CDC's Diagnostic Test for COVID-19 *Only* and Supplies

Updated Oct. 5, 2021 Print

Summary of Recent Changes

As of August 16, 2020

Added language to reflect the EUA updates to the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel and CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay.

Fact Sheets for CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

- Patient Fact Sheet [137 KB, 2 pages]
- Healthcare Provider Fact Sheet [158 KB, 3 pages]

Previous Updates

CDC has developed two laboratory tests that identify SARS-CoV-2, the virus that causes COVID-19. The first test is only used for COVID-19 diagnosis and was released in February 2020. This test is called the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. A second test, the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay , has been developed to detect SARS-CoV-2, influenza A, and influenza B viruses at the same time. More information on this test is available at CDC's Influenza SARS-CoV-2 Multiplex Assay and Required Supplies.

In early 2020, CDC developed, obtained Emergency Use Authorization (EUA) and began distribution of the CDC 2019-nCoV Real-time RT-PCR Diagnostic Panel to fill a gap at a time when there were no other FDA-cleared or authorized COVID-19 diagnostics. Although the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel filled an important unmet need when it was first developed and deployed, the demand for this test has declined with the authorization of higher-throughput alternatives and multiplexed assays that detect both SARS-CoV-2 and other common respiratory pathogens simultaneously. For this reason, CDC will discontinue the 2019-nCoV Real-Time RT-PCR Diagnostic Panel after December 31, 2021.

Since the 2019-nCoV Real-Time RT-PCR Diagnostic Panel is still performing very well, CDC will continue to make the design specifications for the primers and probes used in this test available on the CDC website for others to use in their own research activities or diagnostic assay development. CDC will also continue to offer a blanket right of reference to the CDC EUA for the 2019-nCoV Real-Time RT-PCR Diagnostic Panel (EUA200001) to anyone who wishes to reference CDC data in their own FDA regulatory submission. CDC's decision to discontinue the 2019-nCoV Real-Time RT-PCR Diagnostic Panel will have no impact on those tests that have referenced CDC EUA data in their EUA submission or on those who plan to do so in the future. The data and submission will remain on file at FDA and available for reference.

CDC is recommending that public health laboratories that routinely conduct influenza testing as well as COVID-19 testing consider transitioning to the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay, a single test that can generate results for SARS-CoV-2, influenza A, and influenza B. The Flu SC2 Multiplex Assay is a resource-efficient way for public health laboratories to meet influenza and SARS-CoV-2 surveillance goals.

IRR Distribution of the 2019-CoV Real-Time RT-PCR Diagnostic Panel

The International Reagent Resource (IRR) will cease distribution of the 2019-nCoV Real-Time RT-PCR Diagnostic Panel and supplies on September 30, 2021. Laboratories can continue to run the Diagnostic Panel under CDC's EUA until December 31, 2021.

CDC has shared the primer and probe sequence design specifications so other laboratories and companies may manufacture their own reagents for research use or for diagnostic use under their own FDA clearance or authorization.

Materials included in the 2019-nCoV Real-Time RT-PCR Diagnostic Panel

The 2019-nCoV Real-Time RT-PCR Diagnostic Panel contains four reagents:

- Three primer-probe mixes for:
  - 2019-nCoV_N1: targets virus nucleocapsid (N) gene for specific detection of SARS-CoV-2
  - 2019-nCoV_N2: targets virus nucleocapsid (N) gene for specific detection of SARS-CoV-2
  - RP: targets human RNase P gene for detection of human nucleic acids; control for sample integrity
- nCoVPC: noninfectious positive control material; yields a positive result in each assay included in the panel

CDC's laboratory test kit for the SARS-CoV-2 virus.

Other materials labs will need to perform the 2019-nCoV Real-Time RT-PCR Diagnostic Panel

The 2019-nCoV Real-Time RT-PCR Diagnostic Panel requires the use of additional authorized materials that are **not included** with the test kit. These materials include PCR reagents and items that are commonly used in clinical laboratories, such as a microfuge, microcentrifuge tubes, pipettes, and pipette tips. They are described in the *Materials Required (But Not Provided)* section of the 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use . Two control materials are also required but not provided; these materials must produce expected results for a test result to be considered valid, as outlined in the 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use . The controls are:

- **Human Specimen Control (HSC):** A human cell culture preparation used as an extraction procedural control to demonstrate successful recovery of nucleic acid, as well as extraction reagent integrity. Acceptable alternatives to HSC are listed in the Instructions for Use.
- **No Template Control (NTC):** Nuclease-free water included in each run. Monitors for reagent and system contamination.

More Resources on the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

- List of Acceptable Commercial Primers and Probes
- Processing of Sputum Specimens for Nucleic Acid Extraction
- Research Use Only RT-PCR Primers and Probes

More Resources for Diagnostic Testing

- Request 2019-nCoV Grown in Cell Culture
- Emergency Use Authorizations for Medical Devices (FDA)

FDA FAQs on Testing for SARS-CoV-2

- Overview of Testing for SARS-CoV-2 (for healthcare providers)
- Testing for COVID-19 (for the public)

Previous Updates

Updates as of December 9, 2020

- In addition to this test, CDC has developed a diagnostic test that can be used to detect SARS-CoV-2, influenza A, and influenza B viruses at the same time. This test is called the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay. More information is available at CDC's Influenza SARS-CoV-2 Multiplex Assay and Required Supplies.

Last Updated Oct. 5, 2021