DiaSorin The Diagnostic Specialist

PRESS RELEASE

DIASORIN LAUNCHES THE LIAISON® IQ WITH A FIRST TEST THAT DETECTS IGG ANTIBODIES AGAINST SARS-COV-2 IN MARKETS ACCEPTING THE CE MARK

- LIAISON® IQ, THE NEW DIASORIN LATEST GENERATION IMMUNOASSAY POINT-OF-CARE PLATFORM, IS AVAILABLE IN MARKETS ACCEPTING CE MARK
- LIAISON® QUICK DETECT COVID TRIMERICS AB IS THE FIRST TEST BASED ON DIASORIN BIOLOGICAL RAW MATERIALS TO BE RUN ON LIAISON® IQ TO DETECT IGG ANTIBODIES AGAINST THE FULL LENGTH TRIMERIC SARS-COV-2 SPIKE PROTEIN IN HUMAN CAPILLARY BLOOD FROM A FINGERSTICK
- LIAISON® QUICK DETECT COVID TRIMERICS AB REPRESENTS AN IDEAL SOLUTION TO DETECT BOTH THE RESPONSE TO A NATURAL INFECTION (ALSO COMING FROM THE MOST COMMON VARIANTS OF COVID-19 VIRUS) AND THE RESPONSE TO A VACCINE FROM COV ID-19
- BOTH THE PLATFORM AND ITS FIRST TEST WILL BE SUBMITTED TO THE U.S. FDA FOR EMERGENCY USE AUTHORIZATION AND CLIA WAIVER

Saluggia - April 20, 2021 - DiaSorin (FTSE MIB: DIA) launched the LIAISON® IQ, its new immunodiagnostic Point-of-Care (POC) reader, and the LIAISON® Quick Detect COVID TrimericS Ab test in countries accepting the CE Mark. This first test available on the LIAISON® IQ detects specific IgG antibodies against SARS-CoV-2 Spike Protein in human capillary blood from a fingerstick in 10 minutes.

Both the platform and the test were developed in partnership with Lumos Diagnostics, as announced on April 6, 2021.

In clinical studies, the test showed a specificity of 97.5% and a sensitivity of 98.0%. The test, which utilizes the full-length trimeric form of the SARS-CoV-2 Spike protein already in use in the recently launched LIAISON® SARS-CoV-2 TrimericS IgG assay, will be an important tool to establish if a patient has had an adaptive immune response to COVID-19 triggered by either a natural infection or by a vaccine.

DiaSorin intends to access this new market starting with a dedicated program in Italy, targeting pharmacies through agreements with distributors to foster capillary placements of the new combined offer of the platform and the antibody assay. Patients will be able to be tested directly in the pharmacies, with a quick time-to-result solution to detect immune response to SARS-CoV-2 with laboratory-setting quality.

The LIAISON® IQ and the LIAISON® Quick Detect COVID IgG Ab will also be available in the U.S. market following the U.S. Food and Drug Administration (FDA) Authorization. DiaSorin, together with Lumos, is also pursuing the development of a SARS-CoV-2 Antigen test to be CE marked and submitted to U.S. FDA for Emergency Use Authorization (EUA) within Q2 2021.

"The CE Marking of our LIAISON IQ and its first test provide us access to the growing lateral flow business in the Point-of-care market, allowing DiaSorin to follow the decentralization trend of diagnostics," commented Carlo Rosa, CEO of DiaSorin Group. "*This is the right timing for entering the immunodiagnostics Point-of-Care business, with a breakthrough lab-quality solution that uses our biological raw materials in a new, nearer-to-patients context. Our decentralized setting IgG test is the perfect solution to check vaccine efficacy, which is a very relevant information in the current context of the pandemic*".

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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, with 26 companies, 4 branches, 5 manufacturing facilities and 5 research and development centers.
For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide.
The extensive diagnostic testing 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