



SPAFID

CONNECT

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Diffusione presunta

Oggetto : DIASORIN COVID-19 TEST HAS
RECEIVED FDA EMERGENCY USE
AUTHORIZATION

Testo del comunicato

Vedi allegato.



DIASORIN COVID-19 TEST HAS RECEIVED FDA EMERGENCY USE AUTHORIZATION

Cypress, California (USA) - March 20, 2020 - DiaSorin Molecular LLC, a division of DiaSorin S.p.A. (FTSE MIB:DIA), announced today that it has received Emergency Use Authorization (EUA) from the FDA for their Simplexa™ COVID-19 Direct kit.

The kit provides a sample-to-answer test for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, directly from nasopharyngeal swab specimens.

The Simplexa COVID-19 Direct kit is designed for use on the LIAISON® MDX and can be utilized by hospital laboratories without the need to send the sample out, allowing for timely testing and results. The kit contains an all-in-one reagent mix, which is ready to use. Only one instrument and one reagent are required to perform the test. It bypasses the need for traditional extraction procedures, enabling rapid detection in a little over an hour which is significantly faster than the up to seven hours currently required by traditional extraction followed by amplification technologies, ultimately allowing prompt decision making regarding isolation of infected patients.

The test is highly specific to COVID-19 and targets several regions of the viral genome to minimize the impact on performance should there be possible future mutations. This ensures the results are highly sensitive and specific providing confidence in diagnostic decision making.

The outbreak, which has now officially been declared a global pandemic by the World Health Organization and declared a National Emergency in the U.S., is driving many countries to implement emergency quarantines and mandate social distancing in order to reduce the spread of the disease. On March 13, DiaSorin Molecular announced it had received federal funds from 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, in order to develop this test. It is important to increase the testing capacity at hospitals across the nation and this funding will accelerate the availability of diagnostic testing in order to help mitigate the potential impact of this virus.

“We are excited for the launch of our COVID-19 test and hope to help reduce the current shortage of tests being experienced by hospitals worldwide”, said Carlo Rosa, CEO of DiaSorin Group. “This test will better enable clinicians to make appropriate diagnostic decisions by providing rapid and accurate results. We know it will play a critical role in containing the pandemic”.



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 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 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”.

HHS/ASPR/BARDA

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