

FACT SHEET FOR HEALTHCARE PROVIDERS

Sorrento Therapeutics

COVISTIX COVID-19 Virus (SARS CoV-2)

Rapid Antigen Detection Test

Coronavirus
Disease 2019
(COVID-19)

Updated: September 2021

This Fact Sheet informs users and healthcare providers of the emergency use of COVISTIX™ by Sorrento Therapeutics, including associated risks and benefits that are currently known.

The COVISTIX COVID-19 Virus (SARS CoV-2) Rapid Antigen Detection Test is authorized for use on nasal (nasopharyngeal or shallow nasal) swab specimens collected from individuals who are suspected of having COVID-19 by their healthcare provider within the first 5 to 7 days of the onset of symptoms or from individuals without symptoms who are suspected of having COVID-19.

Any interpretation of this preliminary test result should be based on comprehensive clinical and laboratory information as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained.

**All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients:
Sorrento Therapeutics - COVISTIX COVID-19 Virus (SARS CoV-2) Rapid Antigen Detection 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 fever or chills, cough, shortness of breath or dyspnea, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea.

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. 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 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 jurisdiction’s website for the most up to date information.

This test is to be performed using only nasal swab (nasopharyngeal or shallow nasal) specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the 5 to 7 days of the onset of symptoms or from individuals without symptoms.

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 COVISTIX COVID-19 Virus (SARS CoV-2) Rapid Antigen Detection Test can be used to test nasal swab (nasopharyngeal or shallow nasal) specimens directly.
- The COVISTIX COVID-19 Virus (SARS CoV-2) Rapid Antigen Detection Test should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider within the first 5 to 7 days or individuals without symptoms who are suspected of having COVID-19.
- The COVISTIX COVID-19 Virus (SARS CoV-2) Rapid Antigen Detection 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.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection

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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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 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 nucleocapsid protein antigens from SARS-CoV-2 virus 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 COVISTIX COVID-19 Virus (SARS CoV-2) Rapid Antigen Detection 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 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 nucleocapsid

protein antigens from SARS-CoV-2 virus were not present in the specimen above the limit of detection. However, a negative test 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. Specimens collected after day 5 to 7 of illness may be more likely to be negative compared with a RT-PCR assay. Therefore, negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

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 especially should 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.

If a false-negative result occurs, risks may arise for the patient. This may include the patient's treatment being delayed or nonexistent or failing to trace infected household members/contacts which may cause increased COVID-19 spread.

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

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collected in **the month of June 2020**. 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 Virus 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 Service's (HHS's) declaration that circumstances exist to justify the emergency use of 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. 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 webpages:

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?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Flab-biosafety-guidelines.html

Isolation Precautions in Healthcare Settings:

<https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>

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

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

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

FDA webpages:

General: <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>

EUAs: (includes links to fact sheet for individuals and manufacturer's instructions) <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>

Technical Support: If you have any questions about the COVISTIX™ Rapid Antigen Detection Test or results, please contact our toll-free Customer Service Line or email us.

Customer Service: 1-800-203-5108
CustomerService@covistix.com
www.covistix.com
www.sorrentotherapeutics.com

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