PRESS RELEASE

DIASORIN RECEIVES FDA 510(K) CLEARANCE FOR THE LIAISON PLEX® BLOOD CULTURE YEAST ASSAY ON THE NEW MULTIPLEXING LIAISON PLEX®

THE LIAISON PLEX® YEAST BLOOD CULTURE ASSAY:

- IS THE SECOND MULTIPLEXING MOLECULAR DIAGNOSTIC PANEL ON THE LIAISON PLEX® TO BE CLEARED BY THE U.S. FDA, AFTER THE RESPIRATORY *FLEX* ASSAY, WHICH RECEIVED CLEARANCE IN MARCH 2024
- IS THE FIRST OF THE THREE PANELS FOR DIAGNOSING BLOODSTREAM INFECTIONS ON THE LIAISON PLEX®, AND ALLOWS IDENTIFICATION OF 16 PATHOGENS COMMONLY ASSOCIATED WITH FUNGEMIA

Saluggia, Italy – June 5, 2024 - Diasorin today announces that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the company's new LIAISON PLEX® Yeast Blood Culture (BCY) Assay, the second molecular multiplexing panel on the LIAISON PLEX® system.

The LIAISON PLEX® Yeast Blood Culture Assay represents the first of three multiplex blood culture panels for the microbiological diagnosis of bloodstream infections on the new multiplexing platform of the Group and detects 16 pathogens commonly associated with fungemia (fungal bloodstream infections). Fungal pathogens are often seen as an emerging threat and are of great concern due to the ease with which they can spread between patients in healthcare settings.

"*This FDA clearance further exemplifies the momentum of the LIAISON PLEX® System"* said Angelo Rago, President of Luminex. *"The LIAISON PLEX® Yeast Blood Culture Assay adds to our already market-leading bloodstream infection portfolio to provide a rapid solution for this critical disease state. The LIAISON PLEX® enables clinical labs and healthcare systems throughout the U.S. to meet their diagnostic and antimicrobial stewardship needs for better patient outcomes."*

The LIAISON PLEX® system is designed to provide increased testing flexibility, and the addition of the LIAISON PLEX® Yeast Blood Culture Assay, which is driven by Gram stain, further complements this goal. Testing only the pathogens noted on Gram stain helps laboratories avoid the costly over-testing that can occur when labs must use the same broad syndromic panels for all patients. For ease of use, the fully automated, sample-to-answer system relies on a streamlined workflow and room-temperature consumables. The hands-on time to operate the system is just two minutes, and results are produced in less than two hours.

"*The clearance of the LIAISON PLEX® Yeast Blood Culture Assay marks another milestone for Diasorin in strengthening its unique positioning in the growing multiplexing industry"* commented Carlo Rosa, CEO of Diasorin. *"We are strongly committed to continue expanding our multiplexing offering on our newly launched LIAISON PLEX® system, which will allow laboratories to adopt this technology with an innovative flexing pricing model, paying only for test results for targets of interest."*

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 39 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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