PRESS RELEASE

BioFire Submits Special 510(k) Application to the FDA for the use of FilmArray® Torch, the New High Throughput FilmArray® System with FilmArray® Respiratory Panel

FilmArray® Torch delivers high throughput, radically smaller footprint

Marcy l'Etoile, France - January 12, 2016 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that BioFire Diagnostics, LLC, its molecular biology affiliate, has submitted the FilmArray® Torch to the U.S. Food and Drug Administration (FDA) for special[1] 510(k) clearance for use with the FilmArray® Respiratory Panel (RP).

The FilmArray® Torch is the latest advancement in syndromic infectious disease molecular testing from BioFire Diagnostics. Providing up to six times more sample throughput per square foot of benchtop space, the high throughput FilmArray® Torch is a fully integrated, random and continuous access multiplex PCR[2] system, designed to meet the throughput demands of any size hospital laboratory.

Scalable by design, the 2-module base configured FilmArray® Torch is capable of testing up to 42 patient samples per day, while the 12-module, fully configured FilmArray® Torch is capable of testing up to 262 patient samples per day[3].

With intuitive instrument control, an integrated barcode scanner, touchscreen interface, and FilmArray® Link technology, the FilmArray® Torch delivers an optimized user experience and seamless integration into laboratory information systems.

"*This submission highlights our continued effort to provide our customers with the most innovative molecular infectious disease diagnostic solutions,*" said Randy Rasmussen, CEO of BioFire Diagnostics. "*The FilmArray® Torch delivers the high sample throughput our customers demand without requiring them to sacrifice valuable benchtop space.*"

The 510(k) submission seeks authorized use of the FilmArray® Torch with the existing FilmArray® RP. The FilmArray® RP is a comprehensive panel of 20 respiratory viruses and bacteria in a single test that is performed directly on nasopharyngeal swab-associated viral transport media. "*In only 4 years, the FilmArray® RP has become the standard of care in the diagnosis of upper respiratory tract infections – it has fundamentally changed the way clinicians diagnose patients,*" added Randy Rasmussen.

BioFire announced its intention to seek 510(k) clearance of the FilmArray® Torch for use with all existing FDA-cleared FilmArray® panels in the coming weeks. Additional panels include: the FilmArray® Blood Culture Identification Panel, the FilmArray® Gastrointestinal Panel and the FilmArray® Meningitis/Encephalitis Panel.

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[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.*

[3] *Based on a 24 hour day.*

FilmArray® is a multiplex PCR system that integrates sample preparation, amplification, and pathogen 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. At the end of September 2015, the global FilmArray installed base in clinical labs increased to about 2,000 systems while revenue nearly doubled underscoring the rapid adoption of syndromic infectious disease testing in the U.S..

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 Euronext Paris market (Symbol: BIM – ISIN: FR0010096479).
Corporate website: www.biomerieux.com
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