GenMark Diagnostics Announces Commercial Launch of its ePlex® Respiratory Pathogen Panel 2 (RP2)

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Updated test provides rapid results for SARS-CoV-2 and other important respiratory pathogens and a simplified workflow

CARLSBAD, Calif., June 29, 2020 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, announced that its ePlex® Respiratory Pathogen 2 (RP2) Panel is now available for U.S. commercial distribution and clinical use. The ePlex RP2 Panel is one of the first rapid-result multiplex panel tests that can identify 21 pathogens, including SARS-CoV-2, to be made available for clinical use. The company also submitted an Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration for the ePlex® Respiratory Pathogen 2 (RP2) Panel earlier this month.

The ePlex RP2 Panel is designed to provide results for SARS-CoV-2 – the virus that causes COVID-19 – in addition to a number of other common respiratory pathogens, including influenza, adenovirus, rhinovirus and respiratory syncytial virus (RSV), in under two hours. The panel also includes a new, simplified workflow making it even easier for labs to run the test. The ability to quickly determine the cause of infections will be vital in the fall and winter when many of these respiratory pathogens are likely to be circulating, along with SARS-CoV-2.

Incorporating the SARS-CoV-2 assay into the existing ePlex RP Panel is intended to streamline the diagnostic process for hospitals by allowing them to check for multiple pathogens with a single test, saving time and resources and improving bed management. A study at two acute large tertiary care hospitals demonstrated that using the ePlex RP panel in the Emergency Department led to earlier patient results which resulted in an 8.4% reduction in hospital admissions.[1]

“The ePlex RP2 Panel is designed to enable clinicians to quickly determine the cause of infection and the best course of treatment. This is especially vital for individuals who are vulnerable, such as the elderly, people with compromised immune systems, and children, and therefore at increased risk for the new coronavirus and other common and often serious respiratory illnesses,” said Scott Mendel, President and CEO of GenMark. “One recent study highlighted that about 20% of COVID-19 patients are also infected with other respiratory pathogens.[2] Syndromic panels that provide broad coverage of viruses and bacteria from one patient sample will be critical this flu season, which is expected to coincide with continued SARS-CoV-2 infections.”

Incorporating the SARS-CoV-2 test into the existing ePlex RP Panel is expected to improve GenMark’s manufacturing efficiency and output and increase the number of respiratory panels (including COVID-19 tests) the company can supply. GenMark continues to invest in manufacturing capacity improvements to scale and meet future testing demand.

The ePlex RP2 Panel is designed for use with the company’s ePlex system, which has been cleared by the FDA for use with the ePlex Respiratory Pathogen (RP) Panel and Blood Culture Identification (BCID) Panels (Gram-positive, Gram-negative and Fungal pathogens). In March, GenMark received EUA for its ePlex SARS-CoV-2 Test. Certified by the FDA under the Clinical Laboratory Improvement Amendments (CLIA) as moderately complex, the ePlex system is easy to operate and can be used in a wide variety of hospital and reference lab settings.

The ePlex RP2 Panel has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00022. Visit https://www.genmarkdx.com/solutions/panels/eplex-panels/respiratory-pathogen-panel/ to learn more about the ePlex RP2 Panel.

About Emergency Use Authorization Status

The GenMark ePlex RP2 Panel 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 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 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. Weiss, Z.F., et. al. Opportunities Revealed for Antimicrobial Stewardship and Clinical Practice with Implementation of a Rapid Respiratory Multiplex Assay. J Clin Micro. 2019; 57(10):e00861-19.
2. Kim, D., et. al. Rates of Co-Infection Between SARS-CoV-2 and Other Respiratory Pathogens. JAMA. 2020; 323(20):2085-2086.

Source: GenMark Diagnostics, Inc.