

## **DIASORIN RECEIVES FDA 510(k) CLEARANCE AND CLIA-WAIVER FOR ITS FIRST ASSAY, THE 4-PLEX RESPIRATORY PANEL, ON THE LIAISON NES MOLECULAR DIAGNOSTICS PLATFORM**

- THE LIAISON NES IS THE NEW DIASORIN MOLECULAR PLATFORM FOR USE IN DECENTRALIZED SETTINGS;
- WITH LIAISON NES, DIASORIN WILL EMPOWER PHYSICIAN OFFICES AND URGENT CARE CENTERS WITH EXPANDED ACCESS TO MOLECULAR DIAGNOSTICS;
- THE FIRST FDA CLEARED AND CLIA WAIVED LIAISON NES TEST PANEL, THE 4-PLEX RESPIRATORY PANEL, DETECTS AND DIFFERENTIATES INFLUENZA A (FLU A), INFLUENZA B (FLU B), RESPIRATORY SYNCYTIAL VIRUS (RSV), AND SARS-CoV-2 IN APPROXIMATELY 15 MINUTES.

**Saluggia, Italy – December 28, 2025** - Diasorin (FTSE MIB: DIA) today announced that it has received 510(k) clearance and CLIA-waiver from the U.S. Food and Drug Administration (FDA) for its first assay, the FLU A/B, RSV & COVID-19 Panel, to be used on the LIAISON NES platform.

The LIAISON NES is a next-generation Point-of-Care (POC) molecular diagnostic platform that has been designed to bring laboratory-quality testing closer to patients, combining speed, accuracy, and ease of use in a compact, fully automated device that enables healthcare providers to perform molecular testing in near-patient settings without the need for specialized laboratory personnel. The platform's three-step workflow requires only seconds of hands-on time and delivers results in approximately 15 minutes, supporting timely clinical decision-making.

The LIAISON NES platform, originally developed in collaboration with one of the leading pharmacy chains in the U.S., can be considered a "next-generation molecular platform" ideally suited for POC settings, due to its unique technical features:

- Operational efficiency: integrated barcode reader, wireless operation, and seamless connectivity;
- Compact design: minimal bench space and lightweight footprint;
- Simplified logistics: dry-swab sampling, cartridge-based format, room-temperature consumables, and minimized contamination risks in decentralized environments.

The first assay available on the LIAISON NES platform detects and differentiates Influenza A, Influenza B, RSV, and SARS-CoV-2. Additional assays for other critical infectious diseases are planned.

*"The LIAISON NES completes our molecular offering, allowing clinicians to deliver fast, accurate results where and when patients need them most and allowing Diasorin to support the diagnostic and antimicrobial stewardship required in today's environment",* said Angelo Rago, President of Luminex.

Diasorin's molecular offering ranges from targeted solutions on the LIAISON MDX, featuring De Novo FDA-authorized specialty assays, to multiplex capabilities on the LIAISON PLEX, the first fully customizable sample-to-answer syndromic molecular platform on the market, and the MAGPIX® platform for high-throughput syndromic testing. This integrated portfolio supports a broad spectrum of diagnostic environment needs, from centralized lab testing to rapid, near-patient diagnostics.

*"We are truly excited about this milestone. Introducing LIAISON NES is not just about adding a next-generation molecular platform to our portfolio, but it marks Diasorin's entry into the molecular POC market, expanding our ability to deliver rapid, high-quality diagnostics closer to patients,"* commented Carlo Rosa, CEO of Diasorin. *"With LIAISON NES, we are redefining accessibility to molecular*



*diagnostics and marking a pivotal moment in Diasorin's growth strategy,"*

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#### **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](http://www.diasorin.com)

#### **FOR ADDITIONAL INFORMATION, PLEASE CONTACT:**

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