PRESS RELEASE

DIASORIN ANNOUNCES 510(K) SUBMISSION FOR LIAISON PLEX® GRAM-NEGATIVE BLOOD CULTURE ASSAY, THE SECOND PANEL FOR THE DIAGNOSIS OF BLOODSTREAM INFECTIONS ON THE LIAISON PLEX®

Saluggia, Italy – September 27, 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-Negative Blood Culture Assay, the second[1] of the three molecular multiplexing panels for Blood Culture identification on the LIAISON PLEX®.

Following the clearance in March 2024 of the LIAISON PLEX® Respiratory *Flex* Assay, and in June 2024 of the LIAISON PLEX® Yeast Blood Culture Assay, Diasorin worked to expand the menu of multiplex blood culture panels for the microbiological diagnosis of bloodstream infections on the new LIAISON PLEX® system. The LIAISON PLEX® Gram-Negative Blood Culture Assay was designed to detect pathogenic Gram-negative bacteria and relevant resistance genes, complement standard-of-care workflows, and reduce operational spending.

Gram-negative bacteria account for approximately 30% of all positive blood cultures and are more antibiotic-resistant than gram-positive bacteria. These bloodstream infections are a frequent cause of sepsis, a serious condition with an average mortality rate of 16% to 40%, which has the unfortunate distinction of being the most expensive cause of hospitalization in the U.S.[2].

The LIAISON PLEX® Gram-Negative Blood Culture Assay provides clinicians with the ability to make targeted treatment decisions in less than two hours after the Gram stain through prompt organism identification and detection of resistance determinants.

The assay features Diasorin's proprietary NanoGrid technology, a unique non-amplified molecular chemistry that helps minimize false positives.

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

"We firmly believe that LIAISON PLEX® provides unique flexibility by enabling clinicians to select the most appropriate blood panel for their patients. This ensures that clinical laboratories can generate reliable results more quickly and cost-effectively," said Angelo Rago, President of Luminex. *"We are committed to developing critically important tests for the platform to expand its application to a broader range of healthcare needs."*

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

[1] LIAISON PLEX® tests that have received U.S. FDA 510(k) clearance: LIAISON PLEX® Respiratory Flex Assay, LIAISON PLEX® Yeast Blood Culture Assay.
[2] U.S. average spending equal to more than $20 billion per year (National Institute of Health (NIH), 2018).

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