Centers for Disease Control and Prevention

2019 Novel Coronavirus

Information for Laboratories 2019-nCoV Requests fo Diagnostic Panels and Virus

How do I order a reagent diagnostic panel?

The International Reagent Resource (IRR) will distribute the diagnostic panel and most of the associated reagents.

Which labs will receive the diagnostic panel?

The Food and Drug Administration (FDA) authorized the Emergency Use Authorization (EUA) on February 4, 2020.

- CDC's diagnostic panel is intended for use by laboratories designated by CDC as qualified, and in the United Stat certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests. This includes U.S. state and local public health laboratories and Department of Defense (DoD) laboratories. The test also will be shipped to qualified international laboratories, such as World Health Organization (WHO) Global Influenza Surveillance Response System (GISRS) laboratories For more information, see the section labeled CDC Laboratory Test Kit Distribution (general audiences).
- Each laboratory that places an order will receive one diagnostic panel initially, and each panel can test 700-800 patient specimens.

This is a picture of CDC's laboratory test kit for the 2019 novel coronavirus (2019-nCoV). CDC is shipping the test kit to laboratories CDC has designated as qualified, including U.S. state and local public health laboratories, Departme of Defense (DOD) laboratories and select international laboratories. The test kits are bolstering global laboratory capacity for detecting 2019-nCov.

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What does the diagnostic panel include?

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel contains the following:

- 2019-nCoV_N1, 2019-nCoV_N2 and 2019-nCoV_N3 primers and probes that target the nucleocapsid (N) gene an designed for both universal detection of SARS-like coronavirus as well as specific detection of the 2019-nCoV;
- RP primers and probes that target the Human RNase P gene; and
- nCoVPC, the 2019-nCoV positive control used in the assay.

What other equipment will labs need to perform tests using the diagnostic panel?

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel also requires the use of additional authorized materials and authorized ancillary reagents that are not included with the test but are commonly used in clinical laboratories and a described in the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use Package Insert.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel requires the following control materials, or other authorized control materials; all controls listed below must generate expected results for a test to be considered valid, as outline the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use:

- Human Specimen Control (HSC): A human cell culture preparation used as an extraction control and positive co for the RNase P primer and probe set that is extracted and tested concurrently with each specimen extraction r
- Positive Control for 2019-nCoV (nCoVPC): Run with each batch of specimens. Monitors for failures of rRT-PCR reagents and reaction conditions.
- No Template Control (NTC): Nuclease-free water included in each run. Monitors for reagent and system contamination.

Should I be testing all patients for 2019-nCoV?

At this time, CDC only recommends diagnostic testing of patients who meet the clinical criteria for a 2019-nCoV patie under investigation (PUI), per Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from Person Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV).

- At this time, PUIs are identified as individuals with a history of travel to China or close contact with a person confirmed to have the 2019 nCoV illness *and* symptoms of respiratory illness such as cough or shortness of bre
- For more information about interpreting test results, see section labeled “Interpretation of test results from CD 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel.”

What safety equipment should labs use when using the diagnostic tool?

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected being infected with 2019-nCoV as outlined in the CDC Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from Persons Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV).

How can my lab get the virus?

The National Institute of Health (NIH)’s Biodefense and Emerging Infections Research Resources Repository (BEI Resources) will provide laboratories with 2019-nCoV.

I believe that I have found a treatment or vaccine for 2019-nCoV. Is CDC the best place to submit my ide

BARDA is providing a portal to support U.S. government medical countermeasure research and development. Interes
stakeholders can learn more here .

Page last reviewed: February 5