You are being given this Fact Sheet because your sample(s) was/were tested for the Coronavirus Disease 2019 (COVID-19) using the Simoa™ SARS-CoV-2 N Protein Antigen 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.

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 spectrum of clinical illness associated with COVID-19 but it likely spreads to others when 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 Simoa SARS-CoV-2 N Protein Antigen Test?
The Simoa SARS-CoV-2 Protein Antigen Test is a type of test called an antigen test. The test is designed to detect proteins from the virus that causes COVID-19 in a nasopharyngeal swab specimen. The presence of viral proteins indicate you may have been infected with the virus and are likely to be contagious.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been infected with the virus that causes COVID-19 based on your previous signs and symptoms (e.g., fever, cough, difficulty breathing) and/or other risk factors and you are within the first 14 days of the onset of symptoms.

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 others in your community.

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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FACT SHEET FOR PATIENTS
Simoa™ SARS-CoV-2 N Protein Antigen Test
Quanterix Corporation

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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 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 of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?
There are no approved available alternative tests. 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.