

Fact Sheet for Patients:

SARS-CoV-2 by PCR Laboratory-Developed Test (LDT)

Physicians Laboratory Services

You have been given this *Fact Sheet* because your sample was submitted to Physicians Laboratory Services to be tested for Coronavirus Disease 2019 (COVID-19) by your healthcare provider.

This *Fact Sheet* contains information to help you understand the risks and benefits of your healthcare provider using this test to assist in the diagnosis of COVID-19. **If you have further questions after reading this *Fact Sheet*, please contact your healthcare provider.**

What is COVID-19?

COVID-19 is caused by the virus SARS-CoV-2, a novel (new) coronavirus. The virus causes mild to severe respiratory illness and has now been identified in over 60 countries since it was first identified in Wuhan, China in 2019.

There is ongoing researching into the virus to further characterize the clinical illness associated with it, but it has been shown to be most likely to spread to others when a person shows symptoms of being sick (e.g. fever, coughing, sneezing, difficulty breathing, etc.).

What is the SARS-CoV-2 by PCR test?

The SARS-CoV-2 by PCR test is a laboratory-developed test that is designed to detect the virus that causes COVID-19 in nasopharyngeal swabs. The swab is inserted into the nasopharynx via the nasal passage(s) to collect your sample for this test. The swab is then placed in a tube and transported to the laboratory to be tested.

Why am I being tested for COVID-19?

Your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your symptoms and/or because:

- You live in or have recently traveled to a place where COVID-19 is reported
- You have been exposed to an individual with suspected/confirmed COVID-19.

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

Potential risks include:

- Possible complications or discomfort during sample collection.
- Possible inaccurate test result (see next column for additional information).

Possible benefits include:

- Along with other clinical information (e.g. your symptoms, your exposure risk, etc.), this result can help your healthcare provider make informed diagnosis and recommendations for your care.
- The result may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if my test result is positive?

A positive test result means it is very likely that you have COVID-19 because the virus was detected in your sample. It is likely you will 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 use your medical history, symptoms, exposure risk, and geographic location in conjunction with this test result to determine your diagnosis and treatment.

What does it mean if my test result is negative?

A negative test result means that the virus was not detected in your sample. If the sample was collected while you had symptoms, this usually means that the virus that causes COVID-19 was not the cause of your illness.

It is possible for the negative result to be incorrect (a false negative result). This means you could have COVID-19 even though the test did not detect the virus. Your healthcare provider will consider the test result with all aspects of your medical presentation in deciding how to care for you and your next steps.

Is this test FDA-approved or FDA-cleared?

No, this test is not approved or cleared by the United States FDA. There are currently no FDA-approved or FDA-cleared PCR tests for SARS-CoV-2, the virus that causes COVID-19. When this happens and other criteria are met, the 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 declaration that circumstances exist to justify the emergency use of *in vitro* diagnostics for the detection of the virus that causes COVID-19. This test is authorized for use for the duration of the COVID-19 declaration, unless it is terminated or revoked by the FDA.

For the most up-to-date information on COVID-19 please visit the CDC COVID-19 website: <https://www.cdc.gov/COVID19>