DiaSorin Molecular Has Attained CE Marking for COVID-19 Test

Cypress, Calif. (April 1, 2020) – DiaSorin Molecular LLC announced today that it has attained CE Marking for their Simplexa™ COVID-19 Direct kit, a sample-to-answer test for the detection of SARS-CoV-2, the virus that causes COVID-19, using nasopharyngeal swab specimens. The company also announced it had received Emergency Use Authorization (EUA) from the FDA on March 20, 2020.

The assay is designed for use on the LIAISON® MDX and consists of an all-in-one reagent mix that is ready to use. Nasopharyngeal swabs can be processed directly in a little over an hour without the need for RNA extraction. It can be utilized by hospital laboratories to speeding up the time to result especially for urgent, inpatient samples.

The test also targets several regions of the viral genome to minimize performance problems should the virus mutate. This ensures highly accurate detection to increase confidence in diagnostic decision making.

With a shortage of tests globally, it is critical to accelerate the availability of diagnostic testing in order to help mitigate the potential impact of this virus. With EUA from the FDA and CE Marking, DiaSorin Molecular will be ramping up production to help global testing efforts during the pandemic.

“We know that Italy, along with all of Europe and the rest of the world, is feeling the impact of the COVID-19 pandemic and are struggling to keep up with testing demands” said John Gerace, president of DiaSorin Molecular. “We are excited to offer an assay that will enable clinicians to make appropriate diagnostic decisions faster and more accurately. We will work closely with hospital laboratories worldwide to ensure they are supported in this difficult time”.

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.

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
This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research, Innovation and Ventures under Contract No. 75A50120C00017.