



NEWS RELEASE

FOR IMMEDIATE RELEASE

The Simplexa COVID-19 Direct Test Receives U.S. FDA 510(K) Clearance

The Simplexa™ COVID-19 Direct Kit is:

- A sample-to-answer test for the detection of SARS-CoV-2 directly from nasopharyngeal or nasal swabs
- Designed for use on the LIAISON® MDX platform and is run directly through the direct amplification disc (DAD), enabling rapid detection in a little over an hour
- Highly specific for SARS-CoV-2 and it targets two regions of the viral genome to minimize the impact of mutations on performance with SARS-CoV-2 and potential variants of concern

Cypress, Calif. (September 14, 2022) – - DiaSorin Molecular announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for their Simplexa™ COVID-19 Direct kit.

The kit provides a sample-to-answer test for the detection of SARS-CoV-2, the virus that causes COVID-19, directly from nasopharyngeal or nasal swab specimens. The Simplexa™ COVID-19 Direct kit is designed for use on the LIAISON® MDX system. This COVID-19 molecular assay can be utilized by hospital or commercial laboratories allowing for timely testing and highly accurate results.

To date, the COVID-19 pandemic has caused almost half a billion cases worldwide and over six million deaths, according to the World Health Organization. It is important to ensure COVID-19 testing capacity at hospitals and commercial facilities across the nation after the FDA Emergency Use Authorization period has ended, to maintain vigilance post-pandemic against SARS-CoV-2 infections. The Simplexa™ COVID-19 Direct assay will ensure a high standard of diagnostic testing in order to help mitigate future potential impacts of this virus.

The Simplexa™ COVID-19 Direct test differs from other automated PCR assays with extraction as it does not require sample pre-treatment, enabling a fast time-to-result, ultimately allowing prompt decision making regarding isolation and treatment of infected patients. The test is highly specific for SARS-CoV-2 and targets two regions of the viral genome to minimize the impact of mutations on the kit performance with SARS-CoV-2 and potential variants of concern. This ensures the results remain highly sensitive and specific providing confidence in diagnostic decision making. 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 No. 75A50121P00007.

DiaSorin remains at the forefront of the fight against the spread of SARS-CoV-2 with a suite of COVID-19 molecular diagnostic products including the Simplexa™ SARS-CoV-2 Variants Direct (RUO) and has submitted to FDA for review the Simplexa™ COVID-19 & Flu A/B Direct assay for differential diagnosis during the flu season.

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“The FDA 510(k) clearance of our COVID-19 test demonstrates our commitment to commercialize products featuring the highest standards of diagnostic testing against COVID-19 and other respiratory pathogens,” said Angelo Rago, President of Luminex, a DiaSorin company. “The Simplexa™ COVID-19 Direct kit will provide a higher level of confidence enabling clinicians to make effective diagnostic decisions with rapid and accurate results.”

About DiaSorin Molecular

DiaSorin Molecular LLC manufactures and distributes innovative molecular diagnostic products for hospital and reference laboratories. The company’s products help laboratories consolidate their testing, streamline processes and increase efficiency. DiaSorin Molecular’s Simplexa molecular diagnostic kits are designed for use on the company’s versatile LIAISON MDX platform. The company provides service and support solutions for its kits and instruments through a global network of offices and distributors. DiaSorin Molecular also markets a range of ASRs (analyte-specific reagents) for use in lab-developed tests.

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