Certificate of Quality

Tickborne : Anaplasma phagocytophilum

VibrantGenomics

Test Information

Test Name: Anaplasma phagocytophilum

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

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

Tickborne : Babesia duncani

VibrantGenomics

Test Information

Test Name: Babesia duncani

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Babesia duncani on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Report Generated Date: 2021-11-17

Certificate of Quality

Tickborne : Babesia microti

VibrantGenomics

Test Information

Test Name: Babesia microti

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Babesia microti on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Tickborne : Bartonella spp.

VibrantGenomics

Test Information

Test Name: Bartonella spp.

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Bartonella spp. on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Tickborne : Borrelia afzelii

VibrantGenomics

Test Information

Test Name: Borrelia afzelii

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia afzelii on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Report Generated Date: 2021-11-17

Certificate of Quality

Tickborne : Borrelia burgdorferi spp.

VibrantGenomics

Test Information

Test Name: Borrelia burgdorferi spp.

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia burgdorferi spp. on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Tickborne : Borrelia garinii

VibrantGenomics

Test Information

Test Name: Borrelia garinii

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia garinii on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Report Generated Date: 2021-11-17

Certificate of Quality

Tickborne : Borrelia lonestari

VibrantGenomics

Test Information

Test Name: Borrelia lonestari

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia lonestari on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Tickborne : Borrelia miyamotoi

VibrantGenomics

Test Information

Test Name: Borrelia miyamotoi

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia miyamotoi on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Tickborne : Borrelia TBRF spp.

VibrantGenomics

Test Information

Test Name: Borrelia TBRF spp.

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia TBRF spp. on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Tickborne : Chlamydophila pneumoniae

VibrantGenomics

Test Information

Test Name: Chlamydophila pneumoniae

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Chlamydophila pneumoniae on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

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

Tickborne : Ehrlichia chaffeensis

VibrantGenomics

Test Information

Test Name: Ehrlichia chaffeensis

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Tickborne : Ehrlichia ewingii

VibrantGenomics

Test Information

Test Name: Ehrlichia ewingii

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Ehrlichia ewingii on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Tickborne : Francisella spp.

VibrantGenomics

Test Information

Test Name: Francisella spp.

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Francisella spp. on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Tickborne : Mycoplasma spp.

VibrantGenomics

Test Information

Test Name: Mycoplasma spp.

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Mycoplasma spp. on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Tickborne : Rickettsia rickettsii

VibrantGenomics

Test Information

Test Name: Rickettsia rickettsii

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Rickettsia rickettsii on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Anaplasma phagocytophilum

VibrantGenomics

Test Information

Test Name: Anaplasma phagocytophilum

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Anaplasma phagocytophilum on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Babesia duncani

VibrantGenomics

Test Information

Test Name: Babesia duncani

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Babesia duncani on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Babesia microti

VibrantGenomics

Test Information

Test Name: Babesia microti

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Babesia microti on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Bartonella elizabethae

VibrantGenomics

Test Information

Test Name: Bartonella elizabethae

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Bartonella elizabethae on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Report Generated Date: 2021-11-17

Certificate of Quality

Lyme : Bartonella henselae

VibrantGenomics

Test Information

Test Name: Bartonella henselae

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Bartonella henselae on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Bartonella quintana

VibrantGenomics

Test Information

Test Name: Bartonella quintana

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Bartonella quintana on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

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

Lyme : Bartonella vinsonii

VibrantGenomics

Test Information

Test Name: Bartonella vinsonii

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia afzelii

VibrantGenomics

Test Information

Test Name: Borrelia afzelii

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia afzelii on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia andersonii

VibrantGenomics

Test Information

Test Name: Borrelia andersonii

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia andersonii on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia bavariensis

VibrantGenomics

Test Information

Test Name: Borrelia bavariensis

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia bavariensis on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia bissettiae

VibrantGenomics

Test Information

Test Name: Borrelia bissettiae

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia bissettiae on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia burgdorferi

VibrantGenomics

Test Information

Test Name: Borrelia burgdorferi

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia burgdorferi on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia californiensis

VibrantGenomics

Test Information

Test Name: Borrelia californiensis

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia californiensis on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia garinii

VibrantGenomics

Test Information

Test Name: Borrelia garinii

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia garinii on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Report Generated Date: 2021-11-17

Certificate of Quality

Lyme : Borrelia hermsii

VibrantGenomics

Test Information

Test Name: Borrelia hermsii

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia hermsii on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia lonestari

VibrantGenomics

Test Information

Test Name: Borrelia lonestari

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia lonestari on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia lusitaniae

VibrantGenomics

Test Information

Test Name: Borrelia lusitaniae

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia lusitaniae on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

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

Lyme : Borrelia maritima

VibrantGenomics

Test Information

Test Name: Borrelia maritima

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia maritima on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia mayonii

VibrantGenomics

Test Information

Test Name: Borrelia mayonii

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia mayonii on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia miyamotoi

VibrantGenomics

Test Information

Test Name: Borrelia miyamotoi

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia miyamotoi on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Report Generated Date: 2021-11-17

Certificate of Quality

Lyme : Borrelia spielmanii

VibrantGenomics

Test Information

Test Name: Borrelia spielmanii

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia spielmanii on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia turcica

VibrantGenomics

Test Information

Test Name: Borrelia turcica

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia turcica on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia turicatae

VibrantGenomics

Test Information

Test Name: Borrelia turicatae

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia turicatae on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia valaisiana

VibrantGenomics

Test Information

Test Name: Borrelia valaisiana

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia valaisiana on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Borrelia yangtzensis

VibrantGenomics

Test Information

Test Name: Borrelia yangtzensis

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Borrelia yangtzensis on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Lyme : Ehrlichia chaffeensis

VibrantGenomics

Test Information

Test Name: Ehrlichia chaffeensis

Reagent Manufacturer: Vibrant

Instrument: ThermoFisher Scientific QuantStudio™ 5 Real-Time PCR System

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 17

QC Frequency: Per run

QC Material: Vibrant Lyme Control

Calibration

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

Calibration Levels: N/A

Calibration Frequency: N/A

Calibrator Material: N/A

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant Genomics uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant Genomics Clinical Laboratory performs PT for Ehrlichia chaffeensis on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-03-01

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

Quality Statement

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Certificate of Quality

Alternative Lyme Criteria IgG

VibrantAmerica

Test Information

Test Name: Alternative Lyme Criteria IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Alternative Lyme Criteria IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Alternative Lyme Criteria IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

Age Group	Gender	Reference Range	Unit
For All Ages	Male / Female	NEGATIVE	units
For All Ages	Male / Female	INDEDTERMINATE	units
For All Ages	Male / Female	POSITIVE	units

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: Qualitative units

Quality Statement

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Alternative Lyme Criteria IgM

VibrantAmerica

Test Information

Test Name: Alternative Lyme Criteria IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Alternative Lyme Criteria IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Alternative Lyme Criteria IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Alternative Lyme Criteria IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

Age Group	Gender	Reference Range	Unit
For All Ages	Male / Female	NEGATIVE	units
For All Ages	Male / Female	INDEDTERMINATE	units
For All Ages	Male / Female	POSITIVE	units

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: Qualitative units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Anaplasma phagocytophilum Msp2 (p44) IgG

VibrantAmerica

Test Information

Test Name: Anaplasma phagocytophilum Msp2 (p44) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Anaplasma phagocytophilum Msp2 (p44) IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Anaplasma phagocytophilum Msp2 (p44) IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Anaplasma phagocytophilum Msp2 (p44) IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Anaplasma phagocytophilum Msp2 (p44) IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Anaplasma phagocytophilum Msp2 (p44) IgM

VibrantAmerica

Test Information

Test Name: Anaplasma phagocytophilum Msp2 (p44) IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Anaplasma phagocytophilum Msp2 (p44) IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Anaplasma phagocytophilum Msp2 (p44) IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Anaplasma phagocytophilum Msp2 (p44) IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Anaplasma phagocytophilum Msp2 (p44) IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Anaplasma phagocytophilum Msp5 IgG

VibrantAmerica

Test Information

Test Name: Anaplasma phagocytophilum Msp5 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Anaplasma phagocytophilum Msp5 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Anaplasma phagocytophilum Msp5 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Anaplasma phagocytophilum Msp5 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Anaplasma phagocytophilum Msp5 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Anaplasma phagocytophilum Msp5 IgM

VibrantAmerica

Test Information

Test Name: Anaplasma phagocytophilum Msp5 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Anaplasma phagocytophilum Msp5 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Anaplasma phagocytophilum Msp5 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Anaplasma phagocytophilum Msp5 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Anaplasma phagocytophilum Msp5 IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Anaplasma phagocytophilum OmpA IgG

VibrantAmerica

Test Information

Test Name: Anaplasma phagocytophilum OmpA IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Anaplasma phagocytophilum OmpA IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Anaplasma phagocytophilum OmpA IgM

VibrantAmerica

Test Information

Test Name: Anaplasma phagocytophilum OmpA IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Anaplasma phagocytophilum OmpA IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Anaplasma phagocytophilum OmpA IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Babesia duncani IgG

Test Information

Test Name: Babesia duncani IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Babesia duncani IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Babesia duncani IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Babesia duncani IgM

Test Information

Test Name: Babesia duncani IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Babesia duncani IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Babesia duncani IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti IRA IgG

Test Information

Test Name: Babesia microti IRA IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Babesia microti IRA IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti IRA IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti IRA IgM

Test Information

Test Name: Babesia microti IRA IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Babesia microti IRA IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Babesia microti IRA IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti IRA IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti p32 IgG

Test Information

Test Name: Babesia microti p32 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Babesia microti p32 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Babesia microti p32 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Babesia microti p32 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti p32 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti p32 IgM

Test Information

Test Name: Babesia microti p32 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Babesia microti p32 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Babesia microti p32 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Babesia microti p32 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti p32 IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti p41 IgG

Test Information

Test Name: Babesia microti p41 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Babesia microti p41 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Babesia microti p41 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Babesia microti p41 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti p41 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti p41 IgM

Test Information

Test Name: Babesia microti p41 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Babesia microti p41 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Babesia microti p41 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Babesia microti p41 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti p41 IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti WCS IgG

Test Information

Test Name: Babesia microti WCS IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Babesia microti WCS IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Babesia microti WCS IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-08

Certificate of Quality

Babesia microti WCS IgM

Test Information

Test Name: Babesia microti WCS IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Babesia microti WCS IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Babesia microti WCS IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Babesia microti WCS IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella elizabethae IgG

Test Information

Test Name: Bartonella elizabethae IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella elizabethae IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella elizabethae IgM

VibrantAmerica

Test Information

Test Name: Bartonella elizabethae IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Bartonella elizabethae IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella elizabethae IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella henselae 17 kDa IgG

VibrantAmerica

Test Information

Test Name: Bartonella henselae 17 kDa IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bartonella henselae 17 kDa IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bartonella henselae 17 kDa IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Bartonella henselae 17 kDa IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Bartonella henselae 17 kDa IgG

VibrantAmerica

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella henselae 17 kDa IgM

VibrantAmerica

Test Information

Test Name: Bartonella henselae 17 kDa IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bartonella henselae 17 kDa IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bartonella henselae 17 kDa IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Bartonella henselae 17 kDa IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella henselae 17 kDa IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella henselae 26 kDa IgG

VibrantAmerica

Test Information

Test Name: Bartonella henselae 26 kDa IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bartonella henselae 26 kDa IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bartonella henselae 26 kDa IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Bartonella henselae 26 kDa IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Bartonella henselae 26 kDa IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella henselae 26 kDa IgM

VibrantAmerica

Test Information

Test Name: Bartonella henselae 26 kDa IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Bartonella henselae 26 kDa IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bartonella henselae 26 kDa IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Bartonella henselae 26 kDa IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Bartonella henselae 26 kDa IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella henselae SucB IgG

VibrantAmerica

Test Information

Test Name: Bartonella henselae SucB IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Bartonella henselae SucB IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella henselae SucB IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella henselae SucB IgM

VibrantAmerica

Test Information

Test Name: Bartonella henselae SucB IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Bartonella henselae SucB IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Bartonella henselae SucB IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella henselae SucB IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella quintana IgG

VibrantAmerica

Test Information

Test Name: Bartonella quintana IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Bartonella quintana IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Bartonella quintana IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella quintana IgM

VibrantAmerica

Test Information

Test Name: Bartonella quintana IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Bartonella quintana IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Bartonella quintana IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella vinsonii IgG

Test Information

Test Name: Bartonella vinsonii IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Bartonella vinsonii IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Bartonella vinsonii IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Bartonella vinsonii IgM

Test Information

Test Name: Bartonella vinsonii IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Bartonella vinsonii IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Bartonella vinsonii IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii BmpA IgG

VibrantAmerica

Test Information

Test Name: Borrelia afzelii BmpA IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia afzelii BmpA IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii BmpA IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii BmpA IgM

VibrantAmerica

Test Information

Test Name: Borrelia afzelii BmpA IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia afzelii BmpA IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia afzelii BmpA IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii BmpA IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii DbpA IgG

VibrantAmerica

Test Information

Test Name: Borrelia afzelii DbpA IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia afzelii DbpA IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii DbpA IgG

Analyte Reference Range

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

Analyte Reportable Range

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Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii DbpA IgM

VibrantAmerica

Test Information

Test Name: Borrelia afzelii DbpA IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia afzelii DbpA IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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Certificate of Quality

Borrelia afzelii DbpA IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii OspA IgG

VibrantAmerica

Test Information

Test Name: Borrelia afzelii OspA IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia afzelii OspA IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia afzelii OspA IgG

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii OspA IgM

Test Information

Test Name: Borrelia afzelii OspA IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia afzelii OspA IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia afzelii OspA IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii OspA IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii OspC IgG

VibrantAmerica

Test Information

Test Name: Borrelia afzelii OspC IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia afzelii OspC IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii OspC IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii OspC IgM

VibrantAmerica

Test Information

Test Name: Borrelia afzelii OspC IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia afzelii OspC IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia afzelii OspC IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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Certificate of Quality

Borrelia afzelii OspC IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii p100 IgG

VibrantAmerica

Test Information

Test Name: Borrelia afzelii p100 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia afzelii p100 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia afzelii p100 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia afzelii p100 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii p100 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii p100 IgM

VibrantAmerica

Test Information

Test Name: Borrelia afzelii p100 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia afzelii p100 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia afzelii p100 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia afzelii p100 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia afzelii p100 IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia andersonii IgG

Test Information

Test Name: Borrelia andersonii IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia andersonii IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia andersonii IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia andersonii IgM

Test Information

Test Name: Borrelia andersonii IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia andersonii IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia andersonii IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia bavariensis DbpA IgG

VibrantAmerica

Test Information

Test Name: Borrelia bavariensis DbpA IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia bavariensis DbpA IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia bavariensis DbpA IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia bavariensis DbpA IgM

VibrantAmerica

Test Information

Test Name: Borrelia bavariensis DbpA IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia bavariensis DbpA IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia bavariensis DbpA IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia bavariensis DbpA IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia bavariensis p58 IgG

VibrantAmerica

Test Information

Test Name: Borrelia bavariensis p58 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia bavariensis p58 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia bavariensis p58 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia bavariensis p58 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia bavariensis p58 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia bavariensis p58 IgM

VibrantAmerica

Test Information

Test Name: Borrelia bavariensis p58 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia bavariensis p58 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia bavariensis p58 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia bavariensis p58 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory 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

Borrelia bavariensis p58 IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia bavariensis VlsE1 IgG

VibrantAmerica

Test Information

Test Name: Borrelia bavariensis VlsE1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia bavariensis VlsE1 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia bavariensis VlsE1 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia bavariensis VlsE1 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia bavariensis VlsE1 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia bavariensis VlsE1 IgM

VibrantAmerica

Test Information

Test Name: Borrelia bavariensis VlsE1 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia bavariensis VlsE1 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia bavariensis VlsE1 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia bavariensis VlsE1 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia bavariensis VlsE1 IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia bissettiae IgG

VibrantAmerica

Test Information

Test Name: Borrelia bissettiae IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia bissettiae IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia bissettiae IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia bissettiae IgM

VibrantAmerica

Test Information

Test Name: Borrelia bissettiae IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia bissettiae IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory 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

Borrelia bissettiae IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi C6 peptide IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi C6 peptide IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi C6 peptide IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi C6 peptide IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi C6 peptide IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Certificate of Quality

Borrelia burgdorferi C6 peptide IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi C6 peptide IgM

Test Information

Test Name: Borrelia burgdorferi C6 peptide IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi C6 peptide IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi C6 peptide IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi C6 peptide IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Certificate of Quality

Borrelia burgdorferi C6 peptide IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi crude extract 297 IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi crude extract 297 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi crude extract 297 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi crude extract 297 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi crude extract 297 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Certificate of Quality

Borrelia burgdorferi crude extract 297 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 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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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi crude extract 297 IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi crude extract 297 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi crude extract 297 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi crude extract 297 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi crude extract 297 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Borrelia burgdorferi crude extract 297 IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi crude extract B31 IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi crude extract B31 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi crude extract B31 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi crude extract B31 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi crude extract B31 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi crude extract B31 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi crude extract B31 IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi crude extract B31 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi crude extract B31 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi crude extract B31 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi crude extract B31 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Borrelia burgdorferi crude extract B31 IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p18 (DbpB) IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p18 (DbpB) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p18 (DbpB) IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p18 (DbpB) IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p18 (DbpB) IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p18 (DbpB) IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p18 (DbpB) IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p18 (DbpB) IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p18 (DbpB) IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p18 (DbpB) IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p18 (DbpB) IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p18 (DbpB) IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p23-25 (OspC) IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p23-25 (OspC) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p23-25 (OspC) IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p23-25 (OspC) IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p23-25 (OspC) IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Borrelia burgdorferi p23-25 (OspC) IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p23-25 (OspC) IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p23-25 (OspC) IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p23-25 (OspC) IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Certificate of Quality

Borrelia burgdorferi p23-25 (OspC) IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p28 IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p28 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p28 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p28 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p28 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p28 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p28 IgM

Test Information

Test Name: Borrelia burgdorferi p28 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p28 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p28 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p28 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Borrelia burgdorferi p28 IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p30 IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p30 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p30 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p30 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p30 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p30 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p30 IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p30 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p30 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p30 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p30 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p30 IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p31 (OspA) IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p31 (OspA) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p31 (OspA) IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p31 (OspA) IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p31 (OspA) IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p31 (OspA) IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p31 (OspA) IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p31 (OspA) IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p31 (OspA) IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p31 (OspA) IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p31 (OspA) IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p31 (OspA) IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p34 (OspB) IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p34 (OspB) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p34 (OspB) IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p34 (OspB) IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p34 (OspB) IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p34 (OspB) IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p34 (OspB) IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p34 (OspB) IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p34 (OspB) IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p34 (OspB) IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p34 (OspB) IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p34 (OspB) IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p39 (BmpA) IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p39 (BmpA) IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p39 (BmpA) IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p39 (BmpA) IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p39 (BmpA) IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

Borrelia burgdorferi p39 (BmpA) IgG

Analyte Reference Range

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p39 (BmpA) IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p39 (BmpA) IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

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510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p39 (BmpA) IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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Certificate of Quality

Borrelia burgdorferi p39 (BmpA) IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p41 IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p41 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p41 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p41 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p41 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p41 IgG

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p41 IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p41 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p41 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p41 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p41 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p41 IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p45 IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p45 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p45 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p45 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p45 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p45 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p45 IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p45 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p45 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p45 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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Certificate of Quality

Borrelia burgdorferi p45 IgM

Analyte Reference Range

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Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p58 IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p58 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p58 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p58 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p58 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p58 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p58 IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p58 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p58 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p58 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p58 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p58 IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p66 IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p66 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p66 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p66 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p66 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p66 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p66 IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p66 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p66 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p66 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p66 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p66 IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p83-93 IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p83-93 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p83-93 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p83-93 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p83-93 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Borrelia burgdorferi p83-93 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi p83-93 IgM

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi p83-93 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi p83-93 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi p83-93 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi p83-93 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Borrelia burgdorferi p83-93 IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi VlsE1 IgG

VibrantAmerica

Test Information

Test Name: Borrelia burgdorferi VlsE1 IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi VlsE1 IgG at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi VlsE1 IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi VlsE1 IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Borrelia burgdorferi VlsE1 IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi VlsE1 IgM

Test Information

Test Name: Borrelia burgdorferi VlsE1 IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

Laboratory Quality Control (QC) is the procedure used to detect and correct potential errors in a labs analytical measurement process prior to the release of patient results. Internal QC, tested identically to patient samples, is performed on a regular basis at Vibrant America Clinical Laboratory to ensure the precision and accuracy of patient sample results. See below for detailed information regarding the QC for Borrelia burgdorferi VlsE1 IgM at Vibrant America Clinical Laboratory.

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia burgdorferi VlsE1 IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia burgdorferi VlsE1 IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: College of American Pathologists

Evaluation Frequency: Twice per year

Last Performed On: 2021-05-01

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia burgdorferi VlsE1 IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia californiensis IgG

VibrantAmerica

Test Information

Test Name: Borrelia californiensis IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia californiensis IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia californiensis IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia californiensis IgM

Test Information

Test Name: Borrelia californiensis IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia californiensis IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory 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

Borrelia californiensis IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia garinii DbpA IgG

VibrantAmerica

Test Information

Test Name: Borrelia garinii DbpA IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia garinii DbpA IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia garinii DbpA IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia garinii DbpA IgM

VibrantAmerica

Test Information

Test Name: Borrelia garinii DbpA IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia garinii DbpA IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia garinii DbpA IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia garinii DbpA IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia garinii OspC IgG

VibrantAmerica

Test Information

Test Name: Borrelia garinii OspC IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia garinii OspC IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia garinii OspC IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia garinii OspC IgM

Test Information

Test Name: Borrelia garinii OspC IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia garinii OspC IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia garinii OspC IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory 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

Borrelia garinii OspC IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia hermsii IgG

VibrantAmerica

Test Information

Test Name: Borrelia hermsii IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia hermsii IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia hermsii IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 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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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia hermsii IgM

Test Information

Test Name: Borrelia hermsii IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia hermsii IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia hermsii IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia lusitaniae IgG

VibrantAmerica

Test Information

Test Name: Borrelia lusitaniae IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia lusitaniae IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia lusitaniae IgG

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia lusitaniae IgM

Test Information

Test Name: Borrelia lusitaniae IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia lusitaniae IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia maritima IgG

VibrantAmerica

Test Information

Test Name: Borrelia maritima IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia maritima IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia maritima IgG

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia maritima IgM

Test Information

Test Name: Borrelia maritima IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia maritima IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia maritima IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia mayonii IgG

VibrantAmerica

Test Information

Test Name: Borrelia mayonii IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia mayonii IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia mayonii IgG

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
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Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia mayonii IgM

VibrantAmerica

Test Information

Test Name: Borrelia mayonii IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia mayonii IgM

Analyte Reference Range

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For All Ages	Male / Female	< 10.1	units

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia miyamotoi IgG

VibrantAmerica

Test Information

Test Name: Borrelia miyamotoi IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia miyamotoi IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia miyamotoi IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia miyamotoi IgM

VibrantAmerica

Test Information

Test Name: Borrelia miyamotoi IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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Certificate of Quality

Borrelia miyamotoi IgM

Analyte Reference Range

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For All Ages	Male / Female	< 10.1	units

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Analyte Reportable Range: 0.1-30 units

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia spielmanii DbpA IgG

VibrantAmerica

Test Information

Test Name: Borrelia spielmanii DbpA IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia spielmanii DbpA IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia spielmanii DbpA IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia spielmanii DbpA IgM

VibrantAmerica

Test Information

Test Name: Borrelia spielmanii DbpA IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia spielmanii DbpA IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia spielmanii DbpA IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia spielmanii DbpA IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia spielmanii OspC IgG

VibrantAmerica

Test Information

Test Name: Borrelia spielmanii OspC IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia spielmanii OspC IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia spielmanii OspC IgG

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia spielmanii OspC IgM

VibrantAmerica

Test Information

Test Name: Borrelia spielmanii OspC IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Borrelia spielmanii OspC IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia spielmanii OspC IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia spielmanii OspC IgM

Analyte Reference Range

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Age Group	Gender	Reference Range	Reference Range Unit
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Analyte Reportable Range

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Analyte Reportable Range: 0.1-30 units

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia turcica IgG

VibrantAmerica

Test Information

Test Name: Borrelia turcica IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

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QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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Certificate of Quality

Borrelia turcica IgG

Analyte Reference Range

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Analyte Reportable Range

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Analyte Reportable Range: 0.1-30 units

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia turcica IgM

Test Information

Test Name: Borrelia turcica IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia turcica IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia turcica IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia turicatae IgG

VibrantAmerica

Test Information

Test Name: Borrelia turicatae IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia turicatae IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory 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

Borrelia turicatae IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia turicatae IgM

VibrantAmerica

Test Information

Test Name: Borrelia turicatae IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia turicatae IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory 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

Borrelia turicatae IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia valaisiana IgG

VibrantAmerica

Test Information

Test Name: Borrelia valaisiana IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia valaisiana IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia valaisiana IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia valaisiana IgM

Test Information

Test Name: Borrelia valaisiana IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia valaisiana IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory 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

Borrelia valaisiana IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia yangtzensis IgG

VibrantAmerica

Test Information

Test Name: Borrelia yangtzensis IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia yangtzensis IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia yangtzensis IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Borrelia yangtzensis IgM

Test Information

Test Name: Borrelia yangtzensis IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Borrelia yangtzensis IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Borrelia yangtzensis IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Vibrant America Clinical Laboratory, 1360 Bayport Avenue, San Carlos, CA 94070. Phone: +1(866)364-0963; FAX: +1(650)508-8260;Email: support@vibrant-america.com

Report Generated Date: 2021-10-08

Certificate of Quality

CDC/IDSA Lyme Criteria IgG

VibrantAmerica

Test Information

Test Name: CDC/IDSA Lyme Criteria IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for CDC/IDSA Lyme Criteria IgG at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for CDC/IDSA Lyme Criteria IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

CDC/IDSA Lyme Criteria IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

Age Group	Gender	Reference Range	Unit
For All Ages	Male / Female	NEGATIVE	units
For All Ages	Male / Female	INDEDTERMINATE	units
For All Ages	Male / Female	POSITIVE	units

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: Qualitative units

Quality Statement

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

CDC/IDSA Lyme Criteria IgM

VibrantAmerica

Test Information

Test Name: CDC/IDSA Lyme Criteria IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for CDC/IDSA Lyme Criteria IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for CDC/IDSA Lyme Criteria IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory 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

CDC/IDSA Lyme Criteria IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

Age Group	Gender	Reference Range	Unit
For All Ages	Male / Female	NEGATIVE	units
For All Ages	Male / Female	INDEDTERMINATE	units
For All Ages	Male / Female	POSITIVE	units

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: Qualitative units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Chlamydophila pneumoniae IgG

VibrantAmerica

Test Information

Test Name: Chlamydophila pneumoniae IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Chlamydophila pneumoniae IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Chlamydophila pneumoniae IgG

VibrantAmerica

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Chlamydophila pneumoniae IgM

VibrantAmerica

Test Information

Test Name: Chlamydophila pneumoniae IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Chlamydophila pneumoniae IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Chlamydophila pneumoniae IgM

VibrantAmerica

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Coxsackie Virus IgG

Test Information

Test Name: Coxsackie Virus IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Coxsackie Virus IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Coxsackie Virus IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Coxsackie Virus IgM

VibrantAmerica

Test Information

Test Name: Coxsackie Virus IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Coxsackie Virus IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Coxsackie Virus IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Ehrlichia chaffeensis IgG

VibrantAmerica

Test Information

Test Name: Ehrlichia chaffeensis IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Ehrlichia chaffeensis IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Ehrlichia chaffeensis IgG

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Ehrlichia chaffeensis IgM

Test Information

Test Name: Ehrlichia chaffeensis IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Ehrlichia chaffeensis IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Mycoplasma pneumoniae IgG

VibrantAmerica

Test Information

Test Name: Mycoplasma pneumoniae IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Mycoplasma pneumoniae IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Mycoplasma pneumoniae IgG

VibrantAmerica

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Mycoplasma pneumoniae IgM

VibrantAmerica

Test Information

Test Name: Mycoplasma pneumoniae IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Mycoplasma pneumoniae IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory is regulated under CLIA and is CAP certified hence qualified to perform high-complexity testing. Laboratory Director: Mervyn Sahud, MD CLIA: 05D2078809 CLF: 00346278
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Report Generated Date: 2021-10-08

Certificate of Quality

Mycoplasma pneumoniae IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Powassan Virus IgG

VibrantAmerica

Test Information

Test Name: Powassan Virus IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Powassan Virus IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Powassan Virus IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Powassan Virus IgM

VibrantAmerica

Test Information

Test Name: Powassan Virus IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Powassan Virus IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Powassan Virus IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Rickettsia typhi OmpB IgG

VibrantAmerica

Test Information

Test Name: Rickettsia typhi OmpB IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Rickettsia typhi OmpB IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Rickettsia typhi OmpB IgG

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Rickettsia typhi OmpB IgM

VibrantAmerica

Test Information

Test Name: Rickettsia typhi OmpB IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rickettsia typhi OmpB IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Rickettsia typhi OmpB IgM on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Rickettsia typhi OmpB IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Rickettsia typhi Surface antigen IgG

VibrantAmerica

Test Information

Test Name: Rickettsia typhi Surface antigen IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Rickettsia typhi Surface antigen IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

The laboratory 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

Rickettsia typhi Surface antigen IgG

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Rickettsia typhi Surface antigen IgM

VibrantAmerica

Test Information

Test Name: Rickettsia typhi Surface antigen IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Rickettsia typhi Surface antigen IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Report Generated Date: 2021-10-08

Certificate of Quality

Rickettsia typhi Surface antigen IgM

Analyte Reference Range

The reference range is defined as the range of test values expected for a designated population of individuals (42 CFR 493).Reference range were established and corresponding 90% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute guidelines. For an FDA approved test method, the clinical laboratory can adopt the manufacturers stated reference range if the patient population gives similar results to those published in the manufacturers package insert.

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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

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Report Generated Date: 2021-10-08

Certificate of Quality

Tickborne Encephalitis Virus IgG

VibrantAmerica

Test Information

Test Name: Tickborne Encephalitis Virus IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

As a clinical laboratory accredited by the College of American Pathologists (CAP), Vibrant America uses Proficiency Testing (PT) programs provided by CAP, an external CMS-approved agency, to constantly and objectively assess the performance of the lab. PT samples are analyzed in the same manner as patient samples, and results are compared to a peer group of laboratories. The purpose is to identify potential problems in laboratory practices, generate corresponding corrective action(s), and improve the overall performance of the lab. Vibrant America Clinical Laboratory performs PT for Tickborne Encephalitis Virus IgG on a regular basis to ensure the highest of standards, and has continuously achieved performance of high quality. Detailed information of the PT evaluation can be found below:

Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Tickborne Encephalitis Virus IgG

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

Tickborne Encephalitis Virus IgM

VibrantAmerica

Test Information

Test Name: Tickborne Encephalitis Virus IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for Tickborne Encephalitis Virus IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

Tickborne Encephalitis Virus IgM

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

West Nile Virus IgG

VibrantAmerica

Test Information

Test Name: West Nile Virus IgG

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

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

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

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

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

West Nile Virus IgG

Analyte Reference Range

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

Analyte Reportable Range

The reportable range is defined as the range of test values over which the relationship between the instrument, kit, or systems measurement response is shown to be valid (US CFR 493 February 28, 1992)

Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-10-08

Certificate of Quality

West Nile Virus IgM

VibrantAmerica

Test Information

Test Name: West Nile Virus IgM

Reagent Manufacturer: Vibrant

Instrument: Hamilton Automation Lab Robotics

Quality Standards

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

FDA/LDT: Lab Developed Test (LDT)

510(K) Number: N/A

ISO Compliance Standard: ISO 13485: 2016

Quality Control

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

QC Levels: 2

QC Frequency: Per run

QC Material: Vibrant Tickborne Control

Calibration

Calibration is the process to establish the relationship between a biomarkers analytical signal and corresponding concentration. The goal is to ensure the precision and accuracy of a testing system by standardizing it with a reference system established by manufacture. Detailed information of the calibration for West Nile Virus IgM at Vibrant America Clinical Laboratory as shown below:

Calibration Levels: 1

Calibration Frequency: Per run

Calibrator Material: Vibrant TickBorne Calibrator

External Quality Assessment / Proficiency Testing

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Quality Assurance Program: Internal PT

Evaluation Frequency: Twice per year

Last Performed On: 2021-06-21

2020 Event 1	2020 Event 2	2021 Event 1
Pass	Pass	Pass

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Certificate of Quality

West Nile Virus IgM

Analyte Reference Range

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Analyte Reportable Range

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Analyte Reportable Range: 0.1-30 units

Quality Statement

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Report Generated Date: 2021-11-24