bioMérieux receives FDA Clearance for BioFire's FilmArray® Respiratory Panel 2 (RP2)

The FilmArray® RP2 reduces sample-to-result time to only 45 minutes while enhancing pathogen coverage and overall sensitivity

Marcy l'Étoile, France - June 1, 2017 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that BioFire Diagnostics, its molecular biology affiliate, has received 510(k) clearance from the FDA for the FilmArray® Respiratory Panel 2 (RP2). The FilmArray® RP2 tests for 21 pathogens (17 viruses and 4 bacteria) responsible for respiratory tract infections and will be commercially available by mid-June 2017. This follows the announcement in April that the FilmArray® Respiratory Panel 2 *plus* (RP2*plus*) is CE marked. The FilmArray® RP2*plus* contains one more pathogen than FilmArray® RP2 - the Middle East Respiratory Syndrome coronavirus (MERS-CoV). The FilmArray® RP2*plus* has been submitted as a *de novo* application to the US FDA.

The FilmArray® RP2 advances the existing FilmArray® Respiratory Panel (RP) by reducing the assay time from about an hour to less than 45 minutes, while also improving overall sensitivity and enhancing several assays. FilmArray® RP2 also includes an additional pathogen, *Bordetella parapertussis*. *B. parapertussis* represents a significant cause of whooping cough and is often missed because of a clinical presentation largely indistinguishable from other viral infections and a lack of reliable diagnostic tests.

Randy Rasmussen, bioMérieux Corporate Vice President of Molecular Biology and CEO of BioFire Diagnostics, said: "*A growing body of evidence strongly supports the added medical value of rapid syndromic infectious disease testing enabled by BioFire's market leading technology. Reducing the turnaround time of FilmArray® Respiratory Panel 2 demonstrates bioMérieux's continued commitment to empower FilmArray® users to better serve patients and improve outcomes.*"

Judy Daly, Ph.D., Professor of Pathology at the University of Utah and Director of Microbiology Laboratories at Primary Children's Medical Center in Salt Lake City, Utah was the principal investigator at one site for the FDA clinical studies of FilmArray® RP2. Dr. Daly states: "*The FilmArray® Respiratory Panel 2 assay is robust, simple-to-use, and provides rapid detection of 21 respiratory pathogens in about 45 minutes. In our experience, the FilmArray® RP2 enables us to provide faster, more accurate, and more comprehensive results and helps improve detection of respiratory pathogens and clinical actionability*".

The FilmArray® RP2 is compatible for use on the FilmArray® 2.0 and FilmArray® Torch systems. The Company plans to continue to make the current FilmArray® RP panel commercially available.

PRESS RELEASE

About the FilmArray® System:

The FilmArray® System is an FDA-cleared and CE-marked multiplex PCR system that integrates sample preparation, amplification, and detection into one closed system. The FilmArray® System requires only two minutes of hands-on time and has a total run time of about 45 to 65 minutes, depending on the panel. The FilmArray® System has the largest infectious disease pathogen menu commercially available composed of:

- FilmArray® Respiratory Panel, a comprehensive panel of 20 respiratory viruses and bacteria performed directly on nasopharyngeal swabs in viral transport media.
- FilmArray® Respiratory Panel 2 (RP2), a comprehensive panel of 21 respiratory viruses and bacteria performed directly on nasopharyngeal swab-associated transport media.
- FilmArray® Respiratory Panel 2 *plus* (RP2*plus*), currently CE-marked and under review with the US FDA, a comprehensive panel of 22 respiratory viruses and bacteria performed directly on nasopharyngeal swab-associated transport media.
- FilmArray® RP EZ for the detection of 11 viral and 3 bacterial pathogens associated with respiratory infections. FDA cleared and CLIA-waived for use in the US only.
- FilmArray® Blood Culture Identification (BCID) Panel, capable of identifying 27 of the most common causes of bloodstream infections and associated antimicrobial resistance directly from positive blood culture.
- FilmArray® Gastrointestinal (GI) Panel, for identification of 22 of the most common viral, bacterial and parasitic causes of infectious diarrhea directly from stool in Cary Blair transport media.
- FilmArray® Meningitis/Encephalitis (ME) Panel, identifying 14 bacterial, viral, and fungal causes of meningitis and encephalitis directly from cerebrospinal fluid.

As of March 31, 2017, the number of FilmArray® Systems installed globally reached about 4,500 units.

About bioMérieux

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for more than 50 years, bioMérieux is present in more than 150 countries through 42 subsidiaries and a large network of distributors. In 2016, revenues reached €2,103 million, with more than 90% of international sales.

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 mainly used for diagnosing infectious diseases. 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 / www.biofiredx.com
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