



## George Mason University Providing COVID-19 Testing with Saliva-Based Advanta Dx SARS-CoV-2 RT-PCR Assay on Biomark HD Platform

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SOUTH SAN FRANCISCO, Calif., Feb. 10, 2021 (GLOBE NEWSWIRE) -- Fluidigm Corporation (Nasdaq:FLDM), an innovative biotechnology tools provider with a vision to improve life through comprehensive health insight, today announced that George Mason University in Fairfax, Va., is providing saliva-based COVID-19 testing using the Advanta™ Dx SARS-CoV-2 RT-PCR Assay on the Fluidigm® Biomark™ HD system.

As part of an expansion of testing capacity for GMU students and employees, the university purchased two Biomark HD systems and has equipped labs on the university's Science and Technology Campus in Manassas, Va., to process the Advanta Dx Assay, with initial plans to run approximately 10,000 tests per week.

"Frequent and reliable testing is the core of our plan to keep students and staff safe at GMU," said Ali Andalibi, PhD, Professor and Senior Associate Dean in the College of Science at GMU. "Adoption of the Advanta Dx SARS-CoV-2 RT-PCR Assay is one element of a plan to greatly expand our capacity. The noninvasive nature of the assay, accuracy and time to results are among key advantages of the Fluidigm system, which we have combined with an automation platform for testing at scale.

"The testing capacity provided by the Fluidigm system, along with systematic precautionary measures such as masks and social distancing, will help us limit the spread of the virus at Mason."

Fluidigm has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the Advanta Dx SARS-CoV-2 RT-PCR Assay, an extraction-free saliva-based test to detect nucleic acid from the SARS-CoV-2 virus in individuals suspected of COVID-19 by their health care providers. The assay does not require collection via invasive nasopharyngeal swab, and the company's submission to the FDA demonstrated 100 percent agreement between saliva results from the Advanta Dx Assay and results from paired nasopharyngeal samples tested with authorized assays.

A growing body of peer-reviewed research is confirming that the accuracy of saliva-based COVID-19 testing is comparable to that of nasopharyngeal-based testing. A systematic review and meta-analysis published in *JAMA Internal Medicine* in January 2021 stated that saliva-based tests have a similar sensitivity and specificity and present an attractive alternative to invasive nasopharyngeal testing.

"Fluidigm is grateful for the opportunity to enable simple, affordable and accessible testing to help keep colleges and universities open and their staffs and students healthy," said Chris Linthwaite, Fluidigm President and CEO. "We are proud of our collaborations with a number of higher education institutions to provide a test with a sample type that is far easier to collect than invasive swabs, and that individuals often prefer from a comfort perspective."

Fluidigm continually conducts *in silico* analyses to determine the effectiveness of the Advanta Dx Assay design to detect SARS-CoV-2. To date, none of the published viral mutations meaningfully impact the regions of the viral genome targeted by the assay's primers and probes.

### Intended Use

The Advanta™ Dx SARS-CoV-2 RT-PCR Assay is a real-time Reverse Transcription (RT) PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in saliva specimens collected without preservatives in a sterile container from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to Laboratories which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in saliva specimens 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 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. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

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.

Other Fluidigm products are provided for Research Use Only. Not for use in diagnostic procedures.

### About Fluidigm

Fluidigm (Nasdaq:FLDM) focuses on the most pressing needs in translational and clinical research, including cancer, immunology, and immunotherapy. Using proprietary CyTOF<sup>®</sup> and microfluidics technologies, we develop, manufacture, and market multi-omic solutions to drive meaningful insights in health and disease, identify biomarkers to inform decisions, and accelerate the development of more effective therapies. Our customers are leading academic, government, pharmaceutical, biotechnology, plant and animal research, and clinical laboratories worldwide. Together with them, we strive to increase the quality of life for all. For more information, visit [fluidigm.com](http://fluidigm.com).

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Fluidigm's ongoing collaboration with the Defense Advanced Research Projects Agency (DARPA) and its Epigenetic Characterization and Observation (ECHO) program includes financial support for development of innovative programs based on our microfluidics technology.

#### **Forward-Looking Statements for Fluidigm**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, among others, statements regarding expectations for specified third parties to conduct COVID-19 testing using the Advanta Dx SARS-CoV-2 RT-PCR Assay, the benefits of implementing the Advanta Dx Assay and saliva-based COVID-19 testing, the numbers of Advanta Dx Assays to be processed by third parties, the benefits of providing tests to certain communities and customers, and demand for the Fluidigm tests. Forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from currently anticipated results, including but not limited to risks relating to the potential adverse effects of the coronavirus pandemic on our business and operating results; the possible loss of key employees, customers, or suppliers; uncertainties in contractual relationships; our ability and/or the ability of the research institutions utilizing our products and technology to obtain and maintain Emergency Use Authorization from the FDA and any other requisite authorizations or approvals to use our products and technology for diagnostic testing purposes; potential changes in priorities or requirements for Emergency Use Authorizations or other regulatory authorizations or approvals; potential limitations of any Emergency Use Authorization or other regulatory authorizations or approvals; potential changes in the priorities of government agencies; challenges inherent in developing, manufacturing, launching, marketing, and selling new products; risks relating to company research and development and distribution plans and capabilities; interruptions or delays in the supply of components or materials for, or manufacturing of, Fluidigm products; potential product performance and quality issues; intellectual property risks; and competition. Information on these and additional risks and uncertainties and other information affecting Fluidigm business and operating results is contained in Fluidigm's Annual Report on Form 10-K for the year ended December 31, 2019, and in its other filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. Fluidigm disclaims any obligation to update these forward-looking statements except as may be required by law.

#### **Available Information**

We use our website ([fluidigm.com](http://fluidigm.com)), investor site ([investors.fluidigm.com](http://investors.fluidigm.com)), corporate Twitter account ([@fluidigm](https://twitter.com/fluidigm)), Facebook page ([facebook.com/Fluidigm](https://facebook.com/Fluidigm)), and LinkedIn page ([linkedin.com/company/fluidigm-corporation](https://linkedin.com/company/fluidigm-corporation)) as channels of distribution of information about our products, our planned financial and other announcements, our attendance at upcoming investor and industry conferences, and other matters. Such information may be deemed material information, and we may use these channels to comply with our disclosure obligations under Regulation FD. Therefore, investors should monitor our website and our social media accounts in addition to following our press releases, SEC filings, public conference calls, and webcasts.

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