



DIASORIN HAS COMPLETED THE STUDIES TO SUPPORT THE LAUNCH BY THE END OF MARCH 2020 OF A RAPID RESPONSE MOLECULAR DIAGNOSTIC TEST FOR THE CURRENT NOVEL CORONAVIRUS (COVID-19)

Saluggia - March 10, 2020 - DiaSorin (FTSE MIB: DIA) announced today that it has completed at the Spallanzani Hospital in Rome and at the Policlinico San Matteo in Pavia, the studies necessary to support the CE marking and FDA EUA submission of an innovative molecular test for the rapid identification of the novel coronavirus COVID-19.

The test is designed for the LIAISON[®] MDX instrument using its Direct Amplification Disc technology (DAD), enabling sample-to-answer results within 60 minutes compared to the 5-7 hours currently necessary to report patient results. This product is expected to be launched in Europe CE marked and submitted to the FDA under the Emergency Use Authorization process by the end of March 2020.

The MDX technology was acquired by DiaSorin S.p.A. in 2016 from 3M Inc., a large US Company, and was originally developed to address the need of fast diagnostic response both for in field military and civil use. Currently over 800 systems are installed in the US and Europe in primary hospitals institutions and are used to diagnose regular seasonal Flu and a variety of other viral and bacterial infections where time to response is critical to decide about the care of the patient. This technology, thanks to the fast time to result and ease of use, is ideal to triage patients for hospital admission and DiaSorin believes it could greatly help the hospital systems to decentralize Coronavirus testing and provide a meaningful improvement to the current admission process of potentially contagious patients.

DiaSorin's test will follow the WHO recommended protocol targeting several regions of the viral genome to minimize the impact of possible future mutations.

“As soon as the sequence information was made available we immediately began working to this project in conjunction with the Reference Centers in Italy and the US to develop fast and accurate molecular assays to provide a response to this outbreak. We have analyzed over 150 viral sequences published today in the world genbank database and designed a diagnostic test intended to detect all the currently known variants of the Coronavirus COVID-19”, said Giulia Minnucci, R&D Director Europe at DiaSorin.

As a specialty diagnostics company, DiaSorin has historically responded quickly to emerging infectious diseases including emergency use authorization for its Simplexa[™] Influenza H1N1 (2009) kit and its LIAISON XL Zika Capture IgM II. The company works closely with global health organizations and FDA during outbreaks with the mission of enabling better management of patients with fast, reliable and clinically actionable assay results.

“The coronavirus outbreak has sparked global alarm and created intense pressure on healthcare systems to provide laboratory testing that detect 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”.*



The Diagnostic Specialist

PRESS RELEASE



DiaSorin

Headquartered in Italy and listed in the FTSE MIB Index, DiaSorin is a global leader in the In Vitro Diagnostic (IVD) field. For over 50 years, the Company has been developing, producing and marketing reagent kits for IVD worldwide.

The Group has a presence on the 5 continents with 25 companies, 5 foreign branches, 5 manufacturing facilities and 5 research centers throughout the world. Through constant investments in research and development, and using its own distinctive expertise in the field of immunodiagnosics to deliver a high level of innovation, DiaSorin offers today the broadest range of specialty tests available in the immunodiagnosics market and new tests in the molecular diagnostics markets, which identify DiaSorin Group as the “Diagnostic Specialist”.

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