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Testo del comunicato

Vedi allegato.

DiaSorin The Diagnostic Specialist

PRESS RELEASE

DiaSorin Simplexa™ COVID-19 & Flu A/B Assay received U.S. FDA 510(k) clearance

The Simplexa™ COVID-19 & Flu A/B Assay:

- provides streamlined workflow to detect flu A, flu B, and SARS-CoV-2 viruses in about an hour with minimal hands-on time
- is designed for use on the LIAISON® MDX instrument and is run directly through the Direct Amplification Disc (DAD)

Saluggia, Italy, March 17, 2023 - DiaSorin (FTSE MIB: DIA) announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its Simplexa™ COVID-19 & Flu A/B Direct assay.

The test can detect and differentiate influenza A, influenza B, and SARS-CoV-2 viruses to help ensure physicians can recommend the most appropriate treatment for each patient.

With flu and COVID-19 circulating widely in the U.S., patients frequently present with non-specific symptoms common to a number of respiratory infections. It is important for physicians to understand which virus or viruses are present in order to select therapies and recommend the most appropriate management plan, such as isolation strategies.

The Simplexa™ COVID-19 & Flu A/B Direct assay offers clinical laboratories a sample-to-answer diagnostic workflow that enables them to generate actionable results efficiently, with minimal hands-on time. The test is a real-time RT-PCR assay performed using nasopharyngeal swab samples. Designed for use on the LIAISON® MDX instrument, the assay detects viruses in a little more than an hour. No separate sample extraction or processing is required and one to eight samples can be tested at one time in a streamlined, simple workflow.

This test adds to the existing FDA-cleared menu of molecular assays used to diagnose the most common respiratory infections during the winter season (Simplexa™ Flu A/B & RSV Direct Gen II) and during the COVID-19 pandemic (Simplexa™ COVID-19 Direct) and will secure long term options to labs after the Emergency Use Authorization (EUA) period has ended, enabling implementation of diagnostic algorithms based on specific lab and/or seasonal needs.

"We are pleased to expand our menu of FDA-cleared tests for customers using the LIAISON® MDX instrument and to provide increased flexibility in workflow and test offerings to help labs respond to seasonal changes in test demand," said Angelo Rago, President of Luminex. *"By pairing flu and COVID-19 testing in one easy-to-use, rapid molecular assay, we hope to ease the burden on clinical labs that would otherwise have to run multiple tests for each patient to get complete answers."*

This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number 75A50121P00007.

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About 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 and is active since 2021 in the Life Science business. For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide.

The Group operates in 5 continents through 41 companies, 4 branches, 10 manufacturing facilities and 9 research and development centers. The extensive diagnostic testing and Life Science 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.0957-4	Numero di Pagine: 4