COVIBLOCK™

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

For professional in vitro diagnostics use only
For prescription use only

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 fingerstick whole blood, venous whole blood, plasma (EDTA, citrate, heparin) or serum as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform high complexity tests.

At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

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.

The Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/ Plasma/ Serum) are not designed to be used for diagnosis of acute infections. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 (Molecular Testing) is necessary.

False positive results for the Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/ Plasma/ Serum) 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 second, different COVID-19 IgG/IgM assay.

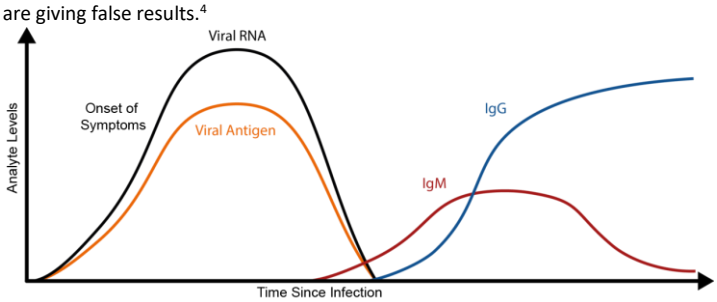
The Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/ Plasma/ Serum) should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or the status of the infection.

SUMMARY

SARS-CoV-2:	novel coronavirus
COVID-19:	novel coronavirus pneumonia

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.[7] Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. About 6% of people with the disease have died.[5] 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.

Patients may only make antibodies to COVID-19 infection a week to 12 days after they first become sick. If doctors rely on the COVID-19 IgG/IgM rapid tests early in the disease, their diagnosis could be wrong. Furthermore, elderly or immunocompromised patients may never (or only much later) develop anti-SARS-CoV-2 antibodies. Reliable detection of IgM antibodies early in infection is also problematic due to cross-reactions resulting in false positive results. Most importantly from a public health perspective, COVID-positive patients are infectious to other people early in infection when the COVID-19 IgG/IgM tests are giving false results.[4]



For illustrative purposes only. This should not be used as a primary reference.

PRINCIPLE

The 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 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.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated 2°C – 30°C (36°F – 86°F). 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

The test cassette contains SARS-CoV-2 specific antigen conjugated gold colloid particles and anti-human IgM, anti-human IgG 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)
- Package Insert (1)
- Disposable Plastic Pipettes (20)

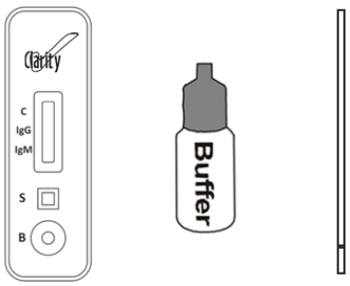
MATERIALS REQUIRED BUT NOT PROVIDED

- Safety Lancet (for fingerstick blood only)
- Micropipette with Tips
- Alcohol Swabs
- Timer
- Centrifuge (for plasma only)
- Specimen collection container

PRECAUTIONS

- For professional in vitro diagnostic use only. 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.
- Use only the buffer solution provided with the kit.
- Avoid cross-contamination of samples by using a new specimen collection container for each sample.

TEST KIT COMPONENTS



SPECIMEN COLLECTION AND PREPARATION

For finger stick whole blood:

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

For venous whole blood, plasma and serum:

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

SPECIMEN PRESERVATION

If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

For serum, or plasma specimens:

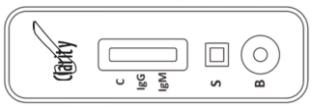
- Stored at 4°C – 8°C (39°F – 46°F) for approximately 7 days;[10] or
- Stored at -20°C (-4°F) up to 3 months;[9] or
- Stored at -80°C (-112°F) for at least 1 year.[9]
- Avoid repeat freezing and thawing.[10]

For Venous whole blood specimens:

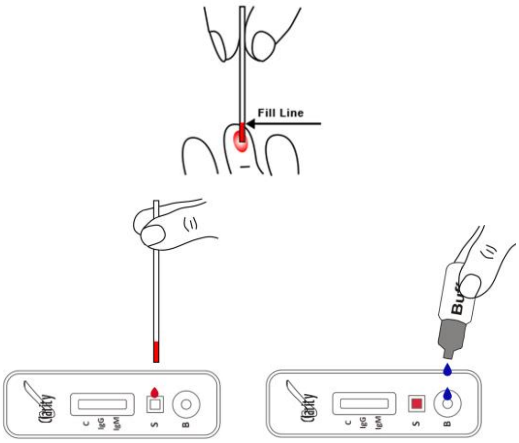
- Venous whole blood may be stored for up to 24 hours at 4°C – 8°C (39°F – 46°F) before testing.[10]
- Do not freeze whole blood specimens.[10]

DIRECTIONS FOR USE

1. Prior to testing, the blood specimen, 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.**

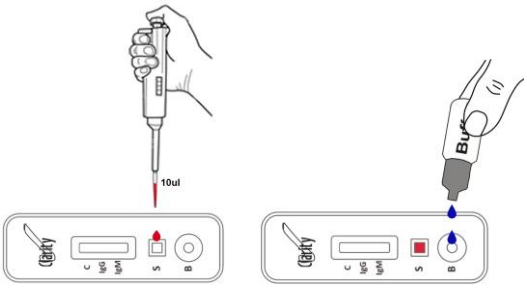


3. **For finger stick whole blood specimen:**
   a. Avoid touching the disposable pipette directly to the finger.
   b. **The pipette provided with the test dispenses approximately 10 µl in one drop even if more blood is aspirated in the pipette.**
   c. Wash the patient's hand with soap and warm water, or clean the fingertip to be punctured with an alcohol pad. Allow to dry completely.
   d. Using a 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. Wipe away the first sign of blood.
   e. 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 blood droplet.
   f. Gently release the pressure to draw up 10µl of blood to the fill line. Do not release the pressure completely. Ensure the blood reaches the fill line with no air bubbles.
   g. Squeeze the disposable pipette to transfer 1 drop of 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. **Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.**

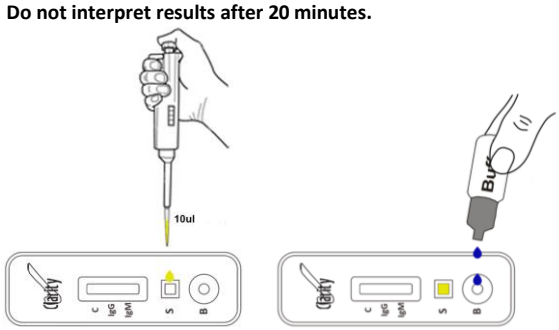


4. **For venous whole blood specimen:**

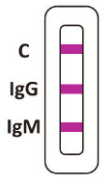
Use lab pipette to transfer 10µl venous whole blood specimen directly onto the specimen well (S) of the test cassette. then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. **Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.**



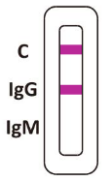
5. **For plasma or serum specimen:**
   a. For plasma specimen, use common anticoagulant, EDTA, Heparin or Citrate. Other anticoagulants have not been validated and may cause a false result.
   b. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed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



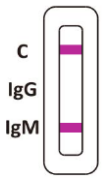
INTERPRETATION OF RESULTS



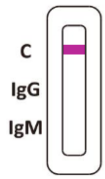
POSITIVE
IgG and IgM POSITIVE: * Three lines appear. If the C-line, M-line, and G-line are all present, it means that SARS-CoV-2 IgG and IgM antibody are detected, and the result is IgG and IgM antibody positive.



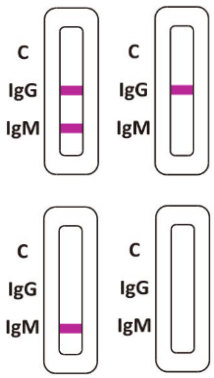
IgG POSITIVE: * Two lines appear. If both the C-line and the G-line appear, it means the IgG antibody against SARS-CoV-2 is detected, and the result is IgG antibody positive.



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 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/ Plasma/ Serum) is for professional in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, plasma or serum 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. 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.
10. Not for the screening of donated blood.
11. This test has not been reviewed by the FDA.

PERFORMANCE CHARACTERISTICS

The Clarity COVIBLOCK™ COVID-19 IgG/IgM Rapid Test Cassette was compared against PCR confirmed results. The retrospective studies included a total of 130 plasma/serum specimens from subjects who has been confirmed positive for COVID-19 by PCR, and 90 plasma/serum/fingerstick whole blood samples which were confirmed negative by PCR.

IgG Results

Method		*Clinical Diagnosis (PCR)*		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	220

Diagnostic Sensitivity: 91.54%
Diagnostic Specificity: 100%

IgM Results

Method		*Clinical Diagnosis (PCR)*		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	220

Diagnostic Sensitivity: 91.54%
Diagnostic Specificity: 100%

SEROCONVERSION

A retrospective clinical study was performed, with a total of 113 positive serum samples collected from 39 patients who were confirmed for SAR-CoV-2 infection using PCR and clinical diagnosis. Days between symptom onset and blood collection date were categorized in 2 groups: 0-7 days, and greater than 8 days.

Days post onset of symptoms	No. of Samples	IgM(+) IgG(-)	IgG(+) IgM(-)	IgM(+) IgG(+)	IgM(-) IgG(-)
0-7 days	32	0	0	1	31
8+ days	81	13	3	59	6

Days post onset of symptoms	IgG Agreement to Clinical Diagnosis	IgM Agreement to Clinical Diagnosis	Combined IgG/IgM Agreement to Clinical Diagnosis
0-7 days	3.13%	3.13%	3.13%
8+ days	76.54%	88.89%	92.59%

CROSS-REACTIVITY

The 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.

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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