

COVID-19 TESTING FACT SHEET FOR HEALTHCARE PROVIDERS AND PATIENTS

SARS-CoV-2 Real-Time RT-PCR Diagnostic Panel Updated: February 08, 2022

This Fact Sheet informs you of the significant known and potential risks and benefits of the Aura Genetics SARS-CoV-2 RT-PCR Assay.

Testing is to be conducted on specimens from people who meet clinical and/or epidemiological criteria for testing.

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, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. 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. Preliminary data show that the median incubation period is approximately 5 days but may range 2-14 days.

- The Aura Genetics SARS-CoV-2 Real-Time RT-PCR Assay can be used to test nasopharyngeal swabs and saliva.
- The Aura Genetics SARS-CoV-2 Real-Time RT-PCR Assay should be ordered for detection of SARS-CoV-2 in individuals who meet the COVID-19 clinical and/or epidemiological criteria for testing.
- Aura Genetics is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions is 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 being infected with 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 RNA from SARS-CoV-2 was detected, and the patient is presumptively 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 decisions should be made with a healthcare provider and follow current CDC guidelines.

The Aura Genetics SARS-CoV-2 Real-Time RT-PCR Assay 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.



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All laboratories using this test must follow the standard confirmatory 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 SARS-CoV-2 RNA 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. A negative result does not exclude the possibility of COVID-19.

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 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.

CDC webpages:

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

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>

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 laboratory tests for the detection and/or diagnosis of COVID-19.

A laboratory test made available under an EUA has not undergone the same type of review as an FDA-approved or cleared test. The 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 laboratory test may be effective in the detection of the virus that causes COVID-19.

Aura Genetics has modified the EUA testing protocol to include nasopharyngeal swabs as a specimen type and has validated the addition according to CLIA guidelines for Laboratory Developed Tests.

Test Kit Manufacturer and Information:

Kit Manufacturer: Applied Biosystems

Kit Name: TaqPath COVID-19 Fast PCR Combo Kit 2.0