PRESS RELEASE

DIASORIN ANNOUNCES 510(K) SUBMISSION FOR LIAISON PLEX® GRAM-POSITIVE BLOOD CULTURE ASSAY, TO COMPLETE THE BLOOD CULTURE PORTFOLIO ON LIAISON PLEX®

Saluggia, Italy – November 11, 2024 - Diasorin (FTSE MIB: DIA) today announced it has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for the LIAISON PLEX® Gram-Positive Blood Culture Assay, the third[1] and final syndromic blood culture panel for the microbiological diagnosis of bloodstream infections on the LIAISON PLEX®.

Following the March 2024 clearance of the LIAISON PLEX® and LIAISON PLEX® Respiratory *Flex* Assay, Diasorin worked to expand the menu of multiplex blood culture panels for the microbiological diagnosis of bloodstream infections on the system. First, the LIAISON PLEX® Yeast Blood Culture Assay received FDA 510(k) clearance in June 2024. Second, the LIAISON PLEX® Gram-Negative Blood Culture Assay was submitted to the FDA in September 2024. The LIAISON PLEX® Gram-Positive Blood Culture Assay is the third panel submitted to the FDA and completes the Blood Culture portfolio on the multiplex system.

The LIAISON PLEX® Gram-Positive Blood Culture Assay provides clinicians with the ability to make targeted treatment decisions in about two hours after the Gram stain, potentially improving diagnostic outcome and treatment of patients.

The assay features Diasorin's proprietary NanoGrid technology, which enables the detection of nucleic acids without having to carry out the conventional amplification reaction, thus minimizing the risk of false positives.

Since panel selection is based on the Gram stain and geared only to Gram-positive pathogens, clinicians are able to improve diagnostic stewardship and control treatment costs, compared to other solutions currently on the market, which include numerous pathogens generally associated with bacteremias, regardless of the Gram staining results.

"With the submission of the LIAISON PLEX® Gram-Positive Blood Culture Assay, we are looking to complete our Blood Culture portfolio, providing unmatched flexibility with our LIAISON PLEX® allowing clinicians to tailor blood culture molecular panels specifically to patients' needs," said Angelo Rago, President of Luminex. *"We look forward to working with the FDA during the review process to ensure broad access to our comprehensive menu of proven in vitro diagnostic products that generate fast, accurate, and cost-effective results to support better patient outcomes."*

[1] · LIAISON PLEX® tests that have received U.S. FDA 510(k) clearance: LIAISON PLEX® Respiratory Flex Assay, LIAISON PLEX® Yeast Blood Culture Assay.
· LIAISON PLEX® test submitted to the U.S. FDA: LIAISON PLEX® Gram-Negative Blood Culture Assay.

About Diasorin

Headquartered in Italy and listed at the Italian Stock Exchange in the FTSE MIB Index, Diasorin is a global leader in the In Vitro Diagnostic (IVD) field and is active since 2021 in the Life Science business. For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide.
The Group operates in 5 continents through 35 companies, 4 branches, 10 manufacturing facilities and 9 research and development centers. The extensive diagnostic testing and Life Science offer, made available through continuous investments in research, positions Diasorin as the player with the broadest range of specialty tests available within the diagnostic market, and identifies the Group as the "Diagnostic Specialist".

More info at www.diasorin.com

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