

DIASORIN RECEIVES 510(k) CLEARANCE FOR ITS SECOND MULTIPLEX MOLECULAR PANEL FOR DIAGNOSING BLOODSTREAM INFECTIONS ON LIAISON PLEX®

THE LIAISON PLEX® GRAM-NEGATIVE BLOOD CULTURE ASSAY:

- IS THE SECOND OF 3 MULTIPLEX MOLECULAR PANELS FOR BLOOD CULTURE PATHOGEN IDENTIFICATION ON THE LIAISON PLEX®;
- DETECTS 27 TARGETS, INCLUDING 19 GRAM-NEGATIVE BACTERIA AND RELEVANT RESISTANCE GENES, COMPLEMENTS STANDARD-OF-CARE WORKFLOWS, AND REDUCES OPERATIONAL SPENDING.

Saluggia, Italy – April 18, 2025 - Diasorin (FTSE MIB: DIA) today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the second¹ of its 3 multiplex molecular panels for blood culture pathogen identification on the LIAISON PLEX® system.

Following clearance in March 2024 for the LIAISON PLEX® Respiratory Flex Assay, and in June 2024 of the LIAISON PLEX® Yeast Blood Culture Assay, Diasorin expanded 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:

- is designed to identify 27 targets, including 19 gram-negative bacteria and 8 relevant resistance gene targets;
- complements standard-of-care workflow;
- reduces operational spending.

Gram-negative bacteria can account for over 30% of positive blood cultures and are generally more resistant to antibiotics compared to gram-positive bacteria. Consequently, they represent a frequent cause of sepsis, a serious condition with a mortality rate that can reach 40%. In the United States, sepsis due to gram-negative bacteria is among the leading and most costly causes of hospitalization².

The LIAISON PLEX® Gram-Negative Blood Culture Assay empowers clinicians to make targeted treatment decisions in approximately two hours after a Gram stain. This assay enhances the effectiveness of treatment protocols by facilitating the swift detection of resistance determinants and pathogenic bacteria including *Escherichia coli*³, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, *Pseudomonas aeruginosa*, *Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., and *Proteus* spp. The panel features Diasorin's proprietary NanoGrid technology together with unique non-amplified molecular chemistry that helps to minimize false results compared to traditional methods.

Since the proper panel selection is based on a prior Gram stain procedure, clinicians can improve their diagnostic stewardship goals as compared to other solutions currently on the market, which instead include a broader set of pathogens typically associated with bacteremia, regardless of Gram stain classification.

"We designed a targeted and cost-effective approach to diagnosing bloodstream infections on the LIAISON PLEX®," said Angelo Rago, President of Luminex. *"By targeting Gram-negative pathogens based on Gram stain results, the LIAISON PLEX® Gram-Negative Blood Culture Assay will enable clinicians to make informed decisions*

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 U.S. average spending equal to more than \$20 billion per year (National Institutes of Health (NIH), 2018).

³ LIAISON PLEX® Gram-Negative Blood Culture Assay will not distinguish *E. coli* from *Shigella* spp. (*S. dysenteriae*, *S. flexneri*, *S. boydii*, and *S. sonnei*).

for their patients, ensuring that clinical laboratories can generate reliable results more quickly and cost-effectively”.

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

FOR ADDITIONAL INFORMATION, PLEASE CONTACT:

INVESTOR RELATIONS

Riccardo Fava

Corporate VP Communication, ESG & Investor Relations
riccardo.fava@diasorin.com

Eugenia Ragazzo

Corporate Investor Relations & ESG Analyst
eugenia.ragazzo@diasorin.com