



DIA SorIN HAS OBTAINED FDA APPROVAL FOR TWO ADDITIONAL SEROLOGY TESTS FOR LYME DISEASE IN THE U.S. MARKET

- DIA SorIN OBTAINED FDA APPROVAL OF BOTH THE LIAISON® LYME IGM AND LIAISON® LYME IGG TESTS
- THESE TESTS ADD TO THE EXISTING LYME DISEASE LINE ALREADY AVAILABLE IN THE U.S. MARKET OFFERING A WIDER RANGE OF FULLY AUTOMATED TESTING OPPORTUNITIES USING BOTH THE STANDARD TWO-TIER LYME TESTING ALGORITHM AND A COMPLETE MODIFIED TWO-TIER TESTING ALGORITHM ON THE LIAISON® XL
- IN CLINICAL TRIALS AN INCREASED SENSITIVITY WAS OBSERVED USING THE LIAISON® LYME IGG AND LIAISON® LYME IGM ASSAYS IN A MODIFIED TWO-TIER TESTING ALGORITHM

Saluggia - February 23, 2021 - DiaSorin (FTSE MIB: DIA) announces that it has received the approval for its LIAISON® Lyme IgM and LIAISON® Lyme IgG tests from the U.S. Food and Drug Administration.

The two new tests add to the already available LIAISON® Lyme Total Antibody Plus test, a fully-automated test for the qualitative determination of both IgG and IgM specific antibodies.

The LIAISON® Lyme IgM and LIAISON® Lyme IgG use chemiluminescence immunoassay (CLIA) technology for the determination of specific IgM and IgG antibodies to *Borrelia burgdorferi*. The combined results represent a highly sensitive and specific screening tool for Lyme disease as the first step in the CDC recommended standard two-tier testing algorithm when confirmed by Western Blot. Additionally, the LIAISON® Lyme IgM and/or LIAISON Lyme IgG assay may be used as the second step of the CDC endorsed modified two-tier testing algorithm in conjunction with the LIAISON® Lyme Total Antibody Plus test as the screening assay.

Dustin Stewart, VP Commercial Operations of DiaSorin Inc., commented *“The launch of these two new serology tests for Lyme disease builds on our legacy of excellence in Lyme disease testing. DiaSorin introduced the first fully automated Lyme disease screening assay in the U.S. in 2007 and we are now proud to offer the first and only fully automated Lyme serology solution using the modified-two tier testing algorithm. This milestone further strengthens our existing positioning as a diagnostic specialty player in the U.S. market, where we now have available a comprehensive set of high quality tests dedicated to Lyme disease to be run on our LIAISON® XL installed base”*.

Lyme is a seasonal disease, with incidence varying greatly by geography in the U.S. and specifically concentrated in the north east and north central areas. The infection is transmitted by tick bites and, at an early stage, fever, chills, muscle and joint aches can appear.

Around 70% of patients in the first 7 to 14 days develop bulls-eye rash and need to be treated with oral antibiotics. At a late stage infected people need to be treated with Intra Venous antibiotics to avoid severe headache, neck stiffness, facial palsy, severe joint pain and swelling (arthritis), nerve pain and dizziness.

The diagnosis of Lyme borreliosis is based on history of exposure to ticks in an endemic area and clinical manifestations, which however may be similar to that of other diseases, making serological detection of *Borrelia* antibodies a fundamental aid to diagnosis.

Tests with high diagnostic accuracy are particularly important for differential diagnosis since additional factors complicate serological findings, such as the fact that early stage of infection may



not show a measurable immune response or that IgM antibodies may persist for months. Additionally, cross-reaction with other infectious diseases or autoimmune disorders may cause false positive antibody response. The use of the new LIAISON® Lyme IgM and/or LIAISON Lyme IgG assay in a modified two tier algorithm demonstrated improved diagnostic performance in clinical trials.

In the U.S. an increased incidence of Lyme disease has been registered over the last decade, with cases almost doubling to nearly 30,000 confirmed cases reported to the CDC per year. A recently released estimate based on insurance records suggests that the disease burden could actually be significantly higher, with up to 476,000 individuals diagnosed and treated for Lyme disease annually.

“We are fully committed to the development of the best Lyme serology assays for detection of Lyme borreliosis at an early stage, a challenge to the diagnostic industry and a growing healthcare threat”, said Carlo Rosa, CEO of DiaSorin Group. “As disclosed at our last Investor Day, we are advancing in the shared project with Qiagen for the development of an innovative test to identify T-cells body reaction that will further strengthen our leadership positioning in Lyme diagnosis testing”.

For additional information, please contact:

Riccardo Fava

Corporate Vice President Communication & Investor Relations

Tel: +39.0161.487988

riccardo.fava@diasorin.it

Emanuela Salvini

Investor Relator

Tel: +39.0161.487567

emanuela.salvini@diasorin.it

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