

Disclaimer: This document has been submitted to the FDA as set forth in Section IV.A of the FDA's Policy for Coronavirus Disease-2019 Tests. The FDA has not yet reviewed this document or the validation data.

Fact Sheet for Recipients

Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA Test

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for detecting neutralizing antibodies to 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, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19 but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What is the Tru-Immune SARS-CoV-2 Neutralizing Antibody ELISA Test?

This test is designed to detect neutralizing antibodies in a blood sample that would indicate that you may have a current or prior COVID-19 infection.

Why was my sample tested?

Testing of your sample(s) will assist with determining if you have neutralizing antibodies to the virus that causes COVID-19.

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

Potential risks include:

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- Possible discomfort or other complications that can arise during sample collection.
- Possible incorrect test results (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?

If you have a positive test result, it is likely that you have previously had COVID-19 and that you have developed an antibody response to the virus. Your healthcare provider will consult 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 a small possibility that this test can give a positive result that is wrong (a false positive result).

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

A negative test result means that neutralizing 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 has not had time to produce neutralizing antibodies to the infection. This means that you could possibly still have the COVID-19 infection even though your 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 Services' (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this 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).