



SPAFID
CONNECT

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Oggetto : DiaSorin CE Marks its new Simplexa™
COVID-19 & Flu A/B Direct Assay

Testo del comunicato

Vedi allegato.



DIASORIN CE MARKS ITS NEW SIMPLEXA™ COVID-19 & FLU A/B DIRECT ASSAY FOR DETECTION AND DIFFERENTIATION OF SARS-CoV-2 AND INFLUENZA IN ONE TEST

- THE SIMPLEXA™ COVID-19 & FLU A/B DIRECT KIT IS A MULTIPLEX MOLECULAR TEST TO DIFFERENTIATE SARS-CoV-2, FLU A AND FLU B VIRUSES
- THE TEST IS DESIGNED FOR USE ON THE LIAISON® MDX PLATFORM AND IS RUN DIRECTLY FROM NASOPHARYNGEAL SWABS ON THE DIRECT AMPLIFICATION DISC (DAD)
- THE ASSAY HAS BROAD STRAIN COVERAGE BOTH FOR INFLUENZA STRAINS AND FOR THE RECENTLY EMERGING SARS-CoV-2 VARIANTS
- THE SIMPLEXA™ COVID-19 & FLU A/B DIRECT KIT IS AVAILABLE IN COUNTRIES ACCEPTING CE MARK AND WILL BE SUBMITTED TO THE U.S. FOOD AND DRUG ADMINISTRATION FOR 510(K) REVIEW

Saluggia, September 18, 2021 - DiaSorin (FTSE MIB: DIA) announced today that it has CE marked its Simplexa™ COVID-19 & Flu A/B Direct kit. The multiplex test allows for the in vitro qualitative detection and differentiation of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A virus and influenza B virus from the same patient sample in one reaction well. The assay is designed for use on the LIAISON® MDX and is run directly from nasopharyngeal swabs (NPS) without the need for off board extraction. The kit will also be submitted to the FDA for 510(k) review.

The assay provides confidence in results through broad strain coverage. Over 80 influenza strains were validated including all of the strains in the CDC panels of the last three years. Emerging SARS-CoV-2 variants including the Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Epsilon (B.1.427/B.1.429), Zeta (P.2), Eta (B.1.525), Iota (B.1.526), Kappa (B.1.617.1), Lambda (C.37), and Mu (B.1.621) variants were also evaluated to ensure diagnostic coverage.

Flu was nearly nonexistent during the 2020/2021 season, which means that the normally high levels of immunity are much lower in the community, leading to the risk for a potentially high spread next season. The upcoming respiratory illness season will be complicated by the presence of SARS-CoV-2 also circulating in the community. The Simplexa COVID-19 & Flu A/B Direct kit provides the ability for laboratories to efficiently run a single, accurate test to detect the most likely causes of respiratory illness during this flu season. This is especially critical given the difficulty to identify the etiology of the infection based solely on a patient's clinical presentation. Accurate diagnosis of the virus causing infection is critical for the management of therapeutic regimens along with infection control efforts.

"We are excited to expand our product offering with the launch of this combination kit for detection of SARS-CoV-2 and influenza that can help address concerns in anticipation of this upcoming flu season," said Michelle Tabb, Chief Scientific Officer of DiaSorin Molecular. *"We are committed to providing flexible testing options with the new combo kit in addition to our stand-alone COVID-19 assay as well as the triplex for Flu A, Flu B and RSV in order to meet laboratory's evolving needs as the world comes back to a new normal."*



The Diagnostic Specialist

PRESS RELEASE



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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 45 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.0957-55

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