



COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/ Serum/ Plasma) Package Insert

A rapid test for the qualitative detection of antibodies (IgG and IgM) to SARS-CoV-2 in whole blood, serum, or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

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 coronavirus. 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.

【PRECAUTIONS】

- For professional 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 uncovered buffer could be stored at room temperature or refrigerated (2-30°C) for 1.5 months at least. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use after the expiration date.

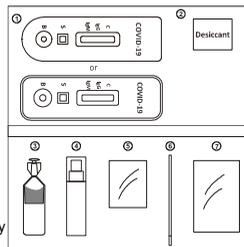
【MATERIALS】

The small pouch contains:

1. Test cassette
2. Desiccant

The large pouch contains:

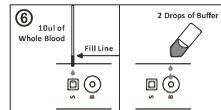
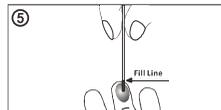
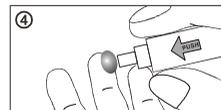
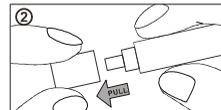
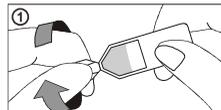
3. Buffer (0.02% Na₂S₂O₃ + 0.025% Kanamycin Sulfate)
4. Sterile lancet
5. Alcohol swab
6. Disposable Dropper/Capillary
7. Package insert



【DIRECTIONS FOR USE】

Allow the test cassette, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

Open the small pouch, remove the test cassette and place it on a clean and level surface. Best results will be obtained if the assay is performed within one hour.

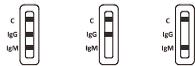


1. Open the large pouch, remove the buffer vial, sterile lancet and other materials. Twist off the tab of the buffer vial without squeezing. Then place it on a clean and level surface.
2. Carefully pull off the sterile lancet cap.
3. Use the provided alcohol swab to clean the puncture site.
4. Push the sterile lancet firmly onto the chosen site. Let a large drop of free-flowing blood collect at the puncture site. To increase blood flow, use the thumb and forefinger to gently apply pressure around the puncture site.
5. Add the blood specimen to the test cassette using either the disposable dropper included in the large pouch.
6. To use the Disposable Dropper: Hold the disposable dropper 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 dropper directly to the finger.
7. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.

NOTE: This test can also be run with serum/plasma specimens according to the following instructions: Draw the serum/plasma specimen up to the Fill Line (approximately 10µl), and transfer the specimen 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. Read results at 10 minutes. Do not interpret results after 20 minutes.

【INTERPRETATION OF RESULTS】

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 and IgM test line region. The color intensities 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.



Positive

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.

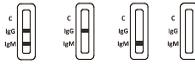
IgM POSITIVE:* Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies and is indicative of primary SARS-COV-2 infection.

NEGATIVE
One colored line appears in the control region (C). No line appears in the test line region (T). Negative results are not definitive. Refer to Limitations of use.



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 Premier Biotech.



Invalid

【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 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.
2. Results from the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) should not be used as the sole basis to diagnose or exclude SARS-COV-2 infection or to inform infection status.
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 characterized by the presence of detectable IgM antibodies 3-7 days after the onset of infection. Secondary SARS-COV-2 infection is 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】

Sensitivity and Specificity

The COVID-19 IgG/IgM Rapid Test Cassette was compared with clinical diagnosis(Confirmed). The study included 446 specimens for IgG and 456 specimens for IgM.

IgG Results

Method	Clinical Diagnosis(Confirmed)			Total Results
	Results	Positive	Negative	
COVID-19 IgG/IgM Rapid Test Cassette for IgG	Positive	75	2	77
	Negative	0	369	
Total Results		75	371	446

Diagnostic Sensitivity:100.0% (95%CI: 96.1%~100.0%)*

Diagnostic Specificity: 99.5% (95%CI: 98.1%~99.9%)*

Accuracy: 99.6% (95%CI: 98.4%~99.9%)*

*Confidence Interval

IgM Results

Method	Clinical Diagnosis(Confirmed)			Total Results
	Results	Positive	Negative	
COVID-19 IgG/IgM Rapid Test Cassette for IgM	Positive	78	3	81
	Negative	7	368	
Total Results		85	371	456

Diagnostic Sensitivity: 91.8% (95%CI: 83.8%~96.6%)*

Diagnostic Specificity: 99.2% (95%CI: 97.7%~99.8%)*

Accuracy: 97.8% (95%CI: 96.0%~98.9%)* *Confidence interval

Cross-reactivity

The COVID-19 IgG/IgM Rapid Test Cassette (whole blood/Serum/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: 20 mg/dL
Albumin: 2 g/dL	Acetylsalicylic Acid: 20 mg/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.

【BIBLIOGRAPHY】

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2. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
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5. 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.

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