FACT SHEET FOR PATIENTS
LumiraDx UK Ltd.  
LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete Assay

Updated: June 30, 2023

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19), influenza A, and/or influenza B using the LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete Assay.

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

What is Influenza?
Influenza (flu) is a contagious respiratory illness caused by influenza viruses. 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 LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete Assay?
The test is designed to simultaneously detect three types of viruses: two types that cause influenza (type A and Type B), and the virus that causes COVID-19 (SARS-CoV-2) in nasopharyngeal swab specimens.

Why was my sample tested?
You were tested because 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), and/or because:

• 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

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

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.

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

What does it mean if I have a negative test result for SARS-CoV-2, influenza A, and/or influenza B viruses?
A negative test result means that the virus that causes COVID-19 was not found in your sample.

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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