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Testo del comunicato

Vedi allegato.

DiaSorin The Diagnostic Specialist

PRESS RELEASE

DIASORIN LAUNCHES WITH CE MARK THE LIAISON® SARS-COV-2 AG, A NEW HIGH-THROUGHPUT ANTIGEN TEST SUPPORTING THE INCREASING TESTING DEMAND IN THE LABORATORY SETTING FOR COVID-19 DETECTION IN SYMPTOMATIC PATIENTS

THE LIAISON® SARS-COV-2 AG:

- ALLOWS, FIRST IN THE MARKET, THE HIGH-THROUGHPUT QUANTITATIVE DETECTION OF SARS-COV-2 VIRAL LOAD IN SYMPTOMATIC PATIENTS THROUGH NASAL AND NASOPHARYNGEAL SWABS
- DELIVERS RESULTS WITH 97.1% SENSITIVITY AND 100.0% SPECIFICITY ON NASAL SWABS AND 94.6% SENSITIVITY AND 99.5% SPECIFICITY ON NASOPHARYNGEAL SWABS, WITHIN 10 DAYS POST ONSET OF SYMPTOMS
- WILL BE RUN ON THE OVER 8,000 CLIA HIGH-THROUGHPUT LIAISON® FAMILY ANALYZERS, ALLOWING FAST RESULTS AND FULL SAMPLE TRACEABILITY

DIASORIN IS CURRENTLY WORKING TO EXTEND LIAISON® SARS-COV-2 AG USE TO SALIVA SPECIMENS

Saluggia - October 26, 2020 - DiaSorin (FTSE MIB: DIA) launched today its new LIAISON® SARS-CoV-2 Ag, a high-throughput antigen test available in markets accepting the CE Mark for quantitative detection of SARS-CoV-2 in symptomatic patients through nasal and nasopharyngeal swabs.
The test will be soon available in the U.S. market, following notification to the U.S. Food and Drug Administration[1].

The new high-throughput antigen test uses chemiluminescence immunoassay (CLIA) technology to determine 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), quantifying the viral load of the infection directly from individuals suspected of COVID-19 by their healthcare provider.
The test is the first in the market to be run on high-throughput analyzers for COVID-19 detection on symptomatic patients.

The LIAISON® SARS-CoV-2 Ag is intended as an aid in diagnosing acute COVID-19 infection and will be offered as an alternative solution in cases where molecular PCR testing availability is lacking, in geographies where PCR technology is too expensive and in those cases where traceability of clinical samples needs to be improved.

In clinical studies, LIAISON® SARS-CoV-2 Ag showed, within 10 days post onset of symptoms, a 97.1% sensitivity and a 100.0% specificity on nasal swabs and a 94.6% sensitivity and a 99.5% specificity on nasopharyngeal swabs.

The new test is designed for use on the over 8,000 CLIA high-throughput analyzers (LIAISON® XL, LIAISON® XS and LIAISON®) installed in laboratories worldwide, delivering up to 140 results per hour and providing full traceability of collected samples.

Chen Even, Chief Commercial Officer of DiaSorin Group, commented: *"The availability of molecular tests is limited and the need for additional reliable diagnostic tools is on the rise. This is why we expanded our existing offer for SARS-CoV-2 detection with our new antigen test, allowing a*

[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).*

safe decentralized sample collection procedure, while maintaining patient sample traceability".

DiaSorin's manufacturing capacity for LIAISON® SARS-CoV-2 Ag is estimated to be up to 10 million tests per month shortly after its launch.

This is the fifth test launched by DiaSorin to support laboratories and healthcare systems in containing the spread of SARS-CoV-2 since the beginning of the COVID-19 pandemic worldwide.

"The increasing circulation of SARS-CoV-2 is a challenge to healthcare systems and it is driving us to provide innovative solutions to support physicians and laboratories in managing the growing demand in testing volumes. Our new antigen test is an innovative solution that allows patients to get a quick and reliable response on their infection status, thus supporting the containment of the virus among the population." commented Carlo Rosa, CEO of DiaSorin Group. *"We are already working on the expansion of the use of our new antigen test to saliva specimens, allowing an even easier, safer and non-invasive sample collection process to be used on a larger amount of individuals".*

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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

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