Sienna™-Clarity COVIBLOCK™

COVID-19 IgG/IgM Rapid Test Cassette
(Whole Blood/ Plasma/ Serum)

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) and venous whole blood (dipotassium EDTA, sodium citrate, sodium heparin). 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. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette should not be used to diagnose acute SARS-CoV-2 infection. Testing 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.

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 positive 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.

The Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette are 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 IgG in IgM test line region. If the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgM test line region.

Therefore, 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 will 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 are coated in the control line region. During testing, the specimen migrates via capillary action along the membrane carries the rabbit-antibodies-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 antibody are coated on the membrane.
The buffer contains 0.02% NaN_3+ 0.025% Kanamycin Sulfate

MATERIALS SUPPLIED

- Individually Pouched Test Cassettes (20)
- Bottle containing 3 ml Buffer (0.02% NaN_3+ 0.025% Kanamycin Sulfate (1) OR single-pack buffer bottles (20)
- Package Insert (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)

PRECAUTIONS

- For professional in vitro diagnostic use only.
- For prescription use 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; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA to perform moderate or high complexity tests.
- 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- This test has been authorized only for 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.
- Humidity and temperature can adversely affect results. 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

- Serum and plasma specimens (Na+ Citrate, Na+ Heparin) that will not be tested immediately can be kept at 2° – 8°C (36 – 46ºF) for up to 5 days.
- Plasma specimens (K_2 EDTA) that will not be tested immediately can be kept at 2° – 8°C (36 – 46ºF) 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.**

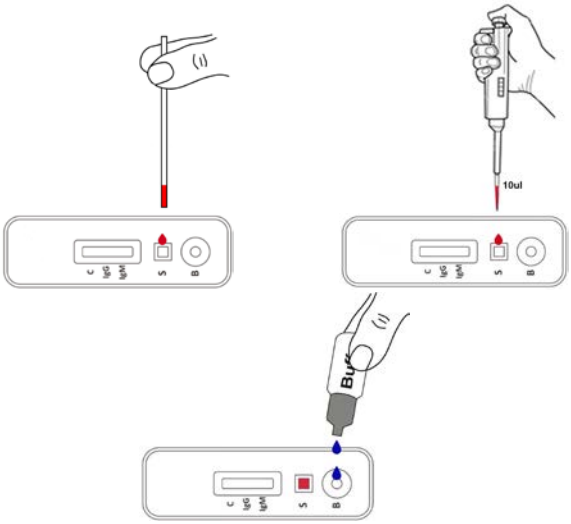
3) **For venous whole blood specimen:**

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:

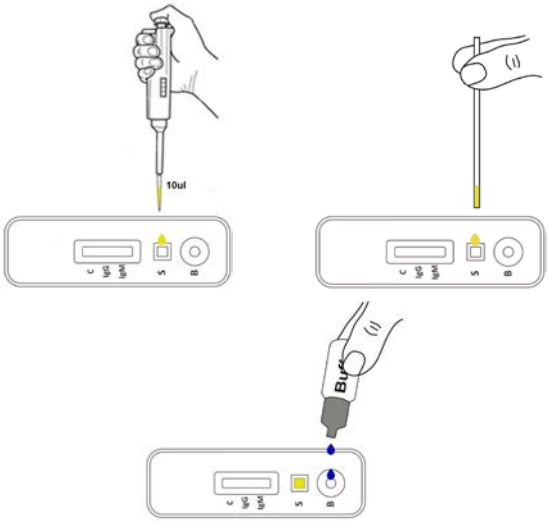
a. **The pipette provided with the test dispenses approximately 10 µl in one drop even if more sample is aspirated in the pipette.**
b. Holding the disposable pipette vertically, squeeze the middle of the disposable pipette between your thumb & index finger, and touch the tip of the pipette to the sample.
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

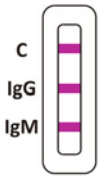


4) **For plasma or serum specimen:**

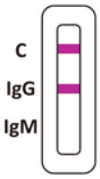
a. For plasma specimen, use common anticoagulant, K_2 EDTA, Na+ Heparin or Na+ Citrate. Other anticoagulants have not been validated and may cause a false result.
b. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Used only clear, non-hemolyzed, non-lipemic specimens.
c. Use 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.**



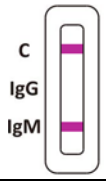
INTERPRETATION OF RESULTS



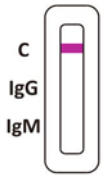
POSITIVE
IgG and IgM POSITIVE: * Three lines appear. If the C-line, M-line, and G-line are all present, it means that SARS-CoV-2 IgG and IgM antibody are detected, and the result is IgG and IgM antibody positive.



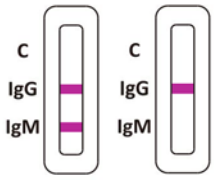
IgG POSITIVE: * Two lines appear. If both the C-line and the G-line appear, it means the IgG antibody against SARS-CoV-2 is detected, and the result is IgG antibody positive.



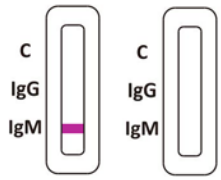
IgM POSITIVE: * Two lines appear. If both the C-line and M-line appears, it means that the IgM antibody against SARS-CoV-2 is detected, and the result is IgM antibody positive.



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, it is recommended that positive and negative controls be tested 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 can be purchased from Clarity Diagnostics (Catalog Number: CD-COV19-GMCTL).

LIMITATIONS

1. For use under the Emergency Use Authorization Only.
2. Use of the Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette is limited to laboratory personnel who have been trained. Not for home use or point of care (POC) use.
3. 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 quantitative test.
4. This test can only be used for the analysis of serum, plasma (K_2 EDTA, Na+ heparin, and Na+ citrate), and venous whole blood (K_2 EDTA, Na+ heparin, and Na+ citrate) samples.
5. Plasma samples obtained from K_2 EDTA anticoagulant should not be tested after one day of storage due to potential for false positive results.
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. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
7. False positive results may occur in individuals with Rheumatoid Factor (RF).
8. 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.
9. 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.
10. Reading test results earlier than 10 minutes after the addition of buffer may yield erroneous results. Do not interpret the result after 20 min.
11. The Sienna™-Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, serum or plasma specimens only.
12. 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.
13. Early after infection, anti-SARS-COV-2 IgM concentrations may be below detectable levels.
14. Do not use with blood obtained from a fingerstick procedure.
15. The test may have lower sensitivity for IgG detection in symptomatic individuals prior to 14 days since symptom onset.
16. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
17. Results from immunosuppressed patients should be interpreted with caution.
18. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
19. 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.
20. 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.
21. 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.
22. Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection or to inform infection status.
23. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.
24. Not for the screening of donated blood.
25. 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 will 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 will 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 will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories will 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 reactive or false non-reactive 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 will 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, "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" as "authorized laboratories."

PERFORMANCE CHARACTERISTICS

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

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.
In the second retrospective study, 113 positive plasma samples (EDTA) and 50 negative serum samples were 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 #1: IgG Positive Agreement Result

Days between collection of PCR comparator 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 collection of PCR comparator 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	IgM NPA	95% CI
10	10	100%	72.25%-100%

Study #2: IgG Positive Agreement Result

Days between collection of PCR comparator 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 collection of PCR comparator 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%

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.

Days between collection of PCR comparator 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%

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 (K_2 EDTA) collected within the US, before October 2019 were tested; 30 presumed negative plasma samples (K_2 EDTA) collected within Cote d-Ivoire, in 2016 were tested; 58 presumed negative plasma samples (K_2 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 (FNLCR) 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 thefalse 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		
	Antibody Positive			Antibody Negative		
Sienna COVID-19 IgG/IgM Rapid Test Cassette (whole blood/serum/-plasma)	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	Total
IgM+, IgG+	27					27
IgM+, IgG-						
IgM-, IgG+	1			1		2
IgM-, IgG-	2			69	10	81
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*.

INTERFERERING 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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LOT	Batch/Lot code	IVD	*In vitro* diagnostic medical device
	Manufacturer	REF	Catalog number
Σ n	Contents sufficient for < n > tests		Consult instructions for use
	Caution, consult accompanying documents	2	Do not reuse
30°C 2°C	Temperature limitation		

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