



BioFire's FilmArray® Meningitis/Encephalitis Panel gets CE marked

FilmArray® expanded menu, with a fourth panel, is the largest available on a molecular biology multiplex platform

Marcy l'Étoile, France – January 26, 2016 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced the availability of BioFire Diagnostics' FilmArray® Meningitis/Encephalitis (ME) Panel in the countries which recognize CE marking. The ME Panel provides unique and highly beneficial medical value, as it addresses the critical unmet need for quick and accurate identification of central nervous system (CNS) infectious agents. The comprehensive ME Panel tests 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 can take days and is not always possible because it can be difficult to obtain enough fluid from each patient to run multiple tests.

The ME Panel received a *de novo* clearance by the U.S. Food and Drug Administration (FDA) in October 2015.

"In Europe, the ME Panel brings a unique opportunity to test simultaneously and rapidly for most bacteria, viruses and fungi found in those pathologies that can be extremely severe and sometimes lethal," states François Simon, MD, Head, Department of Virology, Bacteriology and Hygiene at Hospital Saint-Louis - Lariboisière - Fernand Widal, Paris, France. *"Such an approach will positively impact the management of those patients by helping clinicians and biologists speed the diagnosis of these potentially severe conditions and make much faster decisions on appropriate therapy to prevent complications."*

Randy Rasmussen, bioMérieux Corporate Vice President of Molecular Biology and CEO of BioFire Diagnostics, adds: *"The FilmArray® ME Panel revolutionizes infectious disease testing for CNS infections and patient care. Time is critical for treating these severe diseases and within about an hour FilmArray® provides physicians the complex diagnostic information they need to properly manage their patients."* Rasmussen continues, *"the FilmArray® 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 bacterial meningitis. 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% or more may sustain permanent damage and disability¹.

The ME Panel is cleared for the FilmArray® and FilmArray® 2.0 systems and is commercially available around the globe.

PRESS RELEASE

¹ <http://www.comeningitis.org/facts-about-meningitis/> ; accessed January 22, 2016

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 four panels – upper respiratory, blood culture identification, gastrointestinal and meningitis/encephalitis – all of which are FDA-cleared and CE-marked.

At the end of 2015, the total number of FilmArray® systems installed at customer sites was about 2,500 instruments and sales grew 80% year-on-year demonstrating the rapid adoption of FilmArray® by clinical laboratories.

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 2015, 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 stock market (Symbol: BIM – ISIN: FR0010096479).

Corporate website: www.biomerieux.com - Investors website: www.biomerieux-finance.com

More information on FilmArray® : www.biofiredx.com

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