

DIASORIN SUBMITS THE LIAISON PLEX GASTROINTESTINAL *FLEX* ASSAY TO THE U.S. FDA FOR 510(k) CLEARANCE

THE LIAISON PLEX GASTROINTESTINAL *FLEX* ASSAY:

- IS A FULLY CUSTOMIZABLE PANEL RUNNING ON THE LIAISON PLEX MULTIPLEXING MOLECULAR DIAGNOSTIC PLATFORM;
- DETECTS 24 GASTROINTESTINAL TARGETS, INCLUDING BROAD PARASITE COVERAGE;
- IS DESIGNED TO ENHANCE DIAGNOSTIC STEWARDSHIP, ACCELERATE TURNAROUND TIMES, AND HELP CONTROL HEALTHCARE COSTS;
- WILL COMPLETE THE MAJOR LIAISON PLEX PORTFOLIO, ALONGSIDE THE RESPIRATORY AND BLOOD CULTURE PANELS.

Saluggia, Italy – November 24, 2025 - Diasorin (FTSE MIB: DIA) today announced the submission of a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for its LIAISON PLEX Gastrointestinal *Flex* Assay, the latest addition to its next-generation multiplex molecular diagnostics platform for customizable, sample-to-answer syndromic testing.

The LIAISON PLEX Gastrointestinal *Flex* Assay empowers clinicians to make timely, targeted treatment decisions by rapidly detecting common gastrointestinal pathogens. A key differentiator of the panel is its broad parasites coverage, which sets it apart from most other solutions on the market.

Using Diasorin's proprietary *Flex* Software, laboratories can create custom panels and pay only for the targets they need, tailoring tests to the latest clinical guidelines as well as to the patient's travel history, food exposure, seasonality, clinical presentation, and immune status.

The combination of *Flex* technology with the Gastrointestinal Assay's numerous targets, will help to reduce unnecessary testing, guide better treatment decisions, and improve both patient management and healthcare operational efficiency.

"Diagnostic stewardship is increasingly critical as clinical laboratories navigate financial pressures and personnel shortages. Diasorin is committed to easing this burden by expanding its portfolio of flexible syndromic testing solutions," commented Angelo Rago, President of Luminex. *"This panel will complete the major offering of flexible syndromic testing solutions on the LIAISON PLEX, and we believe it will broaden our reach to potential hospital lab customers, accelerating the platform's impact."*

Once cleared, the LIAISON PLEX Gastrointestinal *Flex* Assay will join Diasorin's growing menu of FDA-cleared syndromic tests, including the LIAISON PLEX Respiratory *Flex* Assay, LIAISON PLEX Yeast Blood Culture Assay, LIAISON PLEX Gram-Negative Blood Culture Assay, and LIAISON PLEX Gram-Positive Blood Culture Assay.

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 31 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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