

(Serum/Plasma/Whole Blood) Rapid card Test

INTRODUCTION:

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary SARS-COV-2 infections.

SUMMARY:

COVID-19(Corona Virus Disease) is the infectious disease caused by the most recently discovered corona virus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. 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 don't develop any symptoms and don't 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. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/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.

PRINCIPLE:

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/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.

SPECIMEN COLLECTION & PRESERVATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer) by venipuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into a new pre-labeled tube.

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Whole blood

Whole blood should be collected over heparin, citrate or EDTA. Mix the whole blood by inversion and use it to the test.

TEST PROCEDURE:

1. Remove the test device from its protective pouch (bring the device to room temperature before opening of the pouch to avoid condensation of moisture on the membrane). Label the device with patient or control identifications and use the device as soon as possible.
2. Using the dropper provided put 25 µL of Whole Blood/Serum/Plasma into the sample well then immediately put 2-3 drops of running buffer. Avoid overflowing.
3. Read the results within 15 to 20 minutes. It is important that the background is clear before the result is read.

IMPORTANT NOTE:

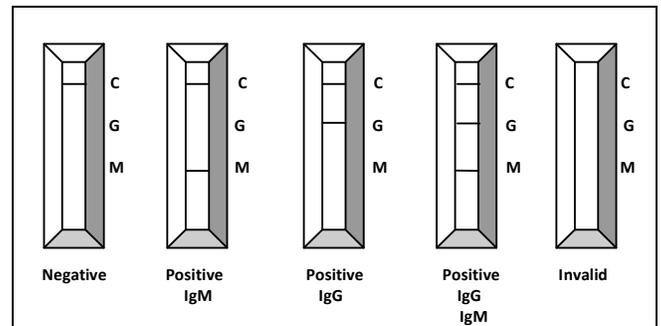
Do not read results after 20 minutes since serum back flow may cause false results.

A Kit Contains:

Pack Size	:	10 Test	25 Test
Disposable test card	:	10 Cards.	25 Cards.
Clearing buffer	:	1 Nos.	1 Nos.

The self life or expiry of the card is printed on the pouch.

INTERPRETATION OF RESULT.



- **Negative:** Only one colored band appears on the control (C) region. No apparent band on the test (T) region.

- **Positive: IgG and IgM POSITIVE:** Three lines appear. One colored line should be in the control line region (C), and two colored lines should appear in IgG test line region. The color intensity of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary SARS-COV-2 infection.
- **IgG POSITIVE:** Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG and is probably indicative of secondary SARS-COV-2 infection.
- **IgM POSITIVE:** Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies and is indicative of primary SARS-COV-2 infection.

- **Invalid:** A total absence of color in either regions or no colored line appears on the control (C) region is an indication of procedure error and / or the test reagent deterioration. Repeat the test with a new device.

PRECAUTIONS:

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. Do not freeze the Kits.
5. Specimen with extremely high concentrations of red blood cells, fibrin should be re-centrifuged before use.

STORAGE AND STABILITY:

The test kit can be stored at temperatures between 4 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

LIMITATIONS:

- a. The 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. Neither the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.
- b. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of SARS-COV-2 antibodies in the specimen and should not be used as the sole criteria for the diagnosis of SARS-COV-2.
- c. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of SARS-COV-2 infection.

SENSITIVITY & SPECIFICITY:

To establish the sensitivity and specificity of Covid-19 IgG/IgM test kit was compared with leading commercial PCR. This kit relative sensitivity and specificity in 305 samples. The agreement is Sensitivity: 97.4% Specificity: 99.3%.

REFERENCES:

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020.
2. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
3. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
4. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.

	Attention, see instructions for use		Consult Instructions For Use
	For in vitro diagnostic use only		Catalog #
	Store between 4-30°C		Do not reuse
	Do not use if package is damaged		Lot Number
	Tests per kit		Date of Manufacturing
	Manufacturer		Use by