NEWS RELEASE **FOR IMMEDIATE RELEASE**

DiaSorin Molecular COVID-19 Test Has Received FDA Emergency Use Authorization

Cypress, Calif. (March 20, 2020) – DiaSorin Molecular LLC announced today that it has received Emergency Use Authorization (EUA) from the FDA for their Simplexa™ COVID-19 Direct kit. The kit provides a sample-to-answer test for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, directly from nasopharyngeal swab specimens.

The Simplexa COVID-19 Direct kit is designed for use on the LIAISON® MDX. It can be utilized by hospital laboratories without the need to send the sample out, allowing for timely testing and results. The kit contains an all-in-one reagent mix which is ready to use. Only one instrument and one reagent are required to perform the test. It bypasses the need for traditional extraction procedures, enabling rapid detection in a little over an hour which is significantly faster than the up to seven hours currently required by traditional extraction followed by amplification technologies, ultimately allowing prompt decision making regarding isolation of infected patients.

The test is highly specific to COVID-19 and targets several regions of the viral genome to minimize the impact on performance should there be possible future mutations. This ensures the results are highly sensitive and specific providing confidence in diagnostic decision making.

The outbreak has now officially been declared a global pandemic by the World Health Organization and the U.S. has declared a National Emergency. Many countries are currently implementing emergency quarantines and mandating social distancing in order to reduce the spread of the disease.

DiaSorin Molecular received federal funds from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, in order to develop this test. It is important to increase the testing capacity at hospitals across the nation and this funding will accelerate the availability of diagnostic testing in order to help mitigate the potential impact of this virus.

“We are excited for the launch of our COVID-19 test and hope to help reduce the current shortage of tests being experienced by hospitals worldwide” said John Gerace, president of DiaSorin Molecular. “This test will better enable clinicians to make appropriate diagnostic decisions by providing rapid and accurate results. We know it will play a critical role in containing the pandemic”.

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.

HHS/ASPR/BARDA

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