GenMark Diagnostics' ePlex® Respiratory Pathogen Panel 2 (RP2) achieves CE Mark

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Molecular syndromic test for COVID-19, influenza and other common respiratory pathogens helps health care professionals prepare for flu season

RP2 Panel at a Glance

- GenMark's ePlex® Respiratory Pathogen Panel 2 (RP2) has achieved CE mark.
- RP2 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, influenza A and B, respiratory syncytial virus (RSV) and rhinovirus.
- The rapid, multiplex molecular testing offered by RP2 will be vital this fall and winter, when COVID-19 coincides with flu and other common respiratory infections, helping doctors quickly diagnose and effectively treat seriously ill patients.

CARLSBAD, Calif., Sept. 14, 2020 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ: GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced that it has achieved CE Mark under the European In-Vitro Diagnostic Devices Directive (98/79/EC) for its ePlex® Respiratory Pathogen Panel 2 (RP2). The molecular test provides results in less than two hours for more than 20 viruses and bacteria that cause common and often serious respiratory infections, including COVID-19, influenza A and B, respiratory syncytial virus (RSV) and rhinovirus. This panel was previously made commercially available in the U.S. and is awaiting Emergency Use Authorization by the FDA.

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

"Fast and comprehensive molecular testing has become even more essential since the arrival of COVID-19," said Scott Mendel, President and CEO of GenMark. "Cold and flu season is right around the corner and while we can't predict what it will be like, healthcare systems and providers must be prepared. Syndromic testing will be vital in helping health care professionals accurately diagnose seriously ill patients with similar symptoms, speeding up treatment and helping improve resource management."

After the 2016-2017 winter flu and virus season, York Teaching Hospitals in in the United Kingdom (including a 700-bed hospital in York and a 300-bed hospital in Scarborough) switched to in-hospital multiplex testing with GenMark's ePlex system. Offsite syndromic testing during the flu season resulted in slow turnaround time and negatively affected bed management, so the benefits of the GenMark RP panel were huge, leading to 9,111 bed days saved the first year (2017-2018) and 13,971 bed days the second year (2018-2019) compared to 2016-2017.[1]

"Getting the results in hours rather than days was a massive improvement and totally revolutionized the way our emergency department works," said Lisa Mead, Head Biomedical Scientist (Acting), York Teaching Hospitals. "When flu season begins this year, we plan to stay ahead of the curve by running GenMark's RP2 test on all patients who are admitted. We are confident that being able to test patients for a wide variety of viruses will make a significant difference in helping us quickly and most effectively manage patients during what is sure to be a challenging flu season now that coronavirus is in the mix."

RP2 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 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 achieved CE Mark.

The ePlex RP2 Panel has been funded in part with federal funds from the United States 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 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 demonstrate the clinical performance and utility of our ePlex RP2 Panel, 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.

Public Relations Contact
Lauren Martin
(815) 592-6296
lmartin@pcipr.com

Investor Relations Contact
Leigh Salvo
(415) 937-5404
ir@genmarkdx.com

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[1] Neish, B, et al. The Clinical Impact of Rapid Winter Respiratory Virus (WRV) Testing in the U.K., The Institute of Biomedical Science Congress 2019.

[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.