FACT SHEET FOR RECIPIENTS

Emergency Use of SARS-CoV-2 Antibody Tests During the COVID-19 Pandemic

April 28, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this General Fact Sheet because your sample(s) is being tested or was tested for antibodies to the virus that causes Coronavirus Disease 2019 (COVID-19) using a SARS-CoV-2 Antibody Test that was authorized for emergency use by FDA. For a list of the tests being referenced in this Fact Sheet, see https://www.fda.gov/media/137471/download

This Fact Sheet contains information to help you understand the risks and benefits of using this test to evaluate your adaptive 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 COVID19 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 this test?

The test is designed to detect antibodies to SARS-CoV-2, the virus that causes COVID-19, in blood 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 blood collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The result, 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 or previously had COVID-19 and that you have developed an antibody response to the virus. 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, and your symptoms, possible exposures, and geographic location of places you have recently traveled. There is also the small chance that this test can give a positive result that is wrong (a false positive result).

It is not known how long antibodies to SARS-CoV-2 will remain present in the body after infection and it is not known if they confer immunity to infection.

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)

- **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.

FACT SHEET FOR RECIPIENTS

Emergency Use of SARS-CoV-2 Antibody Tests During the COVID-19 Pandemic

April 28, 2020

Coronavirus Disease 2019 (COVID-19)

in some people with COVID-19. A negative result may occur if you are tested early in your illness and your body hasn't had time to produce antibodies to 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'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 of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved available alternatives?

There are no approved available alternative tests. FDA has issued EUAs for other antibody tests that can be found at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov.

- **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.