GenMark Receives FDA Emergency Use Authorization for its ePlex® SARS-CoV-2 Test

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COVID-19 diagnosis in under two hours now available globally in hospitals on company's ePlex System

Unique sample-to-answer capability enables near patient testing for the most critical patient populations

CARLSBAD, Calif., March 19, 2020 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced that the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for the company's ePlex SARS-CoV-2 Test.

GenMark's test was developed for the qualitative detection of SARS-CoV-2 virus in nasopharyngeal swab samples for patients suspected of COVID-19 by their health care provider. Rapid and easy detection of SARS-CoV-2 is becoming increasingly critical and customers are adopting the ePlex test based on the workflow and ease-of use to address this urgent need. The test is exclusively for use on the company's ePlex system, which had a global installed base of more than 500 analyzers as of December 31, 2019. The ePlex sample-to-answer system provides an automated solution to the diagnostic process and provides results in under two hours with the capacity to process up to 96 tests per 8-hour shift. The ePlex system's modular and expandable design enables near-patient COVID-19 testing to be widely accessible to meet the needs of various types of laboratories, from small decentralized sites, to large central hospitals and laboratories.

"Because ePlex enables near-patient testing and is available in hospitals and labs across the United States and in more than 30 countries, results can be returned to doctors and patients more rapidly than with other platforms. Our unique ability to quickly diagnose and begin treatment of critically ill patients addresses the challenges associated with the coronavirus pandemic. We are proud of our team's ability to rapidly respond to this urgent public health crisis," said Scott Mendel, Interim Chief Executive Officer. "The FDA's Emergency Use Authorization of our test supports GenMark's commitment to provide critical and actionable diagnostic information to healthcare providers so that they can better manage their patients."

Initial customer validations of the ePlex® SARS-CoV-2 (RUO) Test were met with positive laboratory customer feedback, including from both existing customers and new sites. GenMark is one of the first companies to commercialize a rapid sample-to-answer test to help meet the critical testing need during this public health crisis and has provided nearly ten thousand tests to customers since the beginning of March.

"GenMark reached out to us several weeks ago to ask for our help to run the first patient samples on their RUO ePlex SARS-CoV-2 Test," said David T. Pride, MD, PhD, director of the Clinical Molecular Microbiology Laboratory and associate director of the Microbiology Laboratory at UC San Diego Health. "We completed the validation and were the first lab in the U.S. to go live with the ePlex test."

GenMark is continuing to invest in additional manufacturing capacity with current capability to supply approximately 100,000 ePlex tests per month to support near patient testing. "Demand for our tests has been extraordinary, especially as centralized testing supply has been limited. Our team is working 24/7 to fight this global pandemic and we are taking every step possible to continue this pace, including consulting with local, state, and federal agencies. The COVID-19 outbreak highlights the value of rapid, near-patient multiplex molecular diagnostics to the global healthcare ecosystem that enables better patient triage, bed management, and patient care decisions," concluded Mendel.

About ePlex SARS-CoV-2 Test
The ePlex SARS-CoV-2 Test can be used to test nasopharyngeal swab (NPS) specimens. The ePlex SARS-CoV-2 Test should be ordered for the qualitative detection of SARS-CoV-2 in individuals suspected of COVID-19 by their health provider. The ePlex SARS-CoV-2 Test is authorized for use in qualified laboratories designated by CDC and in the U.S., certified under CLIA to perform high complexity tests. A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 (formerly 2019-nCoV) was detected, and the patient is presumptively infected with COVID-19 and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines. All laboratories using this test must follow the standard confirmatory testing and reporting guidelines according to their appropriate public health authorities. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. A negative test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities.

About Emergency Use Authorization Status
The GenMark ePlex SARS-CoV-2 Test has been 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 approved or 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 approved or 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 eSensor 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: 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 SARS-CoV-2 Test from the FDA and demonstrate its clinical performance and utility, the continued progression of the associated public health emergency, 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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