

DIASORIN OBTAINS FDA EMERGENCY USE AUTHORIZATION AND BARDA FUNDING FOR SARS-CoV-2 IGG SEROLOGY KIT FOR COVID-19 TESTING IN THE U.S.

Saluggia - April 25, 2020 - 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 S1/S2 IgG test.

The product is one of the first high-throughput assays based on the CLIA (Chemiluminescent ImmunoAssay) technology to receive EUA in the U.S.

DiaSorin recently signed a contract with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services to obtain funding aimed at making the test available in the U.S.

“Widely distributed tests are needed immediately to quickly identify not only people who have an active infection but also those who have recovered,” said BARDA Acting Director Gary Disbrow, Ph.D. *“This knowledge is particularly important for healthcare providers and other critical infrastructure personnel, to return to work after any potential exposure to SARS-CoV-2.”*

The new serological test was validated at Policlinico San Matteo in Pavia, a major Italian reference center for the COVID-19 pandemic.

The test will respond to the need to identify the presence of antibodies in people who have been infected with SARS-CoV-2 and will be available on the 5,000 LIAISON[®] XL platforms installed worldwide, of which 600 are currently installed in U.S. hospital and commercial laboratories. With a throughput of 170 patient samples per hour, the LIAISON[®] XL platform will support an increase in testing capacity and the availability of diagnostic testing in order to mitigate the potential impact of this virus.

DiaSorin is currently scaling up its production capacity in its main facility based in Saluggia, Italy, in order to manufacture several million tests of the LIAISON[®] SARS-CoV-2 assay over the next months, distributing the test worldwide and responding to the global pandemic and public health emergency.

“The authorization of our serology test against COVID-19 in the U.S. confirms the commitment and quality of the job done by our research team in finding solutions to fight the worldwide Coronavirus pandemic,” commented Carlo Rosa, CEO of the DiaSorin Group. *“We believe that both our molecular and serology tests represent valuable and qualitative tools in diagnostics decision-making, positioning once again DiaSorin as the Diagnostic Specialist.”*

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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”.

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