



## **DIASORIN RECEIVES FDA CLEARANCE FOR THE SIMPLEXA™ FLU A/B & RSV DIRECT GEN II ASSAY: A PARTNER TO RUN WITH THE SIMPLEXA™ COVID-19 DIRECT ASSAY**

**Saluggia - September 7, 2020** - DiaSorin (FTSE MIB: DIA) announces 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 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.”*

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### **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, with 26 companies, 4 branches, 5 manufacturing facilities and 5 research and development centers. For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide. The extensive diagnostic testing 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](http://www.diasoringroup.com)