You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the OPTI SARS-CoV-2/ Influenza A/B RT-PCR 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 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 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 OPTI SARS-CoV-2/ Influenza A/B RT-PCR Test?
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.

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.

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.
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 are the approved alternatives?
There are approved/cleared influenza tests. 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

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.