

DIASORIN ANNOUNCES FDA 510(K) CLEARANCE AND CLIA WAIVER FOR THE LIAISON NES GROUP A STREPTOCOCCUS (GAS) ASSAY

- THE LIAISON NES EXPANDS ITS MENU WITH A RAPID MOLECULAR ASSAY FOR GROUP A STREPTOCOCCUS FOLLOWING FDA CLEARANCE OF THE 4-PLEX RESPIRATORY PANEL
- GROUP A STREPTOCOCCUS IS A LEADING BACTERIAL CAUSE OF ACUTE PHARYNGITIS AND A COMMON REASON FOR OUTPATIENT VISITS
- THE LIAISON NES GROUP A STREP TEST DELIVERS DEFINITIVE MOLECULAR RESULTS AT THE POINT OF CARE IN APPROXIMATELY 15 MINUTES

Saluggia, Italy – June 19, 2026 – Diasorin (FTSE MIB: DIA) announced today that it has received 510(k) clearance and CLIA waiver from the U.S. Food and Drug Administration (FDA) for its Group A Streptococcus (GAS) assay, to be used on the LIAISON NES Point-of-Care (POC) molecular diagnostics platform. This milestone follows the FDA clearance of the LIAISON NES FLU A/B, RSV & COVID-19 assay in December 2025, further expanding the platform's menu and clinical utility.

Group A Streptococcus is a leading cause of acute pharyngitis and accounts for millions of healthcare visits each year. Because symptoms of bacterial and viral infections often overlap, accurate and timely identification is critical to support appropriate patient management. Traditional methods may require centralized testing or rely on less sensitive rapid antigen tests, which can delay treatment decisions or require confirmatory testing.

The LIAISON NES addresses these challenges by combining molecular-level accuracy with the speed and simplicity required in decentralized settings, enabling healthcare providers to deliver reliable results during the initial patient visit. Key benefits of the system include:

- **Rapid results:** Provides actionable results as soon as a positive target is amplified, with definitive negative results in approximately 15 minutes, enabling earlier clinical decisions without requiring confirmatory culture;
- **High sensitivity and specificity:** provides molecular-level accuracy with PCR, ensuring reliable POC detection;
- **Simple workflow:** utilizes the identical easy workflow of the previously cleared LIAISON NES FLU A/B, RSV & COVID-19 assay with under one-minute hands-on time and room temperature reagents, optimizing ease-of-use;
- **Point-of-Care ready:** compact, cloud-connected system supports real-time reporting for outpatient and decentralized settings.

By enabling accurate diagnosis in a single visit, the LIAISON NES Group A Strep test supports timely clinical decision-making, reduces the need for follow-up visits, and helps minimize inappropriate antibiotic use.

"The addition of Group A Strep reflects our commitment to expanding the LIAISON NES menu to address high-impact infectious diseases," said Angelo Rago, President of Luminex. *"We continue to*

build a robust pipeline that enhances the clinical value of near-patient molecular testing while reinforcing our leadership in diagnostics.”

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 30 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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