DiaSorin The Diagnostic Specialist

Press Release

DIASORIN RECEIVES FDA EMERGENCY USE AUTHORIZATION FOR THE FIRST, FULLY-AUTOMATED ZIKA IGM TEST

April 06, 2017 - Saluggia (VC) - DiaSorin (FTSE Italia Mid Cap: DIA) is pleased to announce that it has received FDA Emergency Use Authorization (EUA) for the LIAISON® XL Zika Capture IgM assay, a first-of-its-kind, fully-automated serology assay for the detection of Zika virus infections.

"Leveraging over 40 years of infectious disease immunoassay product development and commercialization we were able to develop a first-of-its-kind assay for Zika virus IgM detection", said John Walter, President of DiaSorin Inc. *"Using the proven LIAISON® XL platform along with an innovative assay format, utilizing the Zika NS1 antigen, DiaSorin was able to produce an assay that yields results in as little as 37 minutes after the specimen is placed on the platform."*

The LIAISON® XL Zika Capture IgM assay is intended for the presumptive qualitative detection of Zika virus IgM antibodies in human sera collected from individuals meeting CDC Zika virus clinical criteria *(e.g., a history of clinical signs and symptoms associated with Zika virus infection)* and/or CDC Zika virus epidemiological criteria. Specimens used with the LIAISON® XL Zika Capture IgM Assay should be collected between 8 days and 10 weeks after onset of symptoms or risk of exposure. The assay is intended for use in laboratories in the United States that are certified[1] to perform high or moderate complexity tests, or by similarly qualified non-U.S. laboratories, consistent with the latest CDC testing algorithms for the diagnosis of Zika virus infection. This test has not been FDA-cleared or approved and is only authorized for use for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The most common symptoms of Zika are fever, rash, joint pain, and conjunctivitis, or red eyes. The illness usually is mild with symptoms lasting for several days to a week. People typically do not get sick enough to require hospitalization and they very rarely die of Zika. For this reason, many people might not realize they have been infected. However, Zika virus infection during pregnancy can cause a serious birth defect called microcephaly, as well as other severe fetal brain defects.

Funding for the LIAISON® XL Zika Capture IgM assay was provided by the U.S. Department of Health and Human Services, which granted DiaSorin a $2.6 million contract in the fall of 2016. The project is funded in whole or in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO1002016000027C.

Carlo Rosa, CEO of DiaSorin Group, commented "*I am extremely proud for the excellent job done by our US R&D team based in Stillwater (MN) in achieving this important milestone. Also, I would like to thank the US Department of Health and Human Services for the continuous support*

[1] under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a

provided to DiaSorin during the development of this very innovative assay. Authorization of our Zika test confirms our Group's ability to continuously innovate in the immunoassay market, providing sound and reliable solutions to customers around the globe to rapidly diagnose harmful diseases and support physicians to provide better care to patients."

About DiaSorin Group

Headquartered in Italy and listed in the FTSE Mid Cap Index, DiaSorin is a global leader in the *In Vitro* Diagnostic (IVD) field. For over 40 years the Company has been developing, producing and marketing reagent kits for IVD worldwide. 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 IVD "Diagnostics Specialist."

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