



The Diagnostic Specialist

PRESS RELEASE



DIASORIN LAUNCHES WITH CE MARK THE LIAISON® SARS-CoV-2 TRIMERIC IgG TEST, A NEW QUANTITATIVE SEROLOGY TEST FOR DETERMINATION OF IgG ANTIBODIES AGAINST SARS-CoV-2

THE LIAISON® SARS-CoV-2 TRIMERIC IgG:

- DETECTS AND QUANTIFIES LONG-LASTING IgG IMMUNE RESPONSE AGAINST SARS-CoV-2 IN PATIENTS PREVIOUSLY INFECTED WITH THE VIRUS
- COULD BE USED TO ASSESS ANTIBODY RESPONSE AGAINST THE NATIVE SPIKE PROTEIN OF SARS-CoV-2 FOLLOWING COVID-19 VACCINATION, WHEN AVAILABLE FOR THE SCOPE
- DELIVERS RESULTS WITH 98.7% SENSITIVITY AND 99.5% SPECIFICITY
- MAY BE RUN ON THE OVER 8,000 CLIA HIGH-THROUGHPUT LIAISON® FAMILY ANALYZERS

Saluggia - January 11, 2021 - DiaSorin (FTSE MIB: DIA) launched today its new LIAISON® SARS-CoV-2 TrimericS IgG test, a new quantitative serology test available in markets accepting the CE Mark for determination of IgG antibodies against SARS-CoV-2. The new test could be used to assess antibodies levels in order to determine the efficacy of COVID-19 vaccines, when available for the scope.

The test has been submitted to the U.S. Food and Drug Administration for Emergency Use Authorization (EUA) in the U.S.

The LIAISON® SARS-CoV-2 TrimericS IgG test has been developed using the full length SARS-CoV-2 Spike protein in its Trimeric form, which perfectly mimics the native conformation of the protein.

Available scientific literature¹ has demonstrated that the Trimeric Spike protein used in the new DiaSorin test can detect the full variety of the natural immune response to the virus, instead of limiting the detection to antibodies against single epitopes such as RBD, commonly used by other assays available on the market. This allows to detect a broader population of antibodies generated by the body's immune response, reducing the risk of false negative results. As a consequence, the test is an ideal diagnostic tool which could be used, when available for the scope, to assess COVID-19 vaccines' efficacy.

The test in clinical studies has displayed a sensitivity of 98.7% and a specificity of 99.5% and will be run in the laboratory setting on over 8,000 LIAISON® CLIA family analyzers installed worldwide with a potential throughput of 171 tests per hour.

"We expect a significant demand for this test moving forward both to assess the response in post-vaccination recipients and as a pre-screening tool to assess the starting level of antibodies of each patient" said Chen Even, Chief Commercial Officer of the Group. *"Moreover, the new test will play a fundamental role over the next months, helping maximizing the vaccination campaigns and becoming, in the medium-term, a structural and needed tool to assess antibodies titer levels to SARS-CoV-2"*.

The LIAISON® SARS-CoV-2 TrimericS IgG is the sixth innovative diagnostic tool specifically designed for COVID-19 that DiaSorin developed and it acknowledges the important role of the spike

¹ Liu, L., Wang, P., Nair, M.S. et al. Potent neutralizing antibodies against multiple epitopes on SARS-CoV-2 spike. Nature 584, 450–456 (2020). <https://doi.org/10.1038/s41586-020-2571-7>



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protein of the SARS-CoV-2 in the infection process.

“We are very proud of this new test which we believe will play an important role in the long-term fight against COVID-19,” commented Carlo Rosa, CEO of the Group. “We have proven to be able to move fast and adapt quickly to this evolving scenario, thanks to our researchers who are working continuously to put on the market a high-quality wide range of diagnostic solutions, confirming our positioning as diagnostic specialists”.

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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