DiaSorin received BARDA funding to develop and achieve FDA regulatory authorization, for its LIAISON® SARS-CoV-2 Ag test

Saluggia – March 30, 2021 - DiaSorin (FTSE MIB: DIA) announces that it has received U.S. federal funding from the Biomedical Advanced Research and Development Authority (BARDA) for the development, validation, FDA Emergency Use Authorization (EUA) and submission of 510(k) clearance for the LIAISON® SARS-CoV-2 Ag test.

The test is a high-throughput antigen test that determines the presence of SARS-CoV-2 Nucleocapsid protein antigen in nasal dry swabs and nasopharyngeal swabs eluted in Universal Transport Media for Virus (UTM/VTM).

The LIAISON® SARS-CoV-2 Ag test is intended as an aid in diagnosing acute COVID-19 infection and is offered as an alternative solution when molecular PCR testing availability is lacking or in situations in which PCR technology is too expensive.

In clinical studies, LIAISON® SARS-CoV-2 Ag showed, within 10 days post onset of symptoms, a 97.0% sensitivity and a 100.0% specificity on anterior nasal swabs and a 96.1% sensitivity and a 99.3% specificity on nasopharyngeal swabs.

John Walter, President of DiaSorin, Inc. commented, “We are grateful for the opportunity to partner with BARDA. We believe that lab-based high-throughput antigen tests, such as the LIAISON® SARS-CoV-2 Ag test, which is ideally suited for large volume testing laboratories, will play a key role in this phase of the pandemic.”

This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), Division for Contract management & Acquisitions (CMA) under Contract No. 75A50121P00031.

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About 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

1 Part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services