Validation Study Report
Analytical and Clinical Studies
Vibrant America Clinical Lab
VA-COV-001

Vibrant COVID-19 Ab Assay

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Sponsor: Vibrant America Clinical Lab
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San Carlos, CA 94070

Revision History

Revision	Change Description	Initiator	Date
1	Initial Revision	Karthik Krishna	2020/03/29
2	Additional clinical studies added	Karthik Krishna	2020/04/02

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1. INTRODUCTION

This validation study report covers the analytical and clinical studies performed to validate the Vibrant COVID-19 Ab Assay developed by Vibrant America Clinical Lab.

2. LABORATORIES/SITE LOCATIONS

2.1. Institute Name / Sponsor

Vibrant America Clinical Lab

2.2. Institute Address

1360 Bayport Ave, San Carlos, CA 94070

3. List of Definitions and Abbreviations

Definitions and abbreviations should be added as applicable to the particular Protocol.

Term	Definition
Blinding	A printed, optical, or electronic document used to record information to be reported to the Sponsor regarding the subjects/specimens used in the clinical study.
Case Report Forms	A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).
Clinical Sensitivity	The proportion of patients with a well-defined clinical disorder whose test values are positive or exceed a defined decision limit.
Clinical Specificity	The proportion of subjects who do not have a specified clinical disorder whose test results are negative or within the defined decision limit.
False Negative	A negative test result for a patient or specimen that is positive for the condition or constituent in question.
False Positive	A positive test result for a patient or specimen that is negative for the condition or constituent in question.
Good Clinical Practice	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical studies that provides assurance that the data and reported results are credible and accurate, and that the rights, safety, well-being, integrity, and confidentiality of study subjects are protected.
Good Laboratory Practice	GLP is a quality system that covers the organizational process and the conditions under which non-clinical laboratory studies are planned, performed, monitored, recorded, archived and reported.
Health Insurance Portability and Accountability Act (HIPAA)	US law designed to provide privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals and other health care providers. Developed by the Department of Health and Human Services (HHS), these standards provide patients with access to their medical records and more control over how their personal health information is used and disclosed. HIPAA took effect on April 14, 2003. The Privacy Rule is located at 45 CFR160 and 45 CFR 164 subparts A and E.
Informed Consent Form	A document that describes the rights of the study participants, and includes details about the study, such as its purpose,

Term	Definition
	duration, required procedures, and key contacts. Risks and potential benefits are explained in the Informed Consent Form. Informed Consent is not a contract, and the participant may withdraw from the trial at any time.
Investigational Device Exemption	IDE refers to the regulations under 21 CFR 812. An approved IDE means that the IRB (and FDA for significant risk devices) has approved the Sponsor's study application and all the requirements under 21 CFR 812 are met. An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the Food, Drug, and Cosmetic Act that would apply to medical devices in commercial distribution.
Lot	A defined amount of material that is uniform in its properties and has been produced in one process or series of processes.
Monitoring	An evaluation of clinical or analytical study data carried out by Sponsor personnel or representatives. There are two types: • On-site monitoring - performed at the site(s) at which the clinical or analytical investigation is being conducted. On-site monitoring can identify data entry errors (e.g., discrepancies between source records and CRFs) and missing data in source records or CRFs; provide assurance that study documentation exists; assess the familiarity of the site's study staff with the Protocol and required procedures; and assess compliance with Good Clinical Practices, the Protocol, and Investigational Product accountability. On-site monitoring can also provide a sense of the quality of the overall conduct of the trial at a site. On-site monitoring is particularly critical early in a study, especially if the Protocol is complex, and includes novel procedures with which the Investigator may be unfamiliar. • Centralized (remote) monitoring – performed at a location other than the site(s) at which the clinical or analytical investigation is being conducted. Centralized monitoring processes can provide many of the capabilities of on-site monitoring as well as additional capabilities. Centralized monitoring should be used to the extent that it is appropriate and feasible to achieve risk-based monitoring. Please refer to the FDA document "Guidance for Industry: Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring".
Negative Percent Agreement	The percentage of comparator test negative subjects in whom the new test is also negative.

Term	Definition
Positive Percent Agreement	The percentage of comparator test positive subjects in whom the new test is also positive.
Precision	Closeness of agreement between independent test/ measurement results obtained under stipulated conditions.
Randomization	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.
Sample	A sample is prepared from the patient specimen and used to obtain information by means of a specific laboratory test.
Specimen	The discrete portion of a body fluid or tissue taken from examination, study, or analysis of one or more quantities or characteristics to determine the character of the whole
Subject	A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A Subject may be in normal health or may have a medical condition or disease.
Test	In the clinical laboratory, a qualitative, semiqualitative, quantitative or semi quantitative procedure for detecting the presence of, or measuring the quantity of an analyte.

Acronym	Corresponding Phrase
CFR	Code of Federal Regulations
CI	Clinical Investigator
CRA	Clinical Research Associate
CRF	Case Report Form
CSM	Clinical Study Manager
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IATA	International Air Transport Association
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IEC	Independent or Institutional Ethics Committee
IRB	Institutional Review Board
ISO	International Organization for Standardization
NPA	Negative Percent Agreement
PPA	Positive Percent Agreement
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

4. DESCRIPTION OF DEVICE(S)

4.1. Investigational Device

The Vibrant COVID-19 Ab assay is a chemiluminescence immunoassay (CLIA) to detect IgG, IgA and IgM antibodies to COVID-19 antigens from patients who are suspected of COVID-19. The antigens tested include:

Antigen Tested	Description
S1 subunit of Spike Protein (S1 SP)	The S1 subunit of the ectodomain mediates binding of the virion to host cell-surface receptors through its receptor-binding domain (RBD)
Receptor Binding Domain (RBD)	Part of the S1 Spike subunit that actually binds to the ACE2 receptor of human epithelial cell
S2 subunit of Spike Protein (S2 SP)	The S2 subunit fuses with both host and viral membranes, by undergoing dramatic structural changes
Nucleoprotein (NP)	Packages the positive strand viral genome RNA into a helical ribonucleocapsid (RNP) and plays a fundamental role during virion assembly through its interactions with the viral genome and membrane protein M. Plays an important role in enhancing the efficiency of subgenomic viral RNA transcription as well as viral replication.

4.1.1. Assay Kit

4.1.1.1. Manufacturing

Purified COVID-19 antigens are bound to the functionalized silicon wafers under conditions that will preserve the antigen in its native state. The wafers are then diced into silicon chips which are then assembled onto a 96-pillar plate with a layout of 8 chips on each pillar (4 chips with COVID-19 antigens and 4 reference chips used in software analysis) using automated semiconductor assembly techniques.

4.1.1.2. Assay Methodology

Diluted patient sera and controls including positive and negative control are added to individual wells allowing the COVID-19 specific antibodies, if present, to bind to the immobilized antigen. Unbound sample is washed away and an enzyme labeled anti-human IgG conjugate (anti-human IgA conjugate and anti-human IgM conjugate in separate plates) is added to each well. After washing away the unbound enzyme labeled conjugate, the remaining enzyme activity is measured by adding a chemiluminescent substrate and measuring the intensity of the signal from each chip scanned. Three 96 pillar plates are used for each assay (1 for IgG

antibody detection, 1 for IgA antibody detection and 1 for IgM antibody detection).

4.1.1.3. Components

Part Number	**Component**
C901100	Vibrant COVID-19 Ab Assay Kit
C901101	Vibrant COVID-19 96 Pillar Plate
C901103	COVID-19 Blocking Buffer
C901104	COVID-19 20X Wash Buffer
C901105	COVID-19 IgG Negative Control
C901106	COVID-19 IgA Negative Control
C901107	COVID-19 IgM Negative Control
C901108	COVID-19 IgG Cut-off Control
C901109	COVID-19 IgA Cut-off Control
C901110	COVID-19 IgM Cut-off Control
C901111	COVID-19 IgG Positive Control
C901112	COVID-19 IgA Positive Control
C901113	COVID-19 IgM Positive Control
C901114	COVID-19 Sample Diluent
C901115	COVID-19 IgG Conjugate
C901116	COVID-19 IgA Conjugate
C901117	COVID-19 IgM Conjugate
C901118	COVID-19 Chemiluminescence Substrate A
C901119	COVID-19 Chemiluminescence Substrate B

4.1.2. Instrument

Part No.	Instrument	Description
107550GR	Quansys Q-View Imager Pro	High-resolution Chemiluminescence imager for microplates
STARB525	Hamilton Microlab STAR	Automated liquid handling system

4.1.3. Software

Part No.	Software	Description
C901102	Vibrant COVID-19 Reporter Software	Software for analyzing and interpreting sample results.

5. Intended Use and Indications for Use

5.1. Intended Use

Vibrant COVID-19 Ab assay is an in-vitro diagnostic test intended for the qualitative detection of IgG, IgA and IgM antibodies to SARS-CoV-2 in human serum collected from individuals who are suspected of COVID-19.

5.2. Indications for Use

Same as intended use

6. Investigational Device Exemption

6.1. Justification of exemption or Process for Filing

Investigations of Vibrant COVID-19 Ab Assay are exempted from 21 CFR 812 of the IDE regulations, based on the exemption regulations below:

Vibrant COVID-19 Ab Assay complies with the labeling requirements in §809.10(c) and the testing:

a. Is noninvasive;
b. Does not require an invasive sampling procedure that presents significant risk;
c. Does not by design or intention introduce energy into a subject; and
d. Is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.

7. Overview of Study Procedure

7.1. Ethical and Regulatory

7.1.1. Regulation and Guidelines

The study was conducted according to relevant regulations and guidelines (GCP Guidelines, 21 CFR Parts 50, 54, 56 and 812, 45 CFR Part 164, and EN 13612:2002, ICH E6). The Investigator was responsible for conduct of the study at his/her site. Study testing was started as soon as protocol approval was obtained, training is completed, operators are proficient and study materials are received.

7.1.2. Institutional Review Board & Independent Ethics Committee Approval

Lab conducting the clinical and analytical studies at each approved participating site approved the Study Protocol and any substantial amendment.

The investigation studies for Vibrant COVID-19 Ab Assay are exempted from IDE and IRB approval.

7.2. Informed Consent Process

The study was conducted under the ethical principles that have their origins in the Declaration of Helsinki.

The serum samples that Vibrant America used for investigation studies were obtained from third-party specimen providers. The related materials including the approved and signed informed consent, or waiver of informed consent from IRB are kept by them.

Vibrant America has an agreement with the specimen suppliers to ensure the compliance with the regulations.

7.3. Subject Confidentiality

With regards to privacy rights, Sponsor and investigational sites adhered to applicable HIPAA regulations. Each protocol included a statement reminding the external site Investigator that study reports and communications should identify individuals enrolled in the study by a study ID only, not by name, initials, lab numbers, or hospital numbers. Whatever study identification method is used, it must allow cross-referencing (by external clinical site personnel, sponsor monitors/auditors, and regulatory agents) between the study Subject Case Report/Assay Results forms and external clinical site sources for demographic and clinical information.

To protect the confidentiality of each subject, each specimen was encoded with an alpha-numeric designation. All subject personal information remained at the site and not provided to the Sponsor or Sponsor designees. The Subject's name does not appear anywhere on the CRF or supporting documentation.

7.4. Required Regulatory Documentation

As per GCP and certain Federal, State, local and institutional requirements, certain documents were provided to the Sponsor by the Clinical Investigator or Study Coordinator from all participating sites. All documents were collected and filed appropriately in the training/analytical/clinical files. These documents include but are not limited to:

- Before Initiation of the Study:
    - A copy of the dated and signed approval of the Protocol.
    - Study Participants Responsibilities
    - CV of Clinical Investigators
    - Training Records
    - Laboratory accreditation
    - Site contact information.
- During the study:

  - Any updates to previously collected documents. Examples: updated lab licenses; updated protocol; updated site contact information
  - Study Material Accountability and Disposition Forms
  - Shipping Records
  - Equipment Logs/Maintenance Records and Temperature Monitoring Logs
  - Completed Protocol Deviation Forms
  - Any documentation related to potential Unanticipated Adverse Device Events
- After the study:
  - Any documentation related to Unanticipated Adverse Device Events
  - Device Accountability: Used, returned or disposed of, as appropriate
  - Equipment Accountability: Used, returned or disposed of, as appropriate
  - Signed Investigator Study Completion Form
  - Letter from Investigator to Sponsor of Trial completion

There may be other regulatory documentation that is required by the Sponsor to provide directly to Regulatory Authorities.

7.5. Curricula Vitae and Log of Staff

CVs of those participating in the study were obtained prior to initiating the study and are filed in the Vibrant COVID-19 Ab Study binder.

7.6. Training and Familiarization

It was the responsibility of the investigator to ensure that all study staff were trained on the Protocol, SOPs, and any applicable procedures. Site operators were trained by Sponsor on the Investigational System and how to conduct all procedures consistent with the Study Protocol and applicable regulatory requirements. A minimum of 2 operators per site were involved in the training. Successful performance of these tests qualified the operators and the laboratory to execute the analytical/clinical tests involved in the study.

7.7. Sample Collection, Receiving, and Storage from Study Sample Supplier

7.7.1. Blood Sample Collection and Serum Extraction

Samples were collected at each site according to the site's standard procedures. As applicable, the total volume and/or amount as well as time of collection were recorded. This study required a target volume of 0.5mL – 1mL but no less than 25 uL of serum sample per subject.

This procedure was performed with serum specimens. Addition of azide or other preservative to the test samples may adversely affect the results. Microbial contaminated, heat-treated, or specimens containing visible particulate were not used. Grossly hemolyzed or lipemic serum or specimens were avoided.

7.7.2. Serum Sample Receiving and Storage

Serum samples were stored at room temperature no longer than 8 hours. If the assay was not completed within 8 hours, the serum samples were refrigerated at 2-8 °C for up to 7 days prior to completing the assay. Frozen specimens were mixed after thawing and prior to testing. Repeated thawing and freezing were avoided.

8. Sample and Product Handling

8.1. Sample Handling

8.1.1. Sample Shipment

Packing slip contained information about all the items that were shipped to the study site and reconciled during post study material handling.

8.1.2. Sample Storage

The serum samples were stored at 2-8 °C for up to 7 days prior to assay. If assay was run after 7 days, the serum samples were stored at -20 °C or lower.

8.2. Investigational Product Handling

8.2.1. COVID-19 Ab Assay Kit Shipment

Packing slip contained information about all the items that were shipped to the study site and reconciled during post study material handling.

8.2.2. COVID-19 Ab Assay Kit Storage

Assay kits storage temperature was between 2-8 °C and not frozen. Reagents are stored and used until the expiration date when handled as directed.

8.2.3. Hamilton / Quansys Instrument

The Hamilton and Quansys instrument was shipped to the study site as per manufacturing packaging instruction.

8.2.4. Vibrant COVID-19 Ab Reporter

The Workstation with preinstalled Vibrant COVID-19 Ab Reporter software was shipped to the study site as per manufacturing packaging instruction.

9. STUDY DESIGN

9.1. Study

9.1.1. Analytical Performance Precision/Reproducibility Study

9.1.1.1. Study details

Two test operators shall test a panel of 6 samples, 4 replicates daily over a period of 5 days for 40 data points per lot resulting in 120 data points. Panel shall consist of positive control, negative control, positive sample, negative sample, a sample with concentration +20% above cut-off, and a sample with concentration -20% below cut-off.

9.1.1.2. Sample Allocation and Testing

Samples = 6
Replicates = 4
Assay Kit Lots = 3
Total Number of Assay Kits = 30
Instrument = 1
Operator = 2
96 Pillar Plate = 24 Samples + 1 Positive + 1 Negative + 1 Cut-off + 69 empty = 96 Wells
Run = 10
Total Number of Days = 5
Sites = 1
Automated

9.1.1.3. Statistical Methods

Reproducibility % = 100 x Number of accurate test results / Total Number of test results

Lot-to-Lot Reproducibility % = 100 x Number of accurate test results / Total Number of test results

Operator-to-Operator Reproducibility % = 100 x Number of accurate test results / Total Number of test results

9.1.1.4. Acceptance Criteria

Reproducibility % > 95% for all samples tested

Lot-to-Lot Reproducibility % > 95% for all samples tested

Operator-to-Operator Reproducibility % > 95% for all samples tested

9.1.1.5. Guidance

CLSI EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition

9.1.2. Analytical Performance Cross Reactivity Study

9.1.2.1. Study details

The following panel of samples shall be tested to determine the cross-reactivity/analytical specificity of the Vibrant COVID-19 Ab assay.

Antibody	Number of samples
Anti-influenza A (IgG, IgA and IgM)	10
Anti- influenza B (IgG, IgA and IgM)	10
Anti-HCV (IgG, IgA and IgM)	10
Anti-HBV (IgG, Ig and IgM)	10
ANA	20
Anti-respiratory syncytial virus	10
Anti-Haemophilus influenzae	5

9.1.2.2. Sample Allocation and Testing

Samples = 75
Replicates = 4
Total Number of Assay Kits = 1
Instrument = 1
Operator = 1
96 Pillar Plate = 75 Samples + 1 Positive + 1 Negative + 1 Cut-off + 18 empty = 96 Wells
Run = 1
Total Number of Days = 1
Sites = 1

9.1.2.3. Statistical Methods

Analytical Specificity % = 100 x Number of accurate test results / Total Number of test results

9.1.2.4. Acceptance Criteria

No false positive results

9.1.2.5. Guidance

FDA Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency

9.1.3. Analytical Performance Class Specificity Study

9.1.3.1. Study details

This study shall evaluate the potential for human IgG/IgA/IgM to cross react and therefore produce false positive results for each individual assay. Five concentrations of total IgG, IgA and IgM are spiked in 1 positive and 1 negative sample with 3 replicates to determine the concentration at which no interference is found. If no interference is demonstrated at high concentration, then testing with low concentration shall be bypassed.

Class Specificity	Concentration Tested
Total IgG	0 mg/dl
	375 mg/dl

Class Specificity	Concentration Tested
	750 mg/dl
	1500 mg/dl
	3000 mg/dl
Total IgA	0 mg/dl
	87.5 mg/dl
	175 mg/dl
	350 mg/dl
	700 mg/dl
Total IgM	0 mg/dl
	62.5 mg/dl
	125 mg/dl
	250 mg/dl
	500 mg/dl

9.1.3.2. Sample Allocation and Testing

Samples = 2*5*3 = 30
Replicates = 3
Assay Kit Lots = 1
Total Number of Assay Kits = 1
Instrument = 1
Operator = 1
96 Pillar Plate = 90 Samples + 1 Positive + 1 Negative + 1 Cut-off + 3 empty = 96 Wells
Run = 1
Total Number of Days = 1
Sites = 1

9.1.3.3. Statistical Methods

Agreement % = 100 x Number of accurate test results / Total Number of test results

9.1.3.4. Acceptance Criteria

Concentration at which Agreement % is 100% is the concentration where no interference is found.

9.1.3.5. Guidance

FDA Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency

9.1.4. Analytical Performance Analytical Specificity Study

9.1.4.1. Study details

This study shall evaluate the potential for common potentially interfering substances to cross react and therefore produce false positive results for each individual assay. Three concentration of each interference substance as detailed below are spiked in 1 positive and 1 negative sample with 3 replicates to determine the

concentration at which no interference is found. If no interference is demonstrated at high concentration, then testing with low concentration shall be bypassed.

Interfering Substance	Concentration Tested
Bilirubin	40 mg/dl
	20 mg/dl
	10 mg/dl
Triglycerides	1000 mg/ml
	500 mg/ml
	250 mg/ml
Hemoglobin	1000 mg/ml
	500 mg/ml
	250 mg/ml
Rheumatoid Factor (RF)	2000 IU/ml
	1000 IU/ml
	500 IU/ml
Cholesterol	100 mg/ml
	50 mg/ml
	25 mg/ml
HAMA	12.5 ng/ml
	25 ng/ml
	50 ng/ml
Ribavirin	25 mg/dl
	50 mg/dl
	100 mg/dl
Levofloxacin	0.5 mg/dl
	1 mg/dl
	2 mg/dl
Azithromycin	0.5 mg/dl
	1 mg/dl
	2 mg/dl
Ceftriaxone sodium	25 mg/dl
	50 mg/dl
	100 mg/dl
Oxymetazoline	1.25 mg/dl
	2.5 mg/dl
	5 mg/dl
Sodium chloride	25 mg/dl
	50 mg/dl
	100 mg/dl
EDTA	12.5 mg/ml
	25 mg/ml
	50 mg/ml
Acetaminophen	50 mg/ml
	100 mg/ml

Interfering Substance	Concentration Tested
	200 mg/ml
Ibuprofen	50 mg/ml
	100 mg/ml
	200 mg/ml
Budesonide	1.25 mg/dl
	2.5 mg/dl
	5 mg/dl

9.1.4.2. Sample Allocation and Testing

Samples = 2*3*16 = 96
Replicates = 3
Assay Kit Lots = 1
Total Number of Assay Kits = 4
Instrument = 1
Operator = 1
96 Pillar Plate = 90 Samples + 1 Positive + 1 Negative + 1 Cut-off + 3 empty = 96 Wells
Run = 4
Total Number of Days = 1
Sites = 1

9.1.4.3. Statistical Methods

Agreement % = 100 x Number of accurate test results / Total Number of test results

9.1.4.4. Acceptance Criteria

Concentration at which Agreement % is 100% is the concentration where no interference is found.

9.1.4.5. Guidance

CLSI EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition

FDA Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency

9.1.5. Analytical Performance Specimen Stability Study

9.1.5.1. Study details

This study shall evaluate the stability of the serum sample when stored refrigerated. Three positive and two negative samples are tested with 3 replicates in each run for a maximum of 7 days. The samples are aliquoted in 7 plates and stored refrigerated. During each day of testing, the well plates are taken from the refrigerator and tested.

9.1.5.2. Sample Allocation and Testing

Samples = 5
Replicates = 3
Assay Kit Lots = 1

Total Number of Assay Kits = 7
Instrument = 1
Operator = 1
96 Pillar Plate = 15 Samples + 1 Positive + 1 Negative + 1 Cut-off + 78 empty = 96 Wells
Run = 7
Total Number of Days = 7
Sites = 1

9.1.5.3. Statistical Methods

Agreement % = 100 x Number of accurate test results / Total Number of test results

9.1.5.4. Acceptance Criteria

Maximum day at which Agreement % is 100% is the sample stability time.

9.1.5.5. Guidance

CLSI EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition

9.1.6. Analytical Performance Specimen Fresh vs Frozen Study

9.1.6.1. Study details

This study shall evaluate the stability of the serum sample when stored frozen compared to when the sample is immediately used. Three positive and two negative samples are tested with 3 replicates in each run for a maximum of 12 weeks. The samples are aliquoted in 12 plates and stored frozen. Every week of testing, the well plates are thawed from the freezer and tested.

9.1.6.2. Sample Allocation and Testing

Samples =5
Replicates = 3
Assay Kit Lots = 1
Total Number of Assay Kits = 12
Instrument = 1
Operator = 1
96 Pillar Plate = 15 Samples + 1 Positive + 1 Negative + 1 Cut-off + 78 empty = 96 Wells
Run = 12
Total Number of Days = 3 months
Sites = 1

9.1.6.3. Statistical Methods

Agreement % = 100 x Number of accurate test results / Total Number of test results

9.1.6.4. Acceptance Criteria

Maximum week at which Agreement % is 100% is the sample stability time.

9.1.6.5. Guidance

CLSI EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition

FDA Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency

9.1.7. Clinical Performance Clinical Sensitivity and Specificity Study

9.1.7.1. Study details

The clinical study shall test a panel containing retrospectively collected patient serum samples that have been previously confirmed infected / not infected by SARS-CoV-2 RT PCR along with healthy controls (samples collected prior to SARS-CoV-2 outbreak) and other disease controls.

The serum samples shall be collected by a licensed healthcare worker and have information regarding the specimen collection date, date of onset of symptoms (if present/known), and comparator method to confirm patients as SARS-Cov-2 infected or not infected.

Disease	**Number of samples**
Clinical positive (SARS-CoV-2 RT PCR)	35
Clinical negative (SARS-CoV-2 RT PCR)	45
Healthy control	132
Lyme disease	20
CMV	4
Hepatitis C	20
Syphilis	6
Celiac disease	26
SLE	26
Rheumatoid arthritis	26

9.1.7.2. Sample Allocation and Testing

Samples = 340
Replicates = 1
Assay Kit Lots = 1
Total Number of Assay Kits = 4
Instrument = 1
Operator = 1
96 Pillar Plate = 90 Samples + 1 Positive + 1 Negative + 1 Cut-off + 3 empty = 96 Wells
Run = 5
Total Number of Days = 1
Sites = 1

9.1.7.3. Statistical Methods

Clinical Sensitivity = 100% x TP/(TP+FN)
Clinical Specificity = 100% x TN/(FP +TN)

Clopper-Pearson formula for calculating confidence interval

9.1.7.4. Acceptance Criteria

Total Clinical Sensitivity > 90%
Total Clinical Specificity > 95%

9.1.7.5. Guidance

CLSI EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition

FDA Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency

9.2. Inclusion/Exclusion Criteria

9.2.1. Inclusion Criteria

As per project/study included, but are not limited to:

- Specific criteria that must be met for subject or apparently healthy subject specimens to be included in the study. All required baseline and screening procedures for enrollment were indicated. If necessary, additional special tests may need to be carried out, to confirm severity of disease state.
- “Apparently healthy” includes individuals who are asymptomatic and have no significant disease or physical condition that prevents them from engaging in physical activity.
- Disease positive and negative sample include specimens with known result of NP swab based microbiological test
- Age: 0-99
- Gender: Study included both male sample and female samples.
- Included a statement that a properly executed, witnessed and signed informed consent shall be obtained from each eligible subject, where applicable. Sample supplier keeps the record of the informed consent as per their procedure.

9.2.2. Exclusion Criteria

Following samples were excluded from the study:

- Inability to comply with the protocol requirements or inability to give informed consent

9.3. Null/Alternative Hypothesis

Not Applicable

9.4. Retest Criteria or Discontinuation Criteria

9.4.1. Retesting Criteria

Retesting Criteria included but are not limited to:

- Sample did not pass the assay QC metrics on the first try

- Instrument malfunction
- Controls must be within specified range before reporting patient results. For failed controls or calibrators, repeat the run.
- If the 96 pillar plate gets damaged or chip falls during the run, a root cause analysis will be done and run can be repeated after justification.

9.4.2. Discontinuation Criteria

Discontinuation Criteria may include but are not limited to:

- If there are insufficient number of samples required for the studies to produce a result
- More than 2 QC failures
- Missed observation(s)

9.5. Materials and Method

Package Insert of Vibrant COVID-19 Ab Assay

9.6. Sample Testing Procedure

Package Insert of Vibrant COVID-19 Ab Assay

9.7. Expected Results

Package Insert of Vibrant COVID-19 Ab Assay

9.8. References

The study complies with FDA guidance's listed below:

1. https://www.fda.gov/RegulatoryInformation/Guidances/ucm071148.htm
2. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm092748.htm
3. https://www.fda.gov/media/135659/download

In addition, it complies with applicable CLSI Guidance's.

10. Data Handling and Statistics

10.1. Generation and Processing of the Data

10.1.1. 96 Pillar Plate Scan and Feature Extraction

96 Pillar plate has 8 chips per pillar. Each pillar included 4 reference chips located on the 4 corners. Quansys Scanner scanned the whole plate and give one single image in 'TIFF' format. Dynamic ROI algorithm was used to align the plate and extract the raw data.

10.1.2. Calculations

The raw data was then converted into test unit value by signal conversion algorithm.

10.2. Data Handling, Storage and Control

10.2.1. Responsibilities of the Investigator

The Investigator was responsible for maintaining all study records and data provided by designee including all study management forms, protocols, correspondence about study related topics, etc.

10.3. Reporting

The software converts the raw data into test value by dividing the signal intensity of the chip by the signal intensity of the corresponding cut-off control which is run in every plate. This is then computed as POSITIVE (if ratio > 1) or NEGATIVE (if ratio <= 1).

This output can be integrated with laboratory LIS system to add additional patient information.

10.4. Study Record Retention

The Investigator ensured that study records are maintained in a Study File. The Study File documents included, but are not limited to:

- Sponsor, IRB, Regulatory Agencies correspondence
- The Protocol, procedures, manuals
- Credentials and training records
- All forms provided by Sponsor
- Other Regulatory documents

Records will be retained in accordance with the requirements of the target countries for commercialization of the Investigational Product or Sponsor requirements whichever is longer.

As per ICH, the Sponsor will retain all records, reports and documentation. These will be retained at least 2 years after the last approval of a marketing application in an ICH region, and until there are no pending or contemplated marketing applications in an ICH region, or at least 2 years have elapsed since the formal discontinuation of clinical development of the Investigational Product, but at least for a period of up to 5 years after the finalization of this study.

US guidelines: An Investigator or Sponsor shall maintain the records required occurring to 812.140 during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

Suggested Sponsor requirements: All subject/study records at external clinical sites shall be maintained for whichever of the following periods is shortest:

- A period of two years after the date on which the FDA approves the marketing of the assay.
- A period of five years after the date on which the results of the study are submitted to the FDA for approval to market the kit.
- A period of five years after the date on which the results of the study are submitted to Sponsor if no FDA application is filed.

10.5. Use of Data

Each investigational site clinical protocol contained a statement that immediately upon completion of the study (or as may be stated in the Institutional Study Agreement), all study data, including the completed, signed and dated Subject Case Report and Assay Results Forms, will be submitted to the Sponsor or Sponsor's representative for review and statistical analysis. The Sponsor/Sponsor's representative may periodically collect data for evaluation during the study.

Each external site clinical protocol included a statement regarding the confidentiality of all information supplied by Sponsor concerning the Investigational Product or mode of operation not previously published.

Each external site clinical protocol also included the obligations of the Investigator to Sponsor (and vice versa) regarding confidentiality and the review of all material related to the study prior to the submission of any publication.

10.6. Data and Statistical Analysis

10.6.1. Analytical Performance Study Acceptance Criteria

See Section 11 Study Design

11. STUDY DOCUMENTATION

11.1. Case Report Forms

N/A.

12. PROTOCOL DEVIATIONS

No protocol deviations were observed during the study.

13. Study Results and Analysis

13.1. Analytical Performance Precision/Reproducibility Study

Two test operators tested a panel of 6 samples, 4 replicates daily over a period of 5 days for a total of 40 data points. Panel consisted of positive control, negative control, positive sample, negative sample, a sample with concentration +20% above cut-off, and a sample with concentration -20% below cut-off. The results are summarized below. Lot-to-Lot and Operator-to-Operator studies are covered within this data analysis.

Antigen	Sample	Sample Type	# of Accurate Results	Total # of Results	Reproducibility %
S1 SP IgG	Sample 1	Positive control	120	120	100%
S1 SP IgG	Sample 2	Negative control	120	120	100%
S1 SP IgG	Sample 3	Positive sample	120	120	100%
S1 SP IgG	Sample 4	Negative sample	120	120	100%
S1 SP IgG	Sample 5	20% above cut-off	118	120	98.3%
S1 SP IgG	Sample 6	20% below cut-off	119	120	99.2%
S1 SP IgA	Sample 1	Positive control	120	120	100%
S1 SP IgA	Sample 2	Negative control	120	120	100%
S1 SP IgA	Sample 3	Positive sample	120	120	100%
S1 SP IgA	Sample 4	Negative sample	120	120	100%
S1 SP IgA	Sample 5	20% above cut-off	120	120	100%
S1 SP IgA	Sample 6	20% below cut-off	118	120	98.3%
S1 SP IgM	Sample 1	Positive control	120	120	100%
S1 SP IgM	Sample 2	Negative control	120	120	100%
S1 SP IgM	Sample 3	Positive sample	120	120	100%
S1 SP IgM	Sample 4	Negative sample	120	120	100%
S1 SP IgM	Sample 5	20% above cut-off	117	120	97.5%
S1 SP IgM	Sample 6	20% below cut-off	116	120	96.7%

Antigen	Sample	Sample Type	# of Accurate Results	Total # of Results	Reproducibility %
RBD IgG	Sample 1	Positive control	120	120	100%
RBD IgG	Sample 2	Negative control	120	120	100%
RBD IgG	Sample 3	Positive sample	120	120	100%
RBD IgG	Sample 4	Negative sample	120	120	100%
RBD IgG	Sample 5	20% above cut-off	120	120	100%
RBD IgG	Sample 6	20% below cut-off	118	120	98.3%
RBD IgA	Sample 1	Positive control	120	120	100%
RBD IgA	Sample 2	Negative control	120	120	100%
RBD IgA	Sample 3	Positive sample	120	120	100%
RBD IgA	Sample 4	Negative sample	120	120	100%
RBD IgA	Sample 5	20% above cut-off	120	120	100%
RBD IgA	Sample 6	20% below cut-off	120	120	100%
RBD IgM	Sample 1	Positive control	120	120	100%
RBD IgM	Sample 2	Negative control	120	120	100%
RBD IgM	Sample 3	Positive sample	120	120	100%
RBD IgM	Sample 4	Negative sample	120	120	100%
RBD IgM	Sample 5	20% above cut-off	119	120	99.2%
RBD IgM	Sample 6	20% below cut-off	116	120	96.7%

Antigen	Sample	Sample Type	# of Accurate Results	Total # of Results	Reproducibility %
S2 SP IgG	Sample 1	Positive control	120	120	100%
S2 SP IgG	Sample 2	Negative control	120	120	100%
S2 SP IgG	Sample 3	Positive sample	120	120	100%
S2 SP IgG	Sample 4	Negative sample	120	120	100%
S2 SP IgG	Sample 5	20% above cut-off	120	120	100%
S2 SP IgG	Sample 6	20% below cut-off	120	120	100%
S2 SP IgA	Sample 1	Positive control	120	120	100%
S2 SP IgA	Sample 2	Negative control	120	120	100%
S2 SP IgA	Sample 3	Positive sample	120	120	100%
S2 SP IgA	Sample 4	Negative sample	120	120	100%
S2 SP IgA	Sample 5	20% above cut-off	119	120	99.2%
S2 SP IgA	Sample 6	20% below cut-off	118	120	98.3%
S2 SP IgM	Sample 1	Positive control	120	120	100%
S2 SP IgM	Sample 2	Negative control	120	120	100%
S2 SP IgM	Sample 3	Positive sample	120	120	100%
S2 SP IgM	Sample 4	Negative sample	120	120	100%
S2 SP IgM	Sample 5	20% above cut-off	119	120	99.2%
S2 SP IgM	Sample 6	20% below cut-off	119	120	99.2%

Antigen	Sample	Sample Type	# of Accurate Results	Total # of Results	Reproducibility %
NP IgG	Sample 1	Positive control	120	120	100%
NP IgG	Sample 2	Negative control	120	120	100%
NP IgG	Sample 3	Positive sample	120	120	100%
NP IgG	Sample 4	Negative sample	120	120	100%
NP IgG	Sample 5	20% above cut-off	118	120	98.3%
NP IgG	Sample 6	20% below cut-off	117	120	97.5%
NP IgA	Sample 1	Positive control	120	120	100%
NP IgA	Sample 2	Negative control	120	120	100%
NP IgA	Sample 3	Positive sample	120	120	100%
NP IgA	Sample 4	Negative sample	120	120	100%
NP IgA	Sample 5	20% above cut-off	120	120	100%
NP IgA	Sample 6	20% below cut-off	118	120	98.3%
NP IgM	Sample 1	Positive control	120	120	100%
NP IgM	Sample 2	Negative control	120	120	100%
NP IgM	Sample 3	Positive sample	120	120	100%
NP IgM	Sample 4	Negative sample	120	120	100%
NP IgM	Sample 5	20% above cut-off	120	120	100%
NP IgM	Sample 6	20% below cut-off	120	120	100%

13.2. Analytical Performance Cross Reactivity Study

The following panel of samples were tested to determine the cross-reactivity/analytical specificity of the Vibrant COVID-19 Ab assay.

Antigen	Antibody	# of samples	# of false positive
S1 SP IgG	Anti-influenza A (IgG, IgA and IgM)	10	0
S1 SP IgG	Anti- influenza B (IgG, IgA and IgM)	10	0
S1 SP IgG	Anti-HCV (IgG, IgA and IgM)	10	0
S1 SP IgG	Anti-HBV (IgG, Ig and IgM)	10	0
S1 SP IgG	ANA	20	0
S1 SP IgG	Anti-respiratory syncytial virus	10	0
S1 SP IgG	Anti-Haemophilus influenzae	5	0
S1 SP IgA	Anti-influenza A (IgG, IgA and IgM)	10	0
S1 SP IgA	Anti- influenza B (IgG, IgA and IgM)	10	0
S1 SP IgA	Anti-HCV (IgG, IgA and IgM)	10	0
S1 SP IgA	Anti-HBV (IgG, Ig and IgM)	10	0
S1 SP IgA	ANA	20	0
S1 SP IgA	Anti-respiratory syncytial virus	10	0
S1 SP IgA	Anti-Haemophilus influenzae	5	0
S1 SP IgM	Anti-influenza A (IgG, IgA and IgM)	10	0
S1 SP IgM	Anti- influenza B (IgG, IgA and IgM)	10	0

Antigen	Antibody	# of samples	# of false positive
S1 SP IgM	Anti-HCV (IgG, IgA and IgM)	10	0
S1 SP IgM	Anti-HBV (IgG, Ig and IgM)	10	0
S1 SP IgM	ANA	20	0
S1 SP IgM	Anti-respiratory syncytial virus	10	0
S1 SP IgM	Anti-Haemophilus influenzae	5	0

Antigen	Antibody	# of samples	# of false positive
RBD IgG	Anti-influenza A (IgG, IgA and IgM)	10	0
RBD IgG	Anti- influenza B (IgG, IgA and IgM)	10	0
RBD IgG	Anti-HCV (IgG, IgA and IgM)	10	0
RBD IgG	Anti-HBV (IgG, Ig and IgM)	10	0
RBD IgG	ANA	20	0
RBD IgG	Anti-respiratory syncytial virus	10	0
RBD IgG	Anti-Haemophilus influenzae	5	0
RBD IgA	Anti-influenza A (IgG, IgA and IgM)	10	0
RBD IgA	Anti- influenza B (IgG, IgA and IgM)	10	0
RBD IgA	Anti-HCV (IgG, IgA and IgM)	10	0
RBD IgA	Anti-HBV (IgG, Ig and IgM)	10	0
RBD IgA	ANA	20	0
RBD IgA	Anti-respiratory syncytial virus	10	0
RBD IgA	Anti-Haemophilus influenzae	5	0
RBD IgM	Anti-influenza A (IgG, IgA and IgM)	10	0
RBD IgM	Anti- influenza B (IgG, IgA and IgM)	10	0
RBD IgM	Anti-HCV (IgG, IgA and IgM)	10	0
RBD IgM	Anti-HBV (IgG, Ig and IgM)	10	0
RBD IgM	ANA	20	0
RBD IgM	Anti-respiratory syncytial virus	10	0
RBD IgM	Anti-Haemophilus influenzae	5	0

Antigen	Antibody	# of samples	# of false positive
S2 SP IgG	Anti-influenza A (IgG, IgA and IgM)	10	0
S2 SP IgG	Anti- influenza B (IgG, IgA and IgM)	10	0
S2 SP IgG	Anti-HCV (IgG, IgA and IgM)	10	0
S2 SP IgG	Anti-HBV (IgG, Ig and IgM)	10	0
S2 SP IgG	ANA	20	0
S2 SP IgG	Anti-respiratory syncytial virus	10	0
S2 SP IgG	Anti-Haemophilus influenzae	5	0
S2 SP IgA	Anti-influenza A (IgG, IgA and IgM)	10	0

Antigen	Antibody	# of samples	# of false positive
S2 SP IgA	Anti- influenza B (IgG, IgA and IgM)	10	0
S2 SP IgA	Anti-HCV (IgG, IgA and IgM)	10	0
S2 SP IgA	Anti-HBV (IgG, Ig and IgM)	10	0
S2 SP IgA	ANA	20	0
S2 SP IgA	Anti-respiratory syncytial virus	10	0
S2 SP IgA	Anti-Haemophilus influenzae	5	0
S2 SP IgM	Anti-influenza A (IgG, IgA and IgM)	10	0
S2 SP IgM	Anti- influenza B (IgG, IgA and IgM)	10	0
S2 SP IgM	Anti-HCV (IgG, IgA and IgM)	10	0
S2 SP IgM	Anti-HBV (IgG, Ig and IgM)	10	0
S2 SP IgM	ANA	20	0
S2 SP IgM	Anti-respiratory syncytial virus	10	0
S2 SP IgM	Anti-Haemophilus influenzae	5	0

Antigen	Antibody	# of samples	# of false positive
NP IgG	Anti-influenza A (IgG, IgA and IgM)	10	0
NP IgG	Anti- influenza B (IgG, IgA and IgM)	10	0
NP IgG	Anti-HCV (IgG, IgA and IgM)	10	0
NP IgG	Anti-HBV (IgG, Ig and IgM)	10	0
NP IgG	ANA	20	0
NP IgG	Anti-respiratory syncytial virus	10	0
NP IgG	Anti-Haemophilus influenzae	5	0
NP IgA	Anti-influenza A (IgG, IgA and IgM)	10	0
NP IgA	Anti- influenza B (IgG, IgA and IgM)	10	0
NP IgA	Anti-HCV (IgG, IgA and IgM)	10	0
NP IgA	Anti-HBV (IgG, Ig and IgM)	10	0
NP IgA	ANA	20	0
NP IgA	Anti-respiratory syncytial virus	10	0
NP IgA	Anti-Haemophilus influenzae	5	0
NP IgM	Anti-influenza A (IgG, IgA and IgM)	10	0
NP IgM	Anti- influenza B (IgG, IgA and IgM)	10	0
NP IgM	Anti-HCV (IgG, IgA and IgM)	10	0
NP IgM	Anti-HBV (IgG, Ig and IgM)	10	0
NP IgM	ANA	20	0
NP IgM	Anti-respiratory syncytial virus	10	0
NP IgM	Anti-Haemophilus influenzae	5	0

13.3. Analytical Performance Class Specificity Study

This study evaluated the potential for human IgG/IgA/IgM to cross react and therefore produce false positive results for each individual assay. The highest concentrations of total IgG, IgA and IgM were spiked in 1 positive and 1 negative sample with 3 replicates and the results are summarized below.

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
S1 SP IgG	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
S1 SP IgG	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
S1 SP IgG	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
S1 SP IgG	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
S1 SP IgG	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
S1 SP IgG	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%
S1 SP IgA	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
S1 SP IgA	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
S1 SP IgA	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
S1 SP IgA	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
S1 SP IgA	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
S1 SP IgA	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%
S1 SP IgM	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
S1 SP IgM	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
S1 SP IgM	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
S1 SP IgM	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
S1 SP IgM	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
S1 SP IgM	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
RBD IgG	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
RBD IgG	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
RBD IgG	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
RBD IgG	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
RBD IgG	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
RBD IgG	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%
RBD IgA	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
RBD IgA	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
RBD IgA	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
RBD IgA	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
RBD IgA	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
RBD IgA	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%
RBD IgM	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
RBD IgM	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
RBD IgM	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
RBD IgM	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
RBD IgM	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
RBD IgM	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
S2 SP IgG	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
S2 SP IgG	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
S2 SP IgG	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
S2 SP IgG	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
S2 SP IgG	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
S2 SP IgG	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%
S2 SP IgA	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
S2 SP IgA	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
S2 SP IgA	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
S2 SP IgA	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
S2 SP IgA	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
S2 SP IgA	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%
S2 SP IgM	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
S2 SP IgM	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
S2 SP IgM	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
S2 SP IgM	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
S2 SP IgM	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
S2 SP IgM	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
NP IgG	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
NP IgG	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
NP IgG	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
NP IgG	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
NP IgG	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
NP IgG	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%
NP IgA	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
NP IgA	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
NP IgA	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
NP IgA	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
NP IgA	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
NP IgA	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%
NP IgM	Sample 1	Positive	Total IgG 3000 mg/dl	3	3	100%
NP IgM	Sample 2	Negative	Total IgG 3000 mg/dl	3	3	100%
NP IgM	Sample 3	Positive	Total IgA 700 mg/dl	3	3	100%
NP IgM	Sample 4	Negative	Total IgA 700 mg/dl	3	3	100%
NP IgM	Sample 5	Positive	Total IgM 500 mg/dl	3	3	100%
NP IgM	Sample 6	Negative	Total IgM 500 mg/dl	3	3	100%

13.4. Analytical Performance Analytical Specificity Study

This study evaluated the potential for common potentially interfering substances to cross react and therefore produce false positive results for each individual assay. The highest concentration of each interference substance as detailed below were spiked in 1 positive and 1 negative sample with 3 replicates and the results are summarized below.

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
S1 SP IgG	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
S1 SP IgG	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
S1 SP IgG	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
S1 SP IgG	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S1 SP IgG	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
S1 SP IgG	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
S1 SP IgG	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
S1 SP IgG	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
S1 SP IgG	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
S1 SP IgG	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
S1 SP IgG	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
S1 SP IgG	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
S1 SP IgG	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
S1 SP IgG	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
S1 SP IgG	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
S1 SP IgG	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
S1 SP IgG	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
S1 SP IgG	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
S1 SP IgG	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
S1 SP IgG	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S1 SP IgG	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
S1 SP IgG	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
S1 SP IgG	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
S1 SP IgG	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
S1 SP IgG	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
S1 SP IgG	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
S1 SP IgG	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
S1 SP IgG	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
S1 SP IgG	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
S1 SP IgG	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
S1 SP IgG	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
S1 SP IgG	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
S1 SP IgA	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
S1 SP IgA	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
S1 SP IgA	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
S1 SP IgA	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S1 SP IgA	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
S1 SP IgA	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
S1 SP IgA	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
S1 SP IgA	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
S1 SP IgA	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
S1 SP IgA	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
S1 SP IgA	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
S1 SP IgA	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
S1 SP IgA	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
S1 SP IgA	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
S1 SP IgA	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
S1 SP IgA	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
S1 SP IgA	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
S1 SP IgA	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
S1 SP IgA	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
S1 SP IgA	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S1 SP IgA	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
S1 SP IgA	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
S1 SP IgA	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
S1 SP IgA	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
S1 SP IgA	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
S1 SP IgA	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
S1 SP IgA	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
S1 SP IgA	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
S1 SP IgA	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
S1 SP IgA	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
S1 SP IgA	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
S1 SP IgA	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
S1 SP IgM	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
S1 SP IgM	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
S1 SP IgM	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
S1 SP IgM	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S1 SP IgM	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
S1 SP IgM	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
S1 SP IgM	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
S1 SP IgM	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
S1 SP IgM	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
S1 SP IgM	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
S1 SP IgM	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
S1 SP IgM	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
S1 SP IgM	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
S1 SP IgM	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
S1 SP IgM	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
S1 SP IgM	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
S1 SP IgM	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
S1 SP IgM	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
S1 SP IgM	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
S1 SP IgM	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S1 SP IgM	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
S1 SP IgM	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
S1 SP IgM	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
S1 SP IgM	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
S1 SP IgM	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
S1 SP IgM	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
S1 SP IgM	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
S1 SP IgM	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
S1 SP IgM	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
S1 SP IgM	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
S1 SP IgM	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
S1 SP IgM	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
RBD IgG	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
RBD IgG	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
RBD IgG	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
RBD IgG	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
RBD IgG	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
RBD IgG	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
RBD IgG	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
RBD IgG	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
RBD IgG	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
RBD IgG	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
RBD IgG	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
RBD IgG	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
RBD IgG	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
RBD IgG	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
RBD IgG	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
RBD IgG	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
RBD IgG	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
RBD IgG	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
RBD IgG	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
RBD IgG	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
RBD IgG	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
RBD IgG	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
RBD IgG	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
RBD IgG	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
RBD IgG	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
RBD IgG	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
RBD IgG	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
RBD IgG	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
RBD IgG	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
RBD IgG	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
RBD IgG	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
RBD IgG	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
RBD IgA	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
RBD IgA	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
RBD IgA	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
RBD IgA	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
RBD IgA	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
RBD IgA	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
RBD IgA	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
RBD IgA	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
RBD IgA	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
RBD IgA	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
RBD IgA	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
RBD IgA	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
RBD IgA	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
RBD IgA	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
RBD IgA	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
RBD IgA	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
RBD IgA	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
RBD IgA	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
RBD IgA	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
RBD IgA	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
RBD IgA	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
RBD IgA	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
RBD IgA	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
RBD IgA	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
RBD IgA	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
RBD IgA	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
RBD IgA	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
RBD IgA	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
RBD IgA	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
RBD IgA	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
RBD IgA	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
RBD IgA	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
RBD IgM	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
RBD IgM	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
RBD IgM	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
RBD IgM	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
RBD IgM	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
RBD IgM	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
RBD IgM	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
RBD IgM	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
RBD IgM	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
RBD IgM	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
RBD IgM	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
RBD IgM	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
RBD IgM	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
RBD IgM	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
RBD IgM	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
RBD IgM	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
RBD IgM	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
RBD IgM	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
RBD IgM	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
RBD IgM	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
RBD IgM	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
RBD IgM	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
RBD IgM	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
RBD IgM	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
RBD IgM	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
RBD IgM	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
RBD IgM	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
RBD IgM	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
RBD IgM	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
RBD IgM	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
RBD IgM	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
RBD IgM	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
S2 SP IgG	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
S2 SP IgG	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
S2 SP IgG	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
S2 SP IgG	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S2 SP IgG	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
S2 SP IgG	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
S2 SP IgG	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
S2 SP IgG	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
S2 SP IgG	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
S2 SP IgG	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
S2 SP IgG	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
S2 SP IgG	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
S2 SP IgG	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
S2 SP IgG	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
S2 SP IgG	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
S2 SP IgG	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
S2 SP IgG	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
S2 SP IgG	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
S2 SP IgG	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
S2 SP IgG	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S2 SP IgG	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
S2 SP IgG	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
S2 SP IgG	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
S2 SP IgG	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
S2 SP IgG	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
S2 SP IgG	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
S2 SP IgG	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
S2 SP IgG	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
S2 SP IgG	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
S2 SP IgG	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
S2 SP IgG	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
S2 SP IgG	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
S2 SP IgA	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
S2 SP IgA	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
S2 SP IgA	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
S2 SP IgA	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S2 SP IgA	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
S2 SP IgA	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
S2 SP IgA	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
S2 SP IgA	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
S2 SP IgA	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
S2 SP IgA	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
S2 SP IgA	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
S2 SP IgA	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
S2 SP IgA	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
S2 SP IgA	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
S2 SP IgA	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
S2 SP IgA	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
S2 SP IgA	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
S2 SP IgA	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
S2 SP IgA	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
S2 SP IgA	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S2 SP IgA	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
S2 SP IgA	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
S2 SP IgA	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
S2 SP IgA	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
S2 SP IgA	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
S2 SP IgA	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
S2 SP IgA	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
S2 SP IgA	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
S2 SP IgA	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
S2 SP IgA	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
S2 SP IgA	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
S2 SP IgA	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
S2 SP IgM	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
S2 SP IgM	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
S2 SP IgM	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
S2 SP IgM	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S2 SP IgM	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
S2 SP IgM	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
S2 SP IgM	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
S2 SP IgM	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
S2 SP IgM	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
S2 SP IgM	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
S2 SP IgM	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
S2 SP IgM	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
S2 SP IgM	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
S2 SP IgM	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
S2 SP IgM	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
S2 SP IgM	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
S2 SP IgM	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
S2 SP IgM	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
S2 SP IgM	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
S2 SP IgM	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
S2 SP IgM	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
S2 SP IgM	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
S2 SP IgM	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
S2 SP IgM	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
S2 SP IgM	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
S2 SP IgM	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
S2 SP IgM	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
S2 SP IgM	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
S2 SP IgM	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
S2 SP IgM	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
S2 SP IgM	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
S2 SP IgM	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
NP IgG	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
NP IgG	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
NP IgG	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
NP IgG	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
NP IgG	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
NP IgG	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
NP IgG	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
NP IgG	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
NP IgG	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
NP IgG	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
NP IgG	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
NP IgG	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
NP IgG	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
NP IgG	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
NP IgG	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
NP IgG	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
NP IgG	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
NP IgG	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
NP IgG	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
NP IgG	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
NP IgG	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
NP IgG	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
NP IgG	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
NP IgG	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
NP IgG	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
NP IgG	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
NP IgG	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
NP IgG	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
NP IgG	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
NP IgG	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
NP IgG	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
NP IgG	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
NP IgA	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
NP IgA	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
NP IgA	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
NP IgA	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
NP IgA	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
NP IgA	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
NP IgA	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
NP IgA	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
NP IgA	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
NP IgA	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
NP IgA	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
NP IgA	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
NP IgA	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
NP IgA	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
NP IgA	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
NP IgA	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
NP IgA	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
NP IgA	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
NP IgA	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
NP IgA	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
NP IgA	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
NP IgA	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
NP IgA	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
NP IgA	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
NP IgA	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
NP IgA	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
NP IgA	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
NP IgA	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
NP IgA	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
NP IgA	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
NP IgA	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
NP IgA	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

Antigen	Sample	Sample Type	Spiked material	# of Accurate Results	Total # of Results	Agreement %
NP IgM	Sample 1	Positive	Bilirubin 40 mg/dl	3	3	100%
NP IgM	Sample 2	Positive	Triglycerides 1000 mg/ml	3	3	100%
NP IgM	Sample 3	Positive	Hemoglobin 1000 mg/ml	3	3	100%
NP IgM	Sample 4	Positive	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
NP IgM	Sample 5	Positive	Cholesterol 100 mg/ml	3	3	100%
NP IgM	Sample 6	Positive	HAMA 12.5 ng/ml	3	3	100%
NP IgM	Sample 7	Positive	Ribavirin 25 mg/dl	3	3	100%
NP IgM	Sample 8	Positive	Levofloxacin 0.5 mg/dl	3	3	100%
NP IgM	Sample 9	Positive	Azithromycin 0.5 mg/dl	3	3	100%
NP IgM	Sample 10	Positive	Ceftriaxone sodium 25 mg/dl	3	3	100%
NP IgM	Sample 11	Positive	Oxymetazoline 1.25 mg/dl	3	3	100%
NP IgM	Sample 12	Positive	Sodium chloride 25 mg/dl	3	3	100%
NP IgM	Sample 13	Positive	EDTA 12.5 mg/ml	3	3	100%
NP IgM	Sample 14	Positive	Acetaminophen 50 mg/ml	3	3	100%
NP IgM	Sample 15	Positive	Ibuprofen 50 mg/ml	3	3	100%
NP IgM	Sample 16	Positive	Budesonide 1.25 mg/dl	3	3	100%
NP IgM	Sample 17	Negative	Bilirubin 40 mg/dl	3	3	100%
NP IgM	Sample 18	Negative	Triglycerides 1000 mg/ml	3	3	100%
NP IgM	Sample 19	Negative	Hemoglobin 1000 mg/ml	3	3	100%
NP IgM	Sample 20	Negative	Rheumatoid Factor (RF) 2000 IU/ml	3	3	100%
NP IgM	Sample 21	Negative	Cholesterol 100 mg/ml	3	3	100%
NP IgM	Sample 22	Negative	HAMA 12.5 ng/ml	3	3	100%
NP IgM	Sample 23	Negative	Ribavirin 25 mg/dl	3	3	100%
NP IgM	Sample 24	Negative	Levofloxacin 0.5 mg/dl	3	3	100%
NP IgM	Sample 25	Negative	Azithromycin 0.5 mg/dl	3	3	100%
NP IgM	Sample 26	Negative	Ceftriaxone sodium 25 mg/dl	3	3	100%
NP IgM	Sample 27	Negative	Oxymetazoline 1.25 mg/dl	3	3	100%
NP IgM	Sample 28	Negative	Sodium chloride 25 mg/dl	3	3	100%
NP IgM	Sample 29	Negative	EDTA 12.5 mg/ml	3	3	100%
NP IgM	Sample 30	Negative	Acetaminophen 50 mg/ml	3	3	100%
NP IgM	Sample 31	Negative	Ibuprofen 50 mg/ml	3	3	100%
NP IgM	Sample 32	Negative	Budesonide 1.25 mg/dl	3	3	100%

13.5. Analytical Performance Specimen Stability Study

This study evaluated the stability of the serum sample when stored refrigerated. Three positive and two negative samples were tested with 3 replicates in each run for a total of 7 days. The samples were aliquoted in 7 plates and stored refrigerated. During each day of testing, the well plates are taken from the refrigerator and tested. The results are summarized below.

Antigen	Sample	Sample Type	Max. # of days	# of Accurate Results	Total # of Results	Agreement %
S1 SP IgG	Sample 1	Positive	7	21	21	100%
S1 SP IgG	Sample 2	Positive	7	21	21	100%
S1 SP IgG	Sample 3	Positive	7	21	21	100%
S1 SP IgG	Sample 4	Negative	7	21	21	100%
S1 SP IgG	Sample 5	Negative	7	21	21	100%
S1 SP IgA	Sample 1	Positive	7	21	21	100%
S1 SP IgA	Sample 2	Positive	7	21	21	100%
S1 SP IgA	Sample 3	Positive	7	21	21	100%
S1 SP IgA	Sample 4	Negative	7	21	21	100%
S1 SP IgA	Sample 5	Negative	7	21	21	100%
S1 SP IgM	Sample 1	Positive	7	21	21	100%
S1 SP IgM	Sample 2	Positive	7	21	21	100%
S1 SP IgM	Sample 3	Positive	7	21	21	100%
S1 SP IgM	Sample 4	Negative	7	21	21	100%
S1 SP IgM	Sample 5	Negative	7	21	21	100%

Antigen	Sample	Sample Type	Max. # of days	# of Accurate Results	Total # of Results	Agreement %
RBD IgG	Sample 1	Positive	7	21	21	100%
RBD IgG	Sample 2	Positive	7	21	21	100%
RBD IgG	Sample 3	Positive	7	21	21	100%
RBD IgG	Sample 4	Negative	7	21	21	100%
RBD IgG	Sample 5	Negative	7	21	21	100%
RBD IgA	Sample 1	Positive	7	21	21	100%
RBD IgA	Sample 2	Positive	7	21	21	100%
RBD IgA	Sample 3	Positive	7	21	21	100%
RBD IgA	Sample 4	Negative	7	21	21	100%
RBD IgA	Sample 5	Negative	7	21	21	100%
RBD IgM	Sample 1	Positive	7	21	21	100%
RBD IgM	Sample 2	Positive	7	21	21	100%
RBD IgM	Sample 3	Positive	7	21	21	100%
RBD IgM	Sample 4	Negative	7	21	21	100%
RBD IgM	Sample 5	Negative	7	21	21	100%

Antigen	Sample	Sample Type	Max. # of days	# of Accurate Results	Total # of Results	Agreement %
S2 SP IgG	Sample 1	Positive	7	21	21	100%
S2 SP IgG	Sample 2	Positive	7	21	21	100%
S2 SP IgG	Sample 3	Positive	7	21	21	100%
S2 SP IgG	Sample 4	Negative	7	21	21	100%
S2 SP IgG	Sample 5	Negative	7	21	21	100%
S2 SP IgA	Sample 1	Positive	7	21	21	100%
S2 SP IgA	Sample 2	Positive	7	21	21	100%
S2 SP IgA	Sample 3	Positive	7	21	21	100%
S2 SP IgA	Sample 4	Negative	7	21	21	100%
S2 SP IgA	Sample 5	Negative	7	21	21	100%
S2 SP IgM	Sample 1	Positive	7	21	21	100%
S2 SP IgM	Sample 2	Positive	7	21	21	100%
S2 SP IgM	Sample 3	Positive	7	21	21	100%
S2 SP IgM	Sample 4	Negative	7	21	21	100%
S2 SP IgM	Sample 5	Negative	7	21	21	100%

Antigen	Sample	Sample Type	Max. # of days	# of Accurate Results	Total # of Results	Agreement %
NP IgG	Sample 1	Positive	7	21	21	100%
NP IgG	Sample 2	Positive	7	21	21	100%
NP IgG	Sample 3	Positive	7	21	21	100%
NP IgG	Sample 4	Negative	7	21	21	100%
NP IgG	Sample 5	Negative	7	21	21	100%
NP IgA	Sample 1	Positive	7	21	21	100%
NP IgA	Sample 2	Positive	7	21	21	100%
NP IgA	Sample 3	Positive	7	21	21	100%
NP IgA	Sample 4	Negative	7	21	21	100%
NP IgA	Sample 5	Negative	7	21	21	100%
NP IgM	Sample 1	Positive	7	21	21	100%
NP IgM	Sample 2	Positive	7	21	21	100%
NP IgM	Sample 3	Positive	7	21	21	100%
NP IgM	Sample 4	Negative	7	21	21	100%
NP IgM	Sample 5	Negative	7	21	21	100%

13.6. Analytical Performance Specimen Fresh vs Frozen Study

This study evaluates the stability of the serum sample when stored frozen compared to when the sample is immediately used. Three positive and two negative samples were tested with 3 replicates in each run for 1 week. The samples are aliquoted in 12 plates and stored frozen. Every week of testing, the

well plates are thawed from the freezer and tested. This study is ongoing and preliminary results are as below.

Antigen	Sample	Sample Type	Max. # of weeks	# of Accurate Results	Total # of Results	Agreement %
S1 SP IgG	Sample 1	Positive	1	6	6	100%
S1 SP IgG	Sample 2	Positive	1	6	6	100%
S1 SP IgG	Sample 3	Positive	1	6	6	100%
S1 SP IgG	Sample 4	Negative	1	6	6	100%
S1 SP IgG	Sample 5	Negative	1	6	6	100%
S1 SP IgA	Sample 1	Positive	1	6	6	100%
S1 SP IgA	Sample 2	Positive	1	6	6	100%
S1 SP IgA	Sample 3	Positive	1	6	6	100%
S1 SP IgA	Sample 4	Negative	1	6	6	100%
S1 SP IgA	Sample 5	Negative	1	6	6	100%
S1 SP IgM	Sample 1	Positive	1	6	6	100%
S1 SP IgM	Sample 2	Positive	1	6	6	100%
S1 SP IgM	Sample 3	Positive	1	6	6	100%
S1 SP IgM	Sample 4	Negative	1	6	6	100%
S1 SP IgM	Sample 5	Negative	1	6	6	100%

Antigen	Sample	Sample Type	Max. # of weeks	# of Accurate Results	Total # of Results	Agreement %
RBD IgG	Sample 1	Positive	1	6	6	100%
RBD IgG	Sample 2	Positive	1	6	6	100%
RBD IgG	Sample 3	Positive	1	6	6	100%
RBD IgG	Sample 4	Negative	1	6	6	100%
RBD IgG	Sample 5	Negative	1	6	6	100%
RBD IgA	Sample 1	Positive	1	6	6	100%
RBD IgA	Sample 2	Positive	1	6	6	100%
RBD IgA	Sample 3	Positive	1	6	6	100%
RBD IgA	Sample 4	Negative	1	6	6	100%
RBD IgA	Sample 5	Negative	1	6	6	100%
RBD IgM	Sample 1	Positive	1	6	6	100%
RBD IgM	Sample 2	Positive	1	6	6	100%
RBD IgM	Sample 3	Positive	1	6	6	100%
RBD IgM	Sample 4	Negative	1	6	6	100%
RBD IgM	Sample 5	Negative	1	6	6	100%

Antigen	Sample	Sample Type	Max. # of weeks	# of Accurate Results	Total # of Results	Agreement %
S2 SP IgG	Sample 1	Positive	1	6	6	100%
S2 SP IgG	Sample 2	Positive	1	6	6	100%
S2 SP IgG	Sample 3	Positive	1	6	6	100%
S2 SP IgG	Sample 4	Negative	1	6	6	100%
S2 SP IgG	Sample 5	Negative	1	6	6	100%
S2 SP IgA	Sample 1	Positive	1	6	6	100%
S2 SP IgA	Sample 2	Positive	1	6	6	100%
S2 SP IgA	Sample 3	Positive	1	6	6	100%
S2 SP IgA	Sample 4	Negative	1	6	6	100%
S2 SP IgA	Sample 5	Negative	1	6	6	100%
S2 SP IgM	Sample 1	Positive	1	6	6	100%
S2 SP IgM	Sample 2	Positive	1	6	6	100%
S2 SP IgM	Sample 3	Positive	1	6	6	100%
S2 SP IgM	Sample 4	Negative	1	6	6	100%
S2 SP IgM	Sample 5	Negative	1	6	6	100%

Antigen	Sample	Sample Type	Max. # of weeks	# of Accurate Results	Total # of Results	Agreement %
NP IgG	Sample 1	Positive	1	6	6	100%
NP IgG	Sample 2	Positive	1	6	6	100%
NP IgG	Sample 3	Positive	1	6	6	100%
NP IgG	Sample 4	Negative	1	6	6	100%
NP IgG	Sample 5	Negative	1	6	6	100%
NP IgA	Sample 1	Positive	1	6	6	100%
NP IgA	Sample 2	Positive	1	6	6	100%
NP IgA	Sample 3	Positive	1	6	6	100%
NP IgA	Sample 4	Negative	1	6	6	100%
NP IgA	Sample 5	Negative	1	6	6	100%
NP IgM	Sample 1	Positive	1	6	6	100%
NP IgM	Sample 2	Positive	1	6	6	100%
NP IgM	Sample 3	Positive	1	6	6	100%
NP IgM	Sample 4	Negative	1	6	6	100%
NP IgM	Sample 5	Negative	1	6	6	100%

13.7. Clinical Performance Clinical Sensitivity and Specificity Study

The clinical study tested a panel containing retrospectively collected patient serum samples that were previously confirmed infected / not infected by SARS-CoV-2 RT PCR along with healthy controls (samples collected prior to SARS-CoV-2 outbreak) and other disease controls.

Vibrant COVID-19 Ab		**Clinical Diagnosis – NP Swab Positive**		**Total**	**Analysis (95% Confidence)**
		Positive	Controls		
S1 SP IgG	Positive	24	3	27	Sensitivity = 68.57% (52.02% - 81.45%)
	Negative	11	302	313	Specificity = 99.02% (97.15% - 99.67%)
Total		35	305	340	

Vibrant COVID-19 Ab		**Clinical Diagnosis – NP Swab Positive**		**Total**	**Analysis (95% Confidence)**
		Positive	Controls		
S1 SP IgA	Positive	15	1	16	Sensitivity = 42.86% (27.98% - 59.14%)
	Negative	20	304	324	Specificity = 99.67% (98.17% - 99.94%)
Total		35	305	340	

Vibrant COVID-19 Ab		**Clinical Diagnosis – NP Swab Positive**		**Total**	**Analysis (95% Confidence)**
		Positive	Controls		
S1 SP IgM	Positive	28	2	30	Sensitivity = 80.00% (64.11% - 89.96%)
	Negative	7	303	310	Specificity = 99.34% (97.64% - 99.82%)
Total		35	305	340	

Vibrant COVID-19 Ab		**Clinical Diagnosis – NP Swab Positive**		**Total**	**Analysis (95% Confidence)**
		Positive	Controls		
RBD IgG	Positive	23	3	26	Sensitivity = 65.71% (49.15% - 79.17%)
	Negative	12	302	314	Specificity = 99.02% (97.15% - 99.67%)
Total		35	305	340	

Vibrant COVID-19 Ab		Clinical Diagnosis – NP Swab Positive		Total	Analysis (95% Confidence)
		Positive	Controls		
RBD IgA	Positive	18	2	20	Sensitivity = 51.43% (35.57% - 67.01%)
	Negative	17	303	320	Specificity = 99.34% (97.64% - 99.82%)
Total		35	305	340	

Vibrant COVID-19 Ab		Clinical Diagnosis – NP Swab Positive		Total	Analysis (95% Confidence)
		Positive	Controls		
RBD IgM	Positive	21	2	23	Sensitivity = 60.00% (43.57% - 74.45%)
	Negative	14	303	317	Specificity = 99.34% (97.64% - 99.82%)
Total		35	305	340	

Vibrant COVID-19 Ab		Clinical Diagnosis – NP Swab Positive		Total	Analysis (95% Confidence)
		Positive	Controls		
S2 SP IgG	Positive	28	1	29	Sensitivity = 80.00% (64.11% - 89.96%)
	Negative	7	304	311	Specificity = 99.67% (98.17% - 99.94%)
Total		35	305	340	

Vibrant COVID-19 Ab		Clinical Diagnosis – NP Swab Positive		Total	Analysis (95% Confidence)
		Positive	Controls		
S2 SP IgA	Positive	17	0	17	Sensitivity = 48.57% (32.99% - 64.43%)
	Negative	18	305	323	Specificity = 100.00% (98.76% - 100.00%)
Total		35	305	340	

Vibrant COVID-19 Ab		Clinical Diagnosis – NP Swab Positive		Total	Analysis (95% Confidence)
		Positive	Controls		
S2 SP IgM	Positive	31	1	32	Sensitivity = 88.57% (74.05% - 95.47%)
	Negative	4	304	308	Specificity = 99.67% (98.17% - 99.94%)
Total		35	305	340	

Vibrant COVID-19 Ab		Clinical Diagnosis – NP Swab Positive		Total	Analysis (95% Confidence)
		Positive	Controls		
NP IgG	Positive	25	4	29	Sensitivity = 71.43% (54.95% - 83.67%)
	Negative	10	301	311	Specificity = 98.69% (96.68% - 99.49%)
Total		35	305	340	

Vibrant COVID-19 Ab		Clinical Diagnosis – NP Swab Positive		Total	Analysis (95% Confidence)
		Positive	Controls		
NP IgA	Positive	13	1	14	Sensitivity = 37.14% (23.16% - 53.66%)
	Negative	22	304	326	Specificity = 99.67% (98.17% - 99.94%)
Total		35	305	340	

Vibrant COVID-19 Ab		Clinical Diagnosis – NP Swab Positive		Total	Analysis (95% Confidence)
		Positive	Controls		
NP IgM	Positive	24	1	25	Sensitivity = 68.57% (52.02% - 81.45%)
	Negative	11	304	315	Specificity = 99.67% (98.17% - 99.94%)
Total		35	305	340	

Combining all antigens and classes for each antibody, the total clinical sensitivity and specificity are determined as below.

Vibrant COVID-19 Ab		**Clinical Diagnosis – NP Swab Positive**		**Total**	**Analysis (95% Confidence)**
		Positive	Controls		
Overall IgG	Positive	33	5	38	Sensitivity = 94.29% (81.39% - 98.42%)
	Negative	2	300	302	Specificity = 98.36% (96.22% - 99.30%)
Total		35	305	340	

Vibrant COVID-19 Ab		**Clinical Diagnosis – NP Swab Positive**		**Total**	**Analysis (95% Confidence)**
		Positive	Controls		
Overall IgA	Positive	23	3	26	Sensitivity = 65.71% (49.15% - 79.17%)
	Negative	12	302	314	Specificity = 99.02% (97.15% - 99.67%)
Total		35	305	340	

Vibrant COVID-19 Ab		**Clinical Diagnosis – NP Swab Positive**		**Total**	**Analysis (95% Confidence)**
		Positive	Controls		
Overall IgM	Positive	32	4	36	Sensitivity = 91.43% (77.62% - 97.04%)
	Negative	3	301	304	Specificity = 98.69% (96.68% - 99.49%)
Total		35	305	340	

Vibrant COVID-19 Ab		**Clinical Diagnosis – NP Swab Positive**		**Total**	**Analysis (95% Confidence)**
		Positive	Controls		
Overall IgG/IgA/IgM	Positive	34	5	39	Sensitivity = 97.14% (85.47% - 99.50%)
	Negative	1	300	301	Specificity = 98.36% (96.22% - 99.30%)
Total		35	305	340	

14. SUMMARY AND CONCLUSIONS

Pre-determined acceptance criteria for analytical and clinical performance studies of all Vibrant COVID-19 Ab assay have been met as summarized below.

COVID-19 Ab Assay	Acceptance Criteria	Results
Precision/Reproducibility	Reproducibility % > 95%	PASS
Cross Reactivity	No false positive results	PASS
Class Specificity	Agreement % = 100%	PASS
Analytical Specificity	Agreement % = 100%	PASS
Specimen Stability	Agreement % = 100%	PASS
Specimen Fresh vs Frozen	Agreement % = 100%	PASS
Clinical Studies	Total Clinical Sensitivity > 90% Total Clinical Specificity > 95%	PASS