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Related Links

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07/21/2021: Lab Alert: Changes to CDC RT-PCR for SARS-CoV-2 Testing

Audience: Individuals Performing COVID-19 Testing

Level: Laboratory Alert

After December 31, 2021, CDC will withdraw the request to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, the assay first introduced in February 2020 for detection of SARS-CoV-2 only. CDC is providing this advance notice for clinical laboratories to have adequate time to select and implement one of the many FDA-authorized alternatives.

Visit the FDA website for a list of authorized COVID-19 diagnostic methods. For a summary of the performance of FDA-authorized molecular methods with an FDA reference panel, visit this page.

In preparation for this change, CDC recommends clinical laboratories and testing sites that have been using the CDC 2019-nCoV RT-PCR assay select and begin their transition to another FDA-authorized COVID-19 test. CDC encourages laboratories to consider adoption of a multiplexed method that can facilitate detection and differentiation of SARS-CoV-2 and influenza viruses. Such assays can facilitate continued testing for both influenza and SARS-CoV-2 and can save both time and resources as we head into influenza season. Laboratories and testing sites should validate and verify their selected assay within their facility before beginning clinical testing.

Opt in to receive updates from the CDC Laboratory Outreach Communication System (LOCS).

Online resources:

- FAQ: CDC Distribution of COVID-19 Assays
- Guidance for SARS-CoV-2 Point-of-Care Testing
- Interim Guidance for SARS-CoV-2 Antigen Testing
- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19
- Frequently Asked Questions about COVID-19 for Laboratories
- Information for Laboratories about COVID-19
- CDC COVID-19 Website
- Clinical Laboratory COVID-19 Response Weekly Calls
- CDC Laboratory Outreach Communication System (LOCS)

If you have any questions, please contact us at LOCS@cdc.gov.

Thank you,

The Laboratory Outreach Communication System

Laboratory Outreach Communication System (LOCS) | Division of Laboratory Systems (DLS)

Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

Centers for Disease Control and Prevention (CDC)

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