

FACT SHEET FOR HEALTHCARE PROVIDERS

Centers for Disease Control and Prevention (CDC)
Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay

Updated: August 5, 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 Centers for Disease Control and Prevention's (CDC's) Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay.

The Flu SC2 Multiplex Assay is a multiplexed reverse transcription polymerase chain reaction (RT-PCR) test authorized for use with respiratory specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. Symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

All individuals whose specimens are tested with this assay must receive the *Fact Sheet for Patients: Centers for Disease Control and Prevention (CDC) - Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay*

What are the signs and symptoms of COVID-19?

Many patients with confirmed 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 fever or chills, cough, shortness of breath or dyspnea, fatigue, myalgias, headache, new loss of taste or smell, sore throat, congestion or runny nose, 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 incubation period 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 throughout the world, including in the United States. Please check the CDC COVID-19 webpage (see link provided in the "*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 respiratory specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider.

What are the signs and symptoms of influenza?

The signs and symptoms of influenza usually develop suddenly and are similar to those of COVID-19. Common signs and symptoms of influenza are fever, cough, sore throat, runny/stuffy nose, body aches, headache, and fatigue.

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 the "*Where can I go for updates and more information?*" section). The Flu SC2 Multiplex Assay:

- can be used to test upper and lower respiratory specimens (such as nasopharyngeal, oropharyngeal, or nasal swab specimens; bronchoalveolar lavage specimens, sputum; lower respiratory tract aspirates; nasopharyngeal wash/aspirates; or nasal aspirates).
- should be ordered for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, and/or influenza B viruses in individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider.
- is authorized for use in laboratories in the United States certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a that meet requirements to perform high complexity tests.

Specimens should be collected using appropriate infection control precautions. Current guidance is available on the CDC's website (see links provided in the "*Where can I go for updates and more information?*" section).

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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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 the CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)* (see links provided in the “Where can I go for updates and more information?” section).

Can I use the Flu SC2 Multiplex Assay to test asymptomatic individuals?

Asymptomatic or pre-symptomatic individuals can be tested if they are suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. This can include consideration of epidemiologic reason to do so, including contact with persons with probable or confirmed cases of COVID-19 and/or influenza or travel to areas where these viruses are actively circulating. This test is not authorized for use as a broad screening tool.

Negative results obtained from individuals who are not exhibiting clinical signs and symptoms associated with respiratory viral infection at the time of specimen collection should be interpreted with caution. Negative results in asymptomatic or pre-symptomatic individuals cannot be used as definitive evidence that the individual has not been exposed to or infected with SARS-CoV-2, influenza A, and/or influenza B viruses, or to determine whether an individual may be contagious.

What does it mean if the specimen tests positive for SARS-CoV-2, the virus that causes COVID-19?

A positive test result for SARS-CoV-2 indicates that RNA from this virus was detected, and therefore the patient is infected with the virus and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

The Flu SC2 Multiplex Assay has been designed to minimize the likelihood of false-positive test results. However, it is still possible that this test can give a false positive result, especially when used in locations where the prevalence is below 5%. In the event of a false-positive result, risks to individuals 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 individuals with COVID-19, limits in the ability to work, 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 SARS-CoV-2, the virus that causes COVID-19?

A negative test result for SARS-CoV-2 means that RNA from this virus was not present in the specimen or the RNA concentration was below 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. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via the Flu SC2 Multiplex Assay.

When diagnostic testing results are 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 test results for other causes of illness (e.g., other respiratory illnesses) are negative. If COVID-19 is still suspected based on exposure history and clinical findings, retesting should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not

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conducted too early. Risks to an individual from a false-negative test result include: delayed or lack of supportive treatment; lack of monitoring of infected patients 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.

The performance of this test for SARS-CoV-2 was established based on the evaluation of a limited number of clinical specimens. 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 does it mean if the specimen tests positive for influenza A and/or B viruses?

A positive test result for influenza A virus or influenza B virus indicates that RNA from one or both of these viruses was detected, the patient is infected with the virus(es) and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines. Results (positive and negative) for influenza should be interpreted with caution. If a result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared influenza NAATs are available for confirmation if clinically indicated.

The Flu SC2 Multiplex Assay has been designed to minimize the likelihood of false-positive test results. However, in the event of a false-positive result, risks to individuals 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, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of an antiviral medication or other therapy, or other unintended adverse effects.

What does it mean if the specimen tests negative for influenza viruses?

A negative test result for influenza viruses means that influenza A and/or B RNA was not present in the specimen or the RNA concentration was below the limit of detection. However, a negative result does not rule out influenza virus infection and should not be used as the sole basis for treatment or patient management decisions. When diagnostic testing results are 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 influenza. The possibility of a false-negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that influenza is likely, and diagnostic test results for other causes of illness (e.g., other respiratory illness) are negative. If influenza is still suspected based on exposure history and clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities.

Laboratory test results should always be considered in the context of clinical findings and observations and/or epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines. Results (positive and negative) for influenza should be interpreted with caution. If an influenza result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared Influenza NAATs are available for confirmation if clinically indicated.

Risks to individuals from a false-negative Flu SC2 Multiplex Assay result for influenza A or influenza B include: delayed or lack of supportive treatment; lack of monitoring of infected patients and their household or other close contacts for symptoms, resulting in increased risk of spread of influenza within the community; or other unintended adverse events. Risks to an asymptomatic patient from a false-negative Flu SC2 Multiplex Assay result for influenza A or B include: lack of monitoring of infected patients and their household or other close contacts for symptoms, resulting in increased risk of spread of influenza within the community; or other unintended adverse events.

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<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

What does it mean if the specimen tests positive for SARS-CoV-2 and one or both influenza (A and/or B) viruses? Is co-infection possible?

Yes, it is possible for an individual to be infected with influenza A virus, influenza B virus, and/or SARS-CoV-2 simultaneously. A positive test result for the viruses that cause COVID-19 and influenza A and/or B indicates that RNA from these viruses was detected, the patient may be co-infected, and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made with a healthcare provider and follow current CDC guidelines.

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) for the detection and/or diagnosis of 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 the detection of the virus that causes 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?

FDA has approved/cleared certain influenza 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:

Where can I go for updates and more information?

CDC webpages:

COVID-19:

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>

Influenza:

<https://www.cdc.gov/flu/index.htm>

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>

Manufacturer: CDC

CDC Emergency Operations Center (EOC)
1600 Clifton Road
Atlanta, Georgia, USA, 30329
Phone: **CDC EOC (770-488-7100)**

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