



The Diagnostic Specialist

Press Release

DIASORIN LAUNCHES SIMPLEXA GROUP B STREP DIRECT MOLECULAR ASSAY IN THE EUROPEAN MARKET

October 17, 2018 - Saluggia (VC) - DiaSorin (FTSE Mid Cap: DIA) announced to have received CE marking for its new Simplexa Group B Strep Direct assay and it has also been submitted to the FDA under their Premarket Notification process, to obtain 510(k) Clearance.

The new molecular diagnostic test enables the direct in vitro detection of Group B Streptococcus DNA. The assay, designed for use on the LIAISON MDX instrument, is more specific than traditional testing methods and features an efficient and fast workflow.

GBS infection is a leading cause of early-onset neonatal sepsis. An estimated one in five pregnant women around the world carries GBS bacteria, which is a major, yet preventable, cause of maternal and infant infection globally.

Vertical transmission of GBS to the newborn can result in an invasive infection known as early onset disease (EOD). Infants with EOD will present with fever, lethargy, sepsis, pneumonia and, more rarely, meningitis within the first 24 to 48 hours of life.

The World Health Organization estimates that GBS causes an estimated 150,000 preventable stillbirths and infant deaths every year.

“With this CE-marked assay we are pleased to enter the women’s health market” said Michelle Tabb, Chief Scientific Officer at DiaSorin Molecular LLC. *“Our company is driven to help hospitals and clinical labs provide excellent patient care through high-quality molecular assays and we are proud to add GBS to the important disease areas we address.”*

About DiaSorin

Headquartered in Italy and listed in the FTSE Italia Mid Cap 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. 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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