



**SPECIFIC REVEAL™ Rapid AST System,  
newly renamed VITEK® REVEAL™,  
submitted to US FDA for 510(k) clearance**

**Marcy l'Étoile, France, April 7 2023 – bioMérieux, a world leader in the field of in vitro diagnostics, announces that it has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for the VITEK® REVEAL™, formerly known as SPECIFIC REVEAL™ Rapid AST System.**

Every year 11 million people worldwide die of sepsis and 1.3 million of these deaths are attributable to antibiotic-resistant bacteria. For clinicians to save patients' lives and rapidly optimize therapies, fast and accurate antimicrobial susceptibility testing (AST) results and interpretation are critical. In addition to improving patient outcomes, rapid AST also reduces global antimicrobial resistance (AMR) burden by enabling the implementation of effective institutional Antimicrobial Stewardship (AMS) programs.

bioMérieux has been committed for decades to fighting sepsis and AMR. As part of this strategy, [Specific Diagnostics was acquired in 2022](#). The U.S. based company has developed the SPECIFIC REVEAL™ Rapid AST System. This rapid, modular, antimicrobial-susceptibility test platform that can deliver actionable results for Gram-negative bacteria directly from positive blood cultures in an average of five and a half hours<sup>1</sup> enabling same-day treatment decision-making for patients suffering from bacteremic sepsis.

The instrument seamlessly integrates with bioMérieux's unique and comprehensive Sepsis Solution. For this reason it was decided to rename the system to VITEK® REVEAL™ fitting perfectly in our VITEK® ID/AST Brand.

The rapid AST system VITEK® REVEAL™ is already available on-market under CE-IVDD (assay panel) and IVDR (instrument) designation across Europe. 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<sup>2</sup>.

The FDA 510(k) clearance will allow its commercialization in the U.S. and other countries recognizing this authorization.

1. Tibbetts R, George S, Burwell R, Rajeev L, Rhodes PA, Singh P, Samuel L. Performance of the Reveal Rapid Antibiotic Susceptibility Testing System on Gram-Negative Blood Cultures at a Large Urban Hospital. *J Clin Microbiol.* 2022 Jun 15;60(6):e0009822.

2. <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>



## 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 60 years of microbiology expertise with more than 75% of its R&D directed to research on antimicrobial resistance to ensure the current offer evolves to meet customers' AMS needs

## BIOMÉRIEUX GAME CHANGERS FOR 60 YEARS

### *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 2022, revenues reached €3.6 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](http://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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