COVID-19 Antibodies (IgG/IgM) Rapid Test
Frequently Asked Questions

What is the application of COVID-19 Rapid Test?

1. The Antibody rapid test can be used to detect if a person has been exposed to the COVID-19 virus, and whether they have built an immunity to the virus.
2. The test can be used for rapid screening of both symptomatic and asymptomatic carriers. The test is ideal for general population screening (at offices, airports, public places, schools) and for use at hospitals, clinics and test laboratories.
3. The studies suggest that a significant percentage of patients doesn't show any clinical symptoms, thus rapid screening is extremely important in these cases. A person may be able to resume their normal lives and go back to work if they have knowledge about their immunity to the coronavirus.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of Rapid Test, but should only be made by the physician after all clinical and laboratory findings (including molecular diagnostic test) have been evaluated.

What is a COVID-19 IgG/IgM Rapid Test?

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and deferential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. When a person is exposed to the coronavirus, the body starts producing two types of antibodies, IgG and IgM.

What certification does this test has?

The test kit has the following certifications:

- CE-IVD - Marked
- CFDA (China Food and Drug Administration) - Pending
- Emergency Use Authorization (EUA) for US FDA – Pending
- Australian Therapeutic Goods Administration (TGA) - Approved

Is this test clinically tested?

The IgG/IgM Antibodies Rapid Test has been clinical evaluated in 11 different hospitals and medical centers in China. Clinical blood samples collected from SARS-CoV-2 infectious and non-infectious patients were tested with the Rapid Test and the results were compared against the RT-PCR molecular test and clinical diagnosis.

The Rapid Test has also been clinical evaluated by Erasmus MC Viroscience, Rotterdam, NL. The results were compared against the IgG/IgM Rapid Tests by Cellex Inc and InTec Product Inc and RT-PCR molecular test.

Is the test approved by the FDA?

The test has been registered with the FDA and can be sold under Emergency Use Authorization (EUA) Program. The FDA allows the commercial distribution of the test for use by health care providers and laboratories while the test is being reviewed by the FDA. This is in accordance with the FDA policy on March 16, 2020, relating to COVID-19 testing. The FDA registration and EUA application is under the manufacturing entity.

What are the clinical evaluation results?

Of the known positive samples, the IgG test yields a 97.2% agreement, while the IgM test yields an 87.9% agreement.
Of the known negative samples, the IgG test yields a 100% agreement, while the IgM test yields a 100% agreement.

Sensitivity and Specificity:

IgG Result:

Relative Sensitivity: 97.2%
Relative Specificity: 100%

IgM Result:

Relative Sensitivity: 87.9%
Relative Specificity: 100%

What is the detection window for this test?

IgM antibodies are formed initially by the patient at about the time that symptoms first appear. These antibodies will dissipate after about one month. IgG antibodies are second to appear in the body, about one week after symptoms appear. They will continue to be present in the blood stream for prolonged period of time.

Detection Window for IgM:
Symptomatic patients: 3-5 days post symptoms onset and up to 1 month
Asymptomatic patients: 7 days up to 1 month

Detection Window for IgG:
All patients: 7 days post-infection to an extended amount of time

How quickly can Rapid Test yield results?

The result should be ready in 10 minutes. Do not interpret the result after 15 minutes.

What are the limitations of the test?

- The test will only indicate the presence of IgG and IgM antibodies to the SARS-CoV-2 virus in the specimen. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of Rapid Test, but should only be made by the physician after all clinical and laboratory findings (including RT-PCR test) have been evaluated.
- Negative results do not rule out SARS-CoV-2 infection and may be caused by one or more of the below mentioned reasons.
    - The concentration of the novel coronavirus antibodies (IgG and IgM) is below the detection threshold of the device.
    - A patient has been recently exposed to the virus and the antibodies are not present in the specimen yet.

  Follow up testing with a molecular diagnostic test should be considered in order to rule out infection.
- This product is only for qualitative testing.
- Test results can be affected by temperature and humidity.

How does the IgG/IgM Rapid Test work?

The test uses anti-human IgM antibody (test line IgM), anti-human IgG (test line IgG) and goat anti-rabbit IgG (control line C) immobilized on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to recombinant COVID-19 antigens conjugated with colloid gold (COVID-19 conjugates) and rabbit IgG-gold conjugates. When a specimen followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM &/or anti-human IgG) the complex is trapped forming a burgundy colored band which confirm a reactive test result.
Absence of a colored band in the test region indicates a non-reactive test result.

What is the Packaging Content of the COVID-19 Rapid Test?

Each COVID-19 Rapid Test kit contains:

- 25 sealed pouches each containing a test cassette, a dropper and a desiccant
- 25 lancets
- 1 Buffer solution
- 1 package insert

Do we provide any control or additional buffer solutions?
No we cannot.

Is there a refund or replacement available for the test kit?
Unfortunately there is no replacement or refund available for this product.