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CONNECT

Informazione Regolamentata n. 0957-80-2020	Data/Ora Ricezione 16 Settembre 2020 07:25:11	MTA
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Societa' : DiaSorin
Identificativo : 136990
Informazione
Regolamentata
Nome utilizzatore : DIASORINN02 - Fava
Tipologia : REGEM
Data/Ora Ricezione : 16 Settembre 2020 07:25:11
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Diffusione presunta
Oggetto : DiaSorin Simplexa™ COVID-19 Direct
molecular test CE marked for saliva
specimens

Testo del comunicato

Vedi allegato.



The Diagnostic Specialist

PRESS RELEASE



DIA-SORIN SIMPLEXA™ COVID-19 DIRECT MOLECULAR TEST CE MARKED FOR SALIVA SPECIMENS

Saluggia - September 16, 2020 - DiaSorin (FTSE MIB: DIA) announced today that it has attained CE Marking for the addition of saliva specimens for use with the Simplexa COVID-19 Direct assay.

This new specimen claim enables additional flexibility for laboratories to increase capacity, overcome ongoing bottlenecks, and better manage worldwide swab and transport media shortages to detect SARS-CoV-2 RNA in patients suspected of COVID-19 infection.

Saliva specimen collection is conducted using sterile cups without the need for special devices or sample extraction. The patient's self-collection of their saliva sample in a healthcare setting is simple, easy, and non-invasive and reduces the potential risk of COVID-19 exposure for those at the forefront of patient care.

“The addition of saliva specimens is significant and will help hospitals to minimize exposure for their staff and reduce the impact of collection device shortages,” said John Gerace, President of DiaSorin Molecular.

The Simplexa COVID-19 Direct assay is validated on a wide range of specimen types, from both the upper and lower respiratory tract and can be run in parallel with the Simplexa Flu A/B & RSV Direct Gen II assay which was recently launched to address the need for differential diagnosis of Flu, RSV and COVID-19 during the upcoming influenza season.

In addition to CE marking for saliva, the kit received initial EUA designation by FDA on March 2020 and is now authorized for use with nasal swabs, nasopharyngeal swabs, nasal wash/aspirates and bronchoalveolar lavages (BAL).

Carlo Rosa, CEO of DiaSorin Group, commented: *“We are constantly looking to meet the shifting needs of hospitals, and we are excited to provide a high quality test with flexible solutions that enable laboratories to accept additional samples as they continue to play a vital role in this pandemic.”*

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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

Fine Comunicato n.0957-80

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