



NEWS RELEASE

FOR IMMEDIATE RELEASE

## **DiaSorin Molecular CE Marks their new Simplexa™ COVID-19 & Flu A/B Direct Assay for Detection and Differentiation of SARS-CoV-2 and Influenza in One Test.**

Cypress, Calif. (September 20, 2021) – DiaSorin Molecular LLC announced today that it has CE marked its Simplexa™ COVID-19 & Flu A/B Direct kit. The multiplex test allows for the *in vitro* qualitative detection and differentiation of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A virus and influenza B virus from the same patient sample in one reaction well. The assay is designed for use on the LIAISON® MDX and is run directly from nasopharyngeal swabs (NPS) without the need for off board extraction. The kit will also be submitted to the FDA for 510(k) review.

The assay provides confidence in results through broad strain coverage. Over 80 influenza strains were validated including all of the strains in the CDC panels of the last three years. Emerging SARS-CoV-2 variants including the Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Epsilon (B.1.427/B.1.429), Zeta (P.2), Eta (B.1.525), Iota (B.1.526), Kappa (B.1.617.1), Lambda (C.37), and Mu (B.1.621) variants were also evaluated to ensure diagnostic coverage.

Flu was nearly nonexistent during the 2020/2021 season, which means that the normally high levels of immunity are much lower in the community, leading to the risk for a potentially high spread next season. The upcoming respiratory illness season will be complicated by the presence of SARS-CoV-2 also circulating in the community. The Simplexa COVID-19 & Flu A/B Direct kit provides the ability for laboratories to efficiently run a single, accurate test to detect the most likely causes of respiratory illness during this flu season. This is especially critical given the difficulty to identify the etiology of the infection based solely on a patient's clinical presentation. Accurate diagnosis of the virus

causing infection is critical for the management of therapeutic regimens along with infection control efforts.

"We are excited to expand our product offering with the launch of this combination kit for detection of SARS-CoV-2 and influenza that can help address concerns in anticipation of this upcoming flu season" said Michelle Tabb, chief scientific officer of DiaSorin Molecular. "We are committed to providing flexible testing options with the new combo kit in addition to our stand-alone COVID-19 assay as well as the triplex for Flu A, Flu B and RSV in order to meet laboratory's evolving needs as the world comes back to a new normal."

### **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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