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Societa'	:	DiaSorin
Identificativo Informazione Regolamentata	:	133390
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Oggetto	:	The LIAISON® SARS-CoV-2 S1 S2 IgG test receives the approval from ANVISA in Brazil

Testo del comunicato

Vedi allegato.

DiaSorin The Diagnostic Specialist

PRESS RELEASE

THE LIAISON® SARS-COV-2 S1/S2 IGG TEST RECEIVED THE APPROVAL FOR THE COMMERCIALIZATION IN BRAZIL FROM ANVISA

Saluggia - June 3, 2020 - DiaSorin (FTSE MIB: DIA) announces that it has received approval for the commercialization of the LIAISON® SARS-CoV-2 S1/S2 IgG test in Brazil from ANVISA, the Brazilian Health Regulatory Agency. Approval was officially awarded on May 25, 2020.

The LIAISON® SARS-CoV-2 S1/S2 IgG test, conceived and developed by the DiaSorin Italian research center in Gerenzano (Italy), guarantees extremely accurate results, with a sensitivity of 97.4% and a specificity of 98.5%.

The test was CE marked on April 17, 2020 and received the Emergency Use Authorization (EUA) by the American Food and Drug Administration on 25 April for the U.S. territory and by Health Canada, the Canadian government department responsible for federal health policy, on 12 May as the first serological test to receive authorization for the Canadian territory.

The test is based on the chemiluminescence technology for the quantitative and qualitative determination of IgG antibodies against SARS-CoV-2 S1 and S2 proteins in serum or human plasma samples, without cross-reactions with other circulating human coronaviruses in Brazil and worldwide (HCoV-OC43, HCoV-229E, HCoV-NL63 and HCoV-HKU).

The LIAISON® SARS-CoV-2 S1/S2 IgG test identifies neutralizing antibodies and hence represents an important tool for studying the immune response against SARS-CoV-2. The test is currently available on over 5,000 LIAISON® XL platforms installed worldwide, with performance of 170 patient samples per hour and with the first result being released in just 35 minutes, increasing testing capacity and allowing productivity improvement to mitigate the impact of this virus.

"I'm profoundly convinced that our test will assist with the diagnosis of COVID-19 and assess the immunological status of infected patients, providing an indication of the presence of IgG antibodies against SARS-CoV-2 among the Brazilian population", commented Fernando Davico, Corporate Vice President Sales EMEA, APAC & LATAM at DiaSorin. *"Our test represents a concrete diagnostic tool to study the immune response to the virus and understand the circulation of the virus amongst the population and I really hope that it can help the difficult moment that Brazil is facing right now".*

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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 26 companies, 4 foreign branches, 5 manufacturing facilities and 5 research and development centers throughout the world. Through constant investments in research and development, and using its own distinctive expertise in the field of immunodiagnostics to deliver a high level of innovation, DiaSorin offers today the broadest range of specialty tests available in the immunodiagnostics market and new tests in the molecular diagnostics markets, which identify DiaSorin Group as the "Diagnostic Specialist".

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