FACT SHEET FOR PATIENTS

Simoa™ SARS-CoV-2 N Protein Antigen Test

Quanterix Corporation **January 5, 2021**

Coronavirus Disease 2019 (COVID-19)

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.

- **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. 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.

What does it mean if I have a positive test result?

A positive test result for COVID-19 indicates that proteins from the SARS-CoV-2 virus were detected, and you may be infected with the virus and presumed to be contagious. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. Your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, including any symptoms, possible exposure to COVID-19, and the location of places you have recently traveled. There is also the chance that this test can give a positive result that is wrong (a false positive result).

What does it mean if I have a negative test result?

A negative test result for this test means that proteins from SARS-CoV-2 were not found in your specimen. However, a negative result does not rule out COVID-19. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID19. This means that you could possibly still have COVID19 even though the test is negative. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 14 of illness may be more likely to be negative compared to a molecular assay. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

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

What are the differences between antigen tests and other COVID-19 tests?

There are different kinds of tests for diagnosing COVID19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you do not have an additional test to determine if you are infected and may spread the infection to others, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers)

AND

- Other symptoms of COVID-19 are improving **Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation

AND

- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are

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sick: https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.

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.

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