

FACT SHEET FOR HEALTHCARE PROFESSIONALS

ACON Laboratories, Inc.

Flowflex COVID-19 Antigen Home Test

October 4, 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 Flowflex COVID-19 Antigen Home Test.

The Flowflex COVID-19 Antigen Home Test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal samples from individuals 14 years or older or adult collected anterior nasal samples from individuals age 2 years or older.

All individuals who use this assay are required to receive and should carefully review the Flowflex COVID-19 Antigen Home Test Instructions for Use before they use the test.

What are the symptoms of COVID-19?

Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, 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.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. 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 for use at home with self-collected anterior nasal swab specimens from individuals within 7 days of symptom or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal samples from individuals 14 years or older or adult collected anterior nasal samples from individuals age 2 years or older.

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 Flowflex COVID-19 Home Antigen Test can be used to test directly collected Anterior Nasal Swab specimens
- The Flowflex COVID-19 Antigen Home Test can be used to test individuals within 7 days of symptom or without symptoms or other epidemiological reasons to suspect COVID-19 infection.
- The Flowflex COVID-19 Antigen Home Test is for non-prescription home use with self-collected anterior nasal samples from individuals 14 years or older or adult collected anterior nasal samples from individuals age 2 years or older.

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 antigens from SARS-CoV-2 were detected, and the patient is infected with the virus and presumed to be contagious. COVID-19 test results should always be considered in the context of clinical observations and epidemiological data such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient

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management decisions should be made by a healthcare provider and follow current CDC guidelines.

The Flowflex COVID-19 Antigen Home 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 healthcare providers 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 antigens from SARS-CoV-2 were 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 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 7 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results should be treated as presumptive and confirmation 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 to a patient of a false negative include: delayed 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 between March and May 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.

Negative results, particularly in asymptomatic individuals, should be considered to be presumptive and additional testing with a highly sensitive molecular SARS-CoV-2 test may be necessary to help rule out infection.

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 in vitro diagnostics (IVDs)

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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 antigen 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/medicaldevices/device-advice-comprehensive-regulatoryassistance/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/emergencypreparedness-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-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>

FDA webpages:

General: www.fda.gov/novelcoronavirus

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>

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