PRESS RELEASE

bioMérieux receives FDA 510(k) clearance for its VITEK® MS PRIME new MALDI-TOF mass spectrometry identification system

Marcy l'Etoile, France – March 18, 2022 — bioMérieux, a world leader in the field of in vitro diagnostics, announces that VITEK MS PRIME, its new MALDI-TOF[1] mass spectrometry identification system, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA). This next generation system for routine microbial identification in minutes is now commercially available in countries that recognize CE-marking and in the United States.

With time-saving innovations to deliver faster identification results, VITEK® MS PRIME is a compact benchtop system designed to increase laboratory productivity for greater impact to patient care. VITEK® MS PRIME, manufactured by bioMérieux is a result of our constant commitment to support laboratories with tools that provide increased Antimicrobial Stewardship (AMS) efficiency and more effective patient therapy.

Brian Armstrong, Senior Vice President, Clinical Operations, North America emphasized: "*With VITEK® MS PRIME, we provide our U.S. customers with an innovative system that brings greater lab workflow efficiency. Extensive lab input was incorporated into the development of VITEK® MS PRIME so we know the unique and differentiating features like prioritization of urgent samples and continuous "load and go" will be valued*".
Labs will enormously benefit from the greatly reduced hands-on time[2]. This VITEK® MS PRIME system also integrates seamlessly with VITEK® 2 for antimicrobial susceptibility testing and MYLA® middleware for data integration and insights.

"We are really pleased to bring this unique system to labs during the Covid-19 pandemic, when their need for optimal workflow and efficiency are greater than ever," said Pierre Boulud, Chief Operating Officer, Clinical Operations. *"In just 6 months the adoption rate of customers in Europe has been astounding. Extending access to the U.S. means even more labs can benefit from providing critical information more rapidly to clinicians so more effective antimicrobial therapy is prescribed sooner. Our goal is to empower labs to further improve patient management and play a key role in the fight against antimicrobial resistance."*

With 1.3 million[3] deaths worldwide annually, antimicrobial resistance (AMR) is a global health priority. Antimicrobial Stewardship (AMS), a key part of the arsenal to fight resistance, starts with diagnostics. VITEK® MS PRIME positively impacts stewardship

programs by providing even faster, highly accurate pathogen identification making excellent use of the large database of clinically relevant species to support earlier, targeted therapy.

After receiving CE-marking in April 2021, the commercial launch of VITEK® MS PRIME is well underway as planned in many European, Asian and Latin American countries, extending now to the US and to the rest of the world throughout 2022.

ABOUT VITEK® MS PRIME AND MALDI-TOF

VITEK® MS PRIME is a new generation of the VITEK® MS system, launched in 2011 for microorganism identification. VITEK® MS PRIME is a Matrix-Assisted Laser Desorption Ionization Time of Flight mass spectrometer (MALDI-TOF-MS). The device analyzes material from microbial cultures to provide microorganism identification. Samples are submitted to multiple laser shots inside VITEK® MS PRIME. 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 vast comprehensive library owned by bioMérieux, the precise microorganism can be identified quickly and easily. VITEK® MS PRIME has been designed to incorporate additional benefits to further enhance the use of the MALDI-TOF technology.

ABOUT BIOMÉRIEUX’S COMPLETE ANTIMICROBIAL STEWARDSHIP (AMS) SOLUTION

One of bioMérieux’s healthcare mission is to help sustain the use of antibiotic efficiency for generations to come. To support hospitals, institutions and laboratories with their AMS programs, bioMérieux has a complete solution covering antibiotic therapy initiation, optimization and discontinuation. This constantly evolving offer provides labs with timely, accurate results to adjust therapy, transforms data into actionable insights and integrates smoothly into any hospital with its flexible partnership approach. bioMérieux has over 55 years of microbiology expertise with more than 75% of its R&D directed to AMR/AMS research to ensure the current offer evolves to meet customers’ AMS needs.

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ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of in vitro diagnostics for over 55 years, bioMérieux is present in 44 countries and serves more than 160 countries with the support of a large network of distributors. In 2021, revenues reached €3.4 billion, with over 90% of international sales (outside of France).

bioMérieux provides diagnostic solutions (systems, reagents, software and services) 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.

www.biomerieux.com

bioMérieux is listed on the Euronext Paris stock market.
Symbol: BIM – ISIN Code: FR0013280286
Reuters: BIOX.PA/Bloomberg: BIM.FP
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