GenMark Diagnostics Announces Submission of Emergency Use Authorization for its eSensor® SARS-CoV-2 Test

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Leveraging GenMark's eSensor XT-8® platform to expand COVID-19 diagnostic testing capacity

CARLSBAD, Calif., Aug. 17, 2020 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ: GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, announced that it has notified the U.S. Food and Drug Administration (FDA) of the intent to commercially distribute the eSensor® SARS-CoV-2 Test for clinical use. The company has also submitted an Emergency Use Authorization (EUA) to the FDA for its eSensor® SARS-CoV-2 Test.

The eSensor SARS-CoV-2 test utilizes the design principles of GenMark's eSensor Respiratory Viral Panel (RVP), which has been recognized as one of the most sensitive RVP assays available[1]. The eSensor SARS-CoV-2 Test consists of PCR amplification and detection reagents and eSensor SARS-CoV-2 test cartridges which run on GenMark's XT-8 System. The XT-8 is GenMark's legacy multiplex molecular diagnostic system.

"We developed this product and submitted the EUA to leverage our available eSensor test capacity and XT-8 installed base to further help with addressing COVID-19 testing demands," said Scott Mendel, President and CEO of GenMark. "The COVID-19 testing approach for some institutions is better aligned to large batch-based testing for which the eSensor XT-8 workflow is well suited. This provides our over 100 customers still using the eSensor XT-8 system an opportunity to expand their COVID-19 testing capabilities."

The eSensor SARS-CoV-2 Test can provide results for 96 samples in 5 hours. Core labs in the hospital and reference labs have the expertise, equipment and workflow to accommodate 96-well plate processing of clinical specimens and with four batched runs can process 384 specimens per day.

Upon completion of the FDA notification process, GenMark's eSensor SARS-CoV-2 Test is commercially available while under EUA review by the FDA. GenMark earlier this year announced the launch of its ePlex® SARS-CoV-2 Test and the ePlex® Respiratory Pathogen Panel 2 (RP2), which detects 21 pathogens, including SARS-CoV-2, both of which run on the Company's sample-to-answer ePlex System.

About Emergency Use Authorization Status
The GenMark eSensor SARS-CoV-2 Test will be made available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of *in vitro* diagnostics (IVDs) under EUA for the detection and/or diagnosis of COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA cleared IVD. However, based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of COVID-19. The EUA for this test is in effect for the duration of the COVID-19 emergency, unless terminated or revoked (after which the test may no longer be used). An FDA cleared IVD should be used instead of an IVD under EUA, when applicable and available.

About GenMark Diagnostics
GenMark Diagnostics (NASDAQ: GNMK) is a leading provider of multiplex molecular diagnostic solutions designed to enhance patient care, improve key quality metrics, and reduce the total cost-of-care. Utilizing GenMark's proprietary eSensor® detection technology, GenMark's XT-8® and ePlex® systems are designed to support a broad range of molecular diagnostic tests with compact, easy-to-use workstations and self-contained, disposable test cartridges. GenMark's ePlex System: The True Sample-to-Answer Solution™ is designed to optimize laboratory efficiency and address a broad range of infectious disease testing needs, including respiratory, bloodstream and gastrointestinal infections. For more information, visit www.genmarkdx.com.

Forward-Looking Statements
This press release includes forward-looking statements regarding events, trends and business prospects, which may affect our future operating results and financial position. Such statements are subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Some of these risks and uncertainties include, but are not limited to, our ability to successfully obtain full IVD clearance of our ePlex and XT-8 EUA tests from the FDA and demonstrate their clinical performance and utility, the continued progression of the associated public health emergency and associated diagnostic testing demand, our ability to satisfy the supply demands of our customers, and other risks and uncertainties described under the "Risk Factors" in our public filings with the Securities and Exchange Commission. We assume no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made.

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[1] Popowitch, E.B, O'Neill, S.S., Miller, M.B. Comparison of Four Multiplex Assays for the Detection of Respiratory Viruses: Biofire FilmArray RP, GenMark eSensor RVP, Luminex xTAG RVPv1 and Luminex xTAG RVP FAST. J. Clin. Microbiol. 13 March 2013, doi: 10.1128/JCM.03368-12.

Source: GenMark Diagnostics, Inc.