



ImmunoGenomics and Vero Diagnostics Providing COVID-19 Testing with Saliva-Based Advanta Dx SARS-CoV-2 RT-PCR Assay on Biomark HD Platform

September 16, 2020

Regional CLIA-Certified Labs among Growing Number of Customers Expanding SARS-CoV-2 Testing with Fluidigm Technology

SOUTH SAN FRANCISCO, Calif., Sept. 16, 2020 (GLOBE NEWSWIRE) -- Fluidigm Corporation (Nasdaq:FLDM), an innovative biotechnology tools provider with a vision to improve life through comprehensive health insight, today announced that ImmunoGenomics, based in metropolitan Houston, and Vero Diagnostics of Research Triangle Park, North Carolina, are among the Clinical Laboratory Improvement Amendments (CLIA) certified labs now offering testing services using the Advanta™ Dx SARS-CoV-2 RT-PCR Assay on the Fluidigm® Biomark™ HD system.

Fluidigm recently 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. 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 SARS-CoV-2 RT-PCR Assay and results from paired nasopharyngeal samples tested with authorized assays.

"As a scientist-owned-and-operated, CLIA-certified lab, we believe saliva-based testing for COVID-19 via high-throughput PCR is the gold standard of detection for private, public and government testing environments," said Twinkle Patel, ImmunoGenomics President and CEO. "The Fluidigm workflow enables high-throughput processing of samples using established methods certified by the Centers for Disease Control and Prevention and the World Health Organization. This extraordinary throughput is coupled with a robust supply chain and a high degree of accuracy." ImmunoGenomics currently processes approximately 3,000 samples per day using the Advanta Dx SARS-CoV-2 RT-PCR Assay.

"The extraction-free nature of the Fluidigm assay is enabling our lab to eliminate bottlenecks and streamline processing of samples," said Ritesh Shah, Managing Partner and Founder of Vero Diagnostics. "We are processing approximately 3,000 samples per day for medical centers, skilled nursing facilities, urgent care clinics and others. Invasive nasopharyngeal swab-based testing is not sustainable in situations in which regular testing is required. We believe the saliva-based model is the future of COVID testing."

"There are many reasons why high-throughput saliva-based PCR testing is such a powerful tool in grappling with this global health crisis," said Chris Linthwaite, Fluidigm President and CEO. "In addition to small- and medium-sized labs, large public health organizations and major academic centers are adopting our saliva-based test. Health care providers can collect samples far more easily than with the invasive nasopharyngeal swab and still have the samples processed with a test that has been demonstrated to be in 100 percent agreement with authorized nasopharyngeal assays. Furthermore, the Fluidigm test offers rapid turnaround time and avoids supply chain constraints of other approaches.

"We are grateful for the opportunity to play a major role in the response to this pandemic, and we are very pleased with the level of customer interest in our solution."

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, 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 ImmunoGenomics

ImmunoGenomics is a scientist-owned-and-operated CLIA-registered reference laboratory, serving the healthcare community with efficient and accurate data using cutting edge diagnostic platforms and technologies. Our Medical Director, Kevin Rosenblatt, MD, PhD, has extensive experience in the development and implementation of research to clinical application in molecular science. As we continue to assist physicians with diagnostic data using the most sophisticated DNA sequencing technology, our goal is to simplify our process and support providers and patients.

About Vero Diagnostics

Vero Diagnostics is a state-of-the-art clinical laboratory that incorporates the latest technology and methods to provide comprehensive diagnostic testing, including urine and oral fluid drug monitoring, pathogen detection, pharmacogenomics, and blood testing. We take pride in our ability to generate precise and accurate results in a timely manner.

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 benefits and advantages of the Advanta Dx SARS-CoV-2 RT-PCR Assay, including for expansion of COVID-19 testing, and customer demand for and commercialization of the Fluidigm test. 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](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

agnes.lee@fluidigm.com



Source: Fluidigm Corporation