



NEWS RELEASE

FOR IMMEDIATE RELEASE

DiaSorin Molecular to Receive BARDA Funding to Develop a Rapid COVID-19 Test

Cypress, Calif. (March 13, 2020) – DiaSorin Molecular LLC announced today that it will receive federal funds from the Biomedical Advanced Research and Development Authority, 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 a molecular test for qualitative identification of the novel coronavirus SARS-CoV-2, which causes COVID-19 disease, in response to the evolving global health emergency.

The product is expected to be CE marked and submitted to the FDA by the end of March 2020 to consider for Emergency Use Authorization.

The test is designed for use on any of its LIAISON[®] MDX instruments, hundreds of which are currently placed in hospital laboratories around the US. It will utilize its Direct Amplification Disc technology (DAD) enabling fast, sample-to-answer results, hours faster than currently necessary to report patient results by traditional extraction followed by amplification technologies. The rapid turn-around time will allow for prompt decision making in patient management, which is critical to help hospitals contain the current outbreak and guide treatments. DiaSorin Molecular's PCR test will also target several regions of the viral genome to minimize the impact of possible future mutations.

The current outbreak of coronavirus disease was first reported from Wuhan, China on December 31, 2019. After cases were identified in several countries, a global health emergency was declared with more than 4,500 deaths and over 120,000 confirmed cases. On March 11, 2020, the World Health Organization officially declared the outbreak a global pandemic.

As an innovative molecular diagnostic products company, DiaSorin Molecular has historically responded quickly to emerging infectious diseases including emergency use authorization for its Simplexa™ Influenza H1N1 (2009) kit in response to the H1N1 outbreak. The company works closely with global health organizations during outbreaks with the mission of enabling better management of patients with fast, reliable and clinically actionable assay results.

“We are excited to receive this funding and continue with the development of our test” said Michelle Tabb, chief scientific officer at DiaSorin Molecular LLC. “As soon as the sequence information was made available we immediately began working. We have analyzed over 175 viral sequences published in the GeneBank database to develop a test that detects all known isolates of the SARS-CoV-2 virus to ensure laboratories can be confident in the test results”

“The coronavirus outbreak has sparked global alarm and created intense pressure on healthcare systems to provide laboratory testing that detects the new strain of virus,” commented John Gerace, president of DiaSorin Molecular. “It is important to have a coronavirus test that provides accurate results in a timely fashion and enables clinicians to make appropriate diagnostic decisions. As a specialty diagnostics company, we have a duty to respond with urgency by mobilizing our R&D team to develop a molecular solution. It is our hope that our test may help to contain this new outbreak.”

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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