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Oggetto	:	DiaSorin has received BARDA Funding in support of submitting the SIMPLEXA COVID-19 Direct Kit for 510(k) clearance

Testo del comunicato

Vedi allegato.

DiaSorin The Diagnostic Specialist

PRESS RELEASE

DIASORIN MOLECULAR HAS RECEIVED BARDA FUNDING IN SUPPORT OF SUBMITTING THE SIMPLEXA COVID-19 DIRECT KIT FOR 510(K) CLEARANCE AND THE EXPANSION OF MANUFACTURING CAPABILITY FOR ITS PRODUCTION

Cypress, California (USA) - December 29, 2020 - DiaSorin Molecular LLC, a subsidiary of DiaSorin S.p.A. (FTSE MIB:DIA), announces that it has received federal funding from the Biomedical Advanced Research and Development Authority (BARDA)[1] for the validation and submission of the Simplexa COVID-19 Direct Kit for FDA 510(k) clearance and the expansion of manufacturing capability for its production.

The Simplexa COVID-19 Direct Kit detects the presence of the RNA of SARS-CoV-2 virus, and it has been available in countries accepting CE Mark and in the U.S. through the Emergency Use Authorization (EUA) since the end of March 2020.

The test is designed for use on more than 1,200 LIAISON® MDX instruments installed worldwide, the majority of which are installed in laboratories around the U.S.

The solution provides accurate results in around 1 hour, with a demonstrated specificity and sensitivity of 100%. The rapid turn-around time allows for prompt decision making in patient management, which is critical to help hospitals contain the pandemic and guide treatments.

"The funding we received from BARDA to submit our COVID-19 molecular test for FDA 510(k) clearance is very important since it not only underlines our strong brand recognition in the U.S., but also acknowledges the quality of our product," said John Gerace, President of DiaSorin Molecular. *"Moreover, we look forward to further expand our manufacturing capacity in the next months in order to address the significant demand we see in the market for our molecular test, an important diagnostic tool used by healthcare providers against the spread of COVID-19".*

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About 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 25 companies, 5 foreign branches, 5 manufacturing facilities and 5 research 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".

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

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