

FACT SHEET FOR INDIVIDUALS

Laboratory Corporation of America (Labcorp)

Labcorp Seasonal Respiratory Virus RT-PCR DTC Test

May 16, 2022

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because you are collecting an individual anterior nasal swab specimen at home using the Pixel by Labcorp COVID-19+Flu+RSV Test Home Collection Kit and sending your sample for the Coronavirus Disease 2019 (COVID-19), influenza A, influenza B and/or Respiratory Syncytial Virus (RSV) testing using the Labcorp Seasonal Respiratory Virus RT-PCR DTC Test.

This Fact Sheet contains information to help you understand the risks and benefits of using this Direct to Consumer (DTC) product for the diagnosis of COVID-19, influenza and/or RSV. 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 are Influenza and RSV?

Influenza (flu) and RSV are contagious respiratory illnesses caused by influenza viruses and RSV virus.

Influenza viruses can cause mild to severe illness. Serious outcomes of the flu can result in hospitalization or death. Some people, such as older people, young children, and people with certain underlying health conditions, are at higher risk for serious flu complications. There are two main types of influenza viruses: types A and B. Both type A and B influenza viruses regularly spread in people, and are responsible for seasonal flu each year. Influenza viruses can be spread to others before and after a person shows signs and symptoms of being sick.

What is the Labcorp Seasonal Respiratory Virus RT-PCR DTC Test?

The product is designed to aid you in the collection of an anterior nasal swab specimen using the Pixel by Labcorp COVID-19+Flu+RSV Test Home Collection Kit which you then send to the Center for Esoteric Testing, Burlington, NC, or other laboratories designated by Labcorp, for COVID-19, influenza A, influenza B and/or RSV testing with the FDA authorized test called the Labcorp Seasonal Respiratory Virus RT-PCR DTC Test. The test is designed to simultaneously detect four types of viruses: two types that cause influenza (type A and type B), RSV and the virus that causes COVID-19 (SARS-CoV-2) in anterior nasal swab specimens.

Why should my sample be tested?

You may want to have your sample tested because you or 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).

Testing of your sample will help find out if you may have COVID-19.

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).

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- **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.
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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 those you come in contact with.

What does it mean if I have a positive test result for SARS-CoV-2?

If you have a positive test result for the presence of SARS-CoV-2, it is very likely that you have COVID-19. If you have a positive result you should follow up with your healthcare provider who will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms. You should follow the latest CDC guidance to avoid spreading the virus to others, such as self-isolation, to reduce the potential transmission of disease. There is a small 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.

What does it mean if I have a positive test result for influenza A and/or B viruses and/or RSV?

If you have a positive test result for the presence of influenza A, influenza B and/or RSV viruses, it is very likely that you have a viral infection. If you have a positive result for one of these viruses, you should follow up with your healthcare provider who will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms. There is a small chance that this test can give a positive result that is wrong (a false positive result).

What does it mean if I have a positive test result for SARS-CoV-2, influenza (A and/or B) and/or RSV viruses?

It is possible for an individual to be infected with SARS-CoV-2 virus, influenza A virus, influenza B virus, and/or RSV at the same time. You should follow up with your healthcare provider who will

work with you to determine how best to care for you based on the test results along with medical history, and your symptoms.

What does it mean if I have a negative test result for SARS-CoV-2, influenza A, influenza B and RSV viruses?

A negative test result for any of the viruses means that these viruses were not found in your sample. For COVID-19, influenza and RSV, a negative test result for a sample collected while a person has symptoms usually means that SARS-CoV-2, influenza A, influenza B and RSV viruses are unlikely to be the cause your current illness. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with viral diseases. You might test negative if the sample was collected early during your infection.

This means that you could possibly still have COVID-19 even though the test result is negative. If your test is negative, but you continue to have symptoms and/or they get worse, you should reach out to your healthcare provider who will work with you to determine the next steps you should take. For example, your healthcare provider may suggest you need another test to determine if you have contracted a respiratory virus.

If 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
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- **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.

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You should talk with your healthcare provider if you are concerned. 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. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. 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 the virus that causes 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 in vitro diagnostics, unless it is terminated or revoked by FDA (after which the test may no longer be used).

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/deviceadvice-comprehensive-regulatory-assistance/medicaldevice-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-andresponse/mcm-legal-regulatory-and-policyframework/emergency-use-authorization>.

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