bioMérieux receives US FDA 510(k) clearance for its AST System VITEK® REVEAL™

Marcy l'Étoile, France – June 21st, 2024 – bioMérieux, a world leader in *in vitro* diagnostics, today announces that its VITEK® REVEAL™ AST System, reporting results directly from positive blood cultures, has received U.S. Food and Drug Administration (FDA) 510(k) clearance.

Every year 11 million people worldwide die of sepsis[1] and 1.3 million of these deaths are attributable to antibiotic-resistant bacteria[2]. For clinicians to rapidly optimize therapy and improve patient care, fast and accurate antimicrobial susceptibility testing (AST) results and interpretation are critical. In addition, fast AST can enable antimicrobial stewardship (AMS) programs which has the potential to reduce antimicrobial resistance (AMR), identified as a global threat by WHO[3].

As part of its commitment to combat sepsis and AMR, in 2022 bioMérieux acquired Specific Diagnostics, a U.S. based company that has developed an AST system now called VITEK® REVEAL™. The instrument seamlessly integrates into bioMérieux's unique and comprehensive portfolio of diagnostic solutions to address bloodstream infections and sepsis.

The modular VITEK® REVEAL™ AST system can deliver actionable results for gram-negative bacteria directly from positive blood cultures in an average of 5.5-6 hours[4,5] enabling same-day treatment decision-making for patients suffering from bacteremic sepsis.

"Based on its unique, patented metabolomic signature technology, the VITEK® REVEAL™ AST System offers an easy-to-use instrument with a broad antimicrobial coverage, small footprint, and modular design for adaptable throughput, well-suited to address the needs of clinical laboratories." explained Jennifer Zinn, Executive Vice President, Clinical Operations.

"VITEK® REVEAL™ is fully aligned with bioMérieux's priority to provide innovative diagnostics to support antimicrobial stewardship. By integrating this advanced technology in bioMérieux's portfolio, we are increasing the ability of laboratories to deliver AST results as soon as possible, especially in cases of critical bacteremia-associated sepsis, which require urgent and appropriate treatment." added Dr. Charles K. Cooper, Executive Vice President, Chief Medical Officer.

The FDA 510(k) clearance allows the commercialization of VITEK® REVEAL™ in the United States. In August 2022, the FDA granted the system with its Breakthrough Device Designation, which is reserved for medical devices that offer significant advantages over existing cleared alternatives, for which no approved alternatives exist, and/or for which device availability is in the best interest of patients[6]. This AST system is also CE-marked under IVDD* (reagents) and IVDR** (instrument) in Europe.

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(ASPR); Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50122C00057.

[1] *Rudd KE, Johnson SC, Agesa KM, Shackelford KA, Tsoi D, Kievlan DR, et al. Global, regional, and national sepsis incidence and mortality, 1990-2017: analysis for the Global Burden of Disease Study. Lancet (London, England). 2020;395(10219):200-11.*
[2] *Murray CJ. Global Burden of Bacterial Antimicrobial Resistance in 2019: A Systematic Analysis. The Lancet. 2022;399(10325):629-655. doi:https://doi.org/10.1016/S0140-6736(21)02724-0.*
[3] *https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance*
[4] *Rottman M, Rhodes PA, Singh P, Herrmann JL, Jeannot K, Cattoir V, Carbonnelle E, Plesiat P, Williams A, Dortet L. Clinical evaluation of the SPECIFIC REVEAL™ Rapid AST System with Gram-negative bacteremia samples in 6 hospitals in France and England. Poster presented at: 32nd European Congress of Clinical Microbiology & Infectious Diseases (ECCMID); 2022 May; Lisbon, Portugal.*
[5] *BMX.1.129899 Clinical Trial Summary Report (proprietary, on file at bioMerieux).*
[6] *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program*

** In Vitro Diagnostic Directive*
*** In Vitro Diagnostic Regulation*

ABOUT BIOMÉRIEUX'S COMPLETE ANTIMICROBIAL STEWARDSHIP (AMS) SOLUTION

bioMérieux's healthcare mission is to help sustain the use of antibiotic efficacy 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 timely, accurate results to adjust therapy, transforms data into actionable insights, and integrates smoothly into any hospital with its flexible partnership approach. bioMérieux has more than 60 years of microbiology expertise with 75% of its R&D directed to research on antimicrobial resistance to ensure the current offer evolves to meet customers' AMS needs

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics since 1963, bioMérieux is present in 45 countries and serves more than 160 countries with the support of a large network of distributors. In 2023, revenues reached €3.7 billion, with over 90% of 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 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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