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

Updated Aug. 17, 2021 Print

Summary of Recent Changes

As of August 16, 2020

Added language to reflect the EUA updates to 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. The second test, more recently developed, can be used for SARS-CoV-2, influenza A, and influenza B viruses diagnosis at the same time. This test is called the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay. 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 distributed 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 (Diagnostic Panel) after December 31, 2021.

Since the Diagnostic Panel is still performing very well, CDC will continue to make the design of the primers and probes used in the Diagnostic Panel 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 Diagnostic Panel (EUA200001) to anyone who wishes to reference CDC data in their own FDA regulatory submission. CDC's decision to discontinue the Diagnostic Panel and subsequently withdraw the EUA for the 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 a result for SARS-CoV-2, influenza A and influenza B. The Flu SC2 assay is a resource-efficient way for public health laboratories to meet influenza and SARS-CoV-2 surveillance goals.

How to order the 2019-CoV Real-Time RT-PCR Diagnostic Panel

The International Reagent Resource (IRR) will continue to distribute the Diagnostic Panel and supplies to registered state and local public health laboratories until September 30, 2021. Laboratories can continue to run the Diagnostic Panel under CDC's EUA until December 31, 2021.

During the SARS-CoV-2 pandemic, state public health laboratories can authorize county or city laboratories in each state to perform testing. These laboratories must be certified under the Clinical Laboratory Improvement Amendment (CLIA) to perform high-complexity tests, have appropriate laboratory equipment and training, and demonstrate testing proficiency under their state laboratory's stewardship to maintain their status as an IRR-registered laboratory.

The IRR does not supply clinicians, hospitals, or healthcare professionals with testing kits directly. Clinicians, hospitals, and healthcare professionals should refer to the list of CDC-qualified, commercially available lots of primers and probes [110 KB, 1 page] that are acceptable alternatives to the CDC-provided reagents. A link to the list can be found in the *Materials Required (Provided)* section of the authorized 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use . As noted above, laboratories can continue to use these CDC-qualified commercially available reagents with the Diagnostic Panel until December 31, 2021.

In addition, CDC has shared the primer and probe sequence design 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 Diagnostic Panel

The 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 Diagnostic Panel

The 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 Diagnostic Panel Instructions for Use . Two control materials are also required but not provided; these materials must produce expected results in order for a result to be considered valid, as outlined in the 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 Diagnostic Panel

- List of Acceptable Commercial Primers and Probes [110 KB, 1 pages]
- Processing of Sputum Specimens for Nucleic Acid Extraction [128 KB, 1 pages]
- 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.

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