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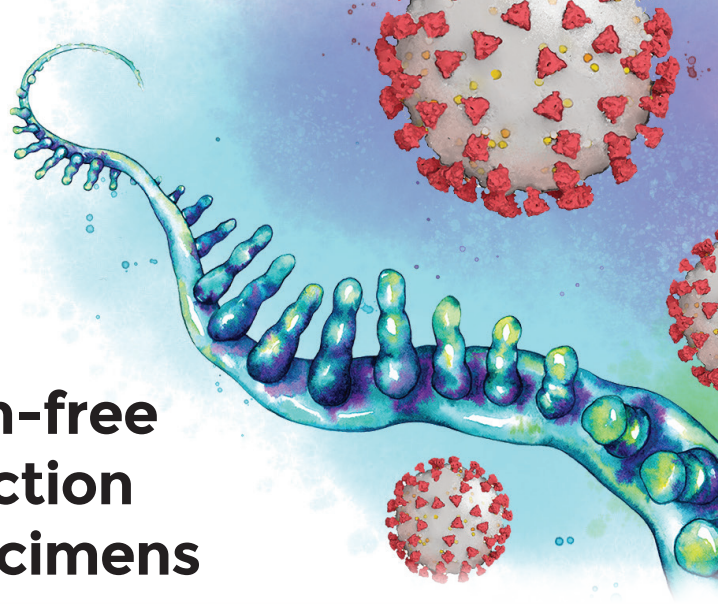

Fluidigm has developed a high-throughput, extraction-free diagnostic test for the detection of SARS-CoV-2 in saliva specimens and filed for FDA EUA

Advanta Dx SARS-CoV-2 RT-PCR Assay

Fluidigm has developed a diagnostic molecular test for the qualitative detection of SARS-CoV-2 in saliva specimens and has filed for FDA Emergency Use Authorization (EUA).

The Advanta™ Dx SARS-CoV-2 RT-PCR Assay is a qPCR-based test that, by taking advantage of Fluidigm's proprietary microfluidics technology and Juno™ and Biomark™ HD systems, enables high throughput and scalable testing of saliva samples from patients suspected of COVID-19 (coronavirus) infection. Featuring extraction-free sample processing, a modular workflow and large batch-sample size, the Advanta Dx SARS-CoV-2 RT-PCR Assay could enhance laboratory testing capacity while providing reliable results to support clinical decision making.

Collaboration

Fluidigm is collaborating with the Washington University School of Medicine in St. Louis to develop the SARS-CoV-2 saliva test and file for EUA.

Test Platform Highlights

Extraction free—
No need for viral RNA extraction kit

High throughput—
192 samples and controls per batch in less than 3 hours of instrument time

Scalable—Modular platform supports concurrent parallel runs to achieve up to 6,000 samples and controls/day/instrument.

Noninvasive—Saliva collection is convenient, stress-free and pain-free.

Simple Low-Labor Workflow

1

Saliva collection

2

Sample prep

or

3

Processing of integrated fluidic circuit (IFC) on Juno (left) or IFC Controller RX

4

qPCR analysis on Biomark HD

Total instrument run time: <3 hours

Intended Use

Advanta™ Dx SARS-CoV-2 RT-PCR Assay is a real-time RT-PCR test intended for the qualitative detection of RNA from the SARS-CoV-2 in saliva specimens from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to Laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in saliva during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Advanta™ Dx SARS-CoV-2 RT-PCR Assay is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The Advanta™ Dx SARS-CoV-2 RT-PCR Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

The close collaboration between teams at Washington University and Fluidigm aided our efforts to quickly develop this high-throughput assay for SARS-CoV-2 that relies on a saliva sample. Such a test could help overcome supply chain bottlenecks that have limited testing for COVID-19 and help identify infections.

—Jeffrey Milbrandt, MD, PhD
Executive Director of the McDonnell Genome Institute and
Head of the Department of Genetics at Washington University School of Medicine

There's an urgent need to simplify testing for COVID-19 so that people who are infected can be easily and quickly identified. The test we developed in collaboration with Fluidigm doesn't require RNA extraction, a time-consuming and expensive step necessary to other tests for SARS-CoV-2. Our test could be easily scaled up and made widely available.

—Richard Head
Director of the Genome Technology Access Center at the McDonnell Genome Institute

Learn more about the assay at **fluidigm.com/covid-19-dx**.

Fluidigm has filed for Emergency Use Authorization with the FDA. The test has been validated by Fluidigm, but the FDA's independent review of this validation is pending. The Advanta Dx SARS-CoV-2 RT-PCR Assay is a real-time RT-PCR test intended for the qualitative detection of RNA from the SARS-CoV-2 in saliva specimens from individuals suspected of COVID-19 by their health care provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high-complexity tests, or by similarly qualified non-U.S. laboratories. The Advanta Dx SARS-CoV-2 RT-PCR Assay is the subject of an EUA filing with the FDA. The FDA may require additional data, validation and/or testing, and may not ultimately provide authorization. An EUA, if granted, does not constitute FDA clearance or approval, but would allow use by authorized laboratories only while the EUA is in effect.

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