Certificate of Quality

VibrantWellness

Gut Commensal : Acinetobacter

Test Information

Test Name: Acinetobacter

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Acinetobacter

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Actinobacteria

Test Information

Test Name: Actinobacteria

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Actinobacteria

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

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Akkermansia muciniphila

Test Information

Test Name: Akkermansia muciniphila

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Akkermansia muciniphila

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Akkermansia

Test Information

Test Name: Akkermansia

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Akkermansia

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Alloprevotella

Test Information

Test Name: Alloprevotella

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Alloprevotella

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	0.0 - 10.0	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Atopobium parvulum

Test Information

Test Name: Atopobium parvulum

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Atopobium parvulum

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Atopobium

Test Information

Test Name: Atopobium

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Atopobium

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Autoimmune health

Test Information

Test Name: Autoimmune health

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Autoimmune health

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	< 2.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Bacillus coagulans

Test Information

Test Name: Bacillus coagulans

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bacillus coagulans

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	0.0 - 10.0	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

Gut Commensal : Bacillus subtilis

Test Information

Test Name: Bacillus subtilis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bacillus subtilis

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Bacteroidales

Test Information

Test Name: Bacteroidales

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bacteroidales

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Bacteroides caccae

Test Information

Test Name: Bacteroides caccae

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bacteroides caccae

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Bacteroides vulgatus

Test Information

Test Name: Bacteroides vulgatus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bacteroides vulgatus

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Bacteroides

Test Information

Test Name: Bacteroides

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bacteroides

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Bacteroidetes

Test Information

Test Name: Bacteroidetes

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bacteroidetes

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

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Bifidobacterium adolescentis

Test Information

Test Name: Bifidobacterium adolescentis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Bifidobacterium adolescentis on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high 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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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Bifidobacterium adolescentis

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Bifidobacterium animalis subspecies lactis

Test Information

Test Name: Bifidobacterium animalis subspecies lactis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bifidobacterium animalis subspecies lactis

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	0.0 - 10.0	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

Gut Commensal : Bifidobacterium animalis

Test Information

Test Name: Bifidobacterium animalis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bifidobacterium animalis

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Bifidobacterium bifidum

Test Information

Test Name: Bifidobacterium bifidum

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bifidobacterium bifidum

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	0.0 - 10.0	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Bifidobacterium breve

Test Information

Test Name: Bifidobacterium breve

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bifidobacterium breve

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

Gut Commensal : Bifidobacterium catenulatum

VibrantWellness

Test Information

Test Name: Bifidobacterium catenulatum

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bifidobacterium catenulatum

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Bifidobacterium dentium

Test Information

Test Name: Bifidobacterium dentium

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bifidobacterium dentium

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

Gut Commensal : Bifidobacterium infantis

VibrantWellness

Test Information

Test Name: Bifidobacterium infantis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bifidobacterium infantis

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Bifidobacterium lactis

Test Information

Test Name: Bifidobacterium lactis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bifidobacterium lactis

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Bifidobacterium longum

Test Information

Test Name: Bifidobacterium longum

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bifidobacterium longum

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	0.0 - 10.0	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

Gut Commensal : Bifidobacterium

Test Information

Test Name: Bifidobacterium

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bifidobacterium

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

Gut Commensal : Blautia hydrogenotorophica

VibrantWellness

Test Information

Test Name: Blautia hydrogenotorophica

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Blautia hydrogenotorophica

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Blautia

Test Information

Test Name: Blautia

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Blautia

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

Gut Commensal : Bradyrhizobiaceae

VibrantWellness

Test Information

Test Name: Bradyrhizobiaceae

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Bradyrhizobiaceae

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Butyricimonas

Test Information

Test Name: Butyricimonas

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Butyricimonas

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Butyrivibrio

Test Information

Test Name: Butyrivibrio

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Butyrivibrio

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Cardiovascular health

Test Information

Test Name: Cardiovascular health

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Cardiovascular health

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	< 2.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Catenibacterium

Test Information

Test Name: Catenibacterium

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Catenibacterium

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	0.0 - 10.0	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

Gut Commensal : Christensenella minuta

Test Information

Test Name: Christensenella minuta

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Christensenella minuta

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Clostridia clusters IV

Test Information

Test Name: Clostridia clusters IV

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Clostridia clusters IV

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Clostridia clusters XIVa

Test Information

Test Name: Clostridia clusters XIVa

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Clostridia clusters XIVa

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Clostridia clusters XVIII

Test Information

Test Name: Clostridia clusters XVIII

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Clostridia clusters XVIII

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Clostridiales Family XIV Incertae Sedis

Test Information

Test Name: Clostridiales Family XIV Incertae Sedis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

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Certificate of Quality

VibrantWellness

Gut Commensal : Clostridiales Family XIV Incertae Sedis

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Clostridium hathewayi

Test Information

Test Name: Clostridium hathewayi

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Clostridium hathewayi

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Clostridium ramosum

Test Information

Test Name: Clostridium ramosum

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Clostridium ramosum

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Clostridium symbiosum

Test Information

Test Name: Clostridium symbiosum

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Clostridium symbiosum

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	< 20.1	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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Certificate of Quality

VibrantWellness

Gut Commensal : Clostridium

Test Information

Test Name: Clostridium

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Clostridium

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	< 20.1	units

Quality Statement

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Certificate of Quality

Gut Commensal : Clotridiales Incertae Sedis IV

VibrantWellness

Test Information

Test Name: Clotridiales Incertae Sedis IV

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Clotridiales Incertae Sedis IV

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Collinsella

Test Information

Test Name: Collinsella

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Collinsella

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Coprococcus

Test Information

Test Name: Coprococcus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Coprococcus

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Desulfovibrio piger

Test Information

Test Name: Desulfovibrio piger

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Desulfovibrio piger

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Desulfovibrio

Test Information

Test Name: Desulfovibrio

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Desulfovibrio

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Dialister invisus

Test Information

Test Name: Dialister invisus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Dialister invisus

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Dorea

Test Information

Test Name: Dorea

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Dorea

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	< 20.1	units

Quality Statement

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

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

Certificate of Quality

Gut Commensal : Eggerthella lenta

Test Information

Test Name: Eggerthella lenta

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Eggerthella lenta

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Enterobacter aerogenes

Test Information

Test Name: Enterobacter aerogenes

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Enterobacter aerogenes

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Enterobacteria

Test Information

Test Name: Enterobacteria

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Enterobacteria

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	< 20.1	units

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Certificate of Quality

VibrantWellness

Gut Commensal : Enterobacteriaceae

Test Information

Test Name: Enterobacteriaceae

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

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Certificate of Quality

VibrantWellness

Gut Commensal : Enterobacteriaceae

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Enterococcus gallinarum

Test Information

Test Name: Enterococcus gallinarum

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Enterococcus gallinarum

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Enterococcus species

Test Information

Test Name: Enterococcus species

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Enterococcus species

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Enterococcus

Test Information

Test Name: Enterococcus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Enterococcus

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Escherichia coli Nissle

Test Information

Test Name: Escherichia coli Nissle

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Escherichia coli Nissle

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Escherichia coli

Test Information

Test Name: Escherichia coli

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Escherichia coli

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	< 20.1	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

Gut Commensal : Eubacterium rectale

Test Information

Test Name: Eubacterium rectale

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Eubacterium rectale

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Eubacterium

Test Information

Test Name: Eubacterium

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Eubacterium

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Euryarchaeota

Test Information

Test Name: Euryarchaeota

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Euryarchaeota

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

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Faecalibacterium prausnitzii

Test Information

Test Name: Faecalibacterium prausnitzii

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Faecalibacterium prausnitzii

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

Gut Commensal : Faecalibacterium

Test Information

Test Name: Faecalibacterium

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Faecalibacterium

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	0.0 - 10.0	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : F/B

Test Information

Test Name: F/B

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : F/B

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	< 1.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Firmicutes

Test Information

Test Name: Firmicutes

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Firmicutes

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

Quality Statement

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Certificate of Quality

Gut Commensal : Fusobacteria

VibrantWellness

Test Information

Test Name: Fusobacteria

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Fusobacteria

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

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

Gut Commensal : Fusobacterium

Test Information

Test Name: Fusobacterium

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Fusobacterium

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Haemophilus

Test Information

Test Name: Haemophilus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Haemophilus

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Hormones

Test Information

Test Name: Hormones

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Hormones

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	< 2.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : IBD

Test Information

Test Name: IBD

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : IBD

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	< 2.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : IBS

Test Information

Test Name: IBS

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : IBS

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	< 2.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Intestinal permeability

Test Information

Test Name: Intestinal permeability

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Intestinal permeability

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	< 2.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

Gut Commensal : Lachnospiraceae

VibrantWellness

Test Information

Test Name: Lachnospiraceae

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lachnospiraceae

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

Gut Commensal : Lactobacillaceae

VibrantWellness

Test Information

Test Name: Lactobacillaceae

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillaceae

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	< 20.1	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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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus acidophilus

Test Information

Test Name: Lactobacillus acidophilus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus acidophilus

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus animalis

Test Information

Test Name: Lactobacillus animalis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus animalis

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus brevis

Test Information

Test Name: Lactobacillus brevis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus brevis

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus bulgaricus

Test Information

Test Name: Lactobacillus bulgaricus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus bulgaricus

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus casei

Test Information

Test Name: Lactobacillus casei

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus casei

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus fermentum

Test Information

Test Name: Lactobacillus fermentum

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus fermentum

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus paracasei

Test Information

Test Name: Lactobacillus paracasei

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus paracasei

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus plantarum

Test Information

Test Name: Lactobacillus plantarum

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus plantarum

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	0.0 - 10.0	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

Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus reuteri

Test Information

Test Name: Lactobacillus reuteri

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus reuteri

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus rhamnosus GG

Test Information

Test Name: Lactobacillus rhamnosus GG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus rhamnosus GG

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus rhamnosus

Test Information

Test Name: Lactobacillus rhamnosus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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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

Gut Commensal : Lactobacillus rhamnosus

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus ruminis

Test Information

Test Name: Lactobacillus ruminis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus ruminis

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus sakei

Test Information

Test Name: Lactobacillus sakei

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus sakei

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus salivarius

Test Information

Test Name: Lactobacillus salivarius

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus salivarius

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactobacillus

Test Information

Test Name: Lactobacillus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactobacillus

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Lactococcus

Test Information

Test Name: Lactococcus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Lactococcus

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	0.0 - 10.0	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

Certificate of Quality

Gut Commensal : Leuconostoc

VibrantWellness

Test Information

Test Name: Leuconostoc

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

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Certificate of Quality

VibrantWellness

Gut Commensal : Leuconostoc

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Liver diseases

Test Information

Test Name: Liver diseases

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Liver diseases

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	< 2.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Metabolic health

Test Information

Test Name: Metabolic health

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Metabolic health

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	< 2.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Methanobrevibacter smithii

Test Information

Test Name: Methanobrevibacter smithii

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

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Certificate of Quality

VibrantWellness

Gut Commensal : Methanobrevibacter smithii

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Methanobrevibacter

Test Information

Test Name: Methanobrevibacter

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

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Certificate of Quality

VibrantWellness

Gut Commensal : Methanobrevibacter

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Micrococcus

Test Information

Test Name: Micrococcus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

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Certificate of Quality

VibrantWellness

Gut Commensal : Micrococcus

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Mycoplana

Test Information

Test Name: Mycoplana

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Mycoplana

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Neurological diseases

Test Information

Test Name: Neurological diseases

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Neurological diseases

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	< 2.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Nutrition

Test Information

Test Name: Nutrition

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Nutrition

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	< 2.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Oscillospira

Test Information

Test Name: Oscillospira

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Oscillospira

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : P/B

Test Information

Test Name: P/B

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : P/B

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	0.00 - 0.48	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Pediococcus

Test Information

Test Name: Pediococcus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Pediococcus

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Peptostreptococcus

Test Information

Test Name: Peptostreptococcus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Peptostreptococcus

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Phascolarctobacterim

Test Information

Test Name: Phascolarctobacterim

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Phascolarctobacterim

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	< 20.1	units

Quality Statement

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Certificate of Quality

Gut Commensal : Porphyromonas gingivalis

VibrantWellness

Test Information

Test Name: Porphyromonas gingivalis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Porphyromonas gingivalis

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Prevotella copri

Test Information

Test Name: Prevotella copri

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Prevotella copri

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	0.0 - 10.0	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Prevotella

Test Information

Test Name: Prevotella

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Prevotella

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	0.0 - 10.0	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

Gut Commensal : Propionibacterium freudenreichii

VibrantWellness

Test Information

Test Name: Propionibacterium freudenreichii

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Propionibacterium freudenreichii

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Propionibacterium

Test Information

Test Name: Propionibacterium

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Propionibacterium

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Proteobacteria

Test Information

Test Name: Proteobacteria

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Proteobacteria

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

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Proteus mirabilis

Test Information

Test Name: Proteus mirabilis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Proteus mirabilis

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Pseudobutyrivibrio

Test Information

Test Name: Pseudobutyrivibrio

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Pseudobutyrivibrio

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Pseudomonas

Test Information

Test Name: Pseudomonas

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Pseudomonas

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Roseburia intestinalis

Test Information

Test Name: Roseburia intestinalis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Roseburia intestinalis

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Roseburia

Test Information

Test Name: Roseburia

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Roseburia

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	0.0 - 10.0	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

Gut Commensal : Ruminococcaceae

VibrantWellness

Test Information

Test Name: Ruminococcaceae

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Ruminococcaceae

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Ruminococcus bromii

Test Information

Test Name: Ruminococcus bromii

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Ruminococcus bromii

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Ruminococcus gnavus

Test Information

Test Name: Ruminococcus gnavus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Ruminococcus gnavus

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Ruminococcus obeum

Test Information

Test Name: Ruminococcus obeum

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Ruminococcus obeum

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Ruminococcus

Test Information

Test Name: Ruminococcus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Ruminococcus

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Saccharomyces boulardii

Test Information

Test Name: Saccharomyces boulardii

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Saccharomyces boulardii

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

Gut Commensal : Shannon's Index

VibrantWellness

Test Information

Test Name: Shannon's Index

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Shannon's Index

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	1.6 - 2.5	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : SIBO

Test Information

Test Name: SIBO

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : SIBO

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	< 2.1	units

Quality Statement

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

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

Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Simpson's Index

Test Information

Test Name: Simpson's Index

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Simpson's Index

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	0.51 - 0.75	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Solobacterium moorei

Test Information

Test Name: Solobacterium moorei

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Solobacterium moorei

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

Gut Commensal : ß-galactosidase producing bacteria

VibrantWellness

Test Information

Test Name: ß-galactosidase producing bacteria

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : ß-galactosidase producing bacteria

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : ß-glucuronidase producing bacteria

Test Information

Test Name: ß-glucuronidase producing bacteria

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : ß-glucuronidase producing bacteria

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Staphylococcaceae

Test Information

Test Name: Staphylococcaceae

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Staphylococcaceae on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high 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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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Staphylococcaceae

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Staphylococcus epidermidis

Test Information

Test Name: Staphylococcus epidermidis

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Staphylococcus epidermidis

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Staphylococcus pasteuri

Test Information

Test Name: Staphylococcus pasteuri

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Staphylococcus pasteuri

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Staphylococcus species

Test Information

Test Name: Staphylococcus species

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Staphylococcus species

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	< 20.1	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

Certificate of Quality

Gut Commensal : Streptococci

VibrantWellness

Test Information

Test Name: Streptococci

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

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Certificate of Quality

VibrantWellness

Gut Commensal : Streptococci

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Streptococcus species

Test Information

Test Name: Streptococcus species

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Streptococcus species

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Streptococcus thermophilus

Test Information

Test Name: Streptococcus thermophilus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Streptococcus thermophilus

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Streptococcus

Test Information

Test Name: Streptococcus

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Streptococcus

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	0.0 - 10.0	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Tyzzerella 4

Test Information

Test Name: Tyzzerella 4

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Tyzzerella 4.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tyzzerella 4 as shown below:

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), an externalCMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results arecompared to a peer group of laboratories. In Laboratory developed tests were peer group statistics are generally not available , internal proficiency testing is used to the assess the performance .The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improvethe overall performance of the lab. Laboratory performs PT for Tyzzerella 4 on a regular basis to ensure the highest of standards, and hascontinuously achieved performance of high 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

Gut Commensal : Tyzzerella 4

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	< 20.1	units

Quality Statement

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Certificate of Quality

VibrantWellness

Gut Commensal : Tyzzerella

Test Information

Test Name: Tyzzerella

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Tyzzerella

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Veillonella

Test Information

Test Name: Veillonella

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Veillonella

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	< 20.1	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Veillonellaceae

Test Information

Test Name: Veillonellaceae

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Veillonellaceae

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	0.0 - 10.0	units

Quality Statement

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Report Generated Date: 2022-03-25

Certificate of Quality

VibrantWellness

Gut Commensal : Verrucomicrobia

Test Information

Test Name: Verrucomicrobia

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Gut Commensal Control

Calibration

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

Calibration Levels: 3

Calibration Frequency: Per run

Calibrator Material: Vibrant Gut Commensal Calibrator

External Quality Assessment / Proficiency Testing

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

Gut Commensal : Verrucomicrobia

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

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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