How to Get CDC's COVID-19 Diagnostic Test and Supplies

Updated June 13, 2020

The CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (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 diagnostic panel's FDA-authorized 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.

On June 12, 2020, FDA granted an amendment to the EUA for the CDC diagnostic test 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

How to order the Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel

The International Reagent Resource (IRR) is distributing the 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 commercially available lots of primers and probes that are acceptable alternatives to the CDC-provided reagents. The list begins on page 7 in the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use Package Insert.

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. 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 starting on page 6 in the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use package insert. Two control materials are also required but not provided; these materials must produce expected results in order for a test 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 package insert.
- **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
- Processing of Sputum Specimens for Nucleic Acid Extraction
- Research Use Only RT-PCR Primers and Probes

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

- Patient Fact Sheet
- Healthcare Provider Fact Sheet

More Resources for Diagnostic Testing

- Request 2019-nCoV grown in cell culture at NIH's BEI Resources Repository
- Information about COVID-19 diagnostic tests under FDA Emergency Use Authorization
- FDA Diagnostic Testing FAQs

Page last reviewed: May 20, 2020

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