



SPAFID CONNECT

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Diffusione presunta

Oggetto : DIASORIN HAS CE MARKED ITS SARS-COV-2 IGG SEROLOGY KIT FOR COVID-19

Testo del comunicato

Vedi allegato.



DIASORIN HAS CE MARKED ITS SARS-CoV-2 IGG SEROLOGY KIT FOR COVID-19

Saluggia - April 17, 2020 - DiaSorin (FTSE MIB: DIA) announced today that it has CE Marked the LIAISON[®] SARS-CoV-2 S1/S2 IgG test and it is submitting the product to the Food and Drug Administration for Emergency Use Authorization (EUA) in the U.S.

The new serological test has been developed in conjunction with the Policlinico San Matteo in Pavia and over 1500 patients have been tested to assess the technical performance of the product. The assay is intended as an aid in the diagnosis of COVID-19 and to assess the immune status of infected patients by providing an indication of presence of neutralizing IgG antibodies against SARS-CoV-2. However, like all other products that detect IgG to SARS-CoV-2, the result of the test cannot be used alone to exclude SARS-CoV-2 infection or to determine whether a patient is still infectious.

The test identifies antibodies against the S1 and S2 proteins of SARS-CoV-2 in the form of anti-S1 and anti-S2 specific IgG antibodies to SARS-CoV-2 in human serum or plasma samples. The test has been proven to correlate with the neutralization assay developed by the Policlinico San Matteo suggesting that it identifies neutralizing antibodies and hence representing an important tool to study the immune response against SARS-CoV-2.

Fabrizio Bonelli, Chief Scientific Officer of the DiaSorin Group, commented, *"Our new assay uses chemiluminescence immunoassay technology for the quantitative and qualitative determination of anti-S1 and anti-S2 specific antibodies to SARS-CoV-2 in human serum or plasma samples. The assay is intended to assess the immune status after natural infection, providing an indication of specific exposure to SARS-CoV-2 and an additional response to the direct detection of the pathogen."*

The LIAISON[®] SARS-CoV-2 S1/S2 IgG kit will be available on the 5,000 LIAISON[®] XL platforms installed worldwide in primary hospital institutions and commercial laboratories, with a throughput of 170 patient samples per hour.

DiaSorin is currently implementing its production capacity in its main facility based in Saluggia, Italy, to manufacture several million tests over the next months, responding to the worldwide pandemic and public health emergency.

"The CE marking of our serology test sets a new achievement in the way we are addressing the fight against COVID-19," commented Carlo Rosa, CEO of the DiaSorin Group. *"We strongly believe that our assay will enable clinicians to fight the Coronavirus outbreak and that it will represent a concrete diagnostic tool to study the immune response to the virus and understand the circulation of the virus among the population."*

For additional information, please contact:

Riccardo Fava
Corporate Vice President Communication & Investor Relations
Tel: +39.0161.487988
riccardo.fava@diasorin.it

Emanuela Salvini
Investor Relator
Tel: +39.0161.487567
emanuela.salvini@diasorin.it



The Diagnostic Specialist

PRESS RELEASE



DiaSorin

Headquartered in Italy and listed in the FTSE MIB Index, DiaSorin is a global leader in the In Vitro Diagnostic (IVD) field. For over 50 years, the Company has been developing, producing and marketing reagent kits for IVD worldwide.

The Group has a presence on the 5 continents with 26 companies, 4 foreign branches, 5 manufacturing facilities and 5 research and development centers throughout the world. Through constant investments in research and development, and using its own distinctive expertise in the field of immunodiagnosics to deliver a high level of innovation, DiaSorin offers today the broadest range of specialty tests available in the immunodiagnosics market and new tests in the molecular diagnostics markets, which identify DiaSorin Group as the “Diagnostic Specialist”.

Fine Comunicato n.0957-23

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