PRESS RELEASE

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

THE LIAISON PLEX® GRAM-POSITIVE BLOOD CULTURE ASSAY:

- COMPLETES THE BLOOD CULTURE PORTFOLIO ON THE LIAISON PLEX®;
- FOCUSES SPECIFICALLY ON GRAM-POSITIVE PATHOGENS, ENABLING CLINICIANS TO ENHANCE DIAGNOSTIC STEWARDSHIP THROUGH TARGETED PANEL SELECTION.

Saluggia, Italy – June 7, 2025 - Diasorin (FTSE MIB: DIA) today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the LIAISON PLEX® Gram-Positive Blood Culture Assay, the final[1] syndromic blood culture panel for the microbiological diagnosis of bloodstream infections on the LIAISON PLEX®.

Diasorin has now received 510(k) clearance from the FDA for both the respiratory[2] and the blood culture portfolio on the LIAISON PLEX®.

The selection of the test panel for diagnosing bloodstream infections takes place as the next step following culture and Gram staining, which are performed by laboratories in cases of suspected bloodstream infection. Based on the Gram stain result, the laboratory can rapidly identify the type of pathogen responsible (yeasts, gram-positive, or gram-negative bacteria) and select the most appropriate and specific molecular panel. This targeted approach helps reduce costs compared to currently available solutions, which instead test for a wide range of pathogens regardless of the Gram stain outcome.

The LIAISON PLEX® Gram-Positive Blood Culture Assay detects 17 targets (13 gram-positive bacteria and 4 relevant resistance gene targets) in under 2 hours, including *Bacillus* spp. and mecC, in addition to the targets currently found on the VERIGENE® Gram-Positive Blood Culture Test, providing clinicians with the ability to make rapid and targeted treatment decisions.

The assay features Diasorin's proprietary NanoGrid technology, which allows the detection of nucleic acids without the need for conventional amplification reactions, thereby minimizing the risk of false positives.

"With this FDA clearance, we are now positioned to offer our expanding customer base a comprehensive and flexible menu of multiplex panels for the diagnosis of bloodstream infections on the LIAISON PLEX®" said Angelo Rago, President of Luminex. *"This milestone provides clinicians with unmatched flexibility to tailor blood culture panels based on individual patient needs. We are committed to continue expanding our offering on the platform to ensure*

[1] The LIAISON PLEX® Blood Culture portfolio consists of 3 panels: LIAISON PLEX® Yeast Blood Culture Assay; LIAISON PLEX® Gram-Negative Blood Culture Assay; LIAISON PLEX® Gram-Positive Blood Culture Assay

[2] LIAISON PLEX® Respiratory *Flex* Assay

broad access to our multiplexing solutions that deliver fast, accurate, and cost-effective results, ultimately supporting improved patient outcomes."

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 34 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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