COVIBLOCK™

COVID-19 IgG/IgM Antibody Test
(Whole Blood, Plasma, or Serum)

INTENDED USE

The Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Plasma/Serum) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, plasma or serum as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. For healthcare professional in vitro diagnostic use only.

COVID-19 (Corona Virus Disease) is the infectious disease caused by the most recently discovered coronavirus. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat, or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but do not develop any symptoms and do not feel unwell. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. About 2% of people with the disease have died. People with fever, cough and difficulty breathing should seek medical attention. People can catch COVID-19 from others who have the virus. The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. These droplets land on objects and surfaces around the person. Other people then catch COVID-19 by touching these objects or surfaces, then touching their eyes, nose, or mouth. People can also catch COVID-19 if they breathe in droplets from a person with COVID-19 who coughs out or exhales droplets. Most estimates of the incubation period for COVID-19 range from 1-14 days.

PRINCIPLE OF TEST

The Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid test Cassette (Whole Blood, Serum, or Plasma) is a rapid test that utilizes a combination of SARS-CoV-2 antigen coated colored particles for the detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma.
The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood, Serum, or Plasma) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antibodies in whole blood, serum, or plasma. 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 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 anti-human IgM. IgM antibodies to SARS-CoV-2, if present in the specimen, reacts with the anti-human IgM and the SARS-CoV-2 antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line 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.

PRECAUTIONS

- For professional healthcare in-vitro diagnostic use only. Do not use after expiration date.
- 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. Observe 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.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use after the expiration date.

REAGENTS AND MATERIALS SUPPLIED

- Individually Pouched Test Cassettes (20)
- Bottle containing 3 ml Buffer (0.02%NaN_3+ 0.025%Kanamycin Sulfate (1)
- Package Insert (1)
- Disposable Plastic Capillaries (20)

MATERIALS REQUIRED BUT NOT PROVIDED

- Safety Lancet
- Micropipette with Tips
- Alcohol Prep Pad

Timer

TEST STORAGE AND STABILITY

The intact test kit can be stored at 2°- 30°C until the expiration date printed on the labels. Exposing the kit to temperatures over 30°C may reduce the shelf life or cause malfunction of the test kit.

SPECIMEN PRESERVATION

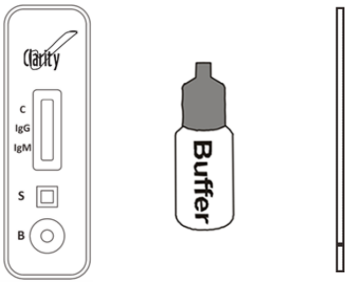
- Specimens should be tested immediately after collection; or
- Stored at 2° – 8°C for 7 days or
- Stored at -20°C up to 3 months; or
- Stored at -80°C for at least 1 year.

Avoid repeat freezing and thawing.

PRECAUTIONS

- Do not use if the pouch is torn or open.
- Wear protective clothing, medical gloves and eye protection while performing the assay.
- Do not eat, drink or smoke in the testing area.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as infectious agents.
- Dispose all specimens and used components into bio-hazard container per regulations.

TEST KIT COMPONENTS



SPECIMEN COLLECTION AND PREPARATION

For finger stick* whole blood:

1. Clean the fingertip to be punctured with an alcohol pad. Allow to dry completely.
2. Using a sterile safety lancet, puncture the surface near the center of the fingertip. Apply gentle pressure around the point of the puncture. If blood specimen is inadequate, gently massage at the finger's base to encourage sufficient blood flow.
3. Holding the capillary vertically, touch the tip of the blood droplet to fill 10µl of blood from the fingertip.

* **Finger stick whole blood must be tested immediately after collection**.

For venous whole blood, plasma and serum:

1. Use standard phlebotomy procedures to collect venipuncture whole blood, serum, and plasma specimen.

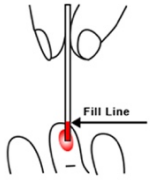
   For plasma specimen, use common anticoagulant, EDTA, Heparin or Sodium Citrate. Other anticoagulants have not been validated and may cause a false result.
2. Specimens that will not be tested immediately can be kept at 2° – 8°C for 7 days.
3. **Do not freeze whole blood specimens.**

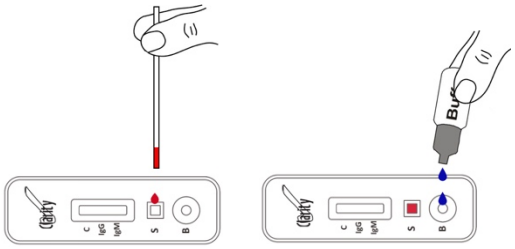
TEST PROCEDURE

1. Prior to testing, the blood specimen, all components of the kit must be equilibrated to room temperature. Mix the specimen before use.
2. Remove the cassette from the foil pouch.

3. **a. For finger stick whole blood specimen:**

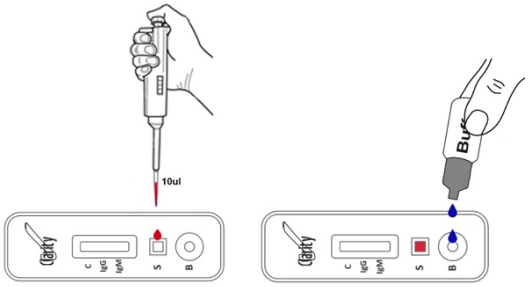
Hold the disposable capillary vertically, aspirate the blood from puncture site and draw the whole blood up to the Fill Line (approximately 10µl), and transfer the whole blood to the specimen well (S) of the test cassette then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. Avoid touching the disposable capillary directly to the finger. **Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.**





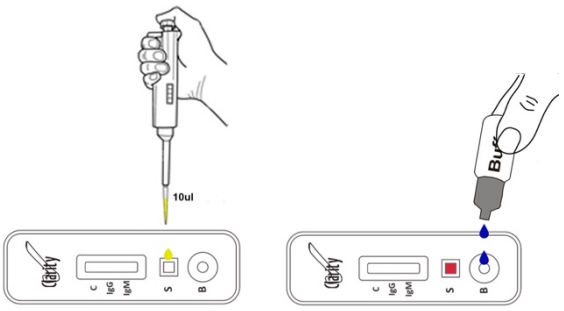
b. For venous whole blood specimen:

Use 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. **Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.**

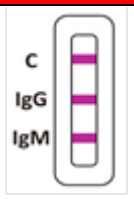


c. For plasma or serum specimen:

Use lab pipette 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. **Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.**

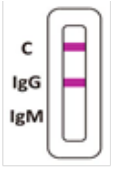


INTERPRETATION OF RESULTS

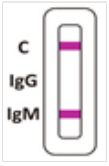


POSITIVE

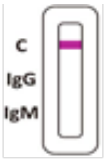
IgG and IgM POSITIVE: * Three lines appear. If the C-line, M-line, and G-line are all present, it means that SARS-CoV-2 IgG and IgM antibody are detected, and the result is that IgG and IgM antibody positive.



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 that the IgG antibody is positive.

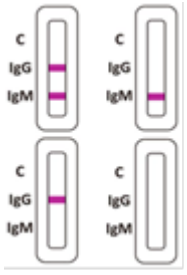


IgM POSITIVE: * Two lines appear. If both the C-line and M-line appears, it means that the IgM antibody against SARS-CoV-2 is detected, and the result is that IgM antibody is positive.



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. 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 Clarity Diagnostics Technical Support at 1-877-485-7877.

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.

LIMITATIONS

1. The Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for 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.
2. Neither the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.
3. In the early onset of fever, anti-SARS-COV-2 IgM concentrations may be below detectable levels.
4. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
5. Results from immunosuppressed patients should be interpreted with caution.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
7. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
8. 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.
9. This test has not been reviewed by the FDA.
10. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
11. Not for the screening of donated blood.

EXPECTED VALUES

Primary SARS-CoV-2 infection is generally characterized by the presence of detectable IgM antibodies 3-7 days after the onset of infection. Secondary SARS-CoV-2 infection is generally characterized by the elevation of SARS-CoV-2-specific IgG. In the majority of the cases, this is accompanied by elevated levels of IgM.

PERFORMANCE CHARACTERISTICS

The Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette was compared with clinical diagnosis (Confirmed). The study included 210 specimens for IgG and IgM.

IgG Results

Method		*Clinical Diagnosis (Confirmed)*		Total Results
The Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	119	0	119
	Negative	11	90	101
Total Results		130	90	210

Diagnostic Sensitivity: 91.54%
Diagnostic Specificity: 100%

IgM Results

Method		*Clinical Diagnosis (Confirmed)*		Total Results
The Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	119	0	119
	Negative	11	90	101
Total Results		130	90	210

Diagnostic Sensitivity: 91.54%
Diagnostic Specificity: 100%

CROSS-REACTIVITY

The Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood, Serum, or Plasma) 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 and HAMA positive specimens. The results showed no cross-reactivity. Some cross reactivity was observed with samples positive for SARS-CoV antibody and 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:	20mg/dL
Albumin:	2 g/dL	Acetylsalicylic Acid:	20mg/dL
Gentisic Acid:	20 mg/dL	Ethanol:	1%
Ascorbic Acid:	2g/dL	Creatine:	200mg/dL
Bilirubin:	1g/dL	Hemoglobin:	1000mg/dL
Oxalic Acid:	60mg/dL	Uric acid:	20mg/mL

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

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6. Lit 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. 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.

LOT	Batch/Lot code	IVD	*In vitro* diagnostic medical device
	Manufacturer	REF	Catalog number
Σn	Contains sufficient for < n > tests		Consult instructions for use
	Caution, consult accompanying documents		Do not reuse
	Temperature limitation	CE	CE Mark

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REF: CD-COV19
Version 06, May 13th, 2020

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