GenMark Diagnostics' ePlex® Respiratory Pathogen Panel 2 (RP2) Receives EUA from FDA

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Combination test for COVID-19, flu and other common respiratory illnesses helps health care professionals prepare for flu season

RP2 Panel at a Glance

- GenMark's ePlex ® Respiratory Pathogen Panel 2 (RP2 Panel) has received Emergency Use Authorization from the FDA.
- The RP2 Panel provides results in less than two hours for more than 20 viruses and bacteria that cause common respiratory infections with similar symptoms, including COVID-19, flu, bronchitis and the common cold.
- The rapid, multiplex molecular testing offered by the RP2 Panel will be vital in preparing for the fall and winter, when COVID-19 will be circulating along with flu and other common respiratory infections, helping doctors quickly and effectively treat seriously ill patients.

CARLSBAD, Calif., Oct. 08, 2020 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ: GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration for its ePlex® Respiratory Pathogen Panel 2 (RP2). In less than two hours, the test provides results for more than 20 viruses and bacteria that cause common and often serious respiratory infections, including COVID-19, flu, bronchitis and the common cold.

A multiplex – or syndromic – test, the RP2 Panel provides rapid results for infections with similar symptoms such as fever, cough and body aches, which will be essential in preparing for fall and winter as the flu season coincides with the ongoing risk of COVID-19.

"COVID-19 is placing a spotlight on the importance of fast, comprehensive molecular testing," said Scott Mendel, President and CEO of GenMark. "While we can't predict what cold and flu season is going to look like this year, we know that we have to arm healthcare providers with the necessary tools to quickly and accurately diagnose the cause of infections in seriously ill patients, so syndromic testing is going to be critical."

Some COVID-19 patients are infected with more than one pathogen, known as coinfection, making accurate identification of the cause of infection even more important. Further, sepsis – a life-threatening response to infection – can be a complication for hospitalized COVID-19 patients, and many receive antibiotics inappropriately.[1] Rapid molecular tests help address the double burden of infections by quickly identifying or ruling out the responsible pathogen or pathogens to enable proper treatment, minimizing unnecessary use of antibiotics, which can save lives and reduce antibiotic resistance.

A small rural hospital west of Dallas, Graham Regional Medical Center, began using RP2 as the COVID-19 surge hit in mid-July. "RP2 provides our hospital with incredible peace of mind and value in helping us serve our patients, which includes a large geriatric patient population that is at increased risk for COVID-19. Since implementing RP2, we went from a seven-to-10-day turnaround time, to getting results in under two hours," said Teri Robertson, BSMT, laboratory director at the hospital in Graham, Texas. "The multiplex test not only benefits patients, but it helps with resource management, in particular, for our staff. One of our nurses recently spiked a fever and we tested her using RP2 and sent her home. Within two hours, the test result indicated she was negative for COVID-19 but positive for rhinovirus (the common cold), so she was able to come back to work as soon as she recovered. A negative result for COVID-19 alone would not have given us the confidence to bring her back to work without knowing the cause of her fever. This is critical to helping us ensure we have staff available to treat patients during the pandemic."

The RP2 Panel includes a new, simplified workflow making it even easier for labs to run the test. Incorporating COVID-19 into the existing ePlex Respiratory Pathogen (RP) Panel streamlines 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.[2]

The ePlex RP2 Panel is also approved as a tool for clinical diagnosis in the European market, having announced CE Mark achievement on Sept. 8, 2020 under the European In-Vitro Diagnostic Devices Directive (98/79/EC).

The ePlex RP2 Panel is designed for use with the company's ePlex system, along with the ePlex RP Panel and Blood Culture Identification (BCID) Panels (gram-positive, gram-negative and fungal pathogens), all of which have been cleared by the FDA and achieved CE Mark. 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 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] Zhou F, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. The Lancet. 2020; 395:1054-62.

[2] 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.

Source: GenMark Diagnostics, Inc.