Coronavirus Disease 2019 (COVID-19)

CDC Diagnostic Tests for COVID-19

Updated July 3, 2020

CDC has developed two laboratory tests that identify SARS-CoV-2, the virus that causes COVID-19. The newer of these tests will also be used to test for influenza A and B viruses. 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.

CDC Influenza SARS-CoV-2 Multiplex Assay

CDC's newest laboratory test, currently in production, will detect 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 will allow 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 to control the spread of influenza and COVID-19 in the community and may help health care providers manage treatment of influenza and COVID-19. The test 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 existing test for SARS CoV-2.

The Flu SC2 test kit was evaluated in CDC laboratories and three other public health laboratories 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 earlier test was designed, which is likely to improve performance of the test.

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. Test kits will be shipped to public health laboratories when production, including quality control and assembly, has been completed. 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

In early 2020, CDC developed its first laboratory test kit for use in testing patient specimens for SARS-CoV-2. The test kit is called the CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)–PCR Diagnostic Panel.

On February 3, 2020, CDC submitted an EUA package to expedite FDA-permitted use of the CDC 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.

Before laboratories use a new test on samples from patients, they must verify the test performance (make sure it

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

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works as expected) using "positive" and "negative" control materials. The positive control should always test positive, and the negative control should always test negative. During validation of the CDC SARS-CoV-2 test, some laboratories discovered a problem with one of the test's three reagents—chemicals required to run a test. The reagent produced a positive result with the negative control, so laboratories could not verify test performance.

To resolve the issue, CDC laboratories determined that this reagent could be left out without affecting test accuracy because of the built-in redundancy in test design. The redundant design saved time by allowing the kits to be used without the reagent. FDA authorized this modification, and new test kits with the two necessary reagents were manufactured and distributed to states. These kits are still in use.

High demand for the reagents needed with this test has resulted in global shortages. Some public health laboratories have been unable to get testing reagents to support their testing volumes, resulting in testing delays. Therefore, CDC laboratories validated 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

FDA approved these changes on June 12, 2020, in an amendment to the test's EUA to allow state public health laboratories and others to use these alternatives.

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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