



## Fluidigm Confirms Advanta Dx SARS-CoV-2 RT-PCR Assay on the Company's Biomark Platform Detects Omicron Variant of COVID-19

December 7, 2021

### ***No Published Viral Mutations to Date, Including Omicron Variant, Meaningfully Impact the Regions of the Viral Genome Targeted by the Assay***

SOUTH SAN FRANCISCO, Calif., Dec. 07, 2021 (GLOBE NEWSWIRE) -- Fluidigm Corporation (NASDAQ:FLDM), an innovative biotechnology tools provider with a vision to improve life through comprehensive health insight, today confirmed that Omicron variant B.1.1.529, designated by the World Health Organization as a Variant of Concern, does not impact the capability of the Fluidigm® Advanta™ Dx SARS-CoV-2 RT-PCR Assay to detect the virus that causes COVID-19, based on *in silico* analyses of the most current databases.

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 impacts the regions of the viral genome targeted by the assay's primers and probes.

"Accurate detection of SARS-CoV-2 Variants of Concern can help assess the spread of circulating variants and determine their potential impact on therapeutics, vaccines and public health programs," said Chris Linthwaite, President and CEO. "Since the early days of the pandemic, Fluidigm technology has helped advance SARS-CoV-2 research, treatment and diagnostic programs with simple, affordable and accessible testing. Since August 2020, millions of samples have been tested for COVID-19 using our assay, offering easy, noninvasive sample collection, accuracy and speed to results."

The Advanta Dx SARS-CoV-2 RT-PCR Assay, designed to be run on the company's Biomark™ platform, is an extraction-free saliva-based test to detect nucleic acid from the SARS-CoV-2 virus in individuals suspected by their health care providers of having COVID-19. 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 an authorized assay.

#### **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 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](https://www.fluidigm.com).

Fluidigm, the Fluidigm logo, Advanta, Biomark and CyTOF are trademarks and/or registered trademarks of Fluidigm Corporation or its affiliates in the United States and/or other countries.

#### **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 the use of Fluidigm's Advanta COVID-19 assays. 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 challenges inherent in developing, manufacturing, launching, marketing, and selling new products; potential product performance and quality issues; intellectual property risks; competition; uncertainties in contractual relationships; and reductions in research and development spending or changes in budget priorities by customers. 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, 2020, 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](#), [investor site](#), corporate [Twitter](#) account, [Facebook](#) page, and [LinkedIn](#) page 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.

**Fluidigm**

**Media:**

Mark Spearman  
Senior Director, Corporate Communications  
650 243 6621  
[mark.spearman@fluidigm.com](mailto:mark.spearman@fluidigm.com)

**Investors:**

Peter DeNardo  
415 389 6400  
[ir@fluidigm.com](mailto:ir@fluidigm.com)



Source: Fluidigm Corporation