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

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Summary of Recent Changes

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.

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]

The CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT–PCR Diagnostic Panel detects the SARS-CoV-2 virus in upper and lower respiratory specimens. It is designed to be used with an existing RT-PCR testing instrument commonly used to test for seasonal influenza virus.

The U.S. Food and Drug Administration (FDA) gave Emergency Use Authorization (EUA) for this test on February 4, 2020. The 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use contain information about the test, its intended use, the test procedure, and performance characteristics. The EUA website has published the FDA Letter of Authorization for the diagnostic panel. The letter defines the authorized use and the conditions of authorization that apply to CDC and to testing laboratories that use this test. Manufacturers and test developers interested in the right of reference to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel performance data are encouraged to read these FAQs.

On June 12, 2020, FDA granted an amendment to the EUA for the 2019-nCoV Real-Time RT-PCR Diagnostic Panel to address global shortages of materials needed to perform the test. This amendment provides alternatives for processing the test:

- Four additional extraction reagents that can be used in the existing extraction methods
- An additional extraction instrument and associated reagents
- A new process that can be used in place of the extraction method when materials for the current method are limited

On July 13, 2020, FDA granted an amendment, to add the Promega Maxwell® RSC 48 as an authorized extraction instrument for use with the 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

On December 1, 2020, FDA granted an amendment to add:

- The option to conduct pooled specimen testing for upper respiratory swab specimens
- Performance data generated with FDA's reference panel
- Promega Maxwell® CSC 48 as a specimen extraction option

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

The International Reagent Resource (IRR) is distributing the 2019-nCoV Real-Time RT-PCR Diagnostic Panel and supplies to registered state and local public health laboratories so they can perform SARS-CoV-2 testing.

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 .In addition, CDC has shared the primer and probe sequences so other laboratories and companies may manufacture their own reagents.

Materials included in the Diagnostic Panel

The CDC 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.

If the diagnostic panel is not available, see the updated instructions for use for acceptable alternatives.

Other materials labs will need to perform the Diagnostic Panel

The CDC 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 authorized CDC 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 in order for a result to be considered valid, as outlined in the CDC 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 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)

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