

Sienna™-Clarity COVIBLOCK™

COVID-19 IgG/IgM Rapid Test Cassette

(Whole Blood/ Plasma/Serum/Fingerstick Whole Blood)

For in vitro diagnostics use only

For prescription use only

For Emergency Use Authorization only

INTENDED USE

The Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette is a membrane-based lateral flow immunoassay intended for the qualitative detection and differentiation of IgG and IgM antibodies to SARS-CoV-2 in human serum, plasma (dipotassium EDTA, sodium citrate, sodium heparin), venous whole blood (dipotassium EDTA, sodium citrate, sodium heparin) and fingerstick whole blood. The Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test should not be used to diagnose acute SARS-CoV-2 infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

Testing of serum, plasma and venous whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform high or moderate complexity tests.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the detection of SARS-CoV-2 antibodies. IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette may occur due to cross reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different SARS-CoV-2 IgG or IgM assay.

Samples should only be tested from individuals that are 15 days or more post symptom onset.

The Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette is only for use under the Food and Drug Administration's Emergency Use Authorization.

PRINCIPLE

The Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid test Cassette (Whole Blood/ Plasma/ Serum) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antibodies in whole blood, plasma, or serum. This test consists of two components, an IgG component, and an IgM component.

In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. The antigen is the receptor binding domain (RBD) of Spike Glycoprotein. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region.

In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. The mixture then migrates upward

on the membrane chromatographically by capillary action and reacts with the anti-human IgM in IgM test line region.

If the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. If the specimen contains IgM antibodies to SARS-CoV-2, a colored line will appear in IgM test line region. If the specimen does not contain antibodies to SARS-CoV-2, no colored line will appear in either of the test line regions, indicating a negative result.

To serve as a procedural control, a colored line should always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

In the control component, goat anti-rabbit antibody is coated in the control line region. During testing, the specimen migrates via capillary action along the membrane carries the rabbit-antibody-coated particles to the control line region. If proper volume of specimen has been added, and the membrane wicking has occurred, Goat anti-rabbit antibody immobilized on the control line region will capture the rabbit-antibodies-coated particles, resulting in a colored line in the control line region.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated 2°C – 30°C (36°F – 86°F). **DO NOT FREEZE.**

The test is stable through the expiration date printed on the sealed pouch. Do not use after the expiration date.

The test must remain in the sealed pouch until use. Use the test within 1 hour after removing from the seal pouch.

REAGENTS

The test cassette contains SARS-CoV-2 spike antigen conjugated gold colloid particles and rabbit IgG antibodies conjugated gold colloid particles on the conjugate pad.

Anti-human IgM, anti-human IgG, goat anti-rabbit antibodies are coated on the membrane.

The buffer contains 0.02% Na₂S₂O₃ + 0.025% Kanamycin Sulfate

MATERIALS SUPPLIED

- Individually Pouched Test Cassettes (20)
- Bottle containing 3 ml Buffer (0.02% Na₂S₂O₃ + 0.025% Kanamycin Sulfate (1) OR single-pack buffer bottles (20)
- Safety lancets (20)
- Alcohol swabs (20)
- Package Insert (1)
- Quick Reference Guide (1)
- Disposable Plastic Pipettes (20)

MATERIALS REQUIRED BUT NOT PROVIDED

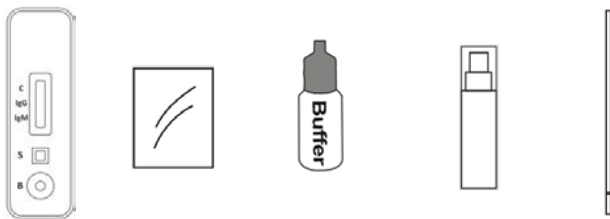
- Micropipette with Tips (10- 100µL)
- Timer
- Centrifuge (for plasma and serum only)
- Specimen collection container
- External positive and negative controls (recombinant anti-SARS-CoV-2 IgG/IgM in negative human serum w/0.1% sodium azide) available for purchase from Clarity Diagnostics (Catalog Number: CD-COV19-GMCTL)

PRECAUTIONS

- For professional in vitro diagnostic use only.
- For prescription use only.
- For use under the Emergency Use Authorization Only. Follow the instructions for use carefully. Reliability of assay results cannot be guaranteed if there is any deviation from the instructions in this package insert.
- This test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA. Testing of serum, plasma and venous whole blood specimens is limited to laboratories certified under CLIA that meet the requirements to perform moderate, high or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e. in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

- This test has been authorized only for detecting the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- Do not use after expiration date.
- Do not use if the pouch is torn or open.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observed established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Once the cassette is removed from the pouch, Use the cassette as soon as possible to avoid being humidified. The cassette is sensitive to humidity as well as to heat.
- Use only the buffer solution provided with the kit.
- Do not use the cassette if the pouch is damaged or the seal is broken.
- Avoid cross-contamination of samples by using a new pipette tip or disposable plastic pipette.

TEST KIT COMPONENTS



SPECIMEN COLLECTION AND PREPARATION

- Use standard phlebotomy procedures to collect venipuncture whole blood, serum, and plasma specimen.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

SPECIMEN PRESERVATION

- Fingerstick whole blood specimens must be tested immediately after collection.
- Serum and plasma specimens (Na+ Citrate, Na+ Heparin) that will not be tested immediately can be kept at 2° – 8°C (36 – 46°F) for up to 5 days.
- Plasma specimens (K₂ EDTA) that will not be tested immediately can be kept at 2° – 8°C (36 – 46°F) for up to 1 day.
- Do not freeze whole blood specimens.
- Do not freeze and thaw the serum and plasma from Na+ heparin specimens more than 3 times.
- Do not freeze and thaw plasma from Na+ citrate specimens more than 1 time.

DIRECTIONS FOR USE

- 1) Prior to testing, the blood specimen and all components of the kit must be equilibrated to room temperature 15°C – 30°C (59°F – 86°F). Mix the specimen before use.
- 2) Remove the cassette from the foil pouch and place on a clean and level surface and **use it within one hour.**



3) For venous whole blood specimen:

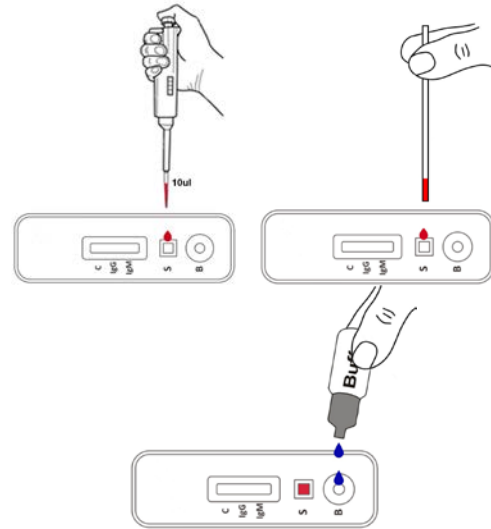
Use the provided disposable pipette/ lab pipette to transfer 10µl venous whole blood specimen directly onto the specimen well (S) of the test cassette. Then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. **Read results at 10 minutes. Do not interpret results after 20 minutes.**

To use the provided disposable pipette:

- a. The pipette provided with the test dispenses approximately 10 µl in one drop even if more sample is aspirated in the pipette.

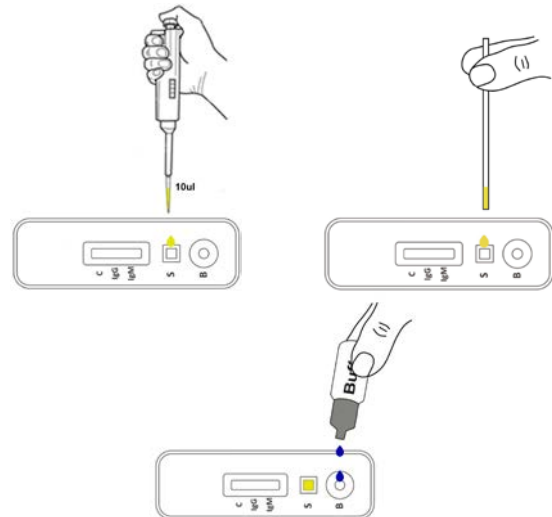
- b. Holding the disposable pipette vertically, squeeze the middle of the disposable pipette between your thumb & index finger, and touch the tip of the pipette to the sample.
- c. Gently release the pressure to draw up 10µl of sample to the fill line. Do not release the pressure completely. Ensure the blood reaches the fill line with no air bubbles.

Squeeze the disposable pipette to transfer 1 drop of whole blood to the specimen well (S) of the test cassette



4) For plasma or serum specimen:

- a. For plasma specimen, use common anticoagulant, K₂ EDTA, Na+ Heparin or Na+ Citrate. Other anticoagulants have not been validated and may cause a false result.
- b. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Used only clear, non-hemolyzed, non-lipemic specimens.
- c. Use the provided disposable pipette/ lab micropipette to transfer 10µl serum or plasma specimen directly onto the specimen well (S) of the test cassette then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. **Read results at 10 minutes. Do not interpret results after 20 minutes.**



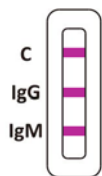
5) For fingerstick whole blood specimen:

- a. Wash the patient's hand with soap and warm water or clean the fingertip to be punctured with an alcohol pad. Allow to dry completely.
- b. Using a safety lancet, apply gentle pressure to puncture the surface near the center of the fingertip. Wipe away the first sign of blood.
- c. Using the provided disposable pipette, collect fingerstick whole blood specimen to the indicated fill line. Avoid touching the disposable pipette directly to the finger.
- d. Squeeze the disposable pipette to transfer 1 drop of whole blood to the specimen well (S) of the test cassette. The

pipette provided with the test dispenses approximately 10 µl in one drop even if more blood is aspirated in the pipette.

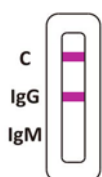
- e. Add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. Wait for the colored line(s) to appear. **Read results at 10 minutes. Do not interpret results after 20 minutes.**

INTERPRETATION OF RESULTS

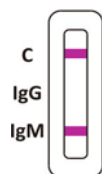


POSITIVE

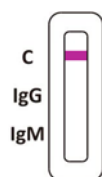
IgG and IgM POSITIVE: * Three lines appear. If the C-line, M-line, and G-line are all present, it means that SARS-CoV-2 IgG and IgM antibody are detected, and the result is IgG and IgM antibody positive.



IgG POSITIVE: * Two lines appear. If both the C-line and the G-line appear, it means the IgG antibody against SARS-CoV-2 is detected, and the result is IgG antibody positive.

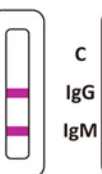


IgM POSITIVE: * Two lines appear. If both the C-line and M-line appears, it means that the IgM antibody against SARS-CoV-2 is detected, and the result is IgM antibody positive.



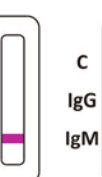
NEGATIVE

One colored line appears in the control region (C). If only C-line appears, indicating that SARS-CoV-2 antibody is not detected, and the result is negative.



INVALID

Control line fails to appear. If C-line is not observed, it is invalid whether there is detection line or not, and the detection should be carried out again.



Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test cassette immediately and contact your distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

Control standards are not supplied with this test cassette; however, testing of positive and negative controls is required as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Negative, and IgG/IgM Positive controls manufactured by Kenlor Industries USA should be purchased from Clarity Diagnostics (Catalog Number: CD-COV19-GMCTL). Users should refer to the instructions for use for the external controls. External controls should be run like human specimens using the instructions described herein. It is recommended that positive and negative controls are tested each time

a new lot is used, when a new operator performs the test, or when the test is run in a new room/laboratory, etc. as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. Not for use in at-home testing settings.
2. The test is limited to the qualitative detection of antibodies specific for the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen. This test cannot be used as a semi-quantitative or quantitative test.
3. This test can only be used for the analysis of serum, plasma (K₂ EDTA, Na⁺ heparin, and Na⁺ citrate), venous whole blood (K₂ EDTA, Na⁺ heparin, and Na⁺ citrate), and fingerstick (capillary) whole blood samples.
4. Plasma samples obtained from K₂ EDTA anticoagulant should not be tested after one day of storage due to potential for false positive results.
5. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Direct testing with a molecular diagnostic should be performed to evaluate for acute infection in symptomatic individuals.
6. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette early after infection is unknown.
7. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
8. False positive results may occur in individuals with Rheumatoid Factor (RF).
9. A negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or if the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody used in the test.
10. The assay procedure and the interpretation of assay result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma, or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
11. Reading test results earlier than 10 minutes after the addition of buffer may yield erroneous results. Do not interpret the result after 20 min.
12. Early after infection, anti-SARS-COV-2 IgM concentrations may be below detectable levels.
13. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
14. Results from immunosuppressed patients should be interpreted with caution.
15. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
16. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an adaptive immune response.
17. Not for the screening of donated blood.
18. The sensitivity of the test is impacted after being opened for 1 hour- the intensity of the test line(s) will become weak. Testing must be performed within 1 hour after opening the pouch.

CONDITIONS OF AUTHORIZATION FOR LABORATORY

The Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

Authorized laboratories using the Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

1. Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media
2. Authorized laboratories using your product must use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Salofa Oy (info@salofa.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Salofa Oy, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The letter of authorization refers to, "authorized laboratories" as the following: Testing of serum, plasma and venous whole blood is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

PERFORMANCE CHARACTERISTICS

The Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette was compared against PCR confirmed results in 3 studies.

Study 1: In the first retrospective study, 70 positive and 10 negative plasma samples (EDTA) collected from China were tested. All nasopharyngeal samples were confirmed using the Novel Coronavirus 2019-nCoV Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) (US FDA EUA authorized). Plasma samples were collected using EDTA anticoagulant and stored at -20°C until tested.

Study #1: IgG Positive Agreement Result

Days between date of PCR comparator test and collection of plasma/serum sample	Number of Samples Tested	IgG Positive results	IgG PPA	95% CI
0-7 days	68	57	83.82%	73.31%-90.72%
8-14 days	2	2	100%	34.24%-100%
≥15 days	0	0	N/A	N/A

Study #1: IgM Positive Agreement Result

Days between date of PCR comparator test and collection of plasma/serum sample	Number of Samples Tested	IgM Positive results	IgM PPA	95% CI
0-7 days	68	61	89.71%	73.31%-90.72%
8-14 days	2	2	100%	34.24%-100%
≥15 days	0	0	N/A	N/A

Study #1: IgG Negative Agreement Result

Number of Samples Tested	Combined IgG & IgM Negative results	NPA	95% CI
10	10	100%	72.25%-100%

Study 2: In the second retrospective study, 113 positive plasma samples (EDTA) and 50 negative serum samples collected from China were tested. All nasopharyngeal samples were confirmed using COVID-19 (ORF 1ab/N) Nucleic Acid Detection Kit (Double fluorescent PCR) (Limit of Detection: 1000 copies/mL). All samples were collected and stored at -20°C until tested.

Study #2: IgG Positive Agreement Result

Days between date of PCR comparator test and collection of plasma/serum sample	Number of Samples Tested	IgG Positive results	IgG PPA	95% CI
0-7 days	0	0	N/A	N/A
8-14 days	0	0	N/A	N/A
≥15 days	60	60	100%	93.98%-100%

Study #2: IgM Positive Agreement Result

Days between date of PCR comparator test and collection of plasma/serum sample	Number of Samples Tested	IgM Positive results	IgM PPA	95% CI
0-7 days	0	0	N/A	N/A
8-14 days	0	0	N/A	N/A
≥15 days	60	56	93.33%	84.07%-97.38%

Study #2: IgG Negative Agreement Result

Number of Samples Tested	Combined IgG & IgM Negative results	NPA	95% CI
50	50	100%	92.81%-100%

Study 3: In the third prospective study, 75 negative fingerstick whole blood samples and 30 positive fingerstick whole blood samples collected from the US were tested. All nasopharyngeal samples were confirmed using the NxTAG CoV Extended Panel Assay (US FDA EUA Authorized). All samples were collected and tested immediately by non-laboratory healthcare professionals.

Study #3: IgG Positive Agreement Result

Days between onset of symptoms and collection of fingerstick whole blood sample	Number of Samples Tested	IgG Positive results	IgG PPA	95% CI
0-7 days	0	0	N/A	N/A
8-14 days	0	0	N/A	N/A
≥15 days	30	28	93.3%	78.7%-98.2%

Study #3: IgM Positive Agreement Result

Days between onset of symptoms and collection of fingerstick whole blood sample	Number of Samples Tested	IgM Positive results	IgM PPA	95% CI
0-7 days	0	0	N/A	N/A
8-14 days	0	0	N/A	N/A
≥15 days	30	25	83.3%	66.4%-92.7%

Study #3: IgG Negative Agreement Result

Number of Samples Tested	Combined IgG & IgM Negative results	NPA	95% CI
75	75	100%	92.81%-100%

SEROCONVERSION

A retrospective clinical study was performed, with a total of 81 serum samples collected from 30 patients who were confirmed for SAR-CoV-

2 infection using PCR. Days between symptom onset and blood collection date were categorized in 3 groups: 0-7 days, 8-14 days and greater than 15 days.

Seroconversion study: Days post-PCR testing

Days between date of PCR comparator test and collection of plasma/serum sample	Number of Samples Tested	IgM Positive results	IgM PPA	IgG Positive results	IgG PPA
0-7 days	26	1	3.85%	1	3.85%
8-14 days	29	25	86.21%	18	62.07%
≥15 days	26	24	92.31%	23	88.46%

Seroconversion study: Days post-symptom onset

Days post onset of symptoms	Number of Samples Tested	Combined Positive results	PPA
0-7 days	26	1	3.85%
8-14 days	29	26	89.66%
≥15 days	26	25	96.15%

NEGATIVE AGREEMENT

The specificity of the Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette was evaluated using a total of 220 plasma/ serum samples collected from individuals, before the COVID-19 outbreak.

In the first study, 80 presumed negative plasma samples (K₂ EDTA) collected within the US, before October 2019 were tested; 30 presumed negative plasma samples (K₂ EDTA) collected within Cote d'Ivoire, in 2016 were tested; 58 presumed negative plasma samples (K₂ EDTA) collected within Uganda, in 1995 were tested. Testing were performed at the Washington University School of Medicine. In the second study, 52 presumed negative serum sample collected within France, between October and November 2019, were tested.

Origin	Sample Type	Number of Samples Tested	Combined IgG & IgM Negative results	NPA	95% CI
United States	Plasma	80	79	98.8%	93.25%-99.78%
Cote d'Ivoire	Plasma	30	29	96.7%	83.33%-99.41%
Uganda*	Plasma	58	52	89.7%	79.22%-95.17%
France	Serum	52	51	98.1%	89.88%-99.66%

*The low NPA performance observed was obtained from samples that were collected in 1995. False positives most likely were attributed to prolonged storage of these samples. NPA was acceptable in all other negative agreement studies.

NCI EVALUATION

The Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette was tested on 06/17/2020 at the Frederick National Laboratory for Cancer Research (FNLRC) sponsored by the National Cancer Institute (NCI). The test was validated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative serum and plasma samples. Each of the 30 antibody-positive samples were confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette Antibody Test. The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers. All antibody-negative samples were collected prior to 2020 and include i) Seventy (70) samples selected without regard to clinical status, "Negatives" and

ii) Ten (10) samples selected from banked serum from HIV+ patients, "HIV+." Testing was performed by one operator using **one** lot of Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette antibody tests. Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008). For the evaluation of cross-reactivity with HIV+, it was determined whether an increased false positive rate among antibody-negative samples with HIV was statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman). The results and data analysis are shown in the tables below.

	Comparator Method			Collected pre-2020		Total
	Antibody Positive			Antibody Negative		
	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	
Sienna COVID-19 IgG/IgM Rapid Test Cassette (whole blood/serum/-plasma)						
IgM+, IgG+	27					27
IgM+, IgG-	1			1		2
IgM-, IgG+	2			69	10	81
IgM-, IgG-						
Total	30			70	10	110

Measure	Estimate	Confidence Interval
IgM Sensitivity	90.0% (27/30)	(74.4%; 96.5%)
IgM Specificity	100% (80/80)	(95.4%; 100%)
IgG Sensitivity	93.3% (28/30)	(78.7%; 98.2%)
IgG Specificity	98.8% (79/80)	(93.3%; 99.8%)
Combined Sensitivity	93.3% (28/30)	(78.7%; 98.2%)
Combined Specificity	98.8% (79/80)	(93.3%; 99.8%)
Combined PPV for prevalence = 5.0%	79.7%	(38%; 95.9%)
Combined NPV for prevalence = 5.0%	99.6%	(98.8%; 99.9%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

Important limitations of the study:

1. Samples were not randomly selected, and sensitivity and specificity estimates may not be indicative of the real-world performance of the device
2. These results are based on serum and plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including finger stick blood.
3. Information about anticoagulants used is not known.
4. The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.

CROSS-REACTIVITY

The Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/ Plasma/ Serum) has been tested for *anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV, ANA and HAMA* positive specimens. The results showed no cross-reactivity. Some cross reactivity was observed with samples positive for *Rheumatoid Factor*. It is possible to cross-react with samples positive for *MERS-CoV* antibody. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as *coronavirus HKU1, NL63, OC43, or 229E*.

INTERFERING SUBSTANCES










The following potentially interfering substances were added to COVID-19 negative specimens.

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Albumin:	2 g/dL	Acetylsalicylic Acid:	20 mg/dL
Gentisic Acid	20 mg/dL	Ethanol:	1%
Ascorbic Acid:	2 g/dL	Creatine:	200 mg/dL
Bilirubin:	1 g/dL	Hemoglobin:	1000 mg/dL
Oxalic Acid:	60 mg/dL	Uric acid:	20 mg/mL

None of the substances at the concentration tested interfered in the assay.

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2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
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5. WHO. Coronavirus disease 2019 (COVID-19) Situation Reports. Available from: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>
6. Liu L, Liu W et al. A preliminary study on serological assay for severe acute 2 respiratory syndrome coronavirus 2 (SARS-CoV-2) in 238 3 admitted hospital patients. Available from: <http://www.medrxiv.org/content/10.1101/2020.03.06.20031856v1.full.pdf>
7. UN - COVID-19 FREQUENTLY ASKED QUESTIONS. Available from: https://www.un.org/sites/un2.un.org/files/new_dhmosh_covid-19_faq.pdf
8. US Food and Drug Administration (FDA). Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff. Issued March 16, 2020. Docket Number FDA-2020-D-0987.

	Batch/Lot code		<i>In vitro</i> diagnostic medical device
	Manufacturer		Catalog number
	Contents sufficient for < n > tests		Consult instructions for use
	Caution, consult accompanying documents		Do not reuse
	Temperature limitation		

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REF: CD-COV19CW/102223/ 102224
Version: 2 (Draft)

December 22, 2020

US Technical Support Contact:
TECH SUPPORT: 1 -877- 485-7877
WWW.CLARITYDIAGNOSTICS.COM
covid19techsupport@claritydiagnostics.com

User Quick Reference Instructions for Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette

This test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA. Testing of serum, plasma and venous whole blood specimens is limited to laboratories certified under CLIA that meet the requirements to perform moderate or high complexity or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.

This test has been authorized only for detecting the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Wear appropriate protective attire for your safety when handling patient samples.

Read through the entire Quick Reference Instructions before beginning a test. For technical assistance, please call 1-877-485-7877

Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.

BEFORE YOU BEGIN

Refer to the package insert for more information.

Test kits should not be used beyond the printed expiration date.

Bring the test kit components needed for one test to room temperature before using.

The Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Antibody Test kit contains the following materials:

- Individually Pouched Test Cassettes (20)
- Bottle containing 3 ml Buffer (1)/ single-pack buffer bottles (20)
- Disposable Plastic Capillaries (20)
- Safety lancets (20)
- Alcohol swabs (20)
- Quick Reference Guide (this document) (1)
- Package Insert (1)

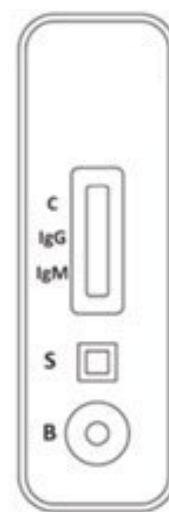
The following materials are also required but are not provided in the kit:

- Timer

PERFORMING THE TEST

Carefully follow these instructions in the order they are listed:

- 1) Remove a test cassette, the bottle of buffer and a disposable plastic capillary from the kit and place them on a level work surface.
- 2) Place a lancet, alcohol prep pads and a timer on the work surface.
- 3) Carefully remove the test cassette from its foil wrapper and place it right-side up on the level surface as shown in the figure below and use it within one hour.



IMPORTANT:

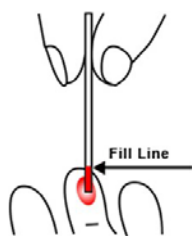
The well that is labeled as “S” is for the blood Sample.

The well that is labeled as “B” is for the test

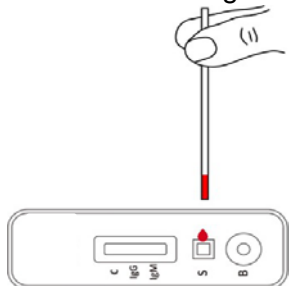
Buffer.

The part of the cassette that includes the C, IgG and IgM is where the results of the test will appear.

- 4) Ask the patient to decide whether they prefer the middle or ring finger be punctured and have the patient gently massage the hand and finger from the palm to the fingertip.
- 5) Open one of the alcohol prep packages and clean the fingertip with the alcohol prep swab. Allow finger to dry completely.
- 6) Use a lancet to puncture the surface of the fingertip. Apply gentle pressure to the base of the finger to help a good-sized drop of blood form at the puncture site.
- 7) Fill one of the capillary tubes provided in the kit to its fill line with blood from fingertip. To do this, squeeze the capillary and place the end of the capillary that is close to the marked fill line in the blood drop. Gently release the pressure and the blood will automatically flow into the tube. Remove the capillary from the blood drop when the column of blood reaches the fill line as shown in the following figure.

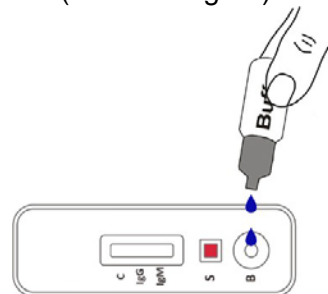


- 8) Transfer the blood from the capillary tube into the Sample well (marked with an S) in the cassette by gently squeezing the capillary as shown in the figure below.



- 9) When the blood has been absorbed from

the sample well into the cassette, add two (2) drops of test buffer into the Buffer well (marked with a B) in the cassette as shown in the figure below. Add the buffer by taking off the cap, flipping the bottle, holding it over the Buffer well and allowing two drops of buffer to drip into the Buffer well (see next figure).



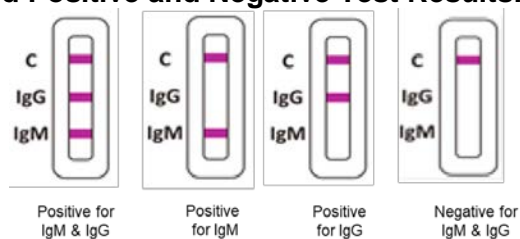
- 10) Immediately after adding the buffer to the Buffer well, set the timer for 10 minutes and start the timer.
- 11) After 10 minutes have passed, read the result as described in the following section. Do not read the result after 20 minutes.

READING THE TEST RESULTS

Up to three reaction lines may appear in the window of the test cassette.

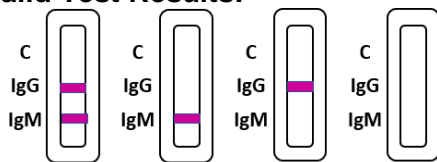
- The line that appears next to the **C (control)** shows that the test worked correctly. If a **C** line does not appear, the test did not work correctly, and the results are not valid even if lines appear next to the G or the M.
- A line that appears next to the **G** when there is also a **C** line shows that IgG antibodies against COVID-19 are present in the sample.
- A line that appears next to the **M** when there is also a **C** line shows that IgM antibodies against COVID-19 are present in the sample.

Valid Positive and Negative Test Results:



Interpretation	C Line	M Line	G Line
Positive for IgM & IgG	Line present	Line present	Line present
Positive for IgM	Line present	Line present	Line absent
Positive for IgG	Line present	Line absent	Line present
Negative	Line present	Line absent	Line absent

Invalid Test Results:



Invalid Tests

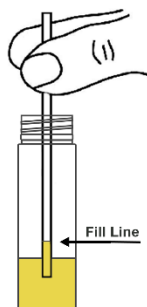
Interpretation	C Line	M Line	G Line
Invalid – repeat test	Line absent	Line present	Line present
Invalid – repeat test	Line absent	Line present	Line absent
Invalid – repeat test	Line absent	Line absent	Line present
Invalid – repeat test	Line absent	Line absent	Line absent

If the result is invalid, repeat the test with a new test cassette.

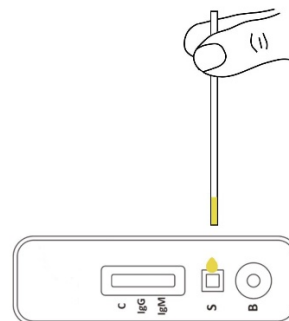
EXTERNAL CONTROL TEST

It is recommended that positive and negative controls are tested each time a new lot is used, when a new operator performs the test, or when the test is run in a new room, etc. to confirm the test procedure and to verify proper test performance.

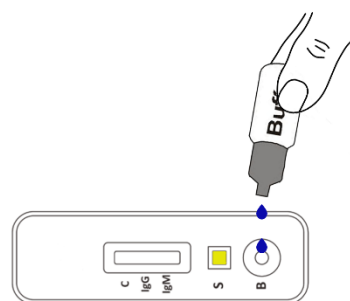
- 1) Remove a test cassette, the bottle of buffer, the control vials (positive & negative) and a disposable plastic capillary from the kit and place them on a level work surface.
- 2) Carefully remove the test cassette from its foil wrapper and place it right-side up on the level surface and use it within one hour.
- 3) Open the control vial. Fill one of the capillary tubes provided in the kit to its fill line with solution from the control vial.



- 4) Transfer the control solution from the capillary tube into the Sample well (S) in the cassette.



- 5) When the control has been absorbed from the sample well into the cassette, add (2) drops of test buffer into the Buffer well (B).



- 6) Immediately after adding the buffer to the Buffer well, set the timer for 10 minutes and start the timer.
- 7) After 10 minutes have passed, read the result as described in the following section. Do not read the result after 20 minutes.

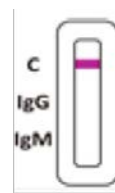
Expected External Control Results

Positive Control

Negative Control



Positive for IgM & IgG



Negative for IgM & IgG



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REF: CD-COV19CW/102223/ 102224

January 4, 2021

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CLARITY
Liquid COVID-19 Human IgM+IgG Antibody Control
(Unassayed)

CATALOG NUMBER: CD-COV19-GMCTL

KIT CONTENT: COVID-19 Liquid IgM+IgG Antibody Control.

1 x 1 ml of Negative Lot Number 274098N Bi-Level Kit: 274010

1 x 1 ml of Positive Lot Number 274099P Exp. Date: March 2021

INTENDED USE:

The Clarity Liquid COVID-19 IgM+IgG antibody serum controls are intended for use as unassayed precision control reagents. These controls are to be used with in vitro immunoassay procedures for the qualitative determination of COVID-19 IgM and IgG antibody in human serum assays. The controls are designed for routine use to provide a means of estimating precision and monitoring system performance. *For use with Sienna™ COVID-19 IgG/IgM Rapid Test Cassette and Clarity COVIBLOCK™ COVID19 IgG/IgM Antibody Test Cassette.*

SUMMARY AND EXPLANATION:

The usefulness of Quality Control materials for monitoring the accuracy and precision of clinical testing is well documented. The Clarity Liquid –COVID-19 Serum Control is designed specifically to be used in qualitative analysis of COVID-19 IgM and IgG antibody assay in serum. The control should be used like a patient sample to assist in the assessment of the analytical procedures and routinely used for the day to day quality control of the assay system. **Clarity Liquid –COVID-19 IgM+IgG serum for antibody assay is liquid, stable for Six Months at a refrigerated temperature of 2-8° C.**

REAGENTS:

The Clarity COVID-19 antibody negative control serum is prepared negative human serum. The Clarity COVID-19 IgG and IgM antibody positive control serum is prepared by mixing appropriate amount of COVID-19 IgM and IgG with other serum until desired concentration of COVID-19 IgG and IgM antibodies are obtained. All sera were preserved with a mixture of 0.1% Sodium azide as preservative. The volume of COVID-19 negative and COVID-19 positive human sera to be used in the preparation was determined by analysis of COVID-19 IgG antibodies in these sera by chromatographic immunoassay with available commercial kits: *For use with Sienna™ COVID-19 IgG/IgM Rapid Test Cassette and Clarity COVIBLOCK™ COVID19 IgG/IgM Antibody Test Cassettes.*

Follow the manufacturer's recommended protocol in assaying Clarity Liquid COVID-19 IgM+IgG antibody control.

WARNINGS AND PRECAUTIONS:

- * **FOR IN VITRO DIAGNOSTIC USE ONLY**
- * **FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY**
- * This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests.
- * This product has been authorized only for detecting the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- * The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- * **BIOHAZARD Caution:** Human source material used in the preparation has been found non-reactive for HBsAg when tested by RIA, and also negative for HIV-1 antibody when tested by ELISA. However, no known test method can assure that a product derived from human source does not contain hepatitis or HIV-1 viruses.
- * **Please Note:** There is no Biohazard related to COVID19 with these controls.
- * If particulate matter is observed in the product, discard the product.
- * **WASTE DISPOSAL METHOD:** The above product contains 0.1% **sodium azide** as preservative. Best disposal method for biological material containing sodium azide is to wash it down the sewer with large excess of water. Disposal should be made in accordance with existing disposal practices. Observe all Federal, State and Local laws.
- * **HANDLE AS IF CAPABLE OF TRANSMITTING HEPATITIS**
- * **NOT FOR INTERNAL USE BY HUMANS OR ANIMALS.**

STORAGE AND STABILITY

STORE AT 2°C – 8°C.

The product is stable up to the expiration date printed on the label if kept at 2-8°C. Once opened it is stable till labelled date of expiration if stored between use at 2-8°C. Do NOT use beyond the expiration date.

This product is warranted to perform as described in its labeling and in the product literature.

PROCEDURE:

The Clarity Liquid COVID-19 IgM+IgG antibody Serum Control should be used like a patient sample to assist in the assessment of the analytical procedures and routinely used for the day to day quality control of the assay system.

**For use with Sienna™ COVID-19 IgG/IgM Rapid Test Cassette and Clarity COVIBLOCK™ COVID19 IgG/IgM Antibody Test Cassettes:
Using Controls with Micropipette:**

Allow the test cassette(s) to equilibrate to room temperature.

Open the Negative Control vial and Pipette 10µl of Negative control, add 10µl of Negative control to the specimen well (S) of the test cassette, then add 2 drops of buffer to the buffer well (B) and start the timer. Wait for colored line to appear. Read Results at 10 minutes. Do not interpret results after 20 minutes.

Open the Positive Control vial and Pipette 10µl of Positive control, add 10µl of Positive control to the specimen well (S) of the test cassette, then add 2 drops of buffer to the buffer well (B) and start the timer. Wait for colored line (s) to appear. Read Results at 10 minutes. Do not interpret results after 20 minutes.

Negative Controls should only produce 1 band, Control Band and Positive Controls should only produce 3 bands, Control Band, IgM and IgG Band. If In-valid results are obtained, please perform the QC test again.

QUALITY CONTROL

SPECIFIC PERFORMANCE CHARACTERISTICS:

Clarity Liquid COVID-19 IgM+IgG ANTIBODY SERUM CONTROL is formulated to give consistent result for use in clinical quality control. It is recommended that each laboratory validate the use of each lot of reagents with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF THE RESULTS:

Once a laboratory has established the range of values for the Liquid COVID-19 IgM+IgG antibody controls it can use those values for routine day to day quality control of clinical test. However, the values are method dependent and different laboratories may observe variations because of differences in techniques, or reagent variation, method modifications and other systemic and random errors. If control testing did not yield the expected results, review the procedure and repeat the test with a new cassette. If the problem persists, discontinue using the test and control immediately and contact the test distributor.

LIMITATION OF THE PROCEDURE:

The Clarity COVID-19 human IgM/IgG antibody Serum Controls are not intended to be used as calibrators and should not be used for calibration of the assays. The controls should be used only when testing venous/fingerstick whole blood, serum, or plasma specimens following protocol of the test kit manufacturer. Performance characteristic of the controls were determined for COVID-



19 human IgM and IgG antibody. Control should be used only in test involving serum; it is not intended for use in test of plasma or other body fluid.

Manufactured for:



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Tech Support : covid19techsupport@claritydiagnostics.com

Tech Support: 1-877-485-7877

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