GnomeDX Files for FDA Emergency Use Authorization for Rapid Turnaround Real-Time RT-PCR COVID-19 Test Utilizing the Fluidigm Biomark HD Platform

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Test Intended to Expand Availability of COVID-19 Screening Resources in Central Ohio

Workflow with Real-Time PCR Using Fluidigm Microfluidics Technology and Reagents

Increasing Number of Labs Adopting the Fluidigm High-Throughput Testing Model

SOUTH SAN FRANCISCO, Calif., and COLUMBUS, Ohio, July 20, 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 Gnome Diagnostics, LLC (GnomeDX), a leading pharmacogenomics testing company, is utilizing Fluidigm® microfluidics technology and reagents in a test developed to detect the SARS-CoV-2 virus, which causes COVID-19.

The Rapid Turnaround Real-Time RT-PCR™ COVID-19 Test, which can be performed via oropharyngeal, nasopharyngeal and nasal swab, is intended to meet growing testing needs for patients, health care workers and other critical populations across central Ohio. GnomeDX has filed for Emergency Use Authorization (EUA) for its extraction-free GnomeDX RT-PCR COVID-19 Test from the U.S. Food and Drug Administration (FDA).

“Supporting our first responders and their patients are among key goals of our test development program,” said Vicky Amann, Vice President for Lab Operations at GnomeDx. “Our CLIA certified genomics lab is ideally suited to this challenge, and we are committed to support our community in any way we can to respond to the pandemic.”

“GnomeDX selected the Fluidigm integrated fluidic circuit technology, reagents and workflow because they provide high-performance sample throughput that is unmatched by microwell plate-based PCR assays for the SARS-CoV-2 virus,” Amann added.

GnomeDX is a high-complexity lab certified under the Clinical Laboratory Improvement Amendments (CLIA) in the United States and eligible under FDA guidance to create its own diagnostic tests for COVID-19. GnomeDX has validated a workflow using assays developed by the Centers for Disease Control and Prevention designed to be run on the Fluidigm Biomark™ HD system.

Because sample collection methods for the test include oropharyngeal and nasal swabs, it does not require invasive nasopharyngeal collection.

COVID-19 testing on the Biomark HD platform provides throughput and cost advantages that reduce the impact of capacity-constrained supply chains. Fluidigm’s microfluidics technology enables processing of more samples per batch and uses a fraction of expensive testing reagents per sample as compared to more traditional, microwell plate-based PCR technology.

“We believe a significant increase in testing capacity remains critical to an effective global response to the COVID-19 crisis,” said Chris Linthwaite, President and CEO of Fluidigm. “As governments, medical institutions and private labs look for solutions, speed, scale and automation are paramount. Since the beginning of the pandemic, we have been supporting labs around the world as they build out testing infrastructure that meets these important criteria.

“The Biomark HD platform can generate as many as 6,000 test results per day on a single instrument. More and more labs are adopting the Fluidigm model of COVID-19 testing, which offers much-needed high-throughput capability per system. We also support multiple approaches to sample collection, having recently filed for Emergency Use Authorization from the FDA for an extraction-free saliva-based test to detect COVID-19.

“We are honored to have been chosen by GnomeDX to provide a platform for its COVID-19 test to provide critically needed testing capacity in central Ohio.”

In early June, Fluidigm filed for Emergency Use Authorization with the FDA for an extraction-free saliva-based test to detect the SARS-CoV-2 virus. The test was developed in collaboration with scientists at the McDonnell Genome Institute and the Department of Genetics at the Washington University School of Medicine in St. Louis.

With respect to the Fluidigm test, Fluidigm has filed for Emergency Use Authorization with the FDA. The test has been validated by Fluidigm, but the FDA’s independent review of this validation is pending. The FDA may require additional data, validation and/or testing, and may not ultimately provide authorization for EUA requests. An EUA, if granted, does not constitute FDA clearance or approval, but would allow use by authorized laboratories only while the EUA is in effect.

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, and plant and animal research 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, 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 products are provided for Research Use Only. Not for use in diagnostic procedures.

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.

About Gnome Diagnostics: GnomeDX is a personalized medicine genetic testing company. Its pharmacogenomic tests help physicians to prescribe the safest and most effective doses of therapeutics based on an individual's unique genetic profile. GnomeDX panel tests can also screen for inherited cardiovascular disease risk, promoting early detection and prevention. GnomeDX's goal is to improve the treatment outcomes for patients, minimize risk and side effects from prescription drugs, and help reduce the overall cost of health care. The GnomeDX Diagnostics testing unit intends to provide COVID-19 assays for safer workplaces and communities under the guidance of health care professionals. The GnomeDX Science unit provides molecular lab services for research and pharmaceutical drug development.

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 potential implementation of Fluidigm microfluidics technology and products for COVID-19 testing and the anticipated features and benefits of, and applications and demand for, such products. 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; our ability and/or the ability of the institutions utilizing our products and technology to obtain 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; 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.

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