GenMark Diagnostics Chosen as Primary Provider of Rapid Diagnostic Testing for Vidant Health

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Largest health system in eastern North Carolina turns to ePlex® platform for fast results on SARS-CoV-2, respiratory and blood stream infections

CARLSBAD, Calif., June 16, 2020 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, has been selected by Vidant Health as its primary provider of rapid diagnostic testing. Vidant is deploying GenMark's ePlex® system across all nine of its hospitals to test for SARS-CoV-2 and other respiratory pathogens, as well as blood stream infections.

The largest health system in eastern North Carolina, Vidant Health, is using GenMark's ePlex SARS-CoV-2 Test – one of the first rapid diagnostic tests for the virus that causes COVID-19 – and will transition to the ePlex Respiratory Pathogen 2 (RP2) Panel once GenMark has submitted the application for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA). The ePlex RP2 Panel is designed to test for SARS-CoV-2 in addition to other common and often serious respiratory pathogens, including influenza, pneumonia, rhinovirus and respiratory syncytial virus (RSV). GenMark's ePlex system provides results in less than two hours for the full suite of ePlex Panels. In addition to using the ePlex RP2 Panel, Vidant Health will also begin using all three of the ePlex® Blood Culture Identification (BCID) panels, which provide the broadest coverage of organisms that can lead to sepsis, along with their resistance genes.

"GenMark's platform is a game-changer, providing us with reliable, high-tech rapid testing at all of our hospitals, from our 974-bed medical center to our 16-bed facilities," said David Harlow, vice president of operations for Vidant Health. "SARS-CoV-2 has changed the way we think about diagnostic testing, particularly as a system with many smaller, rural hospitals. Looking ahead, the ePlex RP2 Panel will help us enormously to rapidly and effectively triage patients to ensure those that are critically ill are quickly moved to our Medical Center if needed, while other patients can be treated closer to home. This will be especially important when the flu, various coronaviruses and other common respiratory pathogens are circulating this fall."

Harlow noted that the ability to get diagnostic test results in near real-time helps providers across all Vidant's facilities quickly determine if they have the capacity to treat ill patients based on their diagnoses, or need to transport them to their larger facilities for care. It also will help them determine which patients can safely proceed with surgery.

"Vidant Health understands that the ability to rapidly test their patients for a variety of respiratory pathogens with syndromic testing is vital to providing high-quality care to their patients and preventing their facilities from becoming overwhelmed," said Scott Mendel, President and CEO of GenMark. "With the onset of the pandemic, this type of testing – for a wide range of pathogens with a single test – has become critical for population and resource management. It's the future of diagnostic testing."

Vidant Medical Center in Greenville is the 21st largest hospital in the country, and the system serves 1.4 million people across 29 counties.

"We're thrilled to partner with GenMark and have been impressed with their service. We've been dealing with a lot of uncertainty across the healthcare industry as a result of the pandemic, but working with GenMark we've been able to get concrete answers about what they could deliver and when, with no ambiguity and no overpromising," said Harlow. "It's given us great peace of mind to be able to plan ahead and not have to wonder if we'll be able to get tests when we need them. We already know GenMark will have them for us."

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.

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.

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 EUA from the FDA for our ePlex RP2 Panel and demonstrate its clinical performance and utility, the continued progression of the associated public health emergency and the FDA's maintenance of the EUA program for tests which are designed to detect SARS-CoV-2, 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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