

FACT SHEET FOR HEALTHCARE PROVIDERS

Simoa™ SARS-CoV-2 N Protein Antigen Test
Quanterix Corporation

May 3, 2021

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Simoa™ SARS-CoV-2 N Protein Antigen Test.

The Simoa SARS-CoV-2 N Protein Antigen Test is for use on nasopharyngeal swab specimens and anterior nasal swab specimens* from individuals suspected of COVID-19 by their healthcare providers within the first 14 days for nasopharyngeal swabs, and within 5 days of

This test is to be performed using nasopharyngeal swab specimens collected from individuals in transport media who are suspected of COVID-19 by their healthcare provider within the first 14 days of the onset of symptoms. Alternatively, this test can be performed using anterior nasal swab specimens collected from individuals in transport media who are suspected of COVID-19 by their healthcare provider within the first 5 days of the onset of symptoms.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Simoa SARS-CoV-2 N Protein Antigen Test.

symptom onset for anterior nasal swab specimens.

***Note:** This test has been validated for use with anterior nares specimens, but FDA's independent review of this validation is pending and the test is being distributed in accordance with the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, Section IV.C.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "Where can I go for updates and more information?" section at the end of this document.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which poses risks to public health. Please check the CDC webpage for the most up to date information.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

- The Simoa SARS-CoV-2 N Protein Antigen Test can be used to test nasopharyngeal swab and anterior nasal swab specimens after the swabs have been added to transport media.
- The Simoa SARS-CoV-2 N Protein Antigen Test should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider and who are within the first 14 days of symptom onset for nasopharyngeal swab specimens, and within 5 days of symptom onset for anterior nasal swab specimens.
- The Simoa SARS-CoV-2 N Protein Antigen Test is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and*

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

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Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19). For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in “Where can I go for updates and more information” section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?

A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The Simoa SARS-CoV-2 N Protein Antigen Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?

A negative test result for this test means that antigens from SARS-CoV-2 were not present in the specimen above the clinical cutoff. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests

that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. Nasopharyngeal specimens collected after day 14 of illness, and anterior nasal swab specimens collected after day 5 of illness, may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results from patients should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient’s recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient’s recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks from a false negative result include delay or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC’s *Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings (Interim Guidance)* (see links provided in “Where can I go for updates and more information” section).

What is an EUA?

The United States (U.S.) FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to

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justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test for nasopharyngeal swabs is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?

There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

Where can I go for updates and more information?

CDC webpages:

General: <https://www.cdc.gov/COVID19>

Symptoms:

<https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

Information for Laboratories: <https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html>

Laboratory Biosafety: <https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html>

Isolation Precautions in Healthcare Settings:

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

Specimen Collection: <https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

Discontinuation of Isolation: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs: (includes links to patient fact sheet and manufacturer's instructions) <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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