



bioMérieux receives FDA 510(k) clearance for its BacT/ALERT[®] VIRTUO™ fully automated blood culture system

Marcy l'Étoile (France) - April 6, 2017 — bioMérieux, a major player in the field of in vitro diagnostics, and the world leader in microbiology, announces that BacT/ALERT® VIRTUO™, its fully automated blood culture system, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA). This innovative blood culture microbial detection system is now commercially available in countries that recognize CE marking and in the United States.

BacT/ALERT® VIRTUO™ is the first continuously-monitoring blood culture microbial detection system to offer "Load & Go" technology, helping labs to streamline their workflow. Personnel of all skill levels can easily load bottles on the instrument at any time throughout the day or night, enabling prompt incubation and reducing hands-on time. Bottle unloading is fully automated with visual and audible alarms and alerts.

BacT/ALERT® VIRTUO™ offers powerful proprietary algorithms, high thermal stability and superior optics which enhance blood culture performance for more rapid time to detection. This translates into faster identification of bloodstream infections.

This unrivalled blood culture system further enriches the BacT/ALERT® product line for blood culture. It offers an integrated configuration with scalable incubation capacity from 428 to 1,712 cells and facilitates the management of high volumes of blood cultures.

A unique blood level detection technology measures the blood volume in each blood culture bottle at the time of loading. This feature helps laboratories track and ensure collection of the recommended blood volume in order to be compliant with accreditation and quality guidelines such as CAP¹ standards. This is a significant benefit to patient care, since the blood volume collected is a critical factor in detecting bloodstream infections.

"We are proud to receive this FDA clearance for BacT/ALERT® VIRTUO™, which allows us to enhance our blood culture offer to our U.S. customers", said François Lacoste, Corporate VP, Clinical Unit at bioMérieux. "This highly automated blood culture solution enables faster detection of pathogens by clinical microbiology laboratories, which is of crucial importance for optimal patient treatment, especially in life-threatening conditions such as bloodstream infections which may progress to severe sepsis."

BacT/ALERT[®] VIRTUO™ utilizes the FAN[®] Plus media which are formulated to optimize antibiotic neutralization with optimal growth performance of microorganisms. These proven blood culture bottles are manufactured at bioMérieux's facility in Durham (NC) where the Company recently invested in an additional blood culture bottle production line.

With BacT/ALERT® VIRTUO™, VITEK® and FilmArray®, bioMérieux offers state-of-the-art integrated microbiology solutions that streamline lab workflow and enhance efficiency. These integrated solutions provide faster, reliable and actionable results to clinicians, leading to improved patient care.

¹ College of American Pathologists

About bioMérieux

Pioneering Diagnostics

A world leader in the field of in vitro diagnostics for more than 50 years, bioMérieux is present in more than 150 countries through 42 subsidiaries and a large network of distributors. In 2016, revenues reached €2,103 million, with more than 90% of international sales.

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 mainly used for diagnosing infectious diseases. 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 U.S. website: www.biomerieux-usa.com Investor website: www.biomerieux-finance.com

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