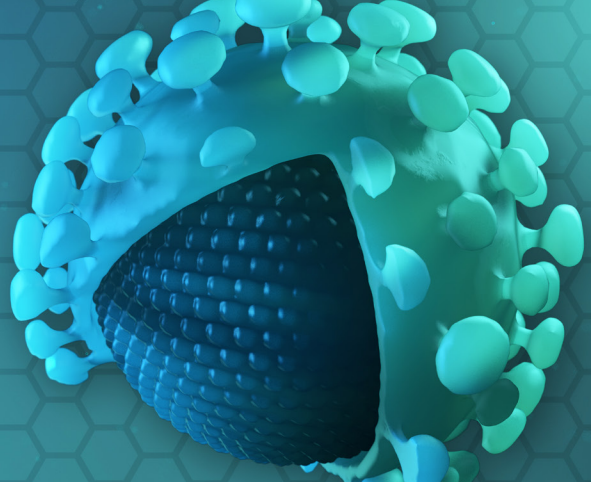
CORONA VIRUS
COVID-19
IgG And IgM Rapid Test



A Rapid Test For The Detection of COVID-19 (Coronavirus)

The COVID-19 IgG and IgM Rapid Test provided by Premier Biotech is used for the qualitative detection of SARS-CoV-2 antibodies in whole blood, serum, or plasma. The procedure is easy to administer and offers reliable results at 10 minutes that remain valid for 20 minutes.

The COVID-19 Pandemic

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. Elderly, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness.

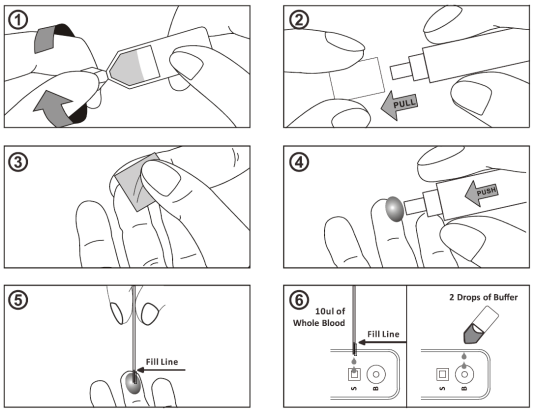
Confident COVID-19 Results

- Fast results in 10 minutes
- Easy to use and highly accurate
- 60 tests/case
- Prompt shipping and delivery

Kit Contents Include:

- Test cassette
- Desiccant, buffer, alcohol swab
- Sterile lancet
- Disposable capillary
- Package insert/procedure guide

Easy To Use Procedure



Note: Test can also be run with serum/plasma specimens

COVID-19 IgG and IgM Rapid Test

On March 16, the U.S. government took an unprecedented step towards access to Coronavirus Disease (COVID-19) testing by allowing developers of certain tests to commercialize the products in the U.S. without the requirement for an FDA approval or Emergency Use Authorization (EUA)[i].

The COVID-19 IgG and IgM Rapid Test is designed to detect the **antibodies** that develop in the body following exposure to Coronavirus. Symptoms of COVID-19 are expected to appear 1-14 days following viral exposure.

Primary infection is characterized by the presence of **detectable IgM antibodies 3-7 days after the onset of infection**. Secondary infection is characterized by the elevation of SARS-COV-2-specific IgG. In most cases, this is accompanied by elevated levels of IgM.

To comply with the regulation, the following statements must be included in any test reports using the COVID-19 Rapid Test:

- 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.

In addition, we have included these statements throughout the product package insert, aligning with the technical sections to which they pertain.

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[i]U.S. 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.