DiaSorin The Diagnostic Specialist

PRESS RELEASE

DIASORIN RECEIVED FDA APPROVAL FOR ITS LIAISON® XL MUREX HIV AB/AG ASSAY, COMPLETING THE HEPATITIS AND RETROVIRUS OFFER IN THE US MARKET

Saluggia, December 1, 2020 - DiaSorin (FTSE MIB: DIA) announces that it has received FDA approval for its LIAISON® XL MUREX HIV Ab/Ag HT Assay, completing its testing solution for Hepatitis and Retroviruses in the U.S. market.

The newly approved assay uses chemiluminescence immunoassay (CLIA) technology for the combined qualitative determination of p24 antigen of human immunodeficiency virus type 1 (HIV-1) and specific antibodies to both human immunodeficiency virus type 1 (group M and group O) and/or human immunodeficiency virus type 2 (HIV-2) in human serum or plasma samples.

Human immunodeficiency virus (HIV) attacks the body's immune system, weakening a person's immunity against infections, such as tuberculosis and some cancers.

HIV continues to be a major global public health issue, having claimed almost 33 million lives so far and currently with around 38 million people positive for the virus worldwide, out of which 1.2 million are in the U.S.

There is currently no effective cure for HIV. Once people get the virus, they have it for life, but with proper medical care, HIV can be controlled. In fact, the number of HIV-related deaths has declined by over 10% over the past five years, as more people gained access to the life-saving treatment and efficient diagnostic tools.

The World Health Organization recommends that every person who may be at risk of HIV should have access to testing. According to the CDC nearly 40% of HIV infections are transmitted by people who do not know they have the virus. For people with undiagnosed HIV, testing is the first step in maintaining a healthy life and preventing transmission. Early diagnosis and early access to treatment has shown clear personal health advantages and health outcomes.

The LIAISON® XL MUREX HIV Ab/Ag HT is designed to be performed on LIAISON® XL analyzers and run in conjunction with a number of additional infectious disease tests often associated with HIV infection, allowing laboratory workflow optimization and better clinical patient management.

The approval of the HIV test falls within the agreement signed with Beckman Coulter in 2016, when the two companies entered into a strategic partnership to bring the LIAISON XL Hepatitis and HIV products to the U.S. market. Since then, both companies have worked together to obtain FDA approval and pursue commercialization in the U.S. of a full line of Hepatitis markers (A, B, C) and HIV assays, which are already available to DiaSorin customers in the rest of the world.

"The approval of our HIV test in the U.S. is an important achievement which strengthens our positioning in the hospital setting and our image and credibility as a reliable and innovative diagnostic player," commented Carlo Rosa, CEO of DiaSorin Group.

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DiaSorin

Headquartered in Italy and listed at the Italian Stock Exchange in the FTSE MIB Index, DiaSorin is a global leader in the In Vitro Diagnostic (IVD) field, with 26 companies, 4 branches, 5 manufacturing facilities and 5 research and development centers.
For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide.
The extensive diagnostic testing offer, made available through continuous investments in research, positions DiaSorin as the player with the broadest range of specialty tests available within the diagnostic market, and identifies the Group as the "Diagnostic Specialist".
More info at www.diasoringroup.com