



NEWS RELEASE

FOR IMMEDIATE RELEASE

DiaSorin Molecular CE marks their new Simplexa™ Flu A/B & RSV Direct Gen II Assay to run with the Simplexa™ COVID-19 Direct assay

Cypress, Calif. (July 7, 2020) – DiaSorin Molecular LLC announced today that it has CE marked its Simplexa™ Flu A/B & RSV Direct Gen II kit. DiaSorin Molecular's latest generation Simplexa Flu A/B & RSV Direct Gen II kit delivers continued comprehensive strain coverage and accurate detection in an efficient and trusted sample-to-answer format that does not require extraction. Collectively, over 100 Flu A, Flu B and RSV strains have been validated, including the 2020/2021 influenza vaccine strains. The Simplexa Flu A/B & RSV Direct Gen II assay is designed for use with the LIAISON® MDX instrument.

The upcoming 2020/2021 flu season will be complicated by the presence of SARS-CoV-2 also circulating in the community. Viral infections caused by Flu A, Flu B, RSV and SARS-CoV-2 have similar clinical presentations, however treatment options are different and thus it is important to differentiate. Additionally, co-infection with SARS-CoV-2 and influenza A or B has been shown to cause increased severity of respiratory disease and the need for a combination therapy. The accurate diagnosis of the virus causing the infection can have major implications for the management of therapeutic regimens, infection control and community mitigation efforts.

The Simplexa Flu A/B & RSV Direct Gen II assay provides flexibility in workflow management for the upcoming flu season as the assay can be run alone or alongside the Simplexa COVID-19 Direct kit. The assays are designed to be performed at the same time allowing for differential diagnosis of COVID-19, influenza, and RSV. DiaSorin Molecular has also submitted the new assay to the FDA for 510(k) clearance.

"We met our goal to have the Simplexa Flu A/B & RSV Direct Gen II assay available in time for use during the upcoming Flu season and for patient samples to be tested, when needed, alongside the COVID-19 Direct assay," said Michelle Tabb, chief scientific officer of DiaSorin Molecular. "This flu season the ability to detect and differentiate between influenza, RSV and COVID-19 will be vital and we are pleased to contribute to this solution."

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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Enclosed: Photo

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