

FACT SHEET FOR RECIPIENTS

Anti-SARS-CoV-2 Rapid Test– Autobio Diagnostics Co., Ltd

Distributed by Hardy Diagnostics in the United States

Updated: May 18, 2020

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for antibodies to the virus that causes Coronavirus Disease 2019 (COVID-19) using the Anti-SARS-CoV-2 Rapid Test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test to evaluate your immune response to SARS-CoV-2, the virus that causes COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:
- <https://www.cdc.gov/COVID19>

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has spread globally, including in the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat, or new loss of taste or smell.

What is the Anti-SARS-CoV-2 Rapid Test?

The test is designed to detect antibodies to the virus that causes COVID-19 in blood specimens, for example serum and plasma specimens.

Why was my sample tested?

Testing of your sample(s) will help assess if you have antibodies to the virus that causes COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result?

The test can yield several possible results. Depending on the result, it may be more likely that you have COVID-19 and that you may need isolation to avoid the spread of the virus to others. Other results may indicate that you were previously infected. Your healthcare provider will work with you to determine how best to care for you based on the test results, along with other factors of your medical history, your symptoms, and possible exposures, and geographic location of places you have recently traveled. There is also the small possibility that this test can give a positive result that is wrong (a false positive result).

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

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What does it mean if I have a negative test result?

A negative test result means that the antibodies to the virus that causes COVID-19 were not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. A negative result may occur if you are tested during the early stages of your illness where your body hasn't had time to produce antibodies to the infection. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS) declaration that circumstances exist to justify the emergency use of *in vitro* diagnostic tests for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning that the test can be used) for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

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