bioMérieux receives U.S. FDA 510(k) Clearance and IVDR CE marking for VITEK® PRO, its new automated ID/AST instrument to support the fight against antimicrobial resistance

Marcy-l'Étoile (France), November 10th, 2026 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that VITEK® PRO has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) and the CE marking under IVDR*. This innovative system for microbial identification (ID) and antimicrobial susceptibility testing (AST) supports clinical laboratories in diagnosing infectious diseases and advancing Antimicrobial Stewardship (AMS) efforts. The commercial launch of the solution is planned to begin in the first quarter of 2027.

Ranked among the top global public health threats by the World Health Organization,[1] antimicrobial resistance (AMR) is estimated to cause 1.27 million deaths in a single year.[2] Accurate identification of microorganisms and timely antimicrobial susceptibility testing are critical for supporting clinical decision-making, improving patient management, and strengthening antimicrobial stewardship (AMS) programs.

Building on more than 35 years of expertise in ID/AST technologies, bioMérieux has developed VITEK® PRO, an easy-to-operate and highly reliable solution for routine microbiology testing. Using a single platform, laboratories can identify the microorganism responsible for an infection and determine antimicrobial susceptibility, helping clinicians select the most appropriate antibiotic therapy. By providing timely results, VITEK® PRO enables clinical decision-making that supports better patient outcomes and contributes to global efforts to combat antimicrobial resistance.

VITEK® PRO offers a flexible capacity design for seamless expansion that can adapt to current and future needs of medium and high volume laboratories. Configured for high efficiency, this instrument helps laboratories improve productivity in increasingly resource-constrained environments, while maintaining high confidence in diagnostic results. VITEK® PRO combines advanced workflow automation and modern digital capabilities, with a broad antimicrobial testing menu meeting local epidemiology requirements.

"Antimicrobial resistance continues to threaten the foundations of modern medicine. Rapid and accurate antimicrobial susceptibility testing is essential to ensure patients receive the most appropriate treatment as early as possible. With VITEK® PRO, we are bringing together decades of expertise in automated microbiology with significant innovations in workflow, software architecture, connectivity, and user experience. This new platform reinforces bioMérieux's commitment to supporting healthcare professionals worldwide in the fight against antimicrobial resistance," stated Céline Roger-Dalbert, Executive Vice President, Research and Development, bioMérieux.

Following the launch of VITEK® COMPACT PRO in 2025, VITEK® PRO becomes the latest addition to the VITEK® family, a trusted portfolio of solutions that supports laboratories in advancing antimicrobial stewardship efforts.

PRESS RELEASE

"For more than 60 years, bioMérieux has been at the forefront of microbiology innovation, helping laboratories around the world advance diagnostic excellence as the global leader in automated ID/AST solutions. Today, with approximately 80% of our portfolio contributing to the fight against antimicrobial resistance, we remain committed to providing solutions that help drive better clinical decisions and improve patient outcomes. VITEK® PRO represents the next step in that commitment, combining innovation, automation, and scalability to meet evolving customer needs. It's part of our broader antimicrobial stewardship offering and our mission to deliver integrated solutions that create meaningful value for laboratories, clinicians, patients, and healthcare systems worldwide," added Jennifer Zinn, Executive Vice President, Clinical Operations, bioMérieux.

In addition to the FDA clearance, VITEK® PRO has also obtained CE marking under IVDR*. bioMérieux plans to initiate the commercial launch in the first quarter of 2027 in selected geographies, including the United States and some European countries, before progressively expanding availability across other regions worldwide in the second quarter of 2027 to replace VITEK® 2 and VITEK® XL systems.

[1] *https://www.who.int/europe/news-room/fact-sheets/item/antimicrobial-resistance*
[2] *Murray C, Ikuta K, Sharara F et al. – Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis – The Lancet, 2022; 399, 629-655*

** In Vitro Diagnostic Regulation EU 2017/746, in force in the European Union.*

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 46 countries and serves more than 160 countries with the support of a large network of distributors. In 2025, revenues reached €4.1 billion, with over 94% 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 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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