



## Helix Specialty Diagnostics Partners with Genomic LTC DX to Provide COVID-19 Testing with Saliva-Based Advanta Dx SARS-CoV-2 RT-PCR Assay on Biomark HD Platform

January 26, 2021

### Major Midwest Labs Targeting 3,000 Tests per Day

SOUTH SAN FRANCISCO, Calif., Jan. 26, 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 Helix Specialty Diagnostics is partnering with Genomic LTC DX to provide COVID-19 testing using the Advanta™ Dx SARS-CoV-2 RT-PCR Assay on the Fluidigm® Biomark™ HD system.

Both Missouri based companies operate major Clinical Laboratory Improvement Amendments (CLIA) certified labs. Helix Specialty Diagnostics leads sample collection for the collaboration, with Genomic LTC DX processing and analyzing the saliva samples via the Advanta Dx Assay on the Biomark HD.

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 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 Assay and results from paired nasopharyngeal samples tested with authorized assays.

A growing body of peer-reviewed research is confirming that the accuracy of saliva-based COVID-19 testing is comparable to that of nasopharyngeal-based collection. A systematic review and meta-analysis published in *JAMA Internal Medicine* in January 2021 stated that saliva-based tests have a similar sensitivity and specificity and present an attractive alternative to invasive nasopharyngeal testing.

"Our experience collecting samples and reporting clinical results at scale is further expanded by Genomic LTC DX processing test samples utilizing the Fluidigm assay on the Biomark HD," said Michael Paulsen, President, Helix Specialty Diagnostics. "High-throughput saliva-based PCR testing is a valuable tool for colleges and universities as well as long-term care facilities, both of which are major customers. We intend to deliver 3,000 tests per day for processing via the Fluidigm system, providing much-needed additional capacity for large-scale testing programs.

"Rapid and reliable COVID-19 testing, made available to all who need it, is essential for a sustained response to the pandemic. As the total number COVID-19 cases in the United States exceeds 25 million, we are gratified by the opportunity to partner with Genomic LTC DX and Fluidigm to meet the needs of our clients."

"Fluidigm is committed to provide the technology to enable simple, affordable and accessible testing capability to help keep colleges and universities open and keep high-risk residents of long-term facilities healthy," said Chris Linthwaite, Fluidigm President and CEO. "We are proud of our collaborations in Missouri in recent months, starting with Washington University in St. Louis, and later with the State of Missouri, which has deployed four Fluidigm systems to various locations. Furthermore, we are excited to expand into the private-sector testing market through Helix Specialty Diagnostics and Genomic LTC DX to expand testing capacity for the state.

"Our 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 various community populations. Furthermore, 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."

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 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<sup>®</sup> 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](http://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 Helix Specialty Diagnostics**

Helix Specialty Diagnostics (HSD) is a CLIA certified high complexity clinical testing laboratory located in Columbia, MO. The ownership of HSD represents over 150 years of healthcare and laboratory experience. HSD is passionate about healthcare and about delivering high quality results to improve patient outcomes. Centrally located in the state, HSD is well-positioned to receive samples from all areas of Missouri and the surrounding states. HSD is committed to working with the employers to help them through this unprecedented time.

### **About Genomic LTC DX**

Genomic LTC DX is the wholly owned division of Boyce and Bynum Pathology Professional Services (BBPPS), dedicated to providing access to advanced diagnostic solutions to patients and clinicians across the Midwest. Established in 1965, Boyce and Bynum Pathology Professional Services is the largest private anatomic pathology reference laboratory in the Midwest, offering a full spectrum of anatomic procedures and operating under the directorship of multi-specialty pathologists who are committed to meeting the needs of the hospitals, specialty clinics, physician offices, and the communities that we serve.

### **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 specified third parties to conduct COVID-19 testing using the Advanta Dx SARS-CoV-2 RT-PCR Assay, the benefits and relative accuracy of saliva-based COVID-19 testing, the numbers of Advanta Dx assays to be processed by third parties, the benefits of providing tests to certain communities and customers, demand for the Fluidigm tests and expansion of testing capacity based on availability of the Fluidigm tests. 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, 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](http://fluidigm.com)), investor site ([investors.fluidigm.com](http://investors.fluidigm.com)), corporate Twitter account ([@fluidigm](https://twitter.com/fluidigm)), Facebook page ([facebook.com/Fluidigm](https://facebook.com/Fluidigm)), and LinkedIn page ([linkedin.com/company/fluidigm-corporation](https://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](mailto:mark.spearman@fluidigm.com)

Investors:

Agnes Lee

Vice President, Investor Relations

650 416 7423

[agnes.lee@fluidigm.com](mailto:agnes.lee@fluidigm.com)



Source: Fluidigm Corporation