



## Coronavirus Disease 2019 (COVID-19)

### CDC Tests for COVID-19

CDC has developed a new laboratory test kit for use in testing patient specimens for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19. The test kit is called the "Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel." It is intended for use with the Applied Biosystems 7500 Fast DX Real-Time PCR Instrument with SDS 1.4 software. This test is intended for use with upper and lower respiratory specimens collected from persons who meet CDC criteria for COVID-19 testing. CDC's test kit is intended for use by laboratories designated by CDC as qualified, and in the United States, certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests. The test kits also will be shipped to qualified international laboratories, such as World Health Organization (WHO) Global Influenza Surveillance Response System (GISRS) laboratories. The test will not be available in U.S. hospitals or other primary care settings. The kits will be distributed through the [International Reagent Resource](#) (IRR)

On Monday, February 3, 2020, CDC submitted an Emergency Use Authorization (EUA) package to the U.S. Food and Drug Administration (FDA) in order to expedite FDA permitted use of the CDC diagnostic panel in the United States. The EUA process enables FDA to consider and authorize the use of unapproved, but potentially life-saving medical or diagnostic products during a public health emergency. The U.S. Secretary of Health and Human Services declared the SARS-CoV-2 virus a U.S. public health emergency on Friday, January 31, 2020. FDA issued the EUA on February 4, 2020. IRR began distribution of the test kits to states, but shortly thereafter performance issues were identified related to a problem in the manufacturing of one of the reagents which led to laboratories not being able to verify the test performance. CDC is remanufacturing the reagents with more robust quality control measures. New tests will be distributed once this issue has been addressed. CDC continues to perform initial and confirmatory testing.



This is a picture of CDC's laboratory test kit for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). CDC is shipping the test kits to laboratories CDC has designated as qualified, including U.S. state and local public health laboratories, Department of Defense (DOD) laboratories and select international laboratories. The test kits are bolstering global laboratory capacity for detecting SARS-CoV-2.

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### Serology Test for COVID-19

CDC is working to develop a new laboratory test to assist with efforts to determine how much of the U.S. population has been exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19.

The serology test will look for the presence of antibodies, which are specific proteins made in response to infections. Antibodies can be found in the blood and in other tissues of those who are tested after infection. The antibodies detected by this test indicate that a person had an immune response to SARS-CoV-2, whether symptoms developed from infection or the infection was asymptomatic. Antibody test results are important in detecting infections with few or no symptoms.

Initial work to develop a serology test for SARS-CoV-2 is underway at CDC. In order to develop the test, CDC needs blood samples from people who had COVID-19 at least 21 days after their symptoms first started. Researchers are currently working to develop the basic parameters for the test, which will be refined as more samples become available. Once the test is developed, CDC will need additional samples to evaluate whether the test works as intended.

## Additional Resources

[Information for Laboratories](#)

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[CDC Grows SARS-CoV-2 Virus in Cell Culture](#)

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[Requests for Diagnostic Tools and Virus](#)

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Content source: [National Center for Immunization and Respiratory Diseases \(NCIRD\)](#), [Division of Viral Diseases](#)