Fluidigm to Offer Millions of Advanta COVID-19 Tests at Low Cost to U.S. Colleges and Universities

October 8, 2020

Fluidigm COVID-19 Campus Safeguard Program Improves Availability of Noninvasive, Saliva-Based SARS-CoV-2 Tests for Higher Education Institutions

High-Throughput, Integrated Testing Platform and Reliable Supply Chain

SOUTH SAN FRANCISCO, Calif., Oct. 08, 2020 (GLOBE NEWSWIRE) -- Fluidigm Corporation (Nasdaq:FLDM), an innovative biotechnology tools provider with a vision to improve life through comprehensive health insight, today announced a program to expand availability of Fluidigm® COVID-19 tests for U.S. colleges and universities. The Fluidigm COVID-19 Campus Safeguard Program will provide millions of noninvasive, saliva-based tests for the SARS-CoV-2 virus to qualifying institutions at a cost as low as $5 per test.

The Advanta™ Dx SARS-CoV-2 RT-PCR Assay on the high-throughput Fluidigm Biomark™ HD system features an integrated testing platform and a reliable supply chain and can be easily combined with commonly available automation platforms.

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 SARSCoV2 virus. The assay does not require collection via invasive nasopharyngeal swab. The company's submission to the FDA demonstrated 100 percent agreement between saliva results from the Advanta Dx SARS-CoV-2 RT-PCR Assay and results from paired nasopharyngeal samples tested with authorized assays.

Development, commercialization and implementation of the Advanta Dx SARS-CoV-2 RT-PCR Assay are supported by a $34 million definitive contract with the National Institutes of Health under the agency's Rapid Acceleration of Diagnostics (RADx) initiative. The RADx initiative fast-tracks development and commercialization of innovative technologies to significantly increase U.S. testing capacity for SARS-CoV-2.

With the scale-up support, the low-cost, saliva-based Advanta Assay will be targeted to all universities and colleges across the United States. Many higher education systems are struggling to deploy affordable testing programs to serve large populations. Fluidigm has a large number of Biomark HD placements in academic clinical laboratories in the United States that meet requirements to perform high-complexity tests in significant numbers.

Many pioneering higher education institutions and labs across the United States, including the University of Pennsylvania, Washington University in St. Louis, OU Medicine, the University of Oklahoma and the Oklahoma Medical Research Foundation (OMRF), have chosen to use Fluidigm microfluidics technology and reagents to test individuals for the SARSCoV2 virus.

"Fluidigm microfluidics enables a tool for testing in a rapid and affordable format," said Joel Guthridge, PhD, Director, Translational Informatics & Clinical Research Resources at OMRF. "This approach allows us to identify positive individuals and quickly assess potential exposures and risk with the goal of keeping our employees and students and their families safer."

"There are many reasons why high-throughput, saliva-based PCR testing for SARS-CoV-2 virus detection is a powerful tool for colleges and universities," said Chris Linthwaite, Fluidigm President and CEO. "Fluidigm's saliva-based PCR test combines an affordable, kitted solution with sample collection that is far easier as compared to invasive swabs, and often preferable for both the health care providers collecting samples and the students and staff being tested. Our test has demonstrated 100 percent agreement with paired samples from authorized nasopharyngeal assays. While antigen testing can be an important element of pandemic response, it is not enough, as PCR virus detection provides greater sensitivity.

"Furthermore, the Fluidigm test avoids supply chain constraints associated with other tests and has received Emergency Use Authorization from the FDA.

"We are grateful for the support of the NIH RADx initiative, which has enabled us to accelerate our production capacity and make the Fluidigm COVID-19 Campus Safeguard Program possible. We will continue to ramp up our capacity, and in the fourth quarter we expect to have six million tests available," Linthwaite said. "We are excited for this opportunity to play a major role in helping to keep students and staff safe as our nation continues to navigate the global health crisis."

The Fluidigm RADx project is supported by the NIH Rapid Acceleration of Diagnostics initiative and has been funded in whole or in part with federal funds from the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under contract No. 75N92020C00009.

Purchases under the Fluidigm COVID-19 Campus Safeguard Program are subject to standard terms and conditions, for U.S. colleges and universities, only while supplies last.

Learn More:

https://go.fluidigm.com/campus-admin

https://go.fluidigm.com/back-to-school

Intended Use
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 health care

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 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. 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.

The Advanta Dx SARS-CoV-2 RT-PCR Assay is for In Vitro Diagnostic Use. It is for Use Under Emergency Use Authorization Only. Rx Only. It has not been FDA cleared or approved. It has been authorized by FDA under an EUA for use by authorized laboratories. It has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. It is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. **Other Fluidigm products are 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.

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 the use of Fluidigm's Advanta COVID-19 assays by U.S. higher education institutions and manufacturing capacity, including the number of tests Fluidigm expects to make available in the fourth quarter of 2020. 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 during 2020; 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 approvals to use our products and technology for diagnostic testing purposes; potential changes in priorities or requirements for Emergency Use Authorizations; potential limitations of any Emergency Use Authorization; 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), investor site (investors.fluidigm.com), corporate Twitter account (@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
agnes.lee@fluidigm.com

Source: Fluidigm Corporation