



Fulgent Genetics Announces FDA Authorization and Launch of At-Home Testing Service for COVID-19

June 16, 2020

Fulgent Genetics has received Emergency Use Authorization from the FDA to provide at-home testing services for SARS-CoV-2, the virus that causes COVID-19

TEMPLE CITY, Calif., June 16, 2020 (GLOBE NEWSWIRE) -- Fulgent Genetics, Inc. (NASDAQ: FLGT) ("Fulgent Genetics" or the "company"), a provider of comprehensive genetic testing solutions, today announced that it has launched an at-home testing solution for the Coronavirus Disease (COVID-19). The company has received Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) for use in the United States.

Fulgent Genetics will be offering the testing service through Picture Genetics, the company's consumer-initiated genetic testing platform, beginning next week. Individuals interested in ordering testing services must qualify for the service through an online eligibility screener, which makes eligibility determinations based on current CDC guidelines while prioritizing those who are most in need of testing. Eligible individuals will receive Fulgent's collection materials in the mail that enable them to self-collect their specimen with a mid-turbinate nasal swab, which will then be sent back to Fulgent's CLIA-certified high-complexity, CAP-accredited laboratory in Temple City, California. By enabling individuals to collect samples themselves, Fulgent's at-home test services conserve valuable time and PPE resources otherwise required to perform these testing services for patients. Patients will receive their results through the Picture Genetics platform within 24-48 hours from receipt of the sample.

Fulgent has partnered with a national clinician network on its at-home COVID-19 test which will oversee the process including approval of each test ordered, monitoring of materials produced, and review of reports provided for patients by Fulgent Genetics after testing is completed.

"We are pleased to be able to offer a convenient and readily available COVID-19 testing solution for individuals at risk of contracting the virus," said Brandon Perthuis, Chief Commercial Officer at Fulgent Genetics. "As the coronavirus continues to spread, options for testing remain limited and many eligible individuals are unable to get the testing they need. We believe our at-home testing service will both enable at-risk individuals, particularly those at the front lines of this pandemic, to more readily access testing solutions, while potentially offering a solution for organizations to screen employees as they return to work. We believe that increasing availability of at-home testing solutions in general will help to alleviate congestion at health care facilities, reduce contribution to more community spread, and offer individuals who are unable to leave their homes a safer and more convenient testing solution," further commented Perthuis. "Since launching our RT-PCR Test (non at-home test) several months ago, we have won several strategic accounts and are processing thousands of tests daily with an average turnaround time of 24 hours from receipt of sample. This at-home COVID-19 test will diversify our go-to-market approach for tests by utilizing our existing consumer-initiated genetic testing platform."

Fulgent Genetics' at-home test service for COVID-19 has been granted an EUA by the FDA only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

Individuals interested in determining their eligibility for at-home test services from Fulgent Genetics can find more information on the Picture Genetics website at www.picturegenetics.com/covid19.

About Fulgent Genetics

Fulgent Genetics is a growing technology company with an initial focus on offering comprehensive genetic testing to provide physicians with clinically actionable diagnostic information they can use to improve the quality of patient care. The company has developed a proprietary technology platform that integrates sophisticated data comparison and suppression algorithms, adaptive learning software, advanced genetic diagnostics tools and integrated laboratory processes. This platform allows the company to offer a broad and flexible test menu and continually expand and improve its proprietary genetic reference library, while maintaining accessible pricing, high accuracy and competitive turnaround times. The company believes its current test menu, which includes approximately 18,000 single-gene tests and more than 850 pre-established, multi-gene, disease-specific panels, offers more genes for testing than its competitors in today's market, which enables it to provide expansive options for test customization and clinically actionable results.

About Picture Genetics

Picture Genetics was founded in 2019 as a division of Fulgent Genetics. Picture Genetics offers consumers direct access to Fulgent's advanced genetic testing and analytics capabilities from the ease and comfort of home, at an affordable price point. Picture Genetics provides a holistic approach to at-home genetic screening by including oversight from independent physicians as well as genetic counseling options to complement Fulgent's comprehensive genetic testing analysis. Picture Genetics currently offers multiple tests that provide medically actionable, clinical-level results with professional medical follow-up in one easy process. Visit www.picturegenetics.com for more information.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of forward-looking statements in this press release include statements about, among other things: anticipated timing, availability, test result processing timing, go-to-market-approach, demand for and effectiveness of the company's testing services for COVID-19.

Forward-looking statements are statements other than historical facts and relate to future events or circumstances or the company's future performance, and they are based on management's current assumptions, expectations and beliefs concerning future developments and their potential effect on the company's business. These forward-looking statements are subject to a number of risks and uncertainties, which may cause the forward-looking events and circumstances described in this press release to not occur, and actual results to differ materially and adversely from those described in or implied by the forward-looking statements. These risks and uncertainties include, among others: the market potential for, and the rate and degree of market adoption of, the company's tests and genetic testing generally; the company's ability to maintain the low internal costs of its business model; the company's ability to maintain an acceptable margin on sales of its tests, particularly in light of increasing competitive pressures and other factors that may continue to reduce the company's sale prices for and margins on its tests; risks related to volatility in the company's results, which can fluctuate significantly from period to period; the company's investments in its infrastructure, including its sales organization and operational capabilities, and the extent to which these investments impact the company's business and performance and enable it to manage any growth it may experience in future periods; the company's level of success in obtaining coverage and adequate reimbursement and collectability levels from third-party payors for its tests; the company's level of success in establishing and obtaining the intended benefits from partnerships, joint ventures or other relationships; the company's compliance with the various evolving and complex laws and regulations applicable to its business and its industry; risks associated with the company's international operations; the company's ability to protect its proprietary technology platform; and general industry, economic, political and market conditions. As a result of these risks and uncertainties, forward-looking statements should not be relied on or viewed as predictions of future events.

The forward-looking statements made in this press release speak only as of the date of this press release, and the company assumes no obligation to update publicly any such forward-looking statements to reflect actual results or to changes in expectations, except as otherwise required by law.

The company's reports filed with the Securities and Exchange Commission, including its annual report on Form 10-Q for the quarter ended March 31, 2020 as filed with the SEC on May 6, 2020 and the other reports it files from time to time, including subsequently filed quarterly and current reports, are made available on the company's website upon their filing with the Securities and Exchange Commission. These reports contain more information about the company, its business and the risks affecting its business.

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