BIOCREDIT

COVID-19 IgG+IgM Duo

IVD

One Step SARS-CoV-2 IgG and IgM Antibody Rapid Test

■ Introduction

2019 novel coronavirus (2019-nCoV) is a single-stranded RNA coronavirus. Coronavirus disease 2019 (COVID-19) is a respiratory illness caused by the 2019-nCoV. 2019-nCoV belongs to the Beta-coronavirus Genus, which also includes Severe Acute Respiratory Syndrome coronavirus (SARS-CoV, 2003) and Middle East Respiratory Syndrome coronavirus (MERS-CoV, 2012). Coronaviruses, 2019-nCoV consist of a four viral proteins named spike (S), envelope (E), membrane (M), and nucleocapsid (N).
Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death. Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.

[Principle of Test]

BIOCREDIT COVID-19 IgG+IgM Duo is a lateral flow immunochromatographic assay for qualitative detection of IgG and IgM specific to SARS-CoV-2 virus in human serum, plasma and whole blood. Anti-human IgG and IgM conjugated with colloidal gold particles will react specifically with the SARS-CoV-2 IgG and IgM antibodies in patient's serum, plasma and whole blood. The colloidal gold conjugated anti-human IgG & IgM and SARS-CoV-2 specific IgG & IgM forms antibody-antibody-gold particle complex then it moves to pre-coated SARS-CoV-2 recombinant antigens on the membrane. The reaction forms antigen-antibody-antibody-gold particle complex then they show as color band at T-line area. The control line (C) is used for procedural control and should always appear if the test is performed correctly.

[Intended Use]

For the qualitative detection of SARS-CoV-2 specific IgG and IgM antibodies in human serum, plasma or whole blood. This test is for in vitro professional diagnostic use and intended as an aid to early diagnosis of COVID-19 infection in patient with clinical symptoms with COVID-19 infection.

■ Kit Components

- Each test device sealed in a foil-pouch with a desiccant
- Assay diluent bottle
- Capillary pipette (optional)
- Instructions for use

■ Specimen Collection and Storage

[Specimen collection]

1. Whole blood:
   1) Capillary whole blood from finger prick
      ① Clean area to be lanced with an alcohol swab.
      ② Squeeze the end of the fingertip and pierce with a sterile lancet.
      ③ Wipe away the first drop of blood with sterile gauze or cotton.
      ④ Take an capillary pipette provided and while squeezing, immerse the open end in the blood drop and then gently release the pressure to draw blood(20㎕).
   2) Venous whole blood from venipuncture: Collect blood by standard venipuncture into a tube containing correct anticoagulant (EDTA, heparin or citrate).
2. Plasma: Collect whole blood into the collection tube (containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture and then centrifuge to obtain the supernatant.
3. Serum: Collect whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Allow blood to clot by leaving it undisturbed for 30 minutes, then centrifuge to obtain the supernatant.

[Specimen storage]

Testing should be performed immediately after specimen collection. Do not leave the specimen at room temperature(1~40℃) for prolonged time. If specimen must be stored, whole blood specimen can be stored at 2~8℃ for 24 hours. Serum and plasma specimens can be stored at 2~8℃ for three days or for longer storage period, freeze below -20℃.

[Precaution]

1. Anticoagulants such as heparin, EDTA or citrate do not affect the test result.
2. Plasma or serum specimens containing precipitates may yield inconsistent test results. Such specimens must be clarified prior to assaying.
3. Use separate disposable capillary pipettes or pipette tips for each sample in order to avoid cross contamination of either samples which can cause erroneous results.

■ Assay Procedure

1. Equilibrate all kit components and specimen to room temperature prior to testing.
2. Remove the test device from foil pouch and place it on a flat and dry surface.
3. Add 10㎕(serum or plasma) or 20㎕(whole blood) of specimen into the sample well(S) of each device using capillary pipette or disposable dropper.
4. Add 3 drops of assay diluent into the buffer well (B) of the device.

* **Please ensure that an appropriate amount of specimen and assay diluent are used for testing. Too much or too little amount of specimen and/or assay diluent may lead to deviation of results.**

5. Read the result within 5~10 minutes.
   *Caution: Do not interpret test results after 10 minutes.

■ Interpretation of Results

[Negative]

The presence of only one red band ("C" control line) within the result window indicates a negative result.

[Positive]

- **IgG Positive:** The control line (C) and IgG line (T) are visible on the test device.
- **IgM Positive:** The control line (C) and IgM line (T) are visible on the test device.

[Invalid]

If the control line fails to appear or test line appears in red faintly within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.

*Note: There is no meaning attributed to line color intensity or width.

■ Performance Characteristics

BIOCREDIT COVID-19 IgG+IgM Duo has been evaluated with panel specimen by PCR. The results are summarized in the following table:

1. Sensitivity and Specificity:

BIOCREDIT COVID-19 IgG+IgM Duo		PCR(5~7 Days)		Sensitivity	Specificity
		Positive	Negative		
IgG	Positive	21	2	84.0%	96.0%
	Negative	4	48		
Total		25	50		
IgM	Positive	22	2	88.0%	96.0%
	Negative	3	48		
Total		25	50		

2. Precision
   Within-run and between run precision has been determined in triplicates of three lots using the following specimen panel: negative, low positive, medium positive and strong positive. All specimens are correctly identified 100% of the time.
3. Cross reactivity
   No cross reactivity was observed for BIOCREDIT COVID-19 IgG+IgM Duo when tested with specimens positive for the following: Syphilis Ab, Hepatitis A virus IgG, Hepatitis B virus Antibody, human immunodeficiency virus IgG, human immunodeficiency virus IgM, Hepatitis C virus Antibody.
4. Interference
   BIOCREDIT COVID-19 IgG+IgM Duo has been tested with 14 potentially interfering endogenous or exogenous substances. The results showed that BIOCREDIT COVID-19 IgG+IgM Duo had no interference with endogenous or exogenous substances.

■ Limitations and Interferences

1. A negative result can occur if the quantity of coronavirus antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
2. A negative test result cannot exclude a recent infection.

■ Precautions

1. For *in vitro* diagnostic use only.
2. The test device is sensitive to humidity as well as heat. Perform the test immediately after removing the test device from the foil pouch.
3. Do not use the test kit if the pouch is damaged or the seal is broken.
4. Decontaminate and dispose of all specimens, reaction kit and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
5. Wear protective clothing, gloves and eye protection while handling specimens. Wash hands afterwards.
6. Repeated freeze-thawing specimen can cause false positive or false negative results.
7. Discard the solid waste by autoclaving at 121℃ for 1 hour.
8. The assay diluent contains less than 0.1% of sodium azide. In case of dermal or eye exposure, wash out thoroughly with running water and seek medical attention if necessary.
9. Do not use it beyond the expiration date.
10. Do not reuse.
11. Do not interchange or mix reagents of different lots.
12. Do not use specimens that are hemolyzed or contaminated with microorganisms as they may cause incorrect test results.
13. Other clinically available tests are required if questionable results are obtained. As with all other diagnostic test, a clinical decision should not be based on the results of this test, but should be made by physician after all clinical and laboratory findings have been evaluated.

■ Package

Refer to the outer packaging

■ Storage Condition

Store at 1~40℃.

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BIOCREDIT

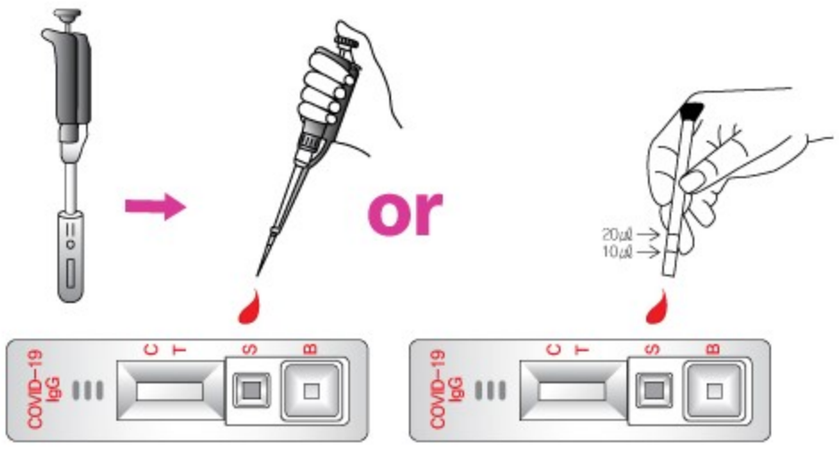
COVID-19 IgG+IgM Duo

Cat.No. G66RHA25

One Step SARS-CoV-2 IgG and IgM Antibody Rapid Test

■ Assay Procedure

[COVID-19 IgG]

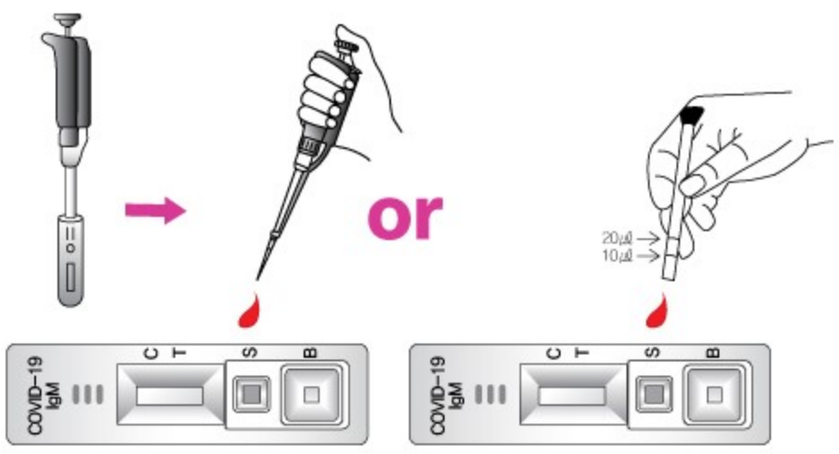


1 Add 10μℓ (serum or plasma) or 20μℓ (whole blood) of specimen into the sample well (S) using provided capillary pipette or micropipette.

2 Add 3 drops of assay diluent into the buffer well (B) of the device.

3 Read the result within 5~10 min.

[COVID-19 IgM]



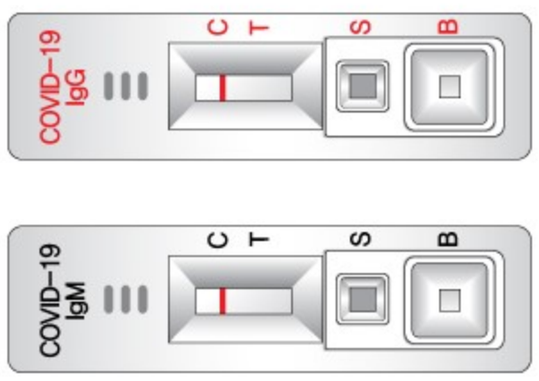
1 Add 10μℓ (serum or plasma) or 20μℓ (whole blood) of specimen into the sample well (S) using provided capillary pipette or micropipette.

2 Add 3 drops of assay diluent into the buffer well (B) of the device.

3 Read the result within 5~10 min.

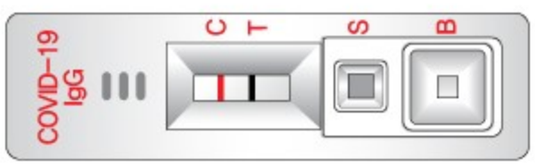
■ Interpretation of Results

Negative

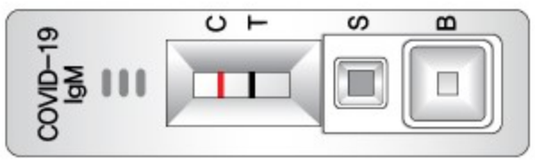


One red line at "C" within the result window.

Positive

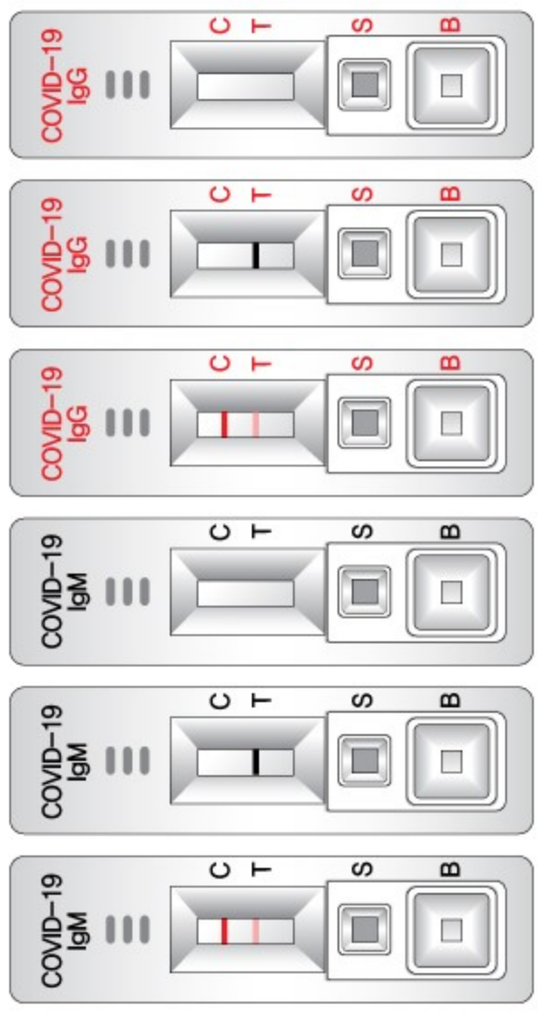


COVID-19 IgG Positive: One band on the control line(C) and the other on the test line(T).



COVID-19 IgM Positive: One band on the control line(C) and the other on the test line(T).

Invalid



No "C" line within the result window. Or test line (T) appears in red faintly. It is recommended that the specimen be retested.

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