You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using BU's Molecular Laboratory Developed Test (LDT) COVID-19 Test (Molecular LDT 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. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, 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

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the Molecular LDT COVID-19 Test?
The Molecular LDT COVID-19 Test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal swabs.

Why was my sample tested?
You are being tested for one of the reasons below:
- 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), or
- You are being tested as part of an asymptomatic screening program even though you do not have symptoms or risk factors for COVID-19; or
- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur; or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19; or
- You and your healthcare provider believe there is another reason to investigate your COVID-19 infection status.

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

The BU Clinical Testing Laboratory may use pooling when testing your specimen, which means they combine your sample with other individuals samples prior to testing and test them as a “pool”. The Laboratory may return a result for the entire pool together or may return individual results.

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 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 those you come in contact with.

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.
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. You should follow CDC guidance to reduce the potential transmission of disease.

If you were tested as part of a pool that returned a positive test result, your sample will be re-tested individually. In most circumstances, you do not need to provide a new sample.

There is a rare possibility that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19 infection. Your healthcare provider will work with you to determine how best to care for you based on the test results along with your medical history, symptoms and exposure risks.

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.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. You might test negative if the sample was collected early during your infection. You could also be exposed to COVID-19 after your sample was collected and then have become infected.

In particular, people infected with COVID-19 but who have no symptoms may not shed enough virus to trigger a positive test. This means that you could possibly still have COVID-19 even though the test result is negative. If your test is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposure, and geographical locations of the places you have recently traveled) in deciding how to care for you. If your test result indicates your specimen was pooled and you have a negative test result, there is a small chance that your result is inaccurate if the level of virus in your body is very low. You should talk to your healthcare provider if you are concerned.

If you have no symptoms but have been tested because your doctor thought you may have been exposed to COVID-19, you should continue to monitor your health and let your healthcare provider know if you develop any symptoms of COVID-19. If you develop symptoms you may need another test to determine if you have contracted the virus causing COVID-19.

If you develop symptoms or your symptoms get worse you should seek medical care. If you have the following symptoms you should seek immediate medical care at the closest emergency room:
- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake up or stay awake
- Bluish lips or face

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

What does it mean if the specimen has an invalid test result?
An invalid test result means that no genetic material was detected and this means the Laboratory could not determine if the result was positive or negative. An invalid result can be caused by an error in obtaining the swab or an error that occurred within the Laboratory. You will need to submit a new sample for processing.
FACT SHEET FOR PATIENTS
The BU Clinical Testing Laboratory Molecular Laboratory Developed Test (LDT) COVID-19 Test

Updated December 13, 2021

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 BU Clinical Testing Laboratory has submitted to the FDA an EUA application for this Molecular LDT COVID-19 Test.

What are the approved alternatives?
Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

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