



FDA Grants Emergency Use Authorization for Home Collection Kit for Advanta Dx SARS-CoV-2 RT-PCR Assay

March 1, 2021

Collaboration Agreement to Market AZOVA COVID-19 Test Collection Kit Online

AZOVA Digital Health Platform Provides Patient Questionnaire, Process for Prescription, Kit Purchase, Sample Collection, and Secure Delivery of Test Results

SOUTH SAN FRANCISCO, Calif., March 01, 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 the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for the AZOVA™ COVID-19 Test Collection Kit for use with the Fluidigm® Advanta™ Dx SARS-CoV-2 RT-PCR Assay on the company's Biomark™ HD platform.

The kit is authorized for at-home self-collection by prescription only for individuals suspected of COVID-19 by their health care providers. Those under the age of 18 may use the kit with adult supervision.

Consumers seeking a COVID-19 test can complete an online health questionnaire provided by Fluidigm's collaboration partner, AZOVA, to enable a health care provider to assess whether a prescription is issued. If so, the consumer can then order the collection kit online for home delivery.

"We are excited about this collaboration with Fluidigm," said Cheryl Lee Eberting, MD, Founder and CEO of AZOVA. "Our goals are to enable any CLIA-certified laboratory that meets the requirements to perform high-complexity tests to process our home collection kits, and to make this kit accessible to as many consumers as possible. By combining a powerful digital health platform with this assay, AZOVA and Fluidigm are opening up much greater access to COVID-19 testing solutions.

"The patient provides a saliva sample as directed in the kit instructions and sends the kit to one of our partner labs using prepaid same-day shipping, and results are shared within 12–72 hours of the time the lab receives the kit. The patient receives text message and email links to securely access results. In addition, AZOVA creates COVID Credentials™ for each patient, an electronic passport that enables one to securely share COVID testing information with others."

The Advanta Dx SARS-CoV-2 RT-PCR Assay 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 authorized assays.

"Our noninvasive, saliva-based test helped deliver a much-needed testing solution for patients and first responders around the world, and we are pleased for the opportunity to introduce the Advanta Dx SARS-CoV-2 RT-PCR Assay into the home-collection market," said Chris Linthwaite, Fluidigm President and CEO. "Entering the home collection market is an important milestone for Fluidigm, and collaborations with forward-thinking companies such as AZOVA to advance into new channels represent a key strategy in fully realizing Fluidigm's role in next-generation diagnostics.

"In addition to technological innovation, collaborations in such areas as telemedicine and new digital health platforms will build upon the beachhead that we have established to penetrate new markets. The digital health revolution is here to stay, and we intend to play a leadership role in this transformation."

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 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.

This test is also for use with saliva specimens that are self-collected at home with or without the supervision of a healthcare provider (HCP) with the AZOVA COVID-19 Test Collection Kit from individuals suspected of COVID-19 by their HCP.

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 individual history and other diagnostic information is necessary to determine individual 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 individual management decisions. Negative results must be combined with clinical observations, individual 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 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.

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.

Fluidigm, the Fluidigm logo, Advanta, Biomark, and CyTOF are trademarks and/or registered trademarks of Fluidigm Corporation in the United States and/or other countries. All other trademarks are the sole property of their respective owners.

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.

About AZOVA

AZOVA provides innovative COVID testing solutions to employers, schools, government entities, airlines, the travel industry and the consumer. AZOVA has created the world's first truly connected laboratory network on the AZOVA Digital Health System platform. With AZOVA, any laboratory or licensed COVID testing location can connect to the global laboratory network to enable access to COVID testing from anywhere across the globe.

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 adoption and use of a home collection kit for the Advanta Dx SARS-CoV-2 RT-PCR Assay, demand for COVID-19 testing and Fluidigm's role in digital health and next generation diagnostics. 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, 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 (fluidigm.com), investor site (investors.fluidigm.com), corporate Twitter account ([@fluidigm](https://twitter.com/fluidigm)), Facebook page (facebook.com/Fluidigm), and LinkedIn page (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.

Fluidigm

Media:

Mark Spearman
Senior Director, Corporate Communications
650 243 6621
mark.spearman@fluidigm.com

Investors:

Agnes Lee
Vice President, Investor Relations
650 416 7423

AZOVA

Media:

Logan Connors
Media Relations
844 MY AZOVA ext. 1028
logan.connors@azova.com

Investors:

Alexander Hume, CFO
385 449 1053
alexander.hume@azova.com



Source: Fluidigm Corporation