

Fact Sheet for Patients:

Interpreting Results from the Abbott RealTime SARS-CoV-2 Assay

March xx, 2020

You are being given this Fact Sheet because your sample(s) were tested for the Coronavirus Disease 2019 (COVID-19) using the Abbott RealTime SARS-CoV-2 Assay.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of 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 2019 Coronavirus Disease (COVID-19) webpage:

<https://www.cdc.gov/nCoV>

What is 2019-nCoV Infection?

COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness in humans and was recently identified in Wuhan, China and has now been identified in over 60 countries, including the United States. Limited information is 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, sneezing, difficulty breathing, etc.).

What is the Abbott RealTime SARS-CoV-2 Assay?

The test is designed to detect virus that causes COVID-19 in nasal swabs.

Why was my sample tested?

Your sample(s) were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of virus that causes COVID-19 is known to occur, and/or
- Because you have been in close contact with an individual suspected of or confirmed to have COVID-19.

The sample(s) collected from you were tested to help find out whether you may have 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.
- Risk that the test result is incorrect (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 2019-nCoV test result?

If you have a positive test result, it is very likely that you are infected with the virus that causes COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). However, 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, such as symptoms, possible exposures, and geographic location of places you have recently traveled.

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

A negative test result means that the virus that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that the virus that causes COVID-19 did not cause your recent illness.

It is possible for this test to give a negative result that is incorrect (false negative) in some people that have COVID-19, meaning you could possibly still have COVID-19 even though the test is negative. Therefore, while a negative test most likely means you do not have COVID-19, 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 (U.S.) 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 use of in vitro diagnostics under EUA for the detection and/or diagnosis 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 2019- nCoV is available at the CDC General webpage: <https://www.cdc.gov/nCoV>.

In addition, please also contact your healthcare provider with any questions/concerns.