Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

CDC's Diagnostic Multiplex Assay for Flu *and* COVID-19 at Public Health Laboratories and Supplies

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The CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay is a real-time reverse-transcriptase 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 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 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 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 multiplex assay's 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 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.

How Public Health Laboratories Order the Flu SC2 Multiplex Assay

The International Reagent Resource (IRR) is distributing the Flu SC2 Multiplex Assay and supplies to registered state and local public health laboratories so that they can perform testing with this assay.

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 Amendment (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
- A positive control FluSC2PC that confirms all four targets in the assay are working correctly

Other materials labs need to perform the assay

The Flu SC2 Multiplex Assay requires the use of additional authorized materials that are not included with the test. These materials include PCR reagents, equipment, and supplies commonly used in clinical laboratories such as a microcentrifuge, microcentrifuge tubes, pipettes, and pipette tips. They are described starting on page 5 in the authorized Flu SC2 Multiplex Assay Instructions for Use . Two control materials are also required but not provided. These materials must produce expected results for a test to be considered valid, as outlined in the 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)

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