PRESS RELEASE

DIASORIN RECEIVES 510(K) CLEARANCE FOR SIMPLEXA COVID-19, FLU A/B & RSV DIRECT KIT ON THE LIAISON MDX FROM THE U.S. FOOD AND DRUG ADMINISTRATION

THE SIMPLEXA COVID-19 / FLU A/B & RSV DIRECT KIT:

- IS A SAMPLE-TO-ANSWER TEST FOR THE DETECTION OF SARS-COV-2, FLU A, FLU B AND RSV DIRECTLY FROM NASOPHARYNGEAL AND NASAL SWABS;
- RUNS ON THE LIAISON MDX SYSTEM USING THE DIRECT AMPLIFICATION DISC (DAD), ENABLING RAPID DETECTION IN APPROXIMATELY 45 MINUTES;
- HAS BROAD COVERAGE FOR INFLUENZA STRAINS, EMERGING SARS-COV-2 VARIANTS AND DETECTION OF BOTH RSV SUBGROUPS A AND B;
- WILL COMPLEMENT DIASORIN EXISTING LIAISON MDX RESPIRATORY PORTFOLIO BY ADDRESSING THE MARKET'S EVOLVING DEMAND, SHIFTING FROM COVID-19 TESTING ONLY TO COVID-19/FLU A/B & RSV TESTING.

Saluggia, Italy – October 31, 2025 - Diasorin (FTSE MIB: DIA) announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Simplexa COVID-19 / Flu A/B & RSV Direct kit, a sample-to-answer test for the detection of SARS-CoV-2, influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) directly from nasopharyngeal and nasal swab specimens.

Designed for use on the LIAISON MDX system, the assay is suitable for both hospital and commercial laboratories, enabling timely and highly accurate differential diagnosis of the 4 primary respiratory viruses circulating during the winter season. Following the COVID-19 pandemic, a resurgence of both influenza virus and RSV, particularly evident since the 2022/2023 season, has underscored the need to detect these pathogens, along with SARS-CoV-2, during peak infection periods. The Simplexa COVID-19 / Flu A/B & RSV Direct kit addresses this need by providing a streamlined solution that delivers accurate and simultaneous detection in a single assay.

The rapid differential detection of four targets in approximately 45 minutes reflects a significant advancement in Simplexa technology on the LIAISON MDX platform, that achieves increased multiplexing capabilities and enhanced speed.

This comprehensive approach enhances the accuracy of respiratory illness diagnosis, which is critical for effective therapeutic management and infection control, especially when clinical presentations alone can be ambiguous. By providing a clearer and more complete understanding of a patient's condition, the test enables healthcare providers to tailor treatment plans more effectively, leading to improved patient outcomes and minimizing unnecessary treatments, making this the test of choice for the respiratory season.

"We are excited to introduce our new 4-plex test enabling detection of SARS-CoV-2, influenza A and B, and RSV, designed to meet the demands of today's respiratory testing landscape," commented Angelo Rago, President of Luminex. *"Our dedication to offering adaptable testing solutions is reflected in the addition of this 4-plex kit to our comprehensive range of COVID-19 and flu testing assays, ensuring that laboratories are equipped to handle dynamic respiratory seasons and evolving healthcare environments."*

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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