CDC Diagnostic Tests for COVID-19

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CDC has developed two laboratory tests that identify SARS-CoV-2, the virus that causes COVID-19. The first test for COVID-19 diagnosis that CDC distributed, released in February 2020, is the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, a test that accurately detects SARS-CoV-2 in respiratory specimens. CDC released a second assay in July 2020, the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay, which permits public health laboratories to run three tests in a single reaction well. The Flu SC2 Multiplex is more efficient in its use of test reagents, allows higher throughput, and simultaneously gives accurate results about the presence of SARS-CoV-2, influenza A, and influenza B nucleic acid in a patient specimen. Symptoms for COVID-19 and the Flu can be similar, so testing for all three viruses at the same time will provide public health officials with information they need to help reduce the spread of these viruses in the community while conserving resources that are in short supply.

Please note: CDC will discontinue the CDC 2019-nCoV Real-time RT-PCR Diagnostic Panel at the end of 2021. For more details, please see the CDC 2019-nCoV Real-time RT-PCR Diagnostic Panel section below.

CDC Influenza SARS-CoV-2 Multiplex Assay

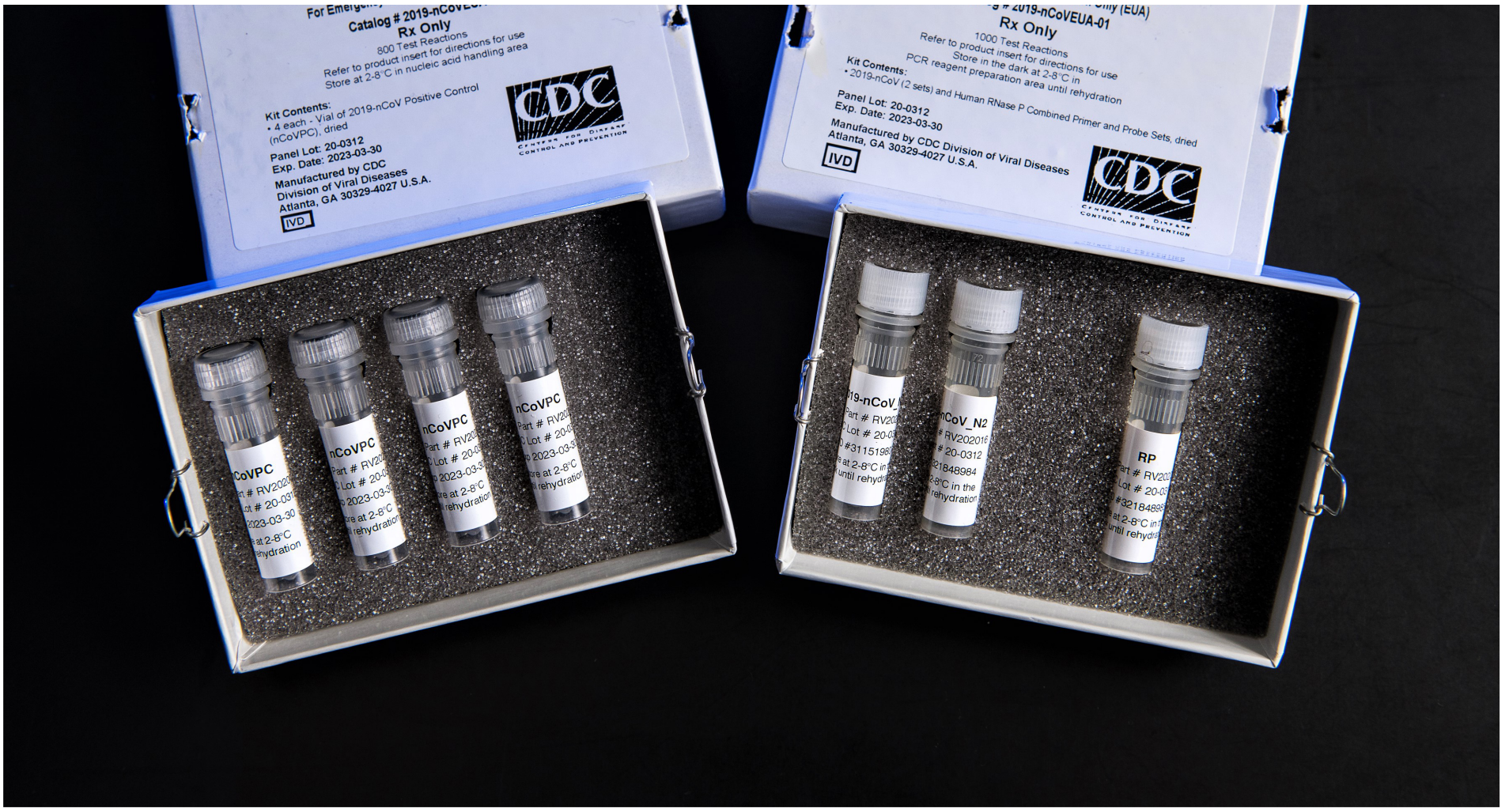
CDC's newest laboratory test, detects two types of influenza viruses (A and B) and SARS-CoV-2 at the same time. This test is called the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay.

A single test that diagnoses current infection with one or more of these viruses allows public health laboratories to continue influenza surveillance while they are also testing for SARS-CoV-2. Information about both viruses will help public health officials control the spread of influenza and COVID-19 in the community and may help health care providers identify co-infections and provide more targeted treatment for influenza and COVID-19. Obtaining this information in a single test, rather than having to run separate SARS-CoV-2 tests and influenza tests, will also allow laboratories to conserve important testing materials that are in short supply and process up to three times as many tests as they can with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel and separate influenza diagnostic tests.

The Flu SC2 Multiplex Assay was evaluated in CDC laboratories and three other public health laboratories prior to launch to ensure that the test works as intended. The Flu SC2 Multiplex Assay was designed using data about SARS-CoV-2 genomes that were not available when the first test was designed, which is likely to improve detection of the SARS-CoV-2 virus as compared to the original CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for use of the Flu SC2 Multiplex Assay on July 2, 2020. The EUA process enables FDA to consider and authorize the use of unapproved but potentially lifesaving medical or diagnostic products during a public health emergency. The U.S Secretary of Health and Human Services declared SARS-CoV-2 to be a U.S. public health emergency on January 31, 2020.

CDC 2019-nCoV RT-PCR Diagnostic Panel



Boxes included in CDC's laboratory test kit for SARS-CoV-2

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On February 3, 2020, CDC submitted an EUA package to expedite FDA-permitted use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in the United States. FDA issued the EUA the next day and CDC sent the test kits to state and local public health laboratories.

CDC developed 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. Since CDC's first test was developed, many commercially available options for SARS-CoV-2 testing have been authorized. Although the CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel filled an important unmet need when it was developed and deployed in early 2020, the demand for this test has declined due to 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 after December 31, 2021.

As the test is still performing very well, CDC will continue to make the design of the primers and probes used in the CDC 2019-nCoV Real-time RT-PCR 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 subsequent withdrawal of the EUA for the Diagnostic Panel will have no impact on those tests that have referenced the 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 encouraging public health laboratories (PHLs) to adopt the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay to enable efficient surveillance for both influenza and SARS-CoV-2, which will save both time and resources for PHLs. Clinical laboratories that had been testing under CDC's EUA using CDC-qualified materials purchased from IDT or BioSearch are encouraged to transition to another FDA-authorized test. If the clinical laboratory conducts influenza diagnostics, CDC encourages the clinical laboratory to consider one of the FDA-authorized tests that can provide results for SARS-CoV-2 and influenza A and B.

Who Can Use These Tests?

CDC tests are provided to U.S. state and local public health laboratories and Department of Defense laboratories that were either previously qualified for being able to perform a similar type of test used to detect influenza or have been recently approved by their state public health laboratory for SARS-CoV-2 testing.

Additional Resources

Information for Laboratories

SARS-CoV-2 Viral Culturing at CDC

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

CDC's Diagnostic Multiplex Assay for Flu and COVID-19

Testing Data in the US

Overview of Testing for SARS-CoV-2 (for healthcare providers)

Testing for COVID-19 (for the public)

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