



bioMérieux receives FDA 510(k) Clearance for its VITEK® COMPACT PRO, a new ID/AST system to fight against antimicrobial resistance

Marcy l'Étoile, France, March 18th, 2025 – bioMérieux, a world leader in the field of *in vitro* diagnostics, announces the U.S. Food and Drug Administration (FDA) 510(k) clearance for VITEK® COMPACT PRO. This innovative system for microorganism identification (ID) and antibiotic susceptibility testing (AST) will benefit clinical laboratories to help diagnose infectious diseases and combat antimicrobial resistance, and industrial laboratories to identify contaminants for ensuring consumer safety.

Every year 11 million people worldwide die of sepsis¹ and 1.3 million of these deaths are attributable to antibiotic-resistant bacteria². Antimicrobial resistance (AMR) continues unabated making detection of resistant pathogens more complex. Clinicians need to receive accurate identification and faster antibiotic susceptibility test (AST) results, to enable timely and optimized patient intervention.

For over 30 years as a global leader in automated ID/AST systems, bioMérieux continues to collaborate with laboratory professionals and clinicians to innovate microbiology solutions for improved patient health management, operating cost efficiencies, and effective antimicrobial stewardship (AMS).

VITEK® COMPACT PRO combines the latest diagnostic technology with the globally acknowledged advantages of its predecessor: VITEK® 2 COMPACT. With an ergonomically advanced design and a simplified workflow, it further enhances the user experience and improves overall efficiency as the laboratory technician has to spend less time for sample loading and processing³. It offers one of the most efficient workflows, fastest routine ID/AST results and microbiology expertise for accurate and confident diagnostics insights⁴. Ideally suited for small and medium-sized laboratories, VITEK® COMPACT PRO will also enable laboratories transitioning from manual workflows to benefit from automation efficiencies.



“For decades, bioMérieux has been an industry leader in microbiology innovation. With the introduction of VITEK® COMPACT PRO, we are continuing this journey and delivering on the specialized needs of our customers – supporting laboratories with simplified, efficient workflows and the latest technology to optimize their experience. Through ongoing expansion of our VITEK® solutions portfolio, bioMérieux continues to strengthen our comprehensive AMR/AMS offer and reinforce our commitment to provide next-generation ID/AST systems to healthcare and laboratory professionals around the world,” commented Jennifer Zinn, Executive Vice President, Clinical Operations.

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“As a leader in the fight against AMR, bioMérieux continuously innovates by developing and renewing its key diagnostic solutions. VITEK® COMPACT PRO delivers fast, accurate and reproducible results comparable to VITEK® 2 and VITEK® 2 COMPACT systems. The ergonomic features, a new intuitive user interface, and an updated software with one of the most comprehensive knowledge database makes VITEK® COMPACT PRO highly appealing to both clinical and industrial laboratories.” added Céline Roger-Dalbert, Executive Vice President, Research and Development.

For industrial applications, VITEK® COMPACT PRO will be used for routine identification of pathogens to ensure the quality and safety of food, pharmaceutical, and cosmetic products.

The commercial launch of VITEK® COMPACT PRO is initially planned in select countries, followed by global launch starting in the second quarter of 2025.

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 bioMérieux proprietary data on file: VITEK® COMPACT PRO vs. VITEK® 2 COMPACT

⁴ Decarli A et al. *JMM*. 2022; 71:001543; bioMérieux proprietary data on file; Rommler W et al. *ASM* 2006; Poster C-123; Heller-Ono A *Seln. of Publications VITEK® 2: bioMérieux White Paper 2008*; Lombardi Vincent J, *Seln. of Publications VITEK® 2: bioMérieux White Paper 2011*; Hooper M et al. *ECCMID 2013*; Poster P-1536; Carvalhaes CG et al. *ECCMID 2023 Poster # P0384*.

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 2024, revenues reached €4 billion, with over 93% 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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