

User Quick Reference Instructions for 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 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)

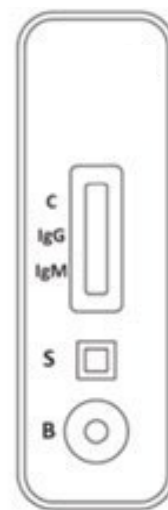
The following materials are also required but are not provided in the kit:

- 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:

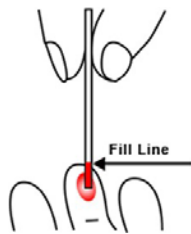
The well that is labeled as “S” is for the blood Sample.

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

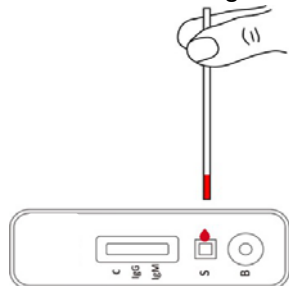
Buffer.

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.

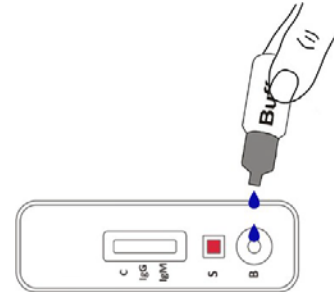


- 8) Transfer the blood from the capillary tube into the Sample well (marked with an S) in the cassette by gently squeezing the capillary as shown in the figure below.



- 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).



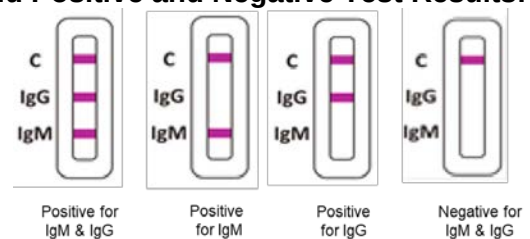
- 10) Immediately after adding the buffer to the Buffer well, set the timer for 10 minutes and start the timer.
- 11) After 10 minutes have passed, read the result as described in the following section. Do not read the result after 20 minutes.

READING THE TEST RESULTS

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

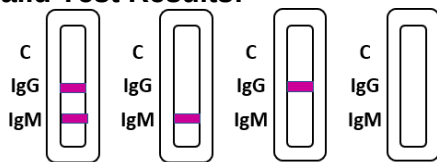
- The line that appears next to the **C (control)** shows that the test worked correctly. If a **C** line does not appear, the test did not work correctly, and the results are not valid even if lines appear next to the G or the M.
- A line that appears next to the **G** when there is also a **C** line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

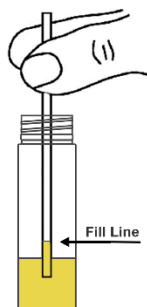
Interpretation	C Line	M Line	G Line
Invalid – repeat test	Line absent	Line present	Line present
Invalid – repeat test	Line absent	Line present	Line absent
Invalid – repeat test	Line absent	Line absent	Line present
Invalid – repeat test	Line absent	Line absent	Line absent

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

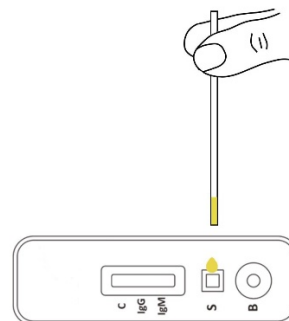
EXTERNAL CONTROL TEST

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.

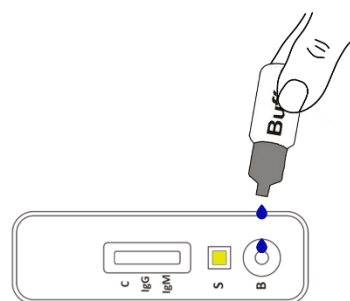
- 1) Remove a test cassette, the bottle of buffer, the control vials (positive & negative) and a disposable plastic capillary from the kit and place them on a level work surface.
- 2) Carefully remove the test cassette from its foil wrapper and place it right-side up on the level surface and use it within 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.

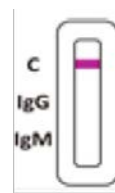
Expected External Control Results

Positive Control

Negative Control



Positive for IgM & IgG



Negative for IgM & IgG



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REF: CD-COV19CW/102223/ 102224

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