

COVID-19 TEST FACT SHEET FOR PATIENTS

University of Illinois at Urbana-Champaign
Molecular Laboratory Developed Test (LDT) COVID-19 Tests

Coronavirus
Disease 2019
(COVID-19)

Your saliva sample was tested for the Coronavirus Disease 2019 (COVID-19) using a Molecular Laboratory Developed Test (LDT). The LDT was validated in the CLIA-registered Veterinary Diagnostic Laboratory at the University of Illinois at Urbana-Champaign under the supervision of a CLIA-certified director.

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 more information, please visit <https://covid19.illinois.edu> where additional resources are listed. You can also talk to your healthcare provider about testing and 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 full spectrum of clinical illness associated with COVID-19, but it likely spreads to others when a person is infected and may or may not show signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). Testing is the only means to know when a person is infected with the virus.

What is the Laboratory Developed Test (LDT)?

This Molecular LDT COVID-19 Test is designed for use in a single laboratory to detect the virus that causes COVID-19 in respiratory specimens, such as saliva. The testing method uses a novel PCR method developed at the University of Illinois at Urbana-Champaign.

Why was my sample tested?

You were tested as part of a campus-wide plan focused on early detection of the COVID-19 virus in support of a safe campus environment. You may have been unknowingly exposed to the virus that causes COVID-19, or there is concern of a virus infection based on your signs and symptoms (e.g., fever, cough, difficulty breathing). You do not need to have symptoms to spread the virus to others.

Testing of the samples will help determine if you 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 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, because being informed will help you in making more responsible healthcare decisions.

Potential risks include:

- Possible incorrect test result because of a test-related false positive or false negative (see below).
- Possible discomfort or other complications that can happen during sample collection.

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 means the test detected genetic material from the virus, and you are very likely actively infected. You will be contacted by a case investigator from the Public Health Department within 24 hours and you should isolate yourself from others to prevent disease spread. There is a small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider and public health professionals will work with you to 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 detected in the sample you submitted. A negative test result for a sample collected while you have symptoms usually means that COVID-19 did not cause your 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 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 all other aspects of your medical history (such as symptoms, possible exposures, and places you have recently traveled) in recommending how to care for you.

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

Is this test FDA-approved or cleared?

No. This test is not approved or cleared by the FDA. The University has validated its test and is performing it in compliance with the requirements of the U.S. Department of Health and Human Services and the Centers for Medicare & Medicaid Services, Clinical Laboratory Improvement Amendment regulations.

Where can I go for updates and more information?

The most up-to-date information on COVID-19 is available at the CDC General webpage:
<https://www.cdc.gov/COVID19>.

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

WEAR A MASK THAT COVERS YOUR NOSE AND MOUTH; DISTANCE YOURSELF AT LEAST 6 FT FROM OTHERS; WASH YOUR HANDS FREQUENTLY; COVER YOUR COUGHS AND SNEEZES; CLEAN AND DISINFECT YOUR SURROUNDINGS; MONITOR YOUR HEALTH DAILY.

IF YOU MUST TRAVEL, GET TESTED UPON YOUR RETURN TO CAMPUS AND AGAIN 4 DAYS LATER OR SOON AFTER YOU BELIEVE YOU HAVE HAD A POSSIBLE EXPOSURE.