



bioMérieux Announces U.S. FDA Clearance for VITEK[®] MS, a Revolutionary Technology which Reduces Microbial Identification from Days to Minutes Reinforcing Medical Value of Diagnostics

*New Technology made possible by a Nobel Prize Winning discovery
holds the promise to improve clinical decision-making for infectious diseases*

Marcy L'Etoile (France) and Durham, NC - August 21, 2013 - bioMérieux today announced that it has been granted U.S. FDA 510(k) *de novo* clearance for VITEK[®] MS, the first clinical mass spectrometry MALDI-TOF-based system available in the U.S. for rapid identification of disease-causing bacteria and yeast. VITEK[®] MS is the latest addition to the VITEK[®] family of products, and it is the first system to enable detection of disease causing microorganisms in minutes: this game-changing technology can significantly improve patient care. The Cleveland Clinic recently named the technique as one of the Top Ten Breakthrough Medical Technologies of 2013.

"bioMérieux has a long history of bringing the most innovative technology to the world of microbiology, so as a world leader in clinical microbiology, we are very proud to be the first to introduce mass spectrometry to U.S. clinical laboratories in 2013, as we celebrate the Company's 50th anniversary," said Alexandre Mérieux, Directeur Général Délégué and Vice President, Microbiology Unit. "For half a century, bioMérieux has introduced pioneering diagnostic innovations to the clinical laboratory and VITEK[®] MS is part of our commitment to transform microbiology diagnostics with innovative solutions providing actionable information for improved medical decisions."

"The ability for laboratories to use one device to identify almost 200 different microorganisms is a significant advance in the timely identification of pathogenic microorganisms," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health at FDA's Center for Devices and Radiological Health. "Rapid identification of harmful microorganisms can improve the care of critically ill patients."

To gain FDA clearance bioMérieux submitted data from a multi-center study consisting of 7,068 clinical isolates. VITEK[®] MS accuracy was compared to 16S Ribosomal RNA gene sequencing, the gold standard, for the following categories of microbial pathogens: anaerobic bacteria, *Enterobacteriaceae*, Gram-positive aerobes, fastidious Gram-negative bacteria, Gram-negative non-*Enterobacteriaceae* and yeast. The overall accuracy of VITEK[®] MS compared to nucleic acid sequencing for these organisms was 93.6 percent.

Scientists from these investigation sites praised the new technology and its potential to improve public health:

"In the battle with infectious diseases, time is a luxury we don't have. MALDI-TOF will have one of the greatest impacts on Clinical Microbiology since the use of molecular amplification methods for the identification of pathogens," said Christine C. Ginocchio, Ph.D., M. T. (ASCP), Senior Medical Director and Chief, Division of Infectious Disease Diagnostics, North Shore-LIJ Health System Laboratories and Professor Hofstra North Shore-LIJ School of Medicine. "This technology will revolutionize how we approach traditional microbial identification. Combined with rapid antimicrobial susceptibility testing we can now provide a diagnosis and treatment options within a time frame that will reduce morbidity and mortality."

Researchers from the Washington University School of Medicine decided to put VITEK[®] MS to a very rigorous test by analyzing a ten-year collection of clinical samples which was initially difficult to identify with traditional methods.

“The question was, if we tested these organisms with MALDI-TOF MS how would we do?” said Dr. Carey-Ann Burnham, Assistant Professor of Pathology and Immunology at Washington University School of Medicine and the Medical Director of Microbiology at Barnes Jewish Hospital. “So, we pulled these samples from the freezer and the answer was very exciting. Nearly all of the isolates were able to be identified with high accuracy in a matter of moments using a single method: MALDI-TOF MS.”

“Hackensack University Medical Center remains committed to staying at the forefront of new technology and treatment methods to better care for our patients, and the VITEK[®] MS is another example of this commitment,” said Robert C. Garrett, president and chief executive officer of Hackensack University Health Network. “We’re conducting a study to see what benefits accrue from diagnosing and treating patients with infectious disease faster and more accurately. Mistreatment and antibiotic overuse are major problems in our healthcare system. They cause prolonged suffering and are very costly. We think VITEK[®] MS, by diagnosing patients faster and allowing for more rapid treatment, should help our bottom line by reducing our expenditures on medication and reducing the length of stay of patients with serious infections.”

The VITEK[®] MS database represents the vast majority of bacterial and fungal infections that afflict humans. As the world leader in clinical microbiology, bioMérieux, holds the largest private strain collection in the world.

For microbiologists who choose mass spectrometry for microbial identification, bioMérieux offers integrated workflow solutions with its VITEK[®] 2 system to ensure optimal user convenience, full sample traceability and quality of results. All of bioMérieux’s systems will be managed with Myla[®] web-based laboratory informatics solution. The fully integrated system will provide the rich connectivity between identification with VITEK[®] MS and antibiotic sensitivity testing with VITEK[®] 2, enhanced information and workflow management.

About VITEK[®] MS and MALDI-TOF

The VITEK[®] MS is a method for microorganism identifications from clinical cultures which enables faster time to results. The VITEK[®] MS is a Matrix-Assisted Laser Desorption Ionization Time of Flight mass spectrometer (MALDI-TOF-MS). The device analyses material from microbial cultures to provide organism identification. Samples are submitted to multiple laser shots inside VITEK[®] MS. The matrix absorbs the laser light and vaporizes, along with the sample, in the process gaining an electrical charge (ionization).

Electric fields then guide the ions into a vacuum tube which separates them according to their weight, with the smaller molecules rising up the column faster than the larger molecules. This “time of flight” creates a series of peaks, which correspond with the different molecules contained in the organism from the sample. All of these peaks create spectra unique to that microorganism. By comparing the spectra to a library owned by bioMérieux, the precise microorganism can be identified very easily.

VITEK[®] MS is an automated solution, which makes its use by lab technicians easier: thanks to Myla[®], it is fully integrated with bioMérieux’s VITEK[®] 2 platform, the world’s leading system for automated identification and antibiotic susceptibility testing. Myla[®] connects the two instruments, automatically combining identification results provided by VITEK[®] MS with the antibiotic susceptibility test results provided by VITEK[®] 2.

About bioMérieux

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for the past 50 years, bioMérieux is present in more than 150 countries through 41 subsidiaries and a large network of distributors. In 2012, revenues reached €1.57 billion with 87% 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).

Additional information can be found at www.bioMérieux-usa.com.

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