



bioMérieux receives FDA clearance for expanded pathogen identification capability on VITEK® MS

With more than 15,000 distinct strains, VITEK® MS provides the microbiology lab with the most comprehensive Mass Spectrometry database to improve clinical decision-making for infectious diseases

Marcy l'Étoile - July 31, 2017 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that VITEK® MS, its MALDI-TOF¹ Mass Spectrometry System for rapid pathogen identification, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the expanded identification of mycobacteria, *Nocardia* and moulds. This database includes more than 15,000 distinct strains to provide extremely high accuracy and, for the first time, enables the safe identification of the *Mycobacterium tuberculosis* (TB) group, the most frequent non-tuberculous mycobacteria (NTM), *Nocardia* and the most medically important moulds. The VITEK® MS system's newly expanded database and Mycobacterium/*Nocardia* and Moulds reagent kits are now commercially available in the U.S..

Mycobacteria, *Nocardia* and moulds are complex organisms to identify, requiring days or weeks of specific culture conditions for appropriate growth and subsequent advanced methods for reliable identification to the species level. With the newly expanded database, bioMérieux's VITEK® MS system now offers simple, rapid, safe and reliable identification of these medically important pathogens, providing clinicians with actionable results to better manage these infections, such as tuberculosis, lung and bone infections, and other serious organ infections.

To gain new FDA clearance for these new species, bioMérieux submitted data from a multi-center study consisting of 2,695 clinical isolates for 47 moulds, 19 mycobacteria, and 12 *Nocardia*. The FDA clearance of *Mycobacterium* species was from both solid and liquid growth media.

"We are honoured to receive the first 510(k) clearance from the FDA for the identification of mycobacteria, Nocardia and moulds on a MALDI-TOF system and to provide our U.S. customers with additional features for the already well adopted VITEK® MS rapid identification system," said François Lacoste, bioMérieux Corporate VP, Clinical Unit. *"As the world leader in microbiology, one of our priorities is to continuously develop high medical value solutions that enable rapid and accurate detection of important microorganisms, with the ultimate goal of improving patient care."*

VITEK® MS is part of bioMérieux's comprehensive and complementary range of ID/AST solutions for infectious disease diagnostics. Together, VITEK® MS for identification and VITEK® 2 for antimicrobial susceptibility testing provide seamless integration and the flexibility needed to optimize laboratory workflow and support appropriate antimicrobial treatment decisions. The combination of VITEK® MS and VITEK® 2 provides confidence in reporting results with speed and accuracy for routine diagnoses, unusual or resistant organisms, or critical clinical situations.

¹ MALDI-TOF : Matrix Assisted Laser Desorption Ionization – Time Of Flight

In cases where microorganisms are resistant to carbapenems (a very broad spectrum antibiotic class), bioMérieux has also developed and received FDA 510(k) clearance for its RAPIDEC® CARBA NP test that enables the detection of carbapenemase producers within two hours. RAPIDEC® CARBA NP helps health professionals make vital treatment decisions and facilitates implementation of infection prevention and control measures.

These highly complementary solutions help improve antibiotic stewardship in the fight against antimicrobial resistance.

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 (systems, reagents, 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 stock market

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Reuters: BIOX.PA / Bloomberg: BIM.FP

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

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