

COVID-19 (SARS-CoV-2)

You are being given this fact sheet because your sample(s) was tested for the virus that causes Coronavirus Disease 2019 (COVID-19) using the NxGen MDx COVID-19 Test.

This fact sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. If you have questions or would like to discuss the information provided after you read this fact sheet, please talk to your healthcare provider.



What Your Results Mean

Positive Results

If you have a positive test result, it is very likely that you have 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). Your healthcare provider will work with you to determine how best to care for you based on the test results, medical history, and your symptoms.

Negative Results

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 COVID-19 did not cause your recent illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative (continued on page 2).

COVID-19 Explained

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. COVID-19 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 about the spectrum of 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 CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel?

The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?

You 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 COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Your samples will help find out if you have COVID-19.

Facts about COVID-19 (SARS-CoV-2) Continued



What Your Results Mean

(Continued from page 1) If this is the case, your healthcare provider will consider the test result together with your 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.

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 the "What Your Results Mean" section for more information).

Is this test FDA-approved or cleared?

No. This test has been validated, but the independent review by the FDA of this validation is pending. When there are no FDA-approved or cleared 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 COVID-19.

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/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.