



BioFire Receives FDA Clearance for FilmArray[®] Torch with FilmArray[®] Respiratory Panel and Submits Special 510(k) Applications for Use with additional FilmArray[®] Panels

FilmArray[®] Torch delivers high throughput, radically smaller footprint

Marcy l'Etoile, France - February 25, 2016 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that BioFire Diagnostics, LLC, its molecular biology affiliate, has received Special 510(k)¹ clearance from the U.S. Food and Drug Administration (FDA) to market the FilmArray[®] Torch for use with the FilmArray[®] Respiratory Panel (RP), and has submitted special 510(k) applications for use with additional FilmArray[®] panels which include Blood Culture Identification, Gastrointestinal and Meningitis/Encephalitis Panels. BioFire anticipates commercial availability of FilmArray[®] Torch this summer in the United States and in the second half of 2016 in Europe.

The FilmArray[®] Torch is the latest advancement in syndromic infectious disease testing from BioFire Diagnostics. Providing up to six times more sample throughput compared to the existing system, the high throughput FilmArray[®] Torch is a fully integrated, random and continuous access multiplex PCR² system designed to meet the throughput demands of any size hospital laboratory.

"True to our pioneering spirit, we are leading the industry with the most innovative molecular infectious disease diagnostic solutions," said Randy Rasmussen, CEO of BioFire Diagnostics. *"FDA clearance of the FilmArray[®] Torch with FilmArray[®] Respiratory Panel and FDA submission for use with additional FilmArray[®] panels within two weeks of each other, highlight the strength of our development team and product pipeline."*

FDA clearance authorizes use of the FilmArray[®] Torch with the existing FilmArray[®] RP. The FilmArray[®] RP is a comprehensive panel of 20 respiratory viruses and bacteria that is performed directly on nasopharyngeal swab-associated viral transport media. *"As the clinical and economic benefits of frontline syndromic infectious disease testing for upper respiratory tract infections continues to be demonstrated in hospitals around the world, customers require increased sample throughput – the FilmArray[®] Torch delivers just that,"* added Randy Rasmussen.

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. In 2015, the rapid growth of the revenue and of the installed base reaching about 2,500 instruments, confirmed the success of FilmArray[®] in the molecular syndromic approach of infectious diseases.

¹ The "Special 510(k): Device Modification" utilizes the design control requirement of the Quality System Regulation (21 CFR 820) and may be submitted for a modification to a device that has been cleared under the 510(k) process.

² Polymerase Chain Reaction.

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, 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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For further information, please visit www.biofiredx.com

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