



## Press Release

### BioFire Receives FDA Clearance for the FilmArray® 2.0 System

*New system delivers higher throughput, single database management and minimized footprint*

**Marcy l'Etoile, France** – February 26, 2015 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that BioFire Diagnostics, LLC, its molecular biology affiliate, received FDA clearance and CE-IVD marking of the FilmArray® 2.0 system. The system is expected to be commercially available by the end of March 2015. This clearance occurs in the very favorable context of the adoption of FilmArray® by clinical laboratories. Since its acquisition, BioFire has reported more than 60% organic growth in sales at December end.

FilmArray® 2.0 features higher throughput, allowing customers random access processing up to 175 samples in a day within a small footprint. FilmArray® 2.0 offers the same strengths of rapidity, ease-of-use, integration and accuracy that characterize the current FilmArray®. Each system accommodates 1 to 8 FilmArray® 2.0 units operated by a single computer. The system is also capable of connecting to Laboratory Information Systems.

“As we develop additional applications for the FilmArray® system, it is essential that customers are able to accommodate high throughput with as small of a footprint as possible,” said Randy Rasmussen, bioMérieux Corporate Vice President of Molecular Biology and CEO of BioFire Diagnostics. “We look forward to introducing the FilmArray® 2.0 system to clinical laboratories throughout the world and are excited for the expected benefits FilmArray®’s syndromic approach will have on the fight against infectious diseases, antibiotic stewardship and more broadly on patient care and healthcare cost reduction.”

FilmArray® is a PCR\* closed-system that integrates all molecular diagnostic steps including sample preparation, amplification, detection and analysis, with only two minutes of hands-on time and has a total run time of about an hour. As of today, the FilmArray® menu includes three FDA-cleared and CE-marked panels: the Respiratory Panel, the Blood Culture Identification Panel and the Gastrointestinal Panel. Additionally, BioFire has initiated studies for its Meningitis-Encephalitis Panel, with FDA submission expected this year.

#### 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 2014, bioMérieux’s 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 market (Symbol: BIM – ISIN: FR0010096479).  
Corporate website: [www.biomerieux.com](http://www.biomerieux.com) Investor website: [www.biomerieux-finance.com](http://www.biomerieux-finance.com)

For further information, please visit [www.BioFireDx.com](http://www.BioFireDx.com)

\* Polymerase Chain Reaction

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