



DIASORIN FURTHERS ITS COLLABORATIONS WITH BARDA TO SUPPORT CLINICAL VALIDATION AND FDA 510(k) CLEARANCE OF THE LIAISON[®] NES SYSTEM, A POC MOLECULAR TESTING SOLUTION

Saluggia, Italy, October 5, 2022 - DiaSorin (FTSE MIB: DIA) announced today that DiaSorin Molecular LLC (Cypress, CA) will collaborate with the Biomedical Advanced Research and Development Authority (BARDA), to support the FDA 510(k) clearance of a CLIA-waived molecular solution for infectious disease testing. DiaSorin will develop, verify, and clinically validate an FDA-cleared and CLIA-waived point-of-care (POC) instrument, known as the LIAISON[®] NES, along with an initial combination test for SARS-CoV-2 and influenza A & B.

The LIAISON[®] NES is designed to allow untrained operators to perform testing for viral and bacterial pathogens using state-of-the-art molecular technology with the intent to support the decentralization of diagnostic testing beyond the hospital setting. Patients will benefit from expanded access to rapid, high-quality diagnostic results at a reduced cost. Furthermore, this diagnostic capability will be important to help combat the spread of new and emerging pathogens. Future product development will focus on additional respiratory infections and sexually transmitted diseases, among others.

The LIAISON[®] NES system minimizes operational, administrative, and supply chain concerns that historically have prevented adoption of POC diagnostics at many near-patient locations. The system aims to overcome these barriers by creating a solution that is rapid (approximately 15 minutes) and easy to perform, alleviates supply chain constraints by providing a long shelf life at room temperature with automatic reordering for an uninterrupted supply of tests. The LIAISON[®] NES system will be fully cloud integrated to automate many tasks required to fully implement POC testing and securely share data in medical as well as other distributed settings.

DiaSorin Molecular LLC, along with recently acquired Luminex Corporation, are part of the DiaSorin Group, which is a well-known diagnostic company with a global presence in hospital and commercial laboratories. The overall company offers lab-based molecular targeted platforms (LIAISON[®] MDX and ARIES[®] systems) and a multiplexing platform (VERIGENE[®]).

“The project is progressing at full speed as a corporate priority to position DiaSorin in decentralized diagnostics - a new and strategic market segment for the company,” said Angelo Rago, President of Luminex and DiaSorin Molecular LLC. *“We are honored to continue our productive collaborations with BARDA to improve access to critical infectious disease tests with the LIAISON[®] NES system.”*

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The Diagnostic Specialist

PRESS RELEASE



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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 43 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.diasoringroup.com