

This Fact Sheet is available to patients who were tested for the virus that causes Coronavirus Disease 2019 (COVID-19) using the MicroGenDX SARS-CoV-2 real-time RT-PCR (rRT-PCR) Diagnostic Assay. 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.

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>

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 MicroGenDX SARS-CoV-2 Diagnostic Assay?

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

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.

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

Potential risks include:

- Possible discomfort from sample collection.

FACT SHEET FOR PATIENTS

Coronavirus Disease 2019 (COVID-19)

SARS-CoV-2 Real-Time RT-PCR Diagnostic Assay

FDA authorized: EUA 200067

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- Possible incorrect test result (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 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.

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 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. 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.

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 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).