FAQ: CDC Distribution of COVID-19 Assays

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What COVID-19 tests does CDC distribute?

At this time, CDC distributes both the 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel and the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay. After September 30, 2021, CDC will no longer distribute the 2019-nCoV Real-Time RT-PCR Diagnostic Panel, and laboratories should transition away from the Diagnostic Panel by the end of 2021.

Are the CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel or the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay commercially available for use by hospital, community, or commercial laboratories?

- No, CDC does not manufacture either the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel or the Flu SC2 Multiplex Assay for use by hospital, community, or commercial laboratories.
- CDC provides both the 2019-nCoV Real-Time RT-PCR Diagnostic Panel and Flu SC2 Multiplex Assay for use in designated state, tribal, local, and territorial government-supported public health laboratories. For more information, check with your health department.
- CDC encourages commercial manufacturers to use the CDC-published assay designs for the 2019-nCoV Real-Time RT-PCR Diagnostic Panel or the Flu SC2 Multiplex Assay to pursue their own Emergency Use Authorization (EUA). Laboratories also can use the published assay designs to create a laboratory-developed test (LDT).

Can a manufacturer use the CDC-published assay designs to develop a commercially available test and submit a request to the US Food and Drug Administration (FDA) for Emergency Use Authorization (EUA)?

- Yes, however, the manufacturer must pursue its own EUA.
- CDC is offering developers the right of reference to both the 2019-nCoV Real-Time RT-PCR Diagnostic Panel and the Flu SC2 Multiplex Assay. The right of reference allows developers seeking EUA to use the performance data already submitted to FDA as part of the 2019-nCoV Real-Time RT-PCR Diagnostic Panel (FDA submission number EUA200001) or CDC EUA request for the Flu SC2 Multiplex Assay (FDA submission number EUA201781). This approach will help developers bring tests to the market more quickly. Tests that use right of reference will not be affected by the discontinuation of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Can a laboratory use the CDC-published assay design to make a laboratory-developed test (LDT)?

- Yes, however, the laboratory will need to manufacture the primers and probes or purchase them from a commercial vendor using the published designs for the 2019-nCoV Real-Time RT-PCR Diagnostic Panel or the Flu SC2 Multiplex Assay.
- The laboratory will need to perform testing to meet all appropriate Clinical Laboratory Improvement Amendment (CLIA) regulations prior to reporting diagnostic results.
- LDTs created using CDC's design would not be authorized under the CDC 2019-nCoV Diagnostic Panel or Flu SC2 Multiplex Assay EUA.

What resources is CDC providing to promote the development of multi-analyte respiratory panels that include SARS-CoV-2 by commercial manufacturers or other laboratories?

- CDC provides:
  - Technical specifications for Flu SC2 Multiplex Assay primers and probes
  - Right of reference to the performance data submitted to FDA as part of the CDC Flu SC2 Multiplex Assay EUA request
- CDC does not provide:
  - Quality control testing
  - Positive controls – refer to the CDC Flu SC2 Multiplex Assay Instructions for Use for additional information
  - Validation panels
    - Exclusivity panels
    - Limit of Detection panels
  - A CDC-manufactured kit to use for comparison or validation purposes

Are there any licenses or intellectual property agreements that manufacturers will need to obtain when pursuing an EUA?

- No license or agreement is necessary to use the CDC-published 2019-nCoV Real-Time RT-PCR Diagnostic Panel or the Flu SC2 Multiplex Assay primer and probe sequences. CDC has published these sequences to allow manufacturers and test developers to use this information for creation and/or distribution of their own test or components.
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel and the Flu SC2 Multiplex Assay use proprietary components from other companies. Developers of commercial tests will need to obtain licenses from the manufacturers of these proprietary components or qualify alternative materials to use in their test.

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