COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) - Technical Overview

INTENDED USE

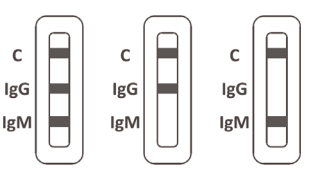
The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary SARS-COV-2 infections. It is intended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

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.

INTERPRETATION OF RESULTS



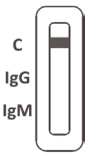
POSITIVE

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.

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.

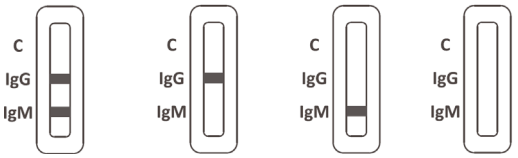
IgM POSITIVE: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies and is indicative of primary SARS-COV-2 infection.

NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-COV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.



NEGATIVE

NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s). Negative test results are not definitive. Please refer to the package insert for detailed interpretation.



INVALID

INVALID: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact Premier Biotech.

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
COVID-19 IgG/IgM Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	75	2	77
	Negative	0	369	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
COVID-19 IgG/IgM Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	78	3	81
	Negative	7	368	375
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 Acetylsalicylic Acid: 20 mg/dL Ascorbic Acid: 2g/dL Hemoglobin: 1000mg/dl	Caffeine: 20 mg/dL Gentisic Acid: 20 mg/dL Creatine: 200mg/dl Oxalic Acid: 60mg/dL	Albumin: 2 g/dL Ethanol: 1% Bilirubin: 1g/dL Uric acid: 20mg/ml

TEST REPORTING

Per the FDA guidance, test reports resulting from the use of the COVID-19 IgG/IgM Rapid Test Cassette for whole blood, plasma and serum must bear the following information:

- This test has not been reviewed by the FDA.
- 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.
- 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.
- 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.
- Not for the screening of donated blood.