



NEWS RELEASE

FOR IMMEDIATE RELEASE

DiaSorin Molecular's Simplexa™ COVID-19 Direct Molecular Test CE Marked for Saliva Specimens

Cypress, Calif. (September 17, 2020) – DiaSorin Molecular LLC 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 recently launched 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 specimens, the assay is also CE marked for use with nasal swabs, nasopharyngeal swabs, nasal wash/aspirates and bronchoalveolar lavages (BAL). It also received initial EUA designation by the FDA on March 19, 2020.

“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”, commented Carlo Rosa, CEO of the DiaSorin Group.

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.

The Simplexa COVID-19 Direct test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens. The Simplexa COVID-19 Direct is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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