COVID-19 IgM/IgG Rapid Test*

The Rapid Test Kit has been developed and launched one of the world's first rapid point-of-care lateral flow immunoassays for the diagnosis of coronavirus infection. The test has been used widely by the Chinese CDC to combat infections and is now available globally. This test detects both early marker and late marker, IgM/IgG antibodies in human finger-prick or venous blood samples.

It can be used for rapid screening of carriers of the virus that are symptomatic or asymptomatic. Recent studies suggest that a high percentage of patients show no clinical symptoms of the virus, thus screening patients is vitally important. The test is ideally suited for hospitals, clinics and test laboratories. The test can also be effectively deployed in businesses, schools, airports, seaports and train stations, etc., giving it the potential to become a compelling force in the fight against this global threat.

Features & Benefits

COVID 19 Rapid IgM-IgG Combined Antibody Test for COVID-19 is used to qualitatively detect IgG and IgM antibodies of the novel coronavirus in human serum, plasma or whole blood in vitro.

Precise

- Works with whole blood, serum, & plasma
- Tests for both IgM and IgG antibodies
- Validated using PCR

Fast

- 15 minutes per test
- Intuitive visual interpretation
- No special equipment needed

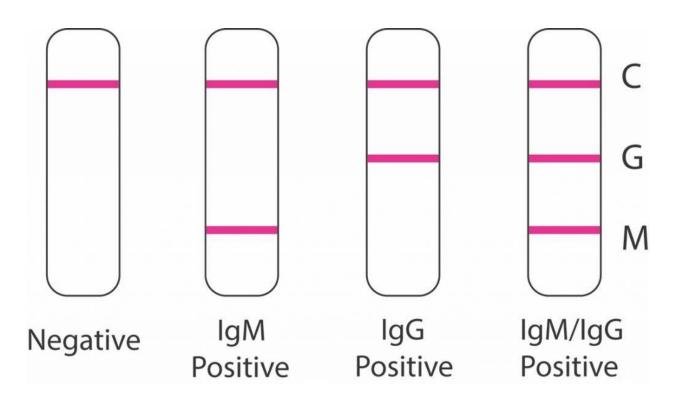
How It Works



<u>Steps</u>

- 1. Collect blood/serum/plasma sample.
- 2. Add blood/serum/plasma sample to sample well.
- 3. Place 2-3 drops of buffer in sample well.
- 4. Read results after 15 minutes.

Results



FAQs

What is COVID-19 lgM-lgG Rapid Test?

Rapid IgM-IgG Combined Antibody Test for COVID-19 is a lateral flow immunoassay used to qualitatively detect IgG and IgM antibodies of the novel coronavirus in human serum, plasma or whole blood in vitro.

How does COVID-19 Rapid Test work?

The test strip contains a colloidal gold-labeled recombinant novel coronavirus antigen and quality control antibody colloidal gold marker, two detection lines (G and M lines) and one quality control line (C) fixed on a nitrocellulose membrane. M is fixed with monoclonal anti-human IgM antibody for detecting the novel coronavirus IgM antibody. G is fixed with monoclonal anti-human IgG antibody for detecting the novel coronavirus IgG antibody. The quality control antibody is fixed on the C line.

How quickly can COVID-19 Rapid Test yield results?

Results are valid 15 minutes after sample and buffer are combined in the cassette sample well.

How accurate is the COVID-19 Rapid Test?

in order to test the detection sensitivity and specificity of the COVID-19 IgG-IgM combined antibody test, blood samples were collected from COVID-19 patients from multiple hospitals and Chinese CDC laboratories. The tests were done separately at each site. A total of 525 cases were tested: 397 (positive) clinically confirmed (including PCR test) SARS-CoV-2-infected patients and 128 non- SARS-CoV-2-infected patients (128 negative). The testing results of vein blood without viral inactivation were summarized in the Table 1. Of the 397 blood sample from SARS-CoV-2-infected patients, 352 tested positive, resulting in a sensitivity of 88.66%. Twelve of the blood samples from the 128 non-SARS-CoV-2 infection patients tested positive, generating a specificity of 90.63%.

What do the result tell me?

A total of three detection lines are possible, with the control (C) line appearing when sample has been flowed through the cassette.

1 | **Negative Result**: If only the quality control line (C) appears and the detection lines G and M are not visible, then no novel coronavirus antibody has been detected and the result is negative.

2 | **Positive Result, M only**: If both the quality control line (C) and the detection line M appears, then the novel coronavirus IgM antibody has been detected and the result is positive for the IgM antibody.

3 | **Positive Result, G only**: If both the quality control line (C) and the detection line G appears, then the novel coronavirus IgG antibody has been detected and the result is positive for the IgG antibody.

4 | **Positive Result, G and M**: If the quality control line (C) and both detection lines G and M appear, then the novel coronavirus IgG and IgM antibodies have been detected and the result is positive for both the IgG and IgM antibodies.

What are the alternatives?

The COVID-19 IgM/IgG Rapid Test can be used to screen patients suspected of having been affected by the novel coronavirus. However, results of test should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods such as nucleic acid PCR test.