FilmArray® Respiratory Panel EZ is CLIA waived by the FDA

Marcy l'Etoile, France - October 11, 2016 – bioMérieux, a world leader in the field of *in vitro* diagnostics, announced that BioFire Diagnostics, LLC, its molecular biology affiliate, received U.S. Food and Drug Administration (FDA) 510(k) clearance and Clinical Laboratory Improvement Amendments (CLIA) waiver for the FilmArray® Respiratory Panel EZ (RP EZ). CLIA waiver permits use of the test outside traditional clinical laboratories in sites such as physician offices and urgent care centers. FilmArray® RP EZ detects 11 viral and 3 bacterial pathogens associated with respiratory infections from a single patient sample and is a simplified version of the CE-IVD, FDA-cleared FilmArray® Respiratory Panel (RP). The FilmArray® RP EZ is designed to run on a single computer/instrument configuration (EZ Configuration) of the FilmArray® 2.0 system. The EZ Configuration provides a simplified user interface and results report.

"The CLIA waiver will make the high medical value associated with FilmArray® even more accessible" said Randy Rasmussen, CEO of BioFire Diagnostics and VP Molecular Biology at bioMérieux. "Syndromic testing is becoming a standard of care for respiratory infections in hospital laboratories. Further decentralization of the FilmArray® across provider networks moves the benefits of syndromic testing nearer to the patient."

FilmArray® RP EZ clinical trials were supported by the U.S. Department of Defense Chemical and Biological Defense program through the Defense Threat Reduction Agency (DTRA). Trial sites included primary care, pediatric, community, and family practice clinics. A mix of adult and pediatric subjects with signs or symptoms of respiratory infection were eligible to participate in the study. Operators in the CLIA-waived setting, comprised primarily of nurses and medical assistants, achieved highly accurate results with overall 96.8% positive agreement and 99.5% negative agreement with an FDA-cleared molecular comparative method.

FilmArray® RP EZ will be available on the U.S. market only, BioFire anticipates commercial launch in November 2016.

ABOUT FILMARRAY®

FilmArray® is a multiplex PCR system that integrates sample preparation, amplification, and detection into one closed system. The FilmArray® requires only two minutes of hands-on time and has a total run time of about an hour.
The FilmArray® menu is composed of:

- FilmArray® Respiratory Panel, a comprehensive panel of 20 respiratory viruses and bacteria performed directly on nasopharyngeal swab-associated viral transport media.
- FilmArray® BCID Panel, capable of identifying 27 of the most common causes of bloodstream infections and antimicrobial resistance directly from positive blood culture.
- FilmArray® GI Panel, for identification of 22 of the most common causes of infectious diarrhea directly from stool in Cary Blair transport media.
- FilmArray® ME Panel, identifying 14 bacterial, viral, and fungal causes of meningitis and encephalitis directly from cerebrospinal fluid.

At the end of June 2016, the number of FilmArray® units installed globally reached about 3,000.

PRESS RELEASE

ABOUT BIOMERIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for 50 years, bioMérieux is present in more than 150 countries through 42 subsidiaries and a large network of distributors. In 2015, bioMérieux's revenues reached €1,965 million with 90% of sales outside of France.

bioMérieux provides diagnostic solutions (reagents, instruments, software) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are used for diagnosing infectious diseases and providing high medical value results for cancer screening and monitoring and cardiovascular emergencies. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

bioMérieux is listed on the Euronext Paris market (Symbol: BIM – ISIN: FR0010096479).
Corporate website: www.biomerieux.com
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