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Oggetto	:	DiaSorin has obtained FDA Emergency Use Authorization for its LIAISON® SARS-CoV-2 Ag for COVID-19 testing in the U.S.

Testo del comunicato

Vedi allegato.

DiaSorin The Diagnostic Specialist

PRESS RELEASE

DIASORIN HAS OBTAINED FDA EMERGENCY USE AUTHORIZATION FOR ITS LIAISON® SARS-COV-2 AG FOR COVID-19 TESTING IN THE U.S.

Saluggia – March 29, 2021 - DiaSorin (FTSE MIB: DIA) announces today it has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration for LIAISON® SARS-CoV-2 Ag, the antigen test for detection of COVID-19 symptomatic patients. The test was already available in the U.S. market following notification to the U.S. Food and Drug Administration on October 26, 2020[1].

The LIAISON® SARS-CoV-2 Ag is one of the first COVID-19 Ag tests in the market to be run on high-throughput analyzers, using chemiluminescence immunoassay technology to determine the presence of SARS-CoV-2 Nucleocapsid protein antigen in anterior nasal dry swabs and nasopharyngeal swabs (eluted in UTM) and is used to assist in the diagnosis of acute COVID-19 infection through qualitative detection of the virus.

In clinical studies, the test 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.

"Laboratories and physicians continue to need additional diagnostic solutions to fight the on-going spread of COVID-19 among the population. We are confident that our new antigen test will help laboratories to manage the growing demand in testing volumes, thus combating against the SARS-CoV-2 virus and the critical challenge to healthcare systems it poses," commented John Walter, President of DiaSorin Inc.

The LIAISON® SARS-CoV-2 Ag test supports laboratories in addressing the significant demand for COVID testing during the current pandemic, driven by the high-throughput offered by its use on the LIAISON® XL platform, which also positions the test as a complementary solution to molecular diagnostic testing.

Carlo Rosa, CEO of DiaSorin Group commented: *"We are pleased that the U.S. Food and Drug Administration authorized our antigen test for use in the U.S. market, as we have been receiving positive feedback on its quality in countries accepting CE Mark where the test has been available since the end of October".*

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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] As part of the U.S. FDA's process for "notification of validation and intent to submit an Emergency Use Authorization" outlined in the Policy *for Coronavirus Disease-2019 Tests, During the Public Health Emergency (Revised).*

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