

FACT SHEET FOR HEALTHCARE PROVIDERS

Xtrava Health

SPERA™ COVID-19 Ag Test

October 12, 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 SPERA™ COVID-19 Ag Test.

The SPERA™ COVID-19 Ag Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swabs from individuals suspected of COVID-19 by their healthcare provider within the first 5 days of symptom onset.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Xtrava Health - SPERA™ COVID-19 Ag Test.

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. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days. For further information on the symptoms of COVID-19 please see the link provided in the “*Where can I go for updates and more information?*” section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC COVID-19 webpage (see link provided in “*Where can I go for updates and more information?*” section at the end of this document) or your local jurisdictions website for the most up to date information.

This test is to be performed only using direct anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

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

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

- The SPERA™ COVID-19 Ag Test can be used to test anterior nasal (NS) swab specimens directly.
- The SPERA™ COVID-19 Ag 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 five days of onset of symptoms.
- The SPERA™ COVID-19 Ag Test is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- Please refer to the SPERA™ COVID-19 Ag Test instructions for use for additional information.

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 personnel protective equipment when collecting and handling specimens from individuals suspected

of being infected with COVID-19, appropriate personal protective equipment should be used as outlined in the CDC Interim Laboratory Biosafety Guidelines for Handling and 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 positive predictive value of diagnostic tests (PPV), including antigen assays, varies with the prevalence of disease. PPV is the percent of positive test results that are true positives (i.e., test results are positive when the infection is present). As disease prevalence decreases, the percent of test results that are false positives (i.e., test results are positive in the absence of infection) increases. When prevalence is very low, false positive results are more likely than true positive results. Positive results may need to be confirmed with a molecular SARS-CoV-2 assay, particularly in individuals without a known SARS-CoV-2 exposure or who are in areas known to have low prevalence of SARS-CoV-2 infections. For low-risk individuals, the CDC recommends that persons who receive a positive antigen test should isolate until they can be confirmed by an RT-PCR test. For further recommendations regarding antigen tests, please see the link provided in “Where can I go for updates and more information?” section.

The SPERA™ COVID-19 Ag 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 antigen from SARS-CoV-2 was not present in the specimen above the limit of detection. 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 decision. 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 the illness increases. In symptomatic individuals, specimens collected after day 5 of illness may be more likely to be negative compared to a RT-PCR assay.

Therefore, negative results 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: a 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).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected

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between 06/04/2021 and 07/22/2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation.

Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

What is an EUA?

The United States 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 Services's (HHS's) declaration that circumstances exist to 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 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. 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. The 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?

CDC Web Pages

General	https://www.cdc.gov/coronavirus/2019-ncov/index.html
Symptoms	https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals	https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html
Information for Laboratories	https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html
Laboratory Biosafety	https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings	https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
Specimen Collection	https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
Infection Control	https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html
Discontinuation of Isolation	https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

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FDA Webpages

General: www.fda.gov/novelcoronavirus

EUAs: (includes links to patient fact sheet and manufacturer's instructions)

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>

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