



NEWS RELEASE

FOR IMMEDIATE RELEASE

DiaSorin Molecular receives FDA clearance for the Simplexa™ Flu A/B & RSV Direct Gen II Assay. A partner to run with the Simplexa™ COVID-19 Direct assay¹

Cypress, Calif. (September 8, 2020) – DiaSorin Molecular LLC announced today that it has received FDA Clearance for its Simplexa™ Flu A/B & RSV Direct Gen II kit. 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, allowing for differential diagnosis of SARS-CoV-2, influenza A (Flu A), influenza B (Flu B), and respiratory syncytial virus (RSV).

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 Flu 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.

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.

“With COVID-19 set to play a major role in the upcoming flu season, it was critical for us to have the Simplexa Flu A/B & RSV Direct Gen II assay available in time for patient samples to be tested, when needed, alongside the Simplexa COVID-19 Direct assay,” said Michelle Tabb, chief scientific officer of DiaSorin Molecular. “Detection and differential diagnosis between influenza, RSV and COVID-19 will be vital this year 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.

¹ The Simplexa COVID-19 Direct kit has not been FDA cleared or approved. The Simplexa COVID-19 Direct kit has been authorized by FDA under an EUA for use by authorized laboratories. The Simplexa COVID-19 Direct kit has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The Simplexa COVID-19 Direct kit 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, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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Enclosed: Photo

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