



**BioFire Diagnostics receives a *de novo* clearance by the FDA for the FilmArray<sup>®</sup> Meningitis/Encephalitis panel continuing its extremely favorable business momentum**

***FilmArray<sup>®</sup> expanded menu, with a fourth panel, is the largest available on a molecular biology multiplex platform***

**Marcy l'Étoile, France** – October 9, 2015 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced, as issued in a press release by the U.S. Food and Drug Administration (FDA) yesterday, that BioFire Diagnostics, its molecular biology affiliate, has received a *de novo* clearance from the FDA for the FilmArray<sup>®</sup> Meningitis/Encephalitis (ME) Panel. With its unique and highly beneficial medical value, this panel is the first to address the critical unmet need for quick and accurate identification of central nervous system infectious agents by utilizing a comprehensive panel to test cerebrospinal fluid (CSF) for the 14 most common pathogens (6 bacteria, 7 viruses and 1 yeast) responsible for community acquired meningitis or encephalitis in about an hour. Currently, testing CSF for multiple organisms is not always possible because it can be difficult to obtain enough fluid from each patient to run multiple tests.

This clearance occurs in the very favorable context of the adoption of FilmArray<sup>®</sup> by clinical laboratories. At the end of June 2015, the installed base of FilmArray<sup>®</sup> systems reached 1,900 instruments and sales more than doubled year-on-year.

"BioFire's ME Panel has the potential to significantly impact patient treatment for cases of suspected meningitis," states Rodrigo Hasbun MD, MPH, Associate Professor of Medicine at the University of Texas Medical School in Houston. "In the United States, current diagnostics are underutilized and not available in a timely manner to alter the empirical treatment for the majority of patients, especially for those who may have viral meningitis and do not benefit from antibiotics."

Randy Rasmussen, bioMérieux Corporate Vice President of Molecular Biology and CEO of BioFire Diagnostics, adds: "The ME Panel highlights the clinical impact the FilmArray<sup>®</sup> brings to infectious disease testing. It quickly and efficiently provides physicians complex diagnostic information, helping them to rapidly diagnose severe infections." Rasmussen continues, "the FilmArray<sup>®</sup> ME Panel further solidifies our leadership in syndromic infectious disease testing with now four IVD panels launched in four years."

More than 1.2 million people every year are affected by meningitis worldwide, resulting in 120,000 deaths globally from the bacterial meningitis form. Bacterial meningitis can occur suddenly in healthy people and even with prompt diagnosis and treatment, approximately 10% of patients may die and up to 20% may sustain permanent damage and disability<sup>1</sup>.

The ME Panel is cleared for the FilmArray<sup>®</sup> and FilmArray<sup>®</sup> 2.0 systems and will be commercially available in the U.S. next month, followed by CE-marking shortly after.

PRESS RELEASE

<sup>1</sup> <http://www.comomeningitis.org/facts-about-meningitis/> ; accessed July 21, 2015

**About FilmArray®:**

FilmArray® is a FDA-cleared and CE-marked multiplex PCR molecular biology system that is easy to use, accurate and rapid. FilmArray® has the largest infectious disease pathogen menu commercially available: it currently comprises 3 other panels – upper respiratory, blood culture identification and gastrointestinal – all of which are FDA-cleared and CE-marked.

**About bioMérieux*****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 2014, revenues reached €1,698 million with 88% 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 NYSE Euronext Paris stock market (Symbol: BIM – ISIN: FR0010096479).

Corporate website: [www.biomerieux.com](http://www.biomerieux.com) - Investors website: [www.biomerieux-finance.com](http://www.biomerieux-finance.com)

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