Certificate of Quality

VibrantWellness

Digestive markers : Acetate

Test Information

Test Name: Acetate

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : Acetate

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	60.2 - 72.8	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: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Beta defensin 2

Test Information

Test Name: Beta defensin 2

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is 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 defensin 2.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure 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 defensin 2 as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose 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 defensin 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: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : Beta defensin 2

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 35.0	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: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Butyrate

Test Information

Test Name: Butyrate

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : Butyrate

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	5.1 - 12.5	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: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Calprotectin

Test Information

Test Name: Calprotectin

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Calprotectin

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 50.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Digestive markers : Chenodeoxycholic acid (CDCA)

Test Information

Test Name: Chenodeoxycholic acid (CDCA)

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : Chenodeoxycholic acid (CDCA)

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 1.26	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: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Cholic acid (CA)

Test Information

Test Name: Cholic acid (CA)

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : Cholic acid (CA)

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 0.37	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: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Deoxycholic acid (DCA)

Test Information

Test Name: Deoxycholic acid (DCA)

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : Deoxycholic acid (DCA)

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	24.25 - 75.85	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: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Fecal Anti Gliadin

Test Information

Test Name: Fecal Anti Gliadin

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : Fecal Anti Gliadin

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 148.1	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: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Fecal Eosinophil Protein X

Test Information

Test Name: Fecal Eosinophil Protein X

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : Fecal Eosinophil Protein X

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 4.9	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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Certificate of Quality

VibrantWellness

Digestive markers : Fecal lactoferrin

Test Information

Test Name: Fecal lactoferrin

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Fecal lactoferrin

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 6.5	units

Quality Statement

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Certificate of Quality

VibrantWellness

Digestive markers : Fecal Occult Blood

Test Information

Test Name: Fecal Occult Blood

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Fecal Occult Blood

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 10.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Fecal Zonulin

Test Information

Test Name: Fecal Zonulin

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Fecal Zonulin

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	25.1 - 160.9	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : LCA/DCA ratio

Test Information

Test Name: LCA/DCA ratio

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : LCA/DCA ratio

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	0.32 - 3.39	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: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Lithocholic acid (LCA)

Test Information

Test Name: Lithocholic acid (LCA)

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Lithocholic acid (LCA)

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	24.16 - 75.76	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Long chain fatty acids

Test Information

Test Name: Long chain fatty acids

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Long chain fatty acids

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	0.9 - 28.2	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Lysozyme

Test Information

Test Name: Lysozyme

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is 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.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure 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 as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : Lysozyme

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 575.1	units

Quality Statement

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The laboratory 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: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Meat fiber

Test Information

Test Name: Meat fiber

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Digestive markers : Meat fiber

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Unit
For All Ages	Male / Female	NOT DETECTED	units
For All Ages	Male / Female	DETECTED	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: 2021-11-17

Certificate of Quality

VibrantWellness

Digestive markers : MMP 9

Test Information

Test Name: MMP 9

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for MMP 9.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for MMP 9 as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for MMP 9 on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : MMP 9

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 0.3	units

Quality Statement

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Certificate of Quality

VibrantWellness

Digestive markers : Pancreatic elastase 1

Test Information

Test Name: Pancreatic elastase 1

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Pancreatic elastase 1

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	100.1 - 200.0	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : pH

Test Information

Test Name: pH

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : pH

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	6.1 - 7.9	units

Quality Statement

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Certificate of Quality

VibrantWellness

Digestive markers : Propionate

Test Information

Test Name: Propionate

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Propionate

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	15.4 - 30.4	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : S100A12

Test Information

Test Name: S100A12

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for S100A12.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for S100A12 as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for S100A12 on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : S100A12

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 50.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : sIgA

Test Information

Test Name: sIgA

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : sIgA

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 857.1	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: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : ß-glucuronidase

Test Information

Test Name: ß-glucuronidase

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : ß-glucuronidase

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	< 2301	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Total Cholesterol

Test Information

Test Name: Total Cholesterol

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : Total Cholesterol

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	0.5 - 5.4	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: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Total Fecal Fat

Test Information

Test Name: Total Fecal Fat

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Total Fecal Fat

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	2.9 - 37.6	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Total Fecal Triglycerides

Test Information

Test Name: Total Fecal Triglycerides

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Total Fecal Triglycerides

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	0.3 - 2.6	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Total Phospholipids

Test Information

Test Name: Total Phospholipids

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Total Phospholipids

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	0.3 - 6.5	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Digestive markers : Total Short chain fatty acids

Test Information

Test Name: Total Short chain fatty acids

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Total Short chain fatty acids

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	45.4 - 210.2	units

Quality Statement

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Certificate of Quality

VibrantWellness

Digestive markers : Valerate

Test Information

Test Name: Valerate

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

The laboratory 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

Digestive markers : Valerate

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Reference Range Unit
For All Ages	Male / Female	0.8 - 3.6	units

Quality Statement

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Certificate of Quality

VibrantWellness

Digestive markers : Vegetable fiber

Test Information

Test Name: Vegetable fiber

Reagent Manufacturer: Vibrant

Instrument: Waters Xevo TQ-XS Mass Spectrometry System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Digestive Markers Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Digestive Markers Calibrator

External Quality Assessment / Proficiency Testing

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

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2022-02

2021 Event 1	2021 Event 2	2022 Event 1
Pass	Pass	Pass

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

VibrantWellness

Digestive markers : Vegetable fiber

Analyte Reference Range

Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable.

Age Group	Gender	Reference Range	Unit
For All Ages	Male / Female	NOT DETECTED	units
For All Ages	Male / Female	DETECTED	units

Quality Statement

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Report Generated Date: 2022-03-25