

COVID-19 TEST FACT SHEET FOR PARTICIPANTS

Molecular Laboratory Developed Test (LTD) COVID-19 Authorized Tests

Coronavirus
Disease 2019
(COVID-19)

Your saliva sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using a Molecular Laboratory Developed Test (LDT) which has been approved for use in the Veterinary Diagnostic Laboratory under the supervision of a CLIA-certified director and issuance of a CLIA-registration number by IDPH.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19.

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which 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 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, cough, difficulty breathing, etc.).

What is the Laboratory Developed Test?

The Molecular LDT COVID-19 Authorized Test is designed for use in a single laboratory to detect the virus that causes COVID-19 in respiratory specimens, such as saliva.

Why was my sample tested?

You were tested as part of a plan focused on early detection of the COVID-19 virus, or you believe you may have been exposed to the virus that causes COVID-19, or because there is concern of a virus infection based on your signs and symptoms (e.g., fever, cough, difficulty breathing, etc.). You may have the virus in your body even if you do not have any symptoms, and you do not need to have symptoms to spread the virus to others.

Testing of the samples will help find out if you may have COVID-19.

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

Potential benefits include:

- The results, along with other information, can help you and 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.

Potential risks include:

- Possible incorrect test result (see below for more information) because of test-related false positives or false negatives. The community will learn more about the limitations of the current test when applied to participants with and without symptoms of the virus.

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>

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. You will need to follow the protocols of your institution 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 determine how best to care for you based on the test results, your 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. A negative test result for a sample collected while you have symptoms usually means that COVID-19 did not cause your recent illness. Less is known when a sample is collected while a person does not have symptoms.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means you could still have COVID-19 even though the test is negative. If this is the case, you and your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to understand the next steps you should take.

Where can I go for updates and more information?

The most up-to-date information on COVID-19 is available at the Coronavirus Disease 2019 (COVID-19) webpage: <https://www.cdc.gov/COVID19>.

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