Fag e 1 IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Grain Zoomer : Gamma hordein IgA

VibrantWellness

Test Information

Test Name: Gamma hordein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gamma hordein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gamma hordein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gamma hordein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : Gamma hordein IgA

Analyte Reference Range

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For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

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Report Generated Date: 2021-10-21

Certificate of Quality

Grain Zoomer : Gamma hordein IgG

VibrantWellness

Test Information

Test Name: Gamma hordein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gamma hordein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gamma hordein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gamma hordein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Grain Zoomer : Gamma hordein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Gamma secalin IgA

Test Information

Test Name: Gamma secalin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gamma secalin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gamma secalin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Gamma secalin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Gamma secalin IgG

Test Information

Test Name: Gamma secalin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gamma secalin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Gamma secalin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Glutelin IgA

Test Information

Test Name: Glutelin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Glutelin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Glutelin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Glutelin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Glutelin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Glutelin IgG

Test Information

Test Name: Glutelin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Glutelin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Glutelin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Glutelin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Glutelin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : HMW secalin IgA

Test Information

Test Name: HMW secalin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for HMW secalin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for HMW secalin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for HMW secalin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : HMW secalin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : HMW secalin IgG

Test Information

Test Name: HMW secalin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for HMW secalin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for HMW secalin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : HMW secalin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Lipid transfer protein IgA

Test Information

Test Name: Lipid transfer protein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lipid transfer protein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lipid transfer protein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lipid transfer protein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : Lipid transfer protein IgA

Analyte Reference Range

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For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

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Report Generated Date: 2021-10-21

Certificate of Quality

Grain Zoomer : Lipid transfer protein IgG

VibrantWellness

Test Information

Test Name: Lipid transfer protein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lipid transfer protein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lipid transfer protein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lipid transfer protein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Grain Zoomer : Lipid transfer protein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Oats Avenalin IgA

Test Information

Test Name: Oats Avenalin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oats Avenalin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oats Avenalin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Oats Avenalin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Oats Avenalin IgG

Test Information

Test Name: Oats Avenalin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oats Avenalin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oats Avenalin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Oats Avenalin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Oats Avenin IgA

Test Information

Test Name: Oats Avenin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oats Avenin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oats Avenin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Oats Avenin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Oats Avenin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Oats Avenin IgG

Test Information

Test Name: Oats Avenin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oats Avenin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oats Avenin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Oats Avenin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : Oats Avenin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Oats Score

Test Information

Test Name: Oats Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oats Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oats Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Oats Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Oats Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Omega secalin IgA

Test Information

Test Name: Omega secalin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Omega secalin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Omega secalin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Omega secalin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Omega secalin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Omega secalin IgG

Test Information

Test Name: Omega secalin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Omega secalin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Omega secalin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Omega secalin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Omega secalin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Peanut-Buckwheat overlap IgA

Test Information

Test Name: Peanut-Buckwheat overlap IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Peanut-Buckwheat overlap IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Peanut-Buckwheat overlap IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Peanut-Buckwheat overlap IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Grain Zoomer : Peanut-Buckwheat overlap IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Peanut-Buckwheat overlap IgG

Test Information

Test Name: Peanut-Buckwheat overlap IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Peanut-Buckwheat overlap IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Peanut-Buckwheat overlap IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Peanut-Buckwheat overlap IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Prolamin IgA

Test Information

Test Name: Prolamin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Prolamin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Prolamin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Prolamin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Grain Zoomer : Prolamin IgG

VibrantWellness

Test Information

Test Name: Prolamin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Prolamin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Prolamin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Prolamin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Prolamin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Albumin IgA

Test Information

Test Name: Quinoa Albumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Quinoa Albumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Quinoa Albumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Quinoa Albumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Albumin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Albumin IgG

Test Information

Test Name: Quinoa Albumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Quinoa Albumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Quinoa Albumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Quinoa Albumin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Albumin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Grain Zoomer : Quinoa Globulin IgA

VibrantWellness

Test Information

Test Name: Quinoa Globulin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Quinoa Globulin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Quinoa Globulin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Quinoa Globulin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Globulin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Grain Zoomer : Quinoa Globulin IgG

VibrantWellness

Test Information

Test Name: Quinoa Globulin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Quinoa Globulin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Quinoa Globulin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Quinoa Globulin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Globulin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

Grain Zoomer : Quinoa Legumin like proteins IgA

VibrantWellness

Test Information

Test Name: Quinoa Legumin like proteins IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Quinoa Legumin like proteins IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Quinoa Legumin like proteins IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Quinoa Legumin like proteins IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

Grain Zoomer : Quinoa Legumin like proteins IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

Grain Zoomer : Quinoa Legumin like proteins IgG

VibrantWellness

Test Information

Test Name: Quinoa Legumin like proteins IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Quinoa Legumin like proteins IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Quinoa Legumin like proteins IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Quinoa Legumin like proteins IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

Grain Zoomer : Quinoa Legumin like proteins IgG

VibrantWellness

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Prolamin IgA

Test Information

Test Name: Quinoa Prolamin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Quinoa Prolamin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Quinoa Prolamin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Quinoa Prolamin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Prolamin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Grain Zoomer : Quinoa Prolamin IgG

VibrantWellness

Test Information

Test Name: Quinoa Prolamin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Quinoa Prolamin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Quinoa Prolamin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Quinoa Prolamin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Prolamin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Grain Zoomer : Quinoa Saponin IgA

VibrantWellness

Test Information

Test Name: Quinoa Saponin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Quinoa Saponin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Quinoa Saponin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Quinoa Saponin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Saponin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Saponin IgG

Test Information

Test Name: Quinoa Saponin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Quinoa Saponin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Quinoa Saponin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Quinoa Saponin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Saponin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Score

Test Information

Test Name: Quinoa Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Quinoa Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Quinoa Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Quinoa Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : Quinoa Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Rice Score

Test Information

Test Name: Rice Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rice Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rice Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Rice Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Rice Score

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Rye Score

Test Information

Test Name: Rye Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rye Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rye Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Rye Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Grain Zoomer : Rye Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Secalin - Gliadin overlap IgA

Test Information

Test Name: Secalin - Gliadin overlap IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Secalin - Gliadin overlap IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Secalin - Gliadin overlap IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Secalin - Gliadin overlap IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Secalin - Gliadin overlap IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Grain Zoomer : Secalin - Gliadin overlap IgG

VibrantWellness

Test Information

Test Name: Secalin - Gliadin overlap IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Secalin - Gliadin overlap IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Secalin - Gliadin overlap IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Secalin - Gliadin overlap IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Albumin IgA

Test Information

Test Name: Sorghum Albumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sorghum Albumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sorghum Albumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sorghum Albumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Albumin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Albumin IgG

Test Information

Test Name: Sorghum Albumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sorghum Albumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sorghum Albumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sorghum Albumin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Albumin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Globulins IgA

Test Information

Test Name: Sorghum Globulins IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sorghum Globulins IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sorghum Globulins IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sorghum Globulins IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Globulins IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Globulins IgG

Test Information

Test Name: Sorghum Globulins IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sorghum Globulins IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sorghum Globulins IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Globulins IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Glutelins IgA

Test Information

Test Name: Sorghum Glutelins IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sorghum Glutelins IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sorghum Glutelins IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sorghum Glutelins IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Glutelins IgA

Analyte Reference Range

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For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Glutelins IgG

Test Information

Test Name: Sorghum Glutelins IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sorghum Glutelins IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sorghum Glutelins IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sorghum Glutelins IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Glutelins IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Kafirin IgA

Test Information

Test Name: Sorghum Kafirin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sorghum Kafirin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sorghum Kafirin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sorghum Kafirin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Kafirin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Kafirin IgG

Test Information

Test Name: Sorghum Kafirin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sorghum Kafirin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sorghum Kafirin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Kafirin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Score

Test Information

Test Name: Sorghum Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sorghum Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sorghum Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sorghum Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Sorghum Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : TBb IgA

Test Information

Test Name: TBb IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for TBb IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for TBb IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for TBb IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : TBb IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : TBb IgG

Test Information

Test Name: TBb IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for TBb IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for TBb IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for TBb IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : TBb IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Albumin IgA

Test Information

Test Name: Teff Albumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Teff Albumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Teff Albumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Teff Albumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Albumin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Albumin IgG

Test Information

Test Name: Teff Albumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Teff Albumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Teff Albumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Teff Albumin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Albumin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Globulin IgA

Test Information

Test Name: Teff Globulin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Teff Globulin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Teff Globulin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Teff Globulin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Globulin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Globulin IgG

Test Information

Test Name: Teff Globulin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Teff Globulin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Teff Globulin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Teff Globulin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Globulin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Glutelin IgA

Test Information

Test Name: Teff Glutelin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Teff Glutelin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Teff Glutelin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Glutelin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Glutelin IgG

Test Information

Test Name: Teff Glutelin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Teff Glutelin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Teff Glutelin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Teff Glutelin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Glutelin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Prolamin IgA

Test Information

Test Name: Teff Prolamin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Teff Prolamin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Teff Prolamin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Teff Prolamin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Prolamin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Prolamin IgG

Test Information

Test Name: Teff Prolamin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Teff Prolamin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Teff Prolamin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Teff Prolamin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Prolamin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Score

Test Information

Test Name: Teff Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Teff Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Teff Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Teff Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Grain Zoomer : Teff Score

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Vicilin like protein IgA

Test Information

Test Name: Vicilin like protein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Vicilin like protein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Vicilin like protein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Vicilin like protein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Grain Zoomer : Vicilin like protein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Grain Zoomer : Vicilin like protein IgG

Test Information

Test Name: Vicilin like protein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Vicilin like protein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Grain Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Vicilin like protein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Grain Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Vicilin like protein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Grain Zoomer : Vicilin like protein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Grain ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Grain Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Barley lectin IgA

Test Information

Test Name: Barley lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Barley lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Barley lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Barley lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Barley lectin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Barley lectin IgG

Test Information

Test Name: Barley lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Barley lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Barley lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Barley lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Barley lectin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Barley Score 2

Test Information

Test Name: Barley Score 2

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Barley Score 2.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Barley Score 2 as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Barley Score 2 on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Barley Score 2

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Bell pepper aquaporin IgA

Test Information

Test Name: Bell pepper aquaporin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bell pepper aquaporin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bell pepper aquaporin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bell pepper aquaporin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Bell pepper aquaporin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Bell pepper aquaporin IgG

Test Information

Test Name: Bell pepper aquaporin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bell pepper aquaporin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bell pepper aquaporin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bell pepper aquaporin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Bell pepper aquaporin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Bell pepper lectin IgA

Test Information

Test Name: Bell pepper lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bell pepper lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bell pepper lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bell pepper lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Lectin Zoomer : Bell pepper lectin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Bell pepper lectin IgG

Test Information

Test Name: Bell pepper lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bell pepper lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bell pepper lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bell pepper lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Lectin Zoomer : Bell pepper lectin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Chickpea lectin IgA

Test Information

Test Name: Chickpea lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chickpea lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chickpea lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chickpea lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Lectin Zoomer : Chickpea lectin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Chickpea lectin IgG

Test Information

Test Name: Chickpea lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chickpea lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chickpea lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chickpea lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Chickpea lectin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Chickpea Score

Test Information

Test Name: Chickpea Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chickpea Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chickpea Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chickpea Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Chickpea Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Corn aquaporin IgA

Test Information

Test Name: Corn aquaporin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn aquaporin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn aquaporin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn aquaporin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Corn aquaporin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Corn aquaporin IgG

Test Information

Test Name: Corn aquaporin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn aquaporin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn aquaporin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn aquaporin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Corn aquaporin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Corn lectin IgA

Test Information

Test Name: Corn lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Corn lectin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Corn lectin IgG

Test Information

Test Name: Corn lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Corn lectin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Corn Score 2

Test Information

Test Name: Corn Score 2

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Corn Score 2.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Corn Score 2 as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Corn Score 2 on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Corn Score 2

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Cucumber lectin IgA

Test Information

Test Name: Cucumber lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Cucumber lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Cucumber lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Cucumber lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Lectin Zoomer : Cucumber lectin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Cucumber lectin IgG

Test Information

Test Name: Cucumber lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Cucumber lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Cucumber lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Cucumber lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Cucumber lectin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Cucumber Score

Test Information

Test Name: Cucumber Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Cucumber Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Cucumber Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Cucumber Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Cucumber Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Green pepper Score

Test Information

Test Name: Green pepper Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Green pepper Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Green pepper Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Green pepper Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Green pepper Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Kidney bean lectin IgA

Test Information

Test Name: Kidney bean lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Kidney bean lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Kidney bean lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Kidney bean lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Kidney bean lectin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Kidney bean lectin IgG

Test Information

Test Name: Kidney bean lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Kidney bean lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Kidney bean lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Kidney bean lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Kidney bean lectin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Kidney bean Score

Test Information

Test Name: Kidney bean Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Kidney bean Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Kidney bean Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Kidney bean Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Kidney bean Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Lentil lectin IgA

Test Information

Test Name: Lentil lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lentil lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lentil lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lentil lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Lentil lectin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Lentil lectin IgG

Test Information

Test Name: Lentil lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lentil lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lentil lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lentil lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Lentil lectin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Lentil Score

Test Information

Test Name: Lentil Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lentil Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lentil Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lentil Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Lentil Score

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Lima bean lectin IgA

Test Information

Test Name: Lima bean lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lima bean lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lima bean lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Lima bean lectin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Lima bean lectin IgG

Test Information

Test Name: Lima bean lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lima bean lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lima bean lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lima bean lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Lima bean lectin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Lima bean Score

Test Information

Test Name: Lima bean Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lima bean Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lima bean Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lima bean Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Lima bean Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Mung bean Score

Test Information

Test Name: Mung bean Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Mung bean Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Mung bean Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Mung bean Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Mung bean Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Mung lectin IgA

Test Information

Test Name: Mung lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Mung lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Mung lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Mung lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Mung lectin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Mung lectin IgG

Test Information

Test Name: Mung lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Mung lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Mung lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Mung lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Mung lectin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Pea lectin IgA

Test Information

Test Name: Pea lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pea lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pea lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pea lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Pea lectin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Pea lectin IgG

Test Information

Test Name: Pea lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pea lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pea lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pea lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Lectin Zoomer : Pea lectin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Pea Score

Test Information

Test Name: Pea Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pea Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pea Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Pea Score

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Peanut lectin IgA

Test Information

Test Name: Peanut lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Peanut lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Peanut lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Peanut lectin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Peanut lectin IgG

Test Information

Test Name: Peanut lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Peanut lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Peanut lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Lectin Zoomer : Peanut lectin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Peanut Score 2

Test Information

Test Name: Peanut Score 2

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Peanut Score 2.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Peanut Score 2 as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Peanut Score 2 on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Lectin Zoomer : Peanut Score 2

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Potato aquaporin IgA

Test Information

Test Name: Potato aquaporin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Potato aquaporin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Potato aquaporin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Potato aquaporin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Potato aquaporin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Potato aquaporin IgG

Test Information

Test Name: Potato aquaporin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Potato aquaporin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Potato aquaporin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Potato aquaporin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Potato lectin IgA

Test Information

Test Name: Potato lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Potato lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Potato lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Potato lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Lectin Zoomer : Potato lectin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Potato lectin IgG

Test Information

Test Name: Potato lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Potato lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Potato lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Potato lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Potato lectin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Potato Score

Test Information

Test Name: Potato Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Potato Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Potato Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Potato Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Potato Score

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Rice lectin IgA

Test Information

Test Name: Rice lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rice lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rice lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Rice lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Rice lectin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Rice lectin IgG

Test Information

Test Name: Rice lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rice lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rice lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Lectin Zoomer : Rice lectin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Rice Score 2

Test Information

Test Name: Rice Score 2

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rice Score 2.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rice Score 2 as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Rice Score 2 on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Rice Score 2

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Rye lectin IgA

Test Information

Test Name: Rye lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rye lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rye lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Rye lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Rye lectin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Rye lectin IgG

Test Information

Test Name: Rye lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rye lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rye lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Rye lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Lectin Zoomer : Rye lectin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Rye Score 2

Test Information

Test Name: Rye Score 2

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rye Score 2.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rye Score 2 as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Rye Score 2 on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Lectin Zoomer : Rye Score 2

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Soy Score 2

Test Information

Test Name: Soy Score 2

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Soy Score 2.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Soy Score 2 as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Soy Score 2 on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Lectin Zoomer : Soy Score 2

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Soybean aquaporin IgA

Test Information

Test Name: Soybean aquaporin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Soybean aquaporin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Soybean aquaporin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Soybean aquaporin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Soybean aquaporin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Soybean aquaporin IgG

Test Information

Test Name: Soybean aquaporin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Soybean aquaporin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Soybean aquaporin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Soybean aquaporin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Soybean aquaporin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Soybean lectin IgA

Test Information

Test Name: Soybean lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Soybean lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Soybean lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Soybean lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Lectin Zoomer : Soybean lectin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Soybean lectin IgG

Test Information

Test Name: Soybean lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Soybean lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Soybean lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Soybean lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Soybean lectin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Spinach aquaporin IgA

Test Information

Test Name: Spinach aquaporin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Spinach aquaporin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Spinach aquaporin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Spinach aquaporin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Spinach aquaporin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Spinach aquaporin IgG

Test Information

Test Name: Spinach aquaporin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Spinach aquaporin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Spinach aquaporin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Lectin Zoomer : Spinach aquaporin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Spinach Score

Test Information

Test Name: Spinach Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Spinach Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Spinach Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Spinach Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Spinach Score

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Tobacco aquaporin IgA

Test Information

Test Name: Tobacco aquaporin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tobacco aquaporin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tobacco aquaporin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Tobacco aquaporin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Lectin Zoomer : Tobacco aquaporin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Tobacco aquaporin IgG

Test Information

Test Name: Tobacco aquaporin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tobacco aquaporin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tobacco aquaporin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Tobacco aquaporin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Tobacco Score

Test Information

Test Name: Tobacco Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tobacco Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tobacco Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Tobacco Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Tobacco Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Tomato aquaporin IgA

Test Information

Test Name: Tomato aquaporin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tomato aquaporin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tomato aquaporin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Tomato aquaporin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Tomato aquaporin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Tomato aquaporin IgG

Test Information

Test Name: Tomato aquaporin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tomato aquaporin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tomato aquaporin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Tomato aquaporin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Tomato aquaporin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Tomato lectin IgA

Test Information

Test Name: Tomato lectin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tomato lectin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tomato lectin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Tomato lectin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Tomato lectin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Tomato lectin IgG

Test Information

Test Name: Tomato lectin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tomato lectin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tomato lectin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Tomato lectin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Tomato lectin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Lectin Zoomer : Tomato Score

Test Information

Test Name: Tomato Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tomato Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Lectin Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tomato Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Lectin Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Tomato Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Lectin Zoomer : Tomato Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Lectin ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Lectin Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha lactalbumin IgA

Test Information

Test Name: Camel Milk Alpha lactalbumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Alpha lactalbumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Alpha lactalbumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Alpha lactalbumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha lactalbumin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha lactalbumin IgG

Test Information

Test Name: Camel Milk Alpha lactalbumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Alpha lactalbumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Alpha lactalbumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Alpha lactalbumin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha lactalbumin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha S1 casein IgA

Test Information

Test Name: Camel Milk Alpha S1 casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Alpha S1 casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Alpha S1 casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Alpha S1 casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha S1 casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha S1 casein IgG

Test Information

Test Name: Camel Milk Alpha S1 casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Alpha S1 casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Alpha S1 casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha S1 casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha S2 casein IgA

Test Information

Test Name: Camel Milk Alpha S2 casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Alpha S2 casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Alpha S2 casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Alpha S2 casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha S2 casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha S2 casein IgG

Test Information

Test Name: Camel Milk Alpha S2 casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Alpha S2 casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Alpha S2 casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Alpha S2 casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Alpha S2 casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Beta casein IgA

Test Information

Test Name: Camel Milk Beta casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Beta casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Beta casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Beta casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Beta casein IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Beta casein IgG

Test Information

Test Name: Camel Milk Beta casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Beta casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Beta casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Beta casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Beta casein IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Chymosin IgA

Test Information

Test Name: Camel Milk Chymosin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Chymosin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Chymosin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Chymosin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Chymosin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Chymosin IgG

Test Information

Test Name: Camel Milk Chymosin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Chymosin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Chymosin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Chymosin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Chymosin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Kappa casein IgA

Test Information

Test Name: Camel Milk Kappa casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Kappa casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Kappa casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Kappa casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Kappa casein IgG

Test Information

Test Name: Camel Milk Kappa casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Kappa casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Kappa casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Kappa casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Kappa casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Lactotransferrin IgA

Test Information

Test Name: Camel Milk Lactotransferrin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Lactotransferrin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Lactotransferrin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Lactotransferrin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Lactotransferrin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Lactotransferrin IgG

Test Information

Test Name: Camel Milk Lactotransferrin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Lactotransferrin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Lactotransferrin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Lactotransferrin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Lactotransferrin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Score

Test Information

Test Name: Camel Milk Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Whey acidic protein IgA

Test Information

Test Name: Camel Milk Whey acidic protein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Whey acidic protein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Whey acidic protein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Whey acidic protein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Whey acidic protein IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Whey acidic protein IgG

Test Information

Test Name: Camel Milk Whey acidic protein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Camel Milk Whey acidic protein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Camel Milk Whey acidic protein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Camel Milk Whey acidic protein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Camel Milk Whey acidic protein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha lactalbumin IgA

Test Information

Test Name: Donkey Milk Alpha lactalbumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Alpha lactalbumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Alpha lactalbumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donkey Milk Alpha lactalbumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha lactalbumin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha lactalbumin IgG

Test Information

Test Name: Donkey Milk Alpha lactalbumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Alpha lactalbumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Alpha lactalbumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha lactalbumin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha S1 casein IgA

Test Information

Test Name: Donkey Milk Alpha S1 casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Alpha S1 casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Alpha S1 casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donkey Milk Alpha S1 casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha S1 casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha S1 casein IgG

Test Information

Test Name: Donkey Milk Alpha S1 casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Alpha S1 casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Alpha S1 casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donkey Milk Alpha S1 casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha S1 casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha S2 casein IgA

Test Information

Test Name: Donkey Milk Alpha S2 casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Alpha S2 casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Alpha S2 casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donkey Milk Alpha S2 casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha S2 casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha S2 casein IgG

Test Information

Test Name: Donkey Milk Alpha S2 casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Alpha S2 casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Alpha S2 casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donkey Milk Alpha S2 casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Alpha S2 casein IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Beta casein IgA

Test Information

Test Name: Donkey Milk Beta casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Beta casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Beta casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donkey Milk Beta casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Beta casein IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Beta casein IgG

Test Information

Test Name: Donkey Milk Beta casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Beta casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Beta casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donkey Milk Beta casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Beta casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Beta lactoglobulin IgA

Test Information

Test Name: Donkey Milk Beta lactoglobulin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Beta lactoglobulin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Beta lactoglobulin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Beta lactoglobulin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Beta lactoglobulin IgG

Test Information

Test Name: Donkey Milk Beta lactoglobulin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Beta lactoglobulin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Beta lactoglobulin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donkey Milk Beta lactoglobulin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Beta lactoglobulin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Kappa casein IgA

Test Information

Test Name: Donkey Milk Kappa casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Kappa casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Kappa casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donkey Milk Kappa casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Kappa casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Kappa casein IgG

Test Information

Test Name: Donkey Milk Kappa casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Kappa casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donkey Milk Kappa casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Kappa casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Score

Test Information

Test Name: Donkey Milk Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donkey Milk Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donkey Milk Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donkey Milk Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Donkey Milk Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha lactalbumin IgA

Test Information

Test Name: Goat Milk Alpha lactalbumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Alpha lactalbumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Alpha lactalbumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Alpha lactalbumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha lactalbumin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha lactalbumin IgG

Test Information

Test Name: Goat Milk Alpha lactalbumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Alpha lactalbumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Alpha lactalbumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Alpha lactalbumin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha lactalbumin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha S1 casein IgA

Test Information

Test Name: Goat Milk Alpha S1 casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Alpha S1 casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Alpha S1 casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Alpha S1 casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha S1 casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha S1 casein IgG

Test Information

Test Name: Goat Milk Alpha S1 casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Alpha S1 casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Alpha S1 casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha S1 casein IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha S2 casein IgA

Test Information

Test Name: Goat Milk Alpha S2 casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Alpha S2 casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Alpha S2 casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Alpha S2 casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha S2 casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha S2 casein IgG

Test Information

Test Name: Goat Milk Alpha S2 casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Alpha S2 casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Alpha S2 casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Alpha S2 casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Alpha S2 casein IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Beta casein IgA

Test Information

Test Name: Goat Milk Beta casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Beta casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Beta casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Beta casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Beta casein IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Beta casein IgG

Test Information

Test Name: Goat Milk Beta casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Beta casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Beta casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Beta casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Beta casein IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Beta lactoglobulin IgA

Test Information

Test Name: Goat Milk Beta lactoglobulin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Beta lactoglobulin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Beta lactoglobulin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Beta lactoglobulin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Beta lactoglobulin IgG

Test Information

Test Name: Goat Milk Beta lactoglobulin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Beta lactoglobulin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Beta lactoglobulin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Kappa casein IgA

Test Information

Test Name: Goat Milk Kappa casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Kappa casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Kappa casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Kappa casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Kappa casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Kappa casein IgG

Test Information

Test Name: Goat Milk Kappa casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Kappa casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Kappa casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Kappa casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Lactoferrin IgA

Test Information

Test Name: Goat Milk Lactoferrin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Lactoferrin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Lactoferrin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Lactoferrin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Lactoferrin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Lactoferrin IgG

Test Information

Test Name: Goat Milk Lactoferrin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Lactoferrin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Lactoferrin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Lactoferrin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

Mammalian Milk Zoomer : Goat Milk Lactoferrin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Lactoperoxidase IgA

Test Information

Test Name: Goat Milk Lactoperoxidase IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Lactoperoxidase IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Lactoperoxidase IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Lactoperoxidase IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Lactoperoxidase IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Lactoperoxidase IgG

Test Information

Test Name: Goat Milk Lactoperoxidase IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Lactoperoxidase IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Lactoperoxidase IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Lactoperoxidase IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Lactoperoxidase IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Score

Test Information

Test Name: Goat Milk Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Goat Milk Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Goat Milk Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Goat Milk Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Goat Milk Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Alpha lactalbumin IgA

Test Information

Test Name: Sheep Milk Alpha lactalbumin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Alpha lactalbumin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Alpha lactalbumin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Alpha lactalbumin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Alpha lactalbumin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Alpha lactalbumin IgG

Test Information

Test Name: Sheep Milk Alpha lactalbumin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Alpha lactalbumin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Alpha lactalbumin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Alpha lactalbumin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Alpha lactalbumin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Alpha S1 casein IgA

Test Information

Test Name: Sheep Milk Alpha S1 casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Alpha S1 casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Alpha S1 casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Alpha S1 casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Alpha S1 casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Alpha S1 casein IgG

Test Information

Test Name: Sheep Milk Alpha S1 casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Alpha S1 casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Alpha S1 casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Alpha S1 casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Alpha S1 casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Beta casein IgA

Test Information

Test Name: Sheep Milk Beta casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Beta casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Beta casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Beta casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Beta casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Beta casein IgG

Test Information

Test Name: Sheep Milk Beta casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Beta casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Beta casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Beta casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Beta casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Beta lactoglobulin IgA

Test Information

Test Name: Sheep Milk Beta lactoglobulin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Beta lactoglobulin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Beta lactoglobulin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Beta lactoglobulin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Beta lactoglobulin IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Beta lactoglobulin IgG

Test Information

Test Name: Sheep Milk Beta lactoglobulin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Beta lactoglobulin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Beta lactoglobulin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Beta lactoglobulin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Beta lactoglobulin IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Mammalian Milk Zoomer : Sheep Milk Chymosin IgA

Test Information

Test Name: Sheep Milk Chymosin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Chymosin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Chymosin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Chymosin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Chymosin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Chymosin IgG

Test Information

Test Name: Sheep Milk Chymosin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Chymosin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Chymosin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Chymosin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Chymosin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Kappa casein IgA

Test Information

Test Name: Sheep Milk Kappa casein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Kappa casein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Kappa casein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Kappa casein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Kappa casein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Kappa casein IgG

Test Information

Test Name: Sheep Milk Kappa casein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Kappa casein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Kappa casein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Kappa casein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Kappa casein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Score

Test Information

Test Name: Sheep Milk Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Uterine milk protein IgA

Test Information

Test Name: Sheep Milk Uterine milk protein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Uterine milk protein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Uterine milk protein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Uterine milk protein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Uterine milk protein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Uterine milk protein IgG

Test Information

Test Name: Sheep Milk Uterine milk protein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sheep Milk Uterine milk protein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Mammalian Milk Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sheep Milk Uterine milk protein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Mammalian Milk Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sheep Milk Uterine milk protein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Mammalian Milk Zoomer : Sheep Milk Uterine milk protein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Mammalian Milk ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Mammalian Milk Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : 2s Albumin - Car I 1 IgA

Test Information

Test Name: 2s Albumin - Car I 1 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 2s Albumin - Car I 1 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 2s Albumin - Car I 1 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 2s Albumin - Car I 1 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : 2s Albumin - Car I 1 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : 2s Albumin - Car I 1 IgG

Test Information

Test Name: 2s Albumin - Car I 1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 2s Albumin - Car I 1 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 2s Albumin - Car I 1 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 2s Albumin - Car I 1 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Nut Zoomer : 2s Albumin - Car I 1 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : 7s globulin IgA

Test Information

Test Name: 7s globulin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 7s globulin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 7s globulin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 7s globulin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : 7s globulin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : 7s globulin IgG

Test Information

Test Name: 7s globulin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 7s globulin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 7s globulin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 7s globulin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : 7s globulin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : 11s globulin - Car I 4 IgA

Test Information

Test Name: 11s globulin - Car I 4 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 11s globulin - Car I 4 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 11s globulin - Car I 4 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 11s globulin - Car I 4 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : 11s globulin - Car I 4 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : 11s globulin - Car I 4 IgG

Test Information

Test Name: 11s globulin - Car I 4 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 11s globulin - Car I 4 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 11s globulin - Car I 4 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 11s globulin - Car I 4 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : 11s globulin - Car I 4 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : 17.4kDa antigen IgA

Test Information

Test Name: 17.4kDa antigen IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 17.4kDa antigen IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 17.4kDa antigen IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 17.4kDa antigen IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : 17.4kDa antigen IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : 17.4kDa antigen IgG

Test Information

Test Name: 17.4kDa antigen IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for 17.4kDa antigen IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for 17.4kDa antigen IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for 17.4kDa antigen IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : 17.4kDa antigen IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Almond Score

Test Information

Test Name: Almond Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Almond Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Almond Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Almond Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Almond Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 1 IgA

Test Information

Test Name: Ana o 1 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ana o 1 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ana o 1 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ana o 1 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 1 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 1 IgG

Test Information

Test Name: Ana o 1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ana o 1 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ana o 1 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ana o 1 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 1 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 2 IgA

Test Information

Test Name: Ana o 2 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ana o 2 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ana o 2 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ana o 2 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 2 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 2 IgG

Test Information

Test Name: Ana o 2 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ana o 2 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ana o 2 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ana o 2 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 2 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 3 IgA

Test Information

Test Name: Ana o 3 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ana o 3 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ana o 3 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ana o 3 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 3 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 3 IgG

Test Information

Test Name: Ana o 3 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ana o 3 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ana o 3 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ana o 3 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Ana o 3 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Ber e 1 IgA

Test Information

Test Name: Ber e 1 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ber e 1 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ber e 1 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ber e 1 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Ber e 1 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Ber e 1 IgG

Test Information

Test Name: Ber e 1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ber e 1 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ber e 1 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ber e 1 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Ber e 1 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Ber e 2 IgA

Test Information

Test Name: Ber e 2 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ber e 2 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ber e 2 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ber e 2 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Nut Zoomer : Ber e 2 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Ber e 2 IgG

Test Information

Test Name: Ber e 2 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ber e 2 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ber e 2 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ber e 2 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Ber e 2 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Brazil Nut Score

Test Information

Test Name: Brazil Nut Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Brazil Nut Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Brazil Nut Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Brazil Nut Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Brazil Nut Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Car I 2 IgA

Test Information

Test Name: Car I 2 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Car I 2 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Car I 2 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Car I 2 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Car I 2 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Car I 2 IgG

Test Information

Test Name: Car I 2 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Car I 2 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Car I 2 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Car I 2 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Car I 2 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Cashew Score

Test Information

Test Name: Cashew Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Cashew Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Cashew Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Cashew Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Cashew Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 1 IgA

Test Information

Test Name: Jug n 1 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug n 1 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug n 1 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug n 1 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 1 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 1 IgG

Test Information

Test Name: Jug n 1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug n 1 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug n 1 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 1 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 2 IgA

Test Information

Test Name: Jug n 2 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug n 2 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug n 2 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug n 2 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 2 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 2 IgG

Test Information

Test Name: Jug n 2 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug n 2 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug n 2 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug n 2 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 2 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 4 IgA

Test Information

Test Name: Jug n 4 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug n 4 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug n 4 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 4 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 4 IgG

Test Information

Test Name: Jug n 4 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug n 4 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug n 4 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug n 4 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 1 IgA

Test Information

Test Name: Jug r 1 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 1 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 1 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug r 1 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 1 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 1 IgG

Test Information

Test Name: Jug r 1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 1 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 1 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 1 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 2 IgA

Test Information

Test Name: Jug r 2 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 2 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 2 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug r 2 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 2 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 2 IgG

Test Information

Test Name: Jug r 2 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 2 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 2 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug r 2 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 2 IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 3 IgA

Test Information

Test Name: Jug r 3 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 3 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 3 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug r 3 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 3 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 3 IgG

Test Information

Test Name: Jug r 3 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 3 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 3 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug r 3 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 3 IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 4 IgA

Test Information

Test Name: Jug r 4 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 4 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 4 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 4 IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 4 IgG

Test Information

Test Name: Jug r 4 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 4 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 4 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 4 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 5 IgA

Test Information

Test Name: Jug r 5 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 5 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 5 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 5 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 5 IgG

Test Information

Test Name: Jug r 5 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 5 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 5 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 5 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 6 IgA

Test Information

Test Name: Jug r 6 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 6 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 6 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug r 6 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 6 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 6 IgG

Test Information

Test Name: Jug r 6 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 6 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 6 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug r 6 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 6 IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 7 IgA

Test Information

Test Name: Jug r 7 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 7 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 7 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug r 7 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 7 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 7 IgG

Test Information

Test Name: Jug r 7 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Jug r 7 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Jug r 7 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Jug r 7 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Jug r 7 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Macadamia nut Score

Test Information

Test Name: Macadamia nut Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Macadamia nut Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Macadamia nut Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Macadamia nut Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Macadamia nut Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pecan Score

Test Information

Test Name: Pecan Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pecan Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pecan Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pecan Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Pecan Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 1 IgA

Test Information

Test Name: Pis v 1 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pis v 1 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pis v 1 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pis v 1 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 1 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 1 IgG

Test Information

Test Name: Pis v 1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pis v 1 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pis v 1 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pis v 1 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 1 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 2 IgA

Test Information

Test Name: Pis v 2 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pis v 2 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pis v 2 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pis v 2 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 2 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 2 IgG

Test Information

Test Name: Pis v 2 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pis v 2 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pis v 2 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pis v 2 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 2 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 3 IgA

Test Information

Test Name: Pis v 3 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pis v 3 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pis v 3 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pis v 3 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 3 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 3 IgG

Test Information

Test Name: Pis v 3 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pis v 3 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pis v 3 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pis v 3 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 3 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 4 IgA

Test Information

Test Name: Pis v 4 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pis v 4 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pis v 4 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 4 IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 4 IgG

Test Information

Test Name: Pis v 4 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pis v 4 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pis v 4 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 4 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 5 IgA

Test Information

Test Name: Pis v 5 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pis v 5 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pis v 5 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pis v 5 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 5 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 5 IgG

Test Information

Test Name: Pis v 5 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pis v 5 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pis v 5 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pis v 5 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pis v 5 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pistachio Score

Test Information

Test Name: Pistachio Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pistachio Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pistachio Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pistachio Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pistachio Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	Arbitrary Chemiluminescence Units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 1 IgA

Test Information

Test Name: Pru du 1 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 1 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 1 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pru du 1 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 1 IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 1 IgG

Test Information

Test Name: Pru du 1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 1 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 1 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pru du 1 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 1 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 2 IgA

Test Information

Test Name: Pru du 2 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 2 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 2 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pru du 2 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 2 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 2 IgG

Test Information

Test Name: Pru du 2 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 2 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 2 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 2 IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 3 IgA

Test Information

Test Name: Pru du 3 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 3 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 3 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 3 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 3 IgG

Test Information

Test Name: Pru du 3 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 3 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 3 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 3 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 4 IgA

Test Information

Test Name: Pru du 4 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 4 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 4 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pru du 4 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 4 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 4 IgG

Test Information

Test Name: Pru du 4 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 4 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 4 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pru du 4 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 4 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 5 IgA

Test Information

Test Name: Pru du 5 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 5 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 5 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pru du 5 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 5 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 5 IgG

Test Information

Test Name: Pru du 5 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 5 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 5 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pru du 5 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 5 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 6 IgA

Test Information

Test Name: Pru du 6 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 6 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 6 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pru du 6 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 6 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 6 IgG

Test Information

Test Name: Pru du 6 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pru du 6 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pru du 6 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pru du 6 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Pru du 6 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Nut Zoomer : Walnut Score

Test Information

Test Name: Walnut Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Walnut Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Nut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Walnut Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Nut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Walnut Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Nut Zoomer : Walnut Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Nut Zoomer TM IgG and IgA kit. The reference ranges have been established for all tests in Nut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara 13 (Defensin 2 & Defensin 3) IgA

Test Information

Test Name: Ara 13 (Defensin 2 & Defensin 3) IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara 13 (Defensin 2 & Defensin 3) IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara 13 (Defensin 2 & Defensin 3) IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara 13 (Defensin 2 & Defensin 3) IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara 13 (Defensin 2 & Defensin 3) IgG

Test Information

Test Name: Ara 13 (Defensin 2 & Defensin 3) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara 13 (Defensin 2 & Defensin 3) IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara 13 (Defensin 2 & Defensin 3) IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara 13 (Defensin 2 & Defensin 3) IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara 13 (Defensin 2 & Defensin 3) IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 1 (Conarachin) IgA

Test Information

Test Name: Ara h 1 (Conarachin) IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 1 (Conarachin) IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 1 (Conarachin) IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 1 (Conarachin) IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 1 (Conarachin) IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 1 (Conarachin) IgG

Test Information

Test Name: Ara h 1 (Conarachin) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 1 (Conarachin) IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 1 (Conarachin) IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 1 (Conarachin) IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 1 (Conarachin) IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 2 (Conglutin 7) IgA

Test Information

Test Name: Ara h 2 (Conglutin 7) IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 2 (Conglutin 7) IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 2 (Conglutin 7) IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 2 (Conglutin 7) IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 2 (Conglutin 7) IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 2 (Conglutin 7) IgG

Test Information

Test Name: Ara h 2 (Conglutin 7) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 2 (Conglutin 7) IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 2 (Conglutin 7) IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 2 (Conglutin 7) IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 2 (Conglutin 7) IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 3 IgA

Test Information

Test Name: Ara h 3 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 3 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 3 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 3 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 3 IgG

Test Information

Test Name: Ara h 3 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 3 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 3 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 3 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 5 IgA

Test Information

Test Name: Ara h 5 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 5 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 5 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 5 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 5 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 5 IgG

Test Information

Test Name: Ara h 5 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 5 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 5 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 5 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 6 (Conglutin 8) IgA

Test Information

Test Name: Ara h 6 (Conglutin 8) IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 6 (Conglutin 8) IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 6 (Conglutin 8) IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 6 (Conglutin 8) IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 6 (Conglutin 8) IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 6 (Conglutin 8) IgG

Test Information

Test Name: Ara h 6 (Conglutin 8) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 6 (Conglutin 8) IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 6 (Conglutin 8) IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 6 (Conglutin 8) IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 7 IgA

Test Information

Test Name: Ara h 7 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 7 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 7 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 7 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 7 IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 7 IgG

Test Information

Test Name: Ara h 7 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 7 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 7 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 7 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 7 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 8, Ara h 8 isoform IgA

Test Information

Test Name: Ara h 8, Ara h 8 isoform IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 8, Ara h 8 isoform IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 8, Ara h 8 isoform IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 8, Ara h 8 isoform IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 8, Ara h 8 isoform IgG

Test Information

Test Name: Ara h 8, Ara h 8 isoform IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 8, Ara h 8 isoform IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 8, Ara h 8 isoform IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 8, Ara h 8 isoform IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 9 IgA

Test Information

Test Name: Ara h 9 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 9 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 9 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 9 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 9 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 9 IgG

Test Information

Test Name: Ara h 9 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 9 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 9 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 9 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 9 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 10 (Oleosin 1) IgA

Test Information

Test Name: Ara h 10 (Oleosin 1) IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 10 (Oleosin 1) IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 10 (Oleosin 1) IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 10 (Oleosin 1) IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 10 (Oleosin 1) IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 10 (Oleosin 1) IgG

Test Information

Test Name: Ara h 10 (Oleosin 1) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 10 (Oleosin 1) IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 10 (Oleosin 1) IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 10 (Oleosin 1) IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 11 (Oleosin 2) IgA

Test Information

Test Name: Ara h 11 (Oleosin 2) IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 11 (Oleosin 2) IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 11 (Oleosin 2) IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 11 (Oleosin 2) IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 11 (Oleosin 2) IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 11 (Oleosin 2) IgG

Test Information

Test Name: Ara h 11 (Oleosin 2) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 11 (Oleosin 2) IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 11 (Oleosin 2) IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 11 (Oleosin 2) IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 11 (Oleosin 2) IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 12 (Defensin 1) IgA

Test Information

Test Name: Ara h 12 (Defensin 1) IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 12 (Defensin 1) IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 12 (Defensin 1) IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 12 (Defensin 1) IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 12 (Defensin 1) IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 12 (Defensin 1) IgG

Test Information

Test Name: Ara h 12 (Defensin 1) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ara h 12 (Defensin 1) IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ara h 12 (Defensin 1) IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ara h 12 (Defensin 1) IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Ara h 12 (Defensin 1) IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Arachin IgA

Test Information

Test Name: Arachin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Arachin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Arachin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Arachin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Arachin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Arachin IgG

Test Information

Test Name: Arachin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Arachin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Arachin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Arachin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Arachin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Glycinin IgA

Test Information

Test Name: Glycinin IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Glycinin IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Glycinin IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Glycinin IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Glycinin IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Glycinin IgG

Test Information

Test Name: Glycinin IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Glycinin IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Glycinin IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Glycinin IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Glycinin IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Oleosin variant A IgA

Test Information

Test Name: Oleosin variant A IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oleosin variant A IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oleosin variant A IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Oleosin variant A IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Oleosin variant A IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Oleosin variant A IgG

Test Information

Test Name: Oleosin variant A IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oleosin variant A IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oleosin variant A IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Oleosin variant A IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Peanut Zoomer : Oleosin variant A IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Oleosin variant B IgA

Test Information

Test Name: Oleosin variant B IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oleosin variant B IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oleosin variant B IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Oleosin variant B IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Oleosin variant B IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Oleosin variant B IgG

Test Information

Test Name: Oleosin variant B IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oleosin variant B IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oleosin variant B IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Oleosin variant B IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Peanut Zoomer : Peanut Zoomer

Test Information

Test Name: Peanut Zoomer

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Peanut Zoomer.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Peanut Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Peanut Zoomer as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Peanut Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Peanut Zoomer on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-09-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Peanut Zoomer : Peanut Zoomer

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Peanut ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Peanut Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Alaska pollock IgA

Test Information

Test Name: Alaska pollock IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Alaska pollock IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Alaska pollock IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Alaska pollock IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Alaska pollock IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Alaska pollock IgG

Test Information

Test Name: Alaska pollock IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Alaska pollock IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Alaska pollock IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Alaska pollock IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Alaska pollock IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Alaska pollock Score

Test Information

Test Name: Alaska pollock Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Alaska pollock Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Alaska pollock Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Alaska pollock Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Alaska pollock Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Albacore Tuna IgA

Test Information

Test Name: Albacore Tuna IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Albacore Tuna IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Albacore Tuna IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Albacore Tuna IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Albacore Tuna IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Albacore Tuna IgG

Test Information

Test Name: Albacore Tuna IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Albacore Tuna IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Albacore Tuna IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Albacore Tuna IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Albacore Tuna IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Alewife IgA

Test Information

Test Name: Alewife IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Alewife IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Alewife IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Alewife IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Alewife IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Alewife IgG

Test Information

Test Name: Alewife IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Alewife IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Alewife IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Alewife IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Alewife IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : American lobster IgA

Test Information

Test Name: American lobster IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for American lobster IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for American lobster IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for American lobster IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : American lobster IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : American lobster IgG

Test Information

Test Name: American lobster IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for American lobster IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for American lobster IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : American lobster IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Anchovies IgA

Test Information

Test Name: Anchovies IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Anchovies IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Anchovies IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Anchovies IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Anchovies IgG

Test Information

Test Name: Anchovies IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Anchovies IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Anchovies IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Anchovies IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Anchovies IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Anchovy Score

Test Information

Test Name: Anchovy Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Anchovy Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Anchovy Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Anchovy Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Anchovy Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Anisakis simplex IgA

Test Information

Test Name: Anisakis simplex IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Anisakis simplex IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Anisakis simplex IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Anisakis simplex IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Anisakis simplex IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Anisakis simplex IgG

Test Information

Test Name: Anisakis simplex IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Anisakis simplex IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Anisakis simplex IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Anisakis simplex IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Anisakis simplex IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Argentine anchoita IgA

Test Information

Test Name: Argentine anchoita IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Argentine anchoita IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Argentine anchoita IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Argentine anchoita IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Argentine anchoita IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Argentine anchoita IgG

Test Information

Test Name: Argentine anchoita IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Argentine anchoita IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Argentine anchoita IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Argentine anchoita IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Argentine anchoita IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Asian sea bass IgA

Test Information

Test Name: Asian sea bass IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Asian sea bass IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Asian sea bass IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Asian sea bass IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Asian sea bass IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Asian sea bass IgG

Test Information

Test Name: Asian sea bass IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Asian sea bass IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Asian sea bass IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Asian sea bass IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Asian sea bass IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic cod IgA

Test Information

Test Name: Atlantic cod IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Atlantic cod IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Atlantic cod IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Atlantic cod IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic cod IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic cod IgG

Test Information

Test Name: Atlantic cod IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Atlantic cod IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Atlantic cod IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Atlantic cod IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic cod IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic herring IgA

Test Information

Test Name: Atlantic herring IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Atlantic herring IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Atlantic herring IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Atlantic herring IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic herring IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic herring IgG

Test Information

Test Name: Atlantic herring IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Atlantic herring IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Atlantic herring IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Atlantic herring IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic herring IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic mackerel IgA

Test Information

Test Name: Atlantic mackerel IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Atlantic mackerel IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Atlantic mackerel IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Atlantic mackerel IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic mackerel IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic mackerel IgG

Test Information

Test Name: Atlantic mackerel IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Atlantic mackerel IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Atlantic mackerel IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic mackerel IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic Oyster IgA

Test Information

Test Name: Atlantic Oyster IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Atlantic Oyster IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Atlantic Oyster IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Atlantic Oyster IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic Oyster IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic Oyster IgG

Test Information

Test Name: Atlantic Oyster IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Atlantic Oyster IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Atlantic Oyster IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Atlantic Oyster IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic Oyster IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic salmon IgA

Test Information

Test Name: Atlantic salmon IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Atlantic salmon IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Atlantic salmon IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Atlantic salmon IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic salmon IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic salmon IgG

Test Information

Test Name: Atlantic salmon IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Atlantic salmon IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Atlantic salmon IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Atlantic salmon IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Atlantic salmon IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Banana prawn IgA

Test Information

Test Name: Banana prawn IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Banana prawn IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Banana prawn IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Banana prawn IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Banana prawn IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Banana prawn IgG

Test Information

Test Name: Banana prawn IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Banana prawn IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Banana prawn IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Banana prawn IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Banana prawn IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Bass IgA

Test Information

Test Name: Bass IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bass IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bass IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bass IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Bass IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Bass IgG

Test Information

Test Name: Bass IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bass IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bass IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bass IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Bass IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Bass Score

Test Information

Test Name: Bass Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bass Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bass Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bass Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Bass Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Bay Scallop IgA

Test Information

Test Name: Bay Scallop IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bay Scallop IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bay Scallop IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bay Scallop IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Bay Scallop IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Bay Scallop IgG

Test Information

Test Name: Bay Scallop IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bay Scallop IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bay Scallop IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Bay Scallop IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Bighead carp IgA

Test Information

Test Name: Bighead carp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bighead carp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bighead carp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bighead carp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Bighead carp IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Bighead carp IgG

Test Information

Test Name: Bighead carp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bighead carp IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bighead carp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bighead carp IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Bighead carp IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue catfish IgA

Test Information

Test Name: Blue catfish IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Blue catfish IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Blue catfish IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Blue catfish IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue catfish IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue catfish IgG

Test Information

Test Name: Blue catfish IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Blue catfish IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Blue catfish IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Blue catfish IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue catfish IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue crab IgA

Test Information

Test Name: Blue crab IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Blue crab IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Blue crab IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue crab IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue crab IgG

Test Information

Test Name: Blue crab IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Blue crab IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Blue crab IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Blue crab IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue crab IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue Mussel IgA

Test Information

Test Name: Blue Mussel IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Blue Mussel IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Blue Mussel IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Blue Mussel IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue Mussel IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue Mussel IgG

Test Information

Test Name: Blue Mussel IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Blue Mussel IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Blue Mussel IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Blue Mussel IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue Mussel IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue mussel Score

Test Information

Test Name: Blue mussel Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Blue mussel Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Blue mussel Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Blue mussel Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Blue mussel Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Bream IgA

Test Information

Test Name: Bream IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bream IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bream IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bream IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Bream IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Bream IgG

Test Information

Test Name: Bream IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bream IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bream IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bream IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Bream IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Brisling sardine IgA

Test Information

Test Name: Brisling sardine IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Brisling sardine IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Brisling sardine IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Brisling sardine IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Brisling sardine IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Brisling sardine IgG

Test Information

Test Name: Brisling sardine IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Brisling sardine IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Brisling sardine IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Brisling sardine IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Brisling sardine IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Brown shrimp IgA

Test Information

Test Name: Brown shrimp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Brown shrimp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Brown shrimp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Brown shrimp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Brown shrimp IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Brown shrimp IgG

Test Information

Test Name: Brown shrimp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Brown shrimp IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Brown shrimp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Brown shrimp IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Brown shrimp IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Calico Scallop IgA

Test Information

Test Name: Calico Scallop IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Calico Scallop IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Calico Scallop IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Calico Scallop IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Calico Scallop IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Calico Scallop IgG

Test Information

Test Name: Calico Scallop IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Calico Scallop IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Calico Scallop IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Calico Scallop IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Calico Scallop IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Carp IgA

Test Information

Test Name: Carp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Carp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Carp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Carp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Carp IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Carp IgG

Test Information

Test Name: Carp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Carp IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Carp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Carp IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Carp IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Carp Score

Test Information

Test Name: Carp Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Carp Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Carp Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Carp Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Carp Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Catfish IgA

Test Information

Test Name: Catfish IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Catfish IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Catfish IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Catfish IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Catfish IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Catfish IgG

Test Information

Test Name: Catfish IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Catfish IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Catfish IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Catfish IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Catfish IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Catfish Score

Test Information

Test Name: Catfish Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Catfish Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Catfish Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Catfish Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Catfish Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Channel catfish IgA

Test Information

Test Name: Channel catfish IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Channel catfish IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Channel catfish IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Channel catfish IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Channel catfish IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Channel catfish IgG

Test Information

Test Name: Channel catfish IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Channel catfish IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Channel catfish IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Channel catfish IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Channel catfish IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinese spiny lobster IgA

Test Information

Test Name: Chinese spiny lobster IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chinese spiny lobster IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chinese spiny lobster IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chinese spiny lobster IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinese spiny lobster IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinese spiny lobster IgG

Test Information

Test Name: Chinese spiny lobster IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chinese spiny lobster IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chinese spiny lobster IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chinese spiny lobster IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinese spiny lobster IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinese white shrimp IgA

Test Information

Test Name: Chinese white shrimp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chinese white shrimp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chinese white shrimp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chinese white shrimp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinese white shrimp IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinese white shrimp IgG

Test Information

Test Name: Chinese white shrimp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chinese white shrimp IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chinese white shrimp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinese white shrimp IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinook salmon IgA

Test Information

Test Name: Chinook salmon IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chinook salmon IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chinook salmon IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chinook salmon IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinook salmon IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinook salmon IgG

Test Information

Test Name: Chinook salmon IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chinook salmon IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chinook salmon IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chinook salmon IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Chinook salmon IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Chub mackerel IgA

Test Information

Test Name: Chub mackerel IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chub mackerel IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chub mackerel IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chub mackerel IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Chub mackerel IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Chub mackerel IgG

Test Information

Test Name: Chub mackerel IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chub mackerel IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chub mackerel IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chub mackerel IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Chub mackerel IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Chum salmon IgA

Test Information

Test Name: Chum salmon IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chum salmon IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chum salmon IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chum salmon IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Chum salmon IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Chum salmon IgG

Test Information

Test Name: Chum salmon IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Chum salmon IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Chum salmon IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Chum salmon IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Chum salmon IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Clam IgA

Test Information

Test Name: Clam IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Clam IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Clam IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Clam IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Clam IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Clam IgG

Test Information

Test Name: Clam IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Clam IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Clam IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Clam IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Clam IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Clam Score

Test Information

Test Name: Clam Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Clam Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Clam Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Clam Score

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Cod and Pollock IgA

Test Information

Test Name: Cod and Pollock IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Cod and Pollock IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Cod and Pollock IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Cod and Pollock IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Cod and Pollock IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Cod and Pollock IgG

Test Information

Test Name: Cod and Pollock IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Cod and Pollock IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Cod and Pollock IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Cod and Pollock IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Cod and Pollock IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Codfish Score

Test Information

Test Name: Codfish Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Codfish Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Codfish Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Codfish Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Codfish Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Coho salmon IgA

Test Information

Test Name: Coho salmon IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Coho salmon IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Coho salmon IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Coho salmon IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Coho salmon IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Coho salmon IgG

Test Information

Test Name: Coho salmon IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Coho salmon IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Coho salmon IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Coho salmon IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Common carp IgA

Test Information

Test Name: Common carp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Common carp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Common carp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Common carp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Common carp IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Common carp IgG

Test Information

Test Name: Common carp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Common carp IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Common carp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Common carp IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Crab IgA

Test Information

Test Name: Crab IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Crab IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Crab IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Crab IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Crab IgG

Test Information

Test Name: Crab IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Crab IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Crab IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Crab IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Crab IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Crab Score

Test Information

Test Name: Crab Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Crab Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Crab Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Crab Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Crab Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Croaker IgA

Test Information

Test Name: Croaker IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Croaker IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Croaker IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Croaker IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Croaker IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Croaker IgG

Test Information

Test Name: Croaker IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Croaker IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Croaker IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Croaker IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Croaker IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Donax Clam IgA

Test Information

Test Name: Donax Clam IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donax Clam IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donax Clam IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donax Clam IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Donax Clam IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Donax Clam IgG

Test Information

Test Name: Donax Clam IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Donax Clam IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Donax Clam IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Donax Clam IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Donax Clam IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Dover sole IgA

Test Information

Test Name: Dover sole IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Dover sole IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Dover sole IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Dover sole IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Dover sole IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Dover sole IgG

Test Information

Test Name: Dover sole IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Dover sole IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Dover sole IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Dover sole IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : European anchovy IgA

Test Information

Test Name: European anchovy IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European anchovy IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European anchovy IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for European anchovy IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : European anchovy IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : European anchovy IgG

Test Information

Test Name: European anchovy IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European anchovy IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European anchovy IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for European anchovy IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : European anchovy IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : European Flat IgA

Test Information

Test Name: European Flat IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European Flat IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European Flat IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for European Flat IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : European Flat IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Seafood Zoomer : European Flat IgG

VibrantWellness

Test Information

Test Name: European Flat IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European Flat IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European Flat IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : European Flat IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : European lobster IgA

Test Information

Test Name: European lobster IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European lobster IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European lobster IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for European lobster IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : European lobster IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : European lobster IgG

Test Information

Test Name: European lobster IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European lobster IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European lobster IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for European lobster IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : European lobster IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : European pilchard IgA

Test Information

Test Name: European pilchard IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European pilchard IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European pilchard IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for European pilchard IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : European pilchard IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : European pilchard IgG

Test Information

Test Name: European pilchard IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European pilchard IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European pilchard IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : European pilchard IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : European plaice IgA

Test Information

Test Name: European plaice IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European plaice IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European plaice IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for European plaice IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : European plaice IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : European plaice IgG

Test Information

Test Name: European plaice IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European plaice IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European plaice IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for European plaice IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : European plaice IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : European snail IgA

Test Information

Test Name: European snail IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European snail IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European snail IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for European snail IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : European snail IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : European snail IgG

Test Information

Test Name: European snail IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for European snail IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for European snail IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for European snail IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : European snail IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Flatfish (Plaice, Sole, Flounder) IgA

Test Information

Test Name: Flatfish (Plaice, Sole, Flounder) IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Flatfish (Plaice, Sole, Flounder) IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Flatfish (Plaice, Sole, Flounder) IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Flatfish (Plaice, Sole, Flounder) IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Flatfish (Plaice, Sole, Flounder) IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Flatfish (Plaice, Sole, Flounder) IgG

Test Information

Test Name: Flatfish (Plaice, Sole, Flounder) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Flatfish (Plaice, Sole, Flounder) IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Flatfish (Plaice, Sole, Flounder) IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Flatfish (Plaice, Sole, Flounder) IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Flatfish (Plaice, Sole, Flounder) IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Flatfish Score

Test Information

Test Name: Flatfish Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Flatfish Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Flatfish Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Flatfish Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Flatfish Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Flathead lobster IgA

Test Information

Test Name: Flathead lobster IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Flathead lobster IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Flathead lobster IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Flathead lobster IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Flathead lobster IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Flathead lobster IgG

Test Information

Test Name: Flathead lobster IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Flathead lobster IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Flathead lobster IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Flathead lobster IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Flathead lobster IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Flounder Score

Test Information

Test Name: Flounder Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Flounder Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Flounder Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Flounder Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Flounder Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Freshwater crab IgA

Test Information

Test Name: Freshwater crab IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Freshwater crab IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Freshwater crab IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Freshwater crab IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Freshwater crab IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Freshwater crab IgG

Test Information

Test Name: Freshwater crab IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Freshwater crab IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Freshwater crab IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Freshwater crab IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Freshwater crab IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Garden snail IgA

Test Information

Test Name: Garden snail IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Garden snail IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Garden snail IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Garden snail IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Garden snail IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Garden snail IgG

Test Information

Test Name: Garden snail IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Garden snail IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Garden snail IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Garden snail IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Garden snail IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Geoduck IgA

Test Information

Test Name: Geoduck IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Geoduck IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Geoduck IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Geoduck IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Geoduck IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Geoduck IgG

Test Information

Test Name: Geoduck IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Geoduck IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Geoduck IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Geoduck IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Giant fresh water prawn IgA

Test Information

Test Name: Giant fresh water prawn IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Giant fresh water prawn IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Giant fresh water prawn IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Giant fresh water prawn IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Giant fresh water prawn IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Giant fresh water prawn IgG

Test Information

Test Name: Giant fresh water prawn IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Giant fresh water prawn IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Giant fresh water prawn IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Giant fresh water prawn IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Giant fresh water prawn IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Giant tiger prawn IgA

Test Information

Test Name: Giant tiger prawn IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Giant tiger prawn IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Giant tiger prawn IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Giant tiger prawn IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Giant tiger prawn IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Giant tiger prawn IgG

Test Information

Test Name: Giant tiger prawn IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Giant tiger prawn IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Giant tiger prawn IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Giant tiger prawn IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Giant tiger prawn IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Greasyback shrimp IgA

Test Information

Test Name: Greasyback shrimp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Greasyback shrimp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Greasyback shrimp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Greasyback shrimp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Greasyback shrimp IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Greasyback shrimp IgG

Test Information

Test Name: Greasyback shrimp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Greasyback shrimp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Greasyback shrimp IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Greasyback shrimp IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Haddock IgA

Test Information

Test Name: Haddock IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Haddock IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Haddock IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Haddock IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Haddock IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Haddock IgG

Test Information

Test Name: Haddock IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Haddock IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Haddock IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Haddock IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Hake IgA

Test Information

Test Name: Hake IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Hake IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Hake IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Hake IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Hake IgG

Test Information

Test Name: Hake IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Hake IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Hake IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Hake IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Hake IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Hard-Shell Clam IgA

Test Information

Test Name: Hard-Shell Clam IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Hard-Shell Clam IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Hard-Shell Clam IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Hard-Shell Clam IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Hard-Shell Clam IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Hard-Shell Clam IgG

Test Information

Test Name: Hard-Shell Clam IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Hard-Shell Clam IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Hard-Shell Clam IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Hard-Shell Clam IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Hard-Shell Clam IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Herring Score

Test Information

Test Name: Herring Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Herring Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Herring Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Herring Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Herring Score

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Horse Mussel IgA

Test Information

Test Name: Horse Mussel IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Horse Mussel IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Horse Mussel IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Horse Mussel IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Horse Mussel IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Horse Mussel IgG

Test Information

Test Name: Horse Mussel IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Horse Mussel IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Horse Mussel IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Horse Mussel IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Horse Mussel IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Icelandic Scallop IgA

Test Information

Test Name: Icelandic Scallop IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Icelandic Scallop IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Icelandic Scallop IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Icelandic Scallop IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Icelandic Scallop IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Icelandic Scallop IgG

Test Information

Test Name: Icelandic Scallop IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Icelandic Scallop IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Icelandic Scallop IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Icelandic Scallop IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Indian mackerel IgA

Test Information

Test Name: Indian mackerel IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Indian mackerel IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Indian mackerel IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Indian mackerel IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Indian mackerel IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Indian mackerel IgG

Test Information

Test Name: Indian mackerel IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Indian mackerel IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Indian mackerel IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Indian mackerel IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Indian mackerel IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Indian oil sardine IgA

Test Information

Test Name: Indian oil sardine IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Indian oil sardine IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Indian oil sardine IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Indian oil sardine IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Indian oil sardine IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Indian oil sardine IgG

Test Information

Test Name: Indian oil sardine IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Indian oil sardine IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Indian oil sardine IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Indian oil sardine IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Indian oil sardine IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Japanese jack mackerel IgA

Test Information

Test Name: Japanese jack mackerel IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Japanese jack mackerel IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Japanese jack mackerel IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Japanese jack mackerel IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Japanese jack mackerel IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

Seafood Zoomer : Japanese jack mackerel IgG

Test Information

Test Name: Japanese jack mackerel IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Japanese jack mackerel IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Japanese jack mackerel IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Japanese jack mackerel IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Japanese jack mackerel IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Japanese Scallop IgA

Test Information

Test Name: Japanese Scallop IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Japanese Scallop IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Japanese Scallop IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Japanese Scallop IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Japanese Scallop IgG

Test Information

Test Name: Japanese Scallop IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Japanese Scallop IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Japanese Scallop IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Japanese Scallop IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Kumamoto Oyster IgA

Test Information

Test Name: Kumamoto Oyster IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Kumamoto Oyster IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Kumamoto Oyster IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Kumamoto Oyster IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Kumamoto Oyster IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Kumamoto Oyster IgG

Test Information

Test Name: Kumamoto Oyster IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Kumamoto Oyster IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Kumamoto Oyster IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Kumamoto Oyster IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Kuruma prawn IgA

Test Information

Test Name: Kuruma prawn IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Kuruma prawn IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Kuruma prawn IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Kuruma prawn IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Kuruma prawn IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Kuruma prawn IgG

Test Information

Test Name: Kuruma prawn IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Kuruma prawn IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Kuruma prawn IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Kuruma prawn IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Kuruma prawn IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Lake Trout Score

Test Information

Test Name: Lake Trout Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lake Trout Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lake Trout Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lake Trout Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Lake Trout Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Largemouth bass IgA

Test Information

Test Name: Largemouth bass IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Largemouth bass IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Largemouth bass IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Largemouth bass IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Largemouth bass IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Largemouth bass IgG

Test Information

Test Name: Largemouth bass IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Largemouth bass IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Largemouth bass IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Largemouth bass IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Largemouth bass IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Lobster IgA

Test Information

Test Name: Lobster IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lobster IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lobster IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lobster IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Lobster IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Lobster IgG

Test Information

Test Name: Lobster IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lobster IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lobster IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lobster IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Lobster IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Lobster Score

Test Information

Test Name: Lobster Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Lobster Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Lobster Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Lobster Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Lobster Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Louisiana crawfish IgA

Test Information

Test Name: Louisiana crawfish IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Louisiana crawfish IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Louisiana crawfish IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Louisiana crawfish IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Louisiana crawfish IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Louisiana crawfish IgG

Test Information

Test Name: Louisiana crawfish IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Louisiana crawfish IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Louisiana crawfish IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Louisiana crawfish IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Louisiana crawfish IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Mackerel and Tuna IgA

Test Information

Test Name: Mackerel and Tuna IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Mackerel and Tuna IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Mackerel and Tuna IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Mackerel and Tuna IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Mackerel and Tuna IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Mackerel and Tuna IgG

Test Information

Test Name: Mackerel and Tuna IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Mackerel and Tuna IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Mackerel and Tuna IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Mackerel and Tuna IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Mackerel and Tuna IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Mackerel Score

Test Information

Test Name: Mackerel Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Mackerel Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Mackerel Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Mackerel Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Mackerel Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Manila Clam IgA

Test Information

Test Name: Manila Clam IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Manila Clam IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Manila Clam IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Manila Clam IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Manila Clam IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Manila Clam IgG

Test Information

Test Name: Manila Clam IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Manila Clam IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Manila Clam IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Manila Clam IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Manila Clam IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Masu salmon IgA

Test Information

Test Name: Masu salmon IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Masu salmon IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Masu salmon IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Masu salmon IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Masu salmon IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Masu salmon IgG

Test Information

Test Name: Masu salmon IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Masu salmon IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Masu salmon IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Masu salmon IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Masu salmon IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Monkfish IgA

Test Information

Test Name: Monkfish IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Monkfish IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Monkfish IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Monkfish IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Monkfish IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Monkfish IgG

Test Information

Test Name: Monkfish IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Monkfish IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Monkfish IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Monkfish IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Monkfish IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Mud crab IgA

Test Information

Test Name: Mud crab IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Mud crab IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Mud crab IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Mud crab IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Mud crab IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Mud crab IgG

Test Information

Test Name: Mud crab IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Mud crab IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Mud crab IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Mud crab IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Mud crab IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Mussel IgA

Test Information

Test Name: Mussel IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Mussel IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Mussel IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Mussel IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Mussel IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Mussel IgG

Test Information

Test Name: Mussel IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Mussel IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Mussel IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Mussel IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Mussel IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Northern red shrimp IgA

Test Information

Test Name: Northern red shrimp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Northern red shrimp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Northern red shrimp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Northern red shrimp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Northern red shrimp IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Northern red shrimp IgG

Test Information

Test Name: Northern red shrimp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Northern red shrimp IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Northern red shrimp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Northern red shrimp IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Northern red shrimp IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Ocean Quahog IgA

Test Information

Test Name: Ocean Quahog IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ocean Quahog IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ocean Quahog IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ocean Quahog IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Ocean Quahog IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Ocean Quahog IgG

Test Information

Test Name: Ocean Quahog IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Ocean Quahog IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Ocean Quahog IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Ocean Quahog IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Ocean Quahog IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Octopus IgA

Test Information

Test Name: Octopus IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Octopus IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Octopus IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Octopus IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Octopus IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Octopus IgG

Test Information

Test Name: Octopus IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Octopus IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Octopus IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Octopus IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Octopus IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Octopus Score

Test Information

Test Name: Octopus Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Octopus Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Octopus Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Octopus Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Octopus Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Olive flounder IgA

Test Information

Test Name: Olive flounder IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Olive flounder IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Olive flounder IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Olive flounder IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Olive flounder IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Olive flounder IgG

Test Information

Test Name: Olive flounder IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Olive flounder IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Olive flounder IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Olive flounder IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Olive flounder IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Olympia Oyster IgA

Test Information

Test Name: Olympia Oyster IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Olympia Oyster IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Olympia Oyster IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Olympia Oyster IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Olympia Oyster IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Olympia Oyster IgG

Test Information

Test Name: Olympia Oyster IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Olympia Oyster IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Olympia Oyster IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Olympia Oyster IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Olympia Oyster IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Orange mud crab IgA

Test Information

Test Name: Orange mud crab IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Orange mud crab IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Orange mud crab IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Orange mud crab IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Orange mud crab IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Orange mud crab IgG

Test Information

Test Name: Orange mud crab IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Orange mud crab IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Orange mud crab IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Orange mud crab IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Orange mud crab IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Oyster IgA

Test Information

Test Name: Oyster IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oyster IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oyster IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Oyster IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Oyster IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Oyster IgG

Test Information

Test Name: Oyster IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oyster IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oyster IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Oyster IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Oyster Score

Test Information

Test Name: Oyster Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Oyster Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Oyster Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Oyster Score

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific cod IgA

Test Information

Test Name: Pacific cod IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pacific cod IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pacific cod IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific cod IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific cod IgG

Test Information

Test Name: Pacific cod IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pacific cod IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pacific cod IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pacific cod IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific cod IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific herring IgA

Test Information

Test Name: Pacific herring IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pacific herring IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pacific herring IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pacific herring IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific herring IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific herring IgG

Test Information

Test Name: Pacific herring IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pacific herring IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pacific herring IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pacific herring IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific herring IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific Oyster IgA

Test Information

Test Name: Pacific Oyster IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pacific Oyster IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pacific Oyster IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pacific Oyster IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific Oyster IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific Oyster IgG

Test Information

Test Name: Pacific Oyster IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pacific Oyster IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pacific Oyster IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pacific Oyster IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pacific Oyster IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Patagonian toothfish IgA

Test Information

Test Name: Patagonian toothfish IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Patagonian toothfish IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Patagonian toothfish IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Patagonian toothfish IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Patagonian toothfish IgG

Test Information

Test Name: Patagonian toothfish IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Patagonian toothfish IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Patagonian toothfish IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Patagonian toothfish IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Penaeid shrimp IgA

Test Information

Test Name: Penaeid shrimp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Penaeid shrimp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Penaeid shrimp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Penaeid shrimp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Penaeid shrimp IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Penaeid shrimp IgG

Test Information

Test Name: Penaeid shrimp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Penaeid shrimp IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Penaeid shrimp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Penaeid shrimp IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Penaeid shrimp IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Peruvian anchoveta IgA

Test Information

Test Name: Peruvian anchoveta IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Peruvian anchoveta IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Peruvian anchoveta IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Peruvian anchoveta IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Peruvian anchoveta IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Peruvian anchoveta IgG

Test Information

Test Name: Peruvian anchoveta IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Peruvian anchoveta IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Peruvian anchoveta IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Peruvian anchoveta IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Peruvian anchoveta IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pilchard Score

Test Information

Test Name: Pilchard Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pilchard Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pilchard Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pilchard Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pilchard Score

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pink salmon IgA

Test Information

Test Name: Pink salmon IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pink salmon IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pink salmon IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pink salmon IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pink salmon IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pink salmon IgG

Test Information

Test Name: Pink salmon IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pink salmon IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pink salmon IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pink salmon IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pink Scallop IgA

Test Information

Test Name: Pink Scallop IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pink Scallop IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pink Scallop IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pink Scallop IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pink Scallop IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pink Scallop IgG

Test Information

Test Name: Pink Scallop IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pink Scallop IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pink Scallop IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pink Scallop IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pink Scallop IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Plaice Score

Test Information

Test Name: Plaice Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Plaice Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Plaice Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Plaice Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Plaice Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Prawn Score

Test Information

Test Name: Prawn Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Prawn Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Prawn Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Prawn Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Prawn Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Prussian carp IgA

Test Information

Test Name: Prussian carp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Prussian carp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Prussian carp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Prussian carp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Prussian carp IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Prussian carp IgG

Test Information

Test Name: Prussian carp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Prussian carp IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Prussian carp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Prussian carp IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Prussian carp IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pufferfish IgA

Test Information

Test Name: Pufferfish IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pufferfish IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pufferfish IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Pufferfish IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pufferfish IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Pufferfish IgG

Test Information

Test Name: Pufferfish IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Pufferfish IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Pufferfish IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Pufferfish IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Queen Scallop IgA

Test Information

Test Name: Queen Scallop IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Queen Scallop IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Queen Scallop IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Queen Scallop IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Queen Scallop IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Queen Scallop IgG

Test Information

Test Name: Queen Scallop IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Queen Scallop IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Queen Scallop IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Queen Scallop IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Queen Scallop IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Rabbitsfoot Mussel IgA

Test Information

Test Name: Rabbitsfoot Mussel IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rabbitsfoot Mussel IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rabbitsfoot Mussel IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Rabbitsfoot Mussel IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Rabbitsfoot Mussel IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Rabbitsfoot Mussel IgG

Test Information

Test Name: Rabbitsfoot Mussel IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rabbitsfoot Mussel IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rabbitsfoot Mussel IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Rabbitsfoot Mussel IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Rabbitsfoot Mussel IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Rainbow trout IgA

Test Information

Test Name: Rainbow trout IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rainbow trout IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rainbow trout IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Rainbow trout IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Rainbow trout IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Rainbow trout IgG

Test Information

Test Name: Rainbow trout IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Rainbow trout IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rainbow trout IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Rainbow trout IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Rainbow trout IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Razor Clam IgA

Test Information

Test Name: Razor Clam IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Razor Clam IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Razor Clam IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Razor Clam IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Razor Clam IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Razor Clam IgG

Test Information

Test Name: Razor Clam IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Razor Clam IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Razor Clam IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Razor Clam IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Razor Clam IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Red king crab IgA

Test Information

Test Name: Red king crab IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Red king crab IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Red king crab IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Red king crab IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Red king crab IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Red king crab IgG

Test Information

Test Name: Red king crab IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Red king crab IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Red king crab IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Red king crab IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Roman snail IgA

Test Information

Test Name: Roman snail IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Roman snail IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Roman snail IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Roman snail IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Roman snail IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Roman snail IgG

Test Information

Test Name: Roman snail IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Roman snail IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Roman snail IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Roman snail IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Roman snail IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Salmon and Trout IgA

Test Information

Test Name: Salmon and Trout IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Salmon and Trout IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Salmon and Trout IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Salmon and Trout IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Salmon and Trout IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Salmon and Trout IgG

Test Information

Test Name: Salmon and Trout IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Salmon and Trout IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Salmon and Trout IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Salmon and Trout IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Salmon and Trout IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Salmon Score

Test Information

Test Name: Salmon Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Salmon Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Salmon Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Salmon Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Salmon Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Sand shrimp IgA

Test Information

Test Name: Sand shrimp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sand shrimp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sand shrimp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sand shrimp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Sand shrimp IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Sand shrimp IgG

Test Information

Test Name: Sand shrimp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sand shrimp IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sand shrimp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sand shrimp IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Sand shrimp IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Sardine Score

Test Information

Test Name: Sardine Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sardine Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sardine Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sardine Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Sardine Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Seafood Zoomer : Sardine, Herring, Pilchard IgA

VibrantWellness

Test Information

Test Name: Sardine, Herring, Pilchard IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sardine, Herring, Pilchard IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sardine, Herring, Pilchard IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sardine, Herring, Pilchard IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Sardine, Herring, Pilchard IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Sardine, Herring, Pilchard IgG

Test Information

Test Name: Sardine, Herring, Pilchard IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sardine, Herring, Pilchard IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sardine, Herring, Pilchard IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sardine, Herring, Pilchard IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Sardine, Herring, Pilchard IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Scallop IgA

Test Information

Test Name: Scallop IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Scallop IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Scallop IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Scallop IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Scallop IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Scallop IgG

Test Information

Test Name: Scallop IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Scallop IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Scallop IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Scallop IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Scallop IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Scallops Score

Test Information

Test Name: Scallops Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Scallops Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Scallops Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Scallops Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Scallops Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Sea Scallop IgA

Test Information

Test Name: Sea Scallop IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sea Scallop IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sea Scallop IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sea Scallop IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Sea Scallop IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Sea Scallop IgG

Test Information

Test Name: Sea Scallop IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sea Scallop IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sea Scallop IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sea Scallop IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Sea Scallop IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Shrimp and Prawn IgA

Test Information

Test Name: Shrimp and Prawn IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Shrimp and Prawn IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Shrimp and Prawn IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Shrimp and Prawn IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Shrimp and Prawn IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Shrimp and Prawn IgG

Test Information

Test Name: Shrimp and Prawn IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Shrimp and Prawn IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Shrimp and Prawn IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Shrimp and Prawn IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Shrimp and Prawn IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Shrimp Score

Test Information

Test Name: Shrimp Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Shrimp Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Shrimp Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Shrimp Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Shrimp Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Silver carp IgA

Test Information

Test Name: Silver carp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Silver carp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Silver carp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Silver carp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Silver carp IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Silver carp IgG

Test Information

Test Name: Silver carp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Silver carp IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Silver carp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Silver carp IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Silver carp IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Skipjack tuna IgA

Test Information

Test Name: Skipjack tuna IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Skipjack tuna IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Skipjack tuna IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Skipjack tuna IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Skipjack tuna IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Skipjack tuna IgG

Test Information

Test Name: Skipjack tuna IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Skipjack tuna IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Skipjack tuna IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Skipjack tuna IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Skipjack tuna IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Snail IgA

Test Information

Test Name: Snail IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Snail IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Snail IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Snail IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Snail IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Snail IgG

Test Information

Test Name: Snail IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Snail IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Snail IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Snail IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Snail IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Snail Score

Test Information

Test Name: Snail Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Snail Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Snail Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Snail Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Snail Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Snuffbox Mussel IgA

Test Information

Test Name: Snuffbox Mussel IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Snuffbox Mussel IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Snuffbox Mussel IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Snuffbox Mussel IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Snuffbox Mussel IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Snuffbox Mussel IgG

Test Information

Test Name: Snuffbox Mussel IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Snuffbox Mussel IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Snuffbox Mussel IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Snuffbox Mussel IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Snuffbox Mussel IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Sockeye salmon IgA

Test Information

Test Name: Sockeye salmon IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sockeye salmon IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sockeye salmon IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sockeye salmon IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Sockeye salmon IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Sockeye salmon IgG

Test Information

Test Name: Sockeye salmon IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sockeye salmon IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sockeye salmon IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sockeye salmon IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Sockeye salmon IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Soft-Shell Clam IgA

Test Information

Test Name: Soft-Shell Clam IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Soft-Shell Clam IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Soft-Shell Clam IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Soft-Shell Clam IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Soft-Shell Clam IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Soft-Shell Clam IgG

Test Information

Test Name: Soft-Shell Clam IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Soft-Shell Clam IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Soft-Shell Clam IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Soft-Shell Clam IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Soft-Shell Clam IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Sole Score

Test Information

Test Name: Sole Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Sole Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Sole Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Sole Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Sole Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Seafood Zoomer : South African spiny lobster IgA

VibrantWellness

Test Information

Test Name: South African spiny lobster IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for South African spiny lobster IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for South African spiny lobster IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for South African spiny lobster IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : South African spiny lobster IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

Seafood Zoomer : South African spiny lobster IgG

VibrantWellness

Test Information

Test Name: South African spiny lobster IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for South African spiny lobster IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for South African spiny lobster IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for South African spiny lobster IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : South African spiny lobster IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Squid IgA

Test Information

Test Name: Squid IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Squid IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Squid IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Squid IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Squid IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Squid IgG

Test Information

Test Name: Squid IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Squid IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Squid IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Squid IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Squid IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Squid Score

Test Information

Test Name: Squid Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Squid Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Squid Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Squid Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Squid Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Striped bass IgA

Test Information

Test Name: Striped bass IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Striped bass IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Striped bass IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Striped bass IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Striped bass IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Striped bass IgG

Test Information

Test Name: Striped bass IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Striped bass IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Striped bass IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Striped bass IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Striped bass IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Surf Clam IgA

Test Information

Test Name: Surf Clam IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Surf Clam IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Surf Clam IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Surf Clam IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Surf Clam IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Surf Clam IgG

Test Information

Test Name: Surf Clam IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Surf Clam IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Surf Clam IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Surf Clam IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Surf Clam IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Swordfish IgA

Test Information

Test Name: Swordfish IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Swordfish IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Swordfish IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Swordfish IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Swordfish IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Swordfish IgG

Test Information

Test Name: Swordfish IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Swordfish IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Swordfish IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Swordfish IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Swordfish IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Tilapia IgA

Test Information

Test Name: Tilapia IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tilapia IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tilapia IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Tilapia IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Tilapia IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Tilapia IgG

Test Information

Test Name: Tilapia IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tilapia IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tilapia IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Tilapia IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Seafood Zoomer : Tilapia IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Tuna Score

Test Information

Test Name: Tuna Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tuna Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tuna Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Tuna Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Tuna Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Weathervane Scallop IgA

Test Information

Test Name: Weathervane Scallop IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Weathervane Scallop IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Weathervane Scallop IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Weathervane Scallop IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Weathervane Scallop IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Weathervane Scallop IgG

Test Information

Test Name: Weathervane Scallop IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Weathervane Scallop IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Weathervane Scallop IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Weathervane Scallop IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Weathervane Scallop IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Whiteleg shrimp IgA

Test Information

Test Name: Whiteleg shrimp IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Whiteleg shrimp IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Whiteleg shrimp IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Whiteleg shrimp IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Whiteleg shrimp IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Whiteleg shrimp IgG

Test Information

Test Name: Whiteleg shrimp IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Whiteleg shrimp IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Whiteleg shrimp IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Whiteleg shrimp IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Whiteleg shrimp IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Yellowfin tuna IgA

Test Information

Test Name: Yellowfin tuna IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Yellowfin tuna IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Yellowfin tuna IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Yellowfin tuna IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Yellowfin tuna IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Yellowfin tuna IgG

Test Information

Test Name: Yellowfin tuna IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Yellowfin tuna IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Yellowfin tuna IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Yellowfin tuna IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Yellowfin tuna IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Zebra Mussel IgA

Test Information

Test Name: Zebra Mussel IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Zebra Mussel IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Zebra Mussel IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Zebra Mussel IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Seafood Zoomer : Zebra Mussel IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Seafood Zoomer : Zebra Mussel IgG

Test Information

Test Name: Zebra Mussel IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Zebra Mussel IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Seafood Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Zebra Mussel IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Seafood Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Zebra Mussel IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Seafood Zoomer : Zebra Mussel IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Seafood ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in seafood Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Cry1Ac GMO protein IgA

Test Information

Test Name: Cry1Ac GMO protein IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Cry1Ac GMO protein IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Cry1Ac GMO protein IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Cry1Ac GMO protein IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Cry1Ac GMO protein IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Cry1Ac GMO protein IgG

Test Information

Test Name: Cry1Ac GMO protein IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Cry1Ac GMO protein IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Cry1Ac GMO protein IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Cry1Ac GMO protein IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Cry1Ac GMO protein IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 1 IgA

Test Information

Test Name: Gly m 1 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 1 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 1 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 1 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 1 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 1 IgG

Test Information

Test Name: Gly m 1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 1 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 1 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 1 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 1 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 2 IgA

Test Information

Test Name: Gly m 2 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 2 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 2 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 2 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 2 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 2 IgG

Test Information

Test Name: Gly m 2 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 2 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 2 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 2 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 2 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 3 IgA

Test Information

Test Name: Gly m 3 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 3 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 3 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 3 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 3 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 3 IgG

Test Information

Test Name: Gly m 3 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 3 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 3 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 3 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 3 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 4 IgA

Test Information

Test Name: Gly m 4 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 4 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 4 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 4 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 4 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 4 IgG

Test Information

Test Name: Gly m 4 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 4 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 4 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 4 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 4 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 5 IgA

Test Information

Test Name: Gly m 5 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 5 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 5 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 5 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 5 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 5 IgG

Test Information

Test Name: Gly m 5 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 5 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 5 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 5 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 5 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 6 IgA

Test Information

Test Name: Gly m 6 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 6 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 6 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 6 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 6 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 6 IgG

Test Information

Test Name: Gly m 6 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 6 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 6 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 6 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 6 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 7 IgA

Test Information

Test Name: Gly m 7 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 7 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 7 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 7 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 7 IgA

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 7 IgG

Test Information

Test Name: Gly m 7 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 7 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 7 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 7 IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 7 IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

Vibrant America Clinical Laboratory is committed to delivering services that consistently meet the requirements and expectations of our customers. The commitment to quality includes considerations involving the use of continually developing methods, good practices, our own desire to constantly improve, and operating under an effective Quality Management System that meets regulatory requirements.

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 8 IgA

Test Information

Test Name: Gly m 8 IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 8 IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 8 IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m 8 IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 8 IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 8 IgG

Test Information

Test Name: Gly m 8 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m 8 IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m 8 IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m 8 IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m Bd 30k IgA

Test Information

Test Name: Gly m Bd 30k IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m Bd 30k IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m Bd 30k IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m Bd 30k IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m Bd 30k IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m Bd 30k IgG

Test Information

Test Name: Gly m Bd 30k IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Gly m Bd 30k IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Gly m Bd 30k IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Gly m Bd 30k IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

VibrantWellness

Soy Zoomer : Gly m Bd 30k IgG

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Kunitz Soybean Trypsin Inhibitor IgA

Test Information

Test Name: Kunitz Soybean Trypsin Inhibitor IgA

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Kunitz Soybean Trypsin Inhibitor IgA.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Kunitz Soybean Trypsin Inhibitor IgA as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Kunitz Soybean Trypsin Inhibitor IgA on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Certificate of Quality

Soy Zoomer : Kunitz Soybean Trypsin Inhibitor IgA

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Kunitz Soybean Trypsin Inhibitor IgG

Test Information

Test Name: Kunitz Soybean Trypsin Inhibitor IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Kunitz Soybean Trypsin Inhibitor IgG.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Kunitz Soybean Trypsin Inhibitor IgG as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Kunitz Soybean Trypsin Inhibitor IgG on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

Soy Zoomer : Kunitz Soybean Trypsin Inhibitor IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21

Certificate of Quality

VibrantWellness

Soy Zoomer : Soy Score

Test Information

Test Name: Soy Score

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Soy Score.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Soy Zoomer Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Soy Score as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Soy Zoomer Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Soy Score on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-01

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

VibrantWellness

Soy Zoomer : Soy Score

Analyte Reference Range

One hundred ninety two serum samples from apparently healthy donors including 96 males ranging in age from 17-86 and 96 females ranging in age from 19-69 were tested with Soy ZoomerTM IgG and IgA kit. The reference ranges have been established for all tests in Soy Zoomer to have index value as shown below ,

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2.1	units

Quality Statement

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Report Generated Date: 2021-10-21