SARS-CoV-2 ANTIBODY TESTING

Aug. 2020

FACT SHEET FOR RECIPIENTS | SARS-CoV-2 IgG assay - Abbott Laboratories Inc.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for detecting 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 D2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

What is COVID-19?

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 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 SARS-CoV-2 IgG assay?

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

Why was my sample tested?

Testing of your sample(s) will help find out 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 continued 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 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, including any previous symptoms, possible exposure to COVID-19, and the location of places you have

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Detach

PARENT/GUARDIAN PERMISSION

The following consent must be completed and returned to blood center staff on the date of donation.

☐ *I, the parent or legal guardian of the individual listed below, hereby consent for my child to be tested for SARS-CoV-2 (COVID) antibody. This consent acknowledges that I have read the information provided about the SARS-CoV-2 antibody test.*

☐ *I DO NOT give authorization for my child's blood to be tested for SARS-CoV-2 antibodies.*

Donor's Printed Name

Date of Birth

School (if applicable)

Parent/Guardian Printed Name

Parent/Guardian Phone Number

Parent or Legal Guardian's Signature

Date

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recently traveled. There is also the chance 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 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 infection. 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. 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).

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 and/or concerns.

ANTIBODY TESTING AT YOUR BLOOD INSTITUTE

Your test result will be mailed to you. Results are expected to arrive within three weeks of your test.

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