

Informazione Regolamentata n. 0957-20-2020

Data/Ora Ricezione 07 Aprile 2020 07:09:35

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Societa' : DiaSorin

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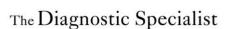
Diffusione presunta

Oggetto : Launch of IgG test to detect immune

response to SARS-COV-2

Testo del comunicato

Vedi allegato.





DIASORIN ANNOUNCES THE LAUNCH OF A FULLY AUTOMATED SEROLOGY TEST TO DETECT ANTIBODIES AGAINST SARS-COV-2 IN COVID-19 PATIENTS WITHIN THE END OF APRIL 2020, ALLOWING IDENTIFICATION OF IMMUNE RESPONSE DEVELOPMENT TO THE VIRUS

Saluggia - April 7, 2020 - DiaSorin (FTSE MIB: DIA) announced today the completion of the studies conducted at the Policlinico San Matteo in Pavia to support the launch of a new serological and high-processing volume test to detect the presence of antibodies in patients infected with the SARS-CoV-2.

The Company is working to obtain the CE mark and the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) by the end of April, 2020.

The new serological test is designed to recognize IgG antibodies directed against the S1 and S2 domains of the SARS-CoV-2 virus spike protein, selected for its ability to provide specificity for SARS-CoV-2 compared to other Coronaviruses. The product has been designed to respond to the need to identify people in the population who have already been infected with the virus, where diagnosis has not been performed with a swab and a molecular diagnostic test.

The test can be performed on the LIAISON® XL platform, which allows fully automated management of the diagnostic process, allowing laboratories to process up to 170 patient sera samples per hour, with a minimum level of intervention required by laboratory operators.

The current install base of LIAISON® XL platforms, approximately 5,000 units worldwide, of which more than 500 in Italy, boasts a widespread geographical presence in primary hospital institutions and commercial laboratories.

The LIAISON® SARS-CoV-2 IgG kit will be made available in the next few days for clinical research and evaluation and will be launched in Europe CE marked and submitted to the FDA under the Emergency Use Authorization process in the following weeks.

"The alarm generated by the Coronavirus pandemic prompted us initially to work on a molecular diagnostic solution that we were able to offer to hospital laboratories very quickly", said Fabrizio Bonelli, Chief Scientific Officer of DiaSorin. "At the same time, we started to work on an immunodiagnostic test to respond to the increasing need to conduct epidemiological investigations to establish the percentage of the population exposed to the virus in the absence of a diagnosis performed with molecular tests on a swab".

Carlo Rosa, CEO of the DiaSorin Group, commented: "The pandemic generated by the spread of coronavirus is urging us to give quick and effective responses to the different laboratories and hospitals' needs. Our molecular diagnostic test is speeding up the diagnosis process of swabs within hospitals, allowing rapid and effective patient triage and reducing the high pressure to which laboratories are subjected to identify the virus. The new test for the detection of IgG antibodies will help identify those who have developed an immune response to the virus as they are already infected".

For additional information, please contact:

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The Diagnostic Specialist

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 immunodiagnostics to deliver a high level of innovation, DiaSorin offers today the broadest range of specialty tests available in the immunodiagnostics market and new tests in the molecular diagnostics markets, which identify DiaSorin Group as the "Diagnostic Specialist".

Fine Comunicato n.09	57-20
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