COVID-19

CDC's Influenza SARS-CoV-2 Multiplex Assay and Required Supplies

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Summary of Recent Changes

Updates as of February 2, 2021

As of February 2, 2021

- Added information on CDC amendment granted by FDA on January 8, 2021

The CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay is a real-time reverse-transcription polymerase chain reaction (RT-PCR) test that detects and differentiates RNA from SARS-CoV-2, influenza A virus, and influenza B virus in upper or lower respiratory specimens. The assay provides a sensitive, nucleic-acid-based diagnostic tool for evaluation of specimens from patients in the acute phase of infection.

Why the CDC Flu SC2 Multiplex Assay Is Important

- Serves as a single test to diagnose infection caused by one of three viruses: SARS-CoV-2, influenza A, and influenza B
- Allows laboratories to process more tests in a given time period
- Gives public health officials information they need in their efforts to control the spread of COVID-19 and flu
- Allows for ongoing flu surveillance while also testing for SARS-CoV-2
- Conserves important testing materials that are in short supply
- Learn more about the benefits of the CDC Flu SC2 Multiplex Assay.

The U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for this test on July 2, 2020.

The CDC Flu SC2 Multiplex Assay FDA-authorized Instructions for Use contains information about the test and its intended use, the test procedure, and the test performance characteristics. The FDA Letter of Authorization for the CDC Flu SC2 Multiplex Assay can be found on the EUA website. The letter defines the authorized use and the conditions of authorization that apply to CDC and other testing laboratories that use this test. Manufacturers and test developers interested in the right of reference to the CDC Flu SC2 Multiplex Assay performance data are encouraged to read these FAQs.

On November 20, 2020, FDA granted an amendment to the EUA for the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay to expand the list of extraction instruments that may be used to prepare samples for testing. This amendment will enable more laboratories to use the test with automated, high throughput specimen preparation instruments, potentially increasing the speed and throughput of testing. Included in this amendment:

- Addition of four automated nucleic acid extraction instrument options
  - QIAcube HT
  - KingFisher Flex
  - MagNA Pure Compact
  - NucliSENS® easyMAG®
- Recommendation to use the JOE filter instead of the VIC filter to view the InfB signal with standard 7500 Fast Dx calibration
- Clarification of verification instructions and dilutions

On January 8, 2021, FDA granted an amendment to the EUA for the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay to expand the list of extraction instruments that may be used to prepare samples for testing and to add an additional authorized manufacturer of primer and probe reagents for use with the test. This amendment will enable more laboratories to use the test with automated, high throughput specimen preparation instruments, potentially increasing the speed and throughput of testing and will increase manufacturing capacity for test reagents. Included in this amendment:

- Addition of two automated nucleic acid extraction instrument options
  - Maxwell® RSC 48
  - Maxwell® CSC 48
- Addition of another authorized manufacturer of primer and probe reagents for use with the CDC Flu SC2 Multiplex Assay.

How Public Health Laboratories Order the CDC Flu SC2 Multiplex Assay

CDC's International Reagent Resource (IRR) is working through the main Public Health Laboratory (PHL) in each state to allocate multiplex kits to their state's network of regional and local PHLs.

During the COVID-19 pandemic, state public health laboratories can authorize county or city laboratories in their state to perform testing. These laboratories must be certified under the Clinical Laboratory Improvement Amendments (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. A list of commercially available primers and probes for use with this test is not available at this time. However, CDC has shared the primers and probes sequences, so other laboratories and companies may manufacture their own reagents.

Materials included in the assay

The CDC Flu SC2 Multiplex Assay is a quadruplex assay that includes:

- One primer mix and one probe mix. Primers and probes target:
  - Virus nucleocapsid (N) gene for specific detection of SARS-CoV-2
  - Matrix (M1) gene for specific detection of influenza A virus
  - Nonstructural 2 (NS2) gene for specific detection of influenza B virus
  - RNase P gene (RP) for specific detection of human nucleic acid that serves as an internal control
- Positive controls: SC2PC and Seasonal Influenza Positive Control (SIPC), that together confirm all four targets in the assay are working correctly

Other materials needed to perform the assay

The CDC Flu SC2 Multiplex Assay requires the use of additional authorized materials that are not included with the test. These materials include RT-PCR reagents, equipment, and supplies commonly used in laboratories such as a microcentrifuge, microcentrifuge tubes, pipettes, and pipette tips. Materials are described in the authorized CDC Flu SC2 Multiplex Assay Instructions for Use. Two control materials are also required but not provided. These control materials must produce expected results for a test to be considered valid, as outlined in the CDC Flu SC2 Multiplex Assay Instructions for Use. The controls are the following:

- **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 Instructions for Use.

- **No template control (NTC):** Nuclease-free water included in each run. This control monitors for reagent and system contamination.

More Resources for the Flu SC2 Multiplex Assay

- Processing of Sputum Specimens for Nucleic Acid Extraction
- Research Use Only Primers and Probes

Fact Sheets for the Flu SC2 Multiplex Assay

- Patient Fact Sheet
- Healthcare Provider Fact Sheet

More Resources for Diagnostic Testing for COVID-19 and Flu

- Request 2019-nCoV Grown in Cell Culture
- Emergency Use Authorizations for Medical Devices (FDA)
- FDA FAQs on Testing for SARS-CoV-2
- Overview of Testing for SARS-CoV-2 (for healthcare providers)
- Testing for COVID-19 (for the public)
- Information for Clinicians on Influenza Virus Testing
- Diagnosing Flu (for the public)

Previous Revisions

Revisions were made on December 11, 2020, to reflect the following:

- Added information on CDC amendment granted by FDA on November 30, 2020

Additional Resources

FAQ: Right of Reference to the CDC Influenza SARS-CoV-2 (Flu SC2) Performance Data for Manufacturers and Test Developers

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