



## The SPECIFIC REVEAL® Rapid AST System has received Breakthrough Device Designation from the U.S. Food and Drug Administration

Marcy l'Étoile, France, August 22<sup>th</sup> 2022 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announces that the U.S. Food and Drug Administration (FDA) has granted its Breakthrough Device Designation for the SPECIFIC REVEAL® Rapid Antimicrobial Susceptibility Test (AST) System. This designation 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>1</sup>.

The Breakthrough Devices Program aims to provide patients and healthcare professionals with timely access to medical devices of public health interest by expediting their development and assessment and prioritizing their clearance review, while preserving the statutory standards for 510(k) clearance.

SPECIFIC REVEAL® Rapid AST System has been developed by Specific Diagnostics, a U.S. company acquired by bioMérieux in May 2022 (*cf. our press release of May 19<sup>th</sup>*).

*"I am very pleased to see the SPECIFIC REVEAL® System win this timely recognition,"* said Paul A. Rhodes, Ph.D., founder and former CEO of Specific Diagnostics. *"This will streamline the process for bioMérieux to bring hospitals across the United States a means to more rapid care for patients suffering from blood infections."*

The SPECIFIC REVEAL® Rapid AST System, already on-market under CE-IVD (assay panel) and IVDR (instrument) designation across Europe, provides phenotypic antibiotic susceptibility test results in an average of 5.5 hours<sup>2</sup> from availability of a positive blood culture, enabling same-day antibiotic decision-making for patients suffering from bacteremic sepsis, one of the most fast-moving and life-threatening of all medical conditions.

*"SPECIFIC REVEAL® is perfectly 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 results in record time, especially in cases of very critical infections such as sepsis, which require urgent and appropriate treatment."* declared Pierre Boulud, Chief Operating Officer, Clinical Operations at bioMérieux.

<sup>1</sup> <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>

<sup>2</sup> Tibbetts R, et al. Performance of the Reveal Rapid Antibiotic Susceptibility Testing System on Gram-Negative Blood Cultures at a Large Urban Hospital. *Journal of Clinical Microbiology*, 2022. / Clinical evaluation of the SPECIFIC REVEAL™ with Gram-negative bacteremia samples in 6 hospitals in France and England – 2021.

### 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 over 55 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.

## 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 2021, revenues reached €3.4 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 agri-food, pharmaceutical and cosmetic products.

[www.biomerieux.com](http://www.biomerieux.com).



bioMérieux is listed on the Euronext Paris stock market.

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