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Utenza - Referente : DIASORINN01 - Ulisse Spada - Valerio Giovanni Vaccarone

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Oggetto : DIASORIN RECEIVES FDA 510(K) CLEARANCE FOR ITS LIAISON PLEX® SYSTEM TOGETHER WITH THE LIAISON PLEX® RESPIRATORY PANEL

Testo del comunicato

See attachment.

DIASORIN RECEIVES FDA 510(k) CLEARANCE FOR ITS LIAISON PLEX[®] SYSTEM, THE NEW MULTIPLEXING PLATFORM OF THE GROUP, TOGETHER WITH THE LIAISON PLEX[®] RESPIRATORY PANEL

THE LIAISON PLEX[®]:

- IS THE NEW FULLY AUTOMATED MULTIPLEXING MOLECULAR DIAGNOSTIC PLATFORM OF DIASORIN, AN ADDITION TO THE EXISTING MULTIPLEXING OFFERINGS
- INTRODUCES TO THE MOLECULAR DIAGNOSTIC MULTIPLEXING MARKET AN INNOVATIVE AND COST-EFFECTIVE *FLEX*[™] TESTING APPROACH, ALLOWING CUSTOMIZATION OF TESTS WITH THE ABILITY TO PROCESS AND PAY FOR DESIRED RESULTS, ENABLING LABORATORIES TO MAXIMIZE TESTING EFFICIENCIES
- HAS RECEIVED FDA 510(k) CLEARANCE, PROVIDING ACCESS TO THE SYNDROMIC MULTIPLEXING MARKET WHICH IS GLOBALLY VALUED AT APPROX. \$ 2.9 BILLION

THE LIAISON PLEX[®] RESPIRATORY *FLEX* ASSAY FOR UPPER RESPIRATORY INFECTION:

- IS THE FIRST PANEL ON THE LIAISON PLEX[®] WHICH RECEIVED FDA 510(k) CLEARANCE AND IT WILL BE FOLLOWED BY BLOOD AND GASTRO-INTESTINAL PANELS, AS COMMUNICATED DURING THE DIASORIN 2023 INVESTOR DAY

Saluggia, Italy - March 3, 2024 - Diasorin (FTSE MIB: DIA) announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the company's new LIAISON PLEX[®] platform as well as its first panel of tests, the LIAISON PLEX[®] Respiratory *Flex* Assay.

The LIAISON PLEX[®] expands and consolidates Diasorin's unique positioning in the multiplexing syndromic market, which is globally worth about \$ 2.9 billion and it is estimated to grow to approximately \$ 4 billion by 2027.

The LIAISON PLEX[®] is uniquely designed to provide full flexibility in the customization of syndromic panels and will allow clinical laboratory staff to overcome the constraint of the "one size fits all" approach for infectious disease syndromic diagnostics.

Custom panels allow for easier adjustment based on seasonal changes and clinical guidance updates as they occur, helping to avoid costly over-testing, which is a limitation of the fixed broad syndromic panels currently available to laboratories. This fully automated, easy to use, sample-to-answer system has a streamlined workflow with room-temperature stable consumables, allowing convenient storage and transportation. The operational hands-on time is only two minutes per sample and results are produced in less than two hours.

"The LIAISON PLEX and its Respiratory Panel will allow clinical laboratories and physicians to tailor tests to the needs of their patient population," said Angelo Rago, President of Luminex. *"The LIAISON PLEX is truly a laboratory's sample-to-customizable answer solution and we believe this will help address the growing demand for diagnostic stewardship, fiscal responsibility, and operational efficiency in clinical labs and healthcare systems throughout the U.S."*

The LIAISON PLEX[®], initially named VERIGENE[®] II by Luminex, is the successor of VERIGENE[®], which is already providing flexible solutions with its Respiratory Panel. The PLEX system extends the *Flex*[™] Testing concept to a new level, by allowing full customization of its existing and upcoming panels, while incorporating full automation. This minimizes sample preparation time and mitigates the risks

of contamination for laboratory technicians. The enhanced flexibility and automation is designed to simultaneously add value for patients, clinicians and payers.

With its unique features and technology, LIAISON PLEX® will support Diasorin's commercial strategy in the U.S. by targeting the hospital segment, leveraging IDNs, teaching institutions and medical centers.

The LIAISON PLEX® Respiratory *Flex* Assay tests for 19 pathogens commonly associated with respiratory infections, including 14 viral and 5 bacterial targets detected from nasopharyngeal swabs, further supporting flexibility and fiscal responsibility with a unique approach to panel testing. However, unlike most panel tests, which elaborate and reveal all results at once, *Flex* testing allows users to generate and pay for a subset of specific results based on a patient's clinical picture.

LIAISON PLEX® Respiratory *Flex* Assay is the first of the 5 panels announced during Diasorin 2023 Investor Day: Blood Culture panels (yeast, Gram-positive and Gram-negative) and Gastrointestinal panel are currently under development, and will be submitted to the U.S. FDA in 2024 and 2025, respectively.

Compared to standard panel testing, the *Flex* method can improve clinical utility and reimbursement rates, ensuring a more cost-effective approach for patients. Through the application of panel testing, patient care can be optimized by differential diagnosis and treatment in support of diagnostic stewardship efforts, thereby reducing unnecessary patient therapies and costly over testing.

"The clearance of the LIAISON PLEX along with its first panel marks a significant and strategic milestone for Diasorin after the Luminex acquisition, delivering to the market an innovative platform that is uniquely positioned in the growing multiplexing industry" commented Carlo Rosa, CEO of Diasorin. *"The flex technology exemplifies our forward-looking approach to diagnostic development, tackling the current limitations of the multiplexing market with a fully automated and customizable panel, and providing customers with the needed flexibility to adopt this technology in a cost-effective manner."*

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.it

Eugenia Ragazzo

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

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Numero di Pagine: 4