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Societa'	:	DiaSorin
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Oggetto	:	DiaSorin’s LIAISON® SARS-CoV-2 TrimericS IgG test receives FDA Emergency Use Authorization for the U.S. market

Testo del comunicato

Vedi allegato.

DiaSorin The Diagnostic Specialist

PRESS RELEASE

DIASORIN'S LIAISON® SARS-COV-2 TRIMERICS IGG TEST RECEIVES FDA EMERGENCY USE AUTHORIZATION FOR THE U.S. MARKET

THE LIAISON® SARS-COV-2 TRIMERICS IGG:

- IS INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF IGG IMMUNE RESPONSE AGAINST SARS-COV-2 IN PATIENTS PREVIOUSLY INFECTED WITH THE VIRUS
- IS TO BE RUN ON THE CLIA HIGH-THROUGHPUT LIAISON® XL PLATFORM

Saluggia – May 20, 2021 - DiaSorin (FTSE MIB: DIA) announced today that it has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration for the LIAISON® SARS-CoV-2 TrimericS IgG test, intended for the qualitative and semi-quantitative detection of anti-trimeric spike protein IgG antibodies to SARS-CoV-2 in human serum and plasma.

The test has been available in countries accepting the CE Mark since January 11, 2021 for both detection and quantification of the IgG immune response.

The LIAISON® SARS-CoV-2 TrimericS IgG test has been developed using the Trimeric form of the full length SARS-CoV-2 Spike protein, the form closest to the native conformation of the protein itself; therefore it can be used to identify individuals with an adaptive immune response to SARS-CoV-2.

"We are pleased to have achieved EUA authorization for our LIAISON® SARS-CoV-2 TrimericS IgG test. The dedication of our development team has allowed us once again to provide an innovative solution to help meet the continuing demand for additional diagnostic solutions to fight the on-going spread of COVID-19" commented John Walter, President of DiaSorin Inc.

The test is the sixth innovative COVID-19 diagnostic tool designed by DiaSorin and available in the U.S. and it can be run in the laboratory setting on the LIAISON® XL analyzers. The analyzer automatically calculates the SARS-CoV-2 IgG antibody levels expressed as Arbitrary Units (AU/mL) and grades the results[1].

"The test approved today underlines our commitment to continuously provide new innovative diagnostic tools to the U.S. market, supporting laboratories in fighting and containing the current pandemic," said Carlo Rosa, CEO of the Group. "*We will continue to focus our efforts to launch new tests in the U.S., a market that is strategic for our future growth."*

[1] Additional information available in the "LIAISON SARS-CoV-2 TrimericS IgG" Instructions for use

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PRESS RELEASE

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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

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