



NEWS RELEASE

FOR IMMEDIATE RELEASE

DiaSorin Molecular Attains CE Mark for Simplexa™ Group B Strep Direct Molecular Assay

Cypress, Calif. (October 18, 2018) – DiaSorin Molecular LLC announced today that it has attained CE marking for its new Simplexa™ Group B Strep Direct assay. Designed for use on the LIAISON® MDX instrument, the highly sensitive assay enables the direct *in vitro* detection of Group B Streptococcus (GBS DNA). GBS infection is a significant challenge in the health management of women and newborns. The new assay is more specific than traditional testing methods and features an efficient, fast workflow. This assay has also been submitted to the FDA under their Premarket Notification process, to obtain 510(k) clearance.

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. “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 Molecular

DiaSorin Molecular LLC manufactures and distributes innovative molecular diagnostic products for hospital and reference laboratories. The company's products help laboratories consolidate their testing, streamline processes and increase efficiency. DiaSorin Molecular's Simplexa molecular diagnostic kits are designed for use on the company's versatile LIAISON MDX platform. The company provides service and support solutions for its kits and instruments through a global network of offices and distributors. DiaSorin Molecular also markets a range of ASRs (analyte-specific reagents) for use in lab-developed tests.

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Enclosed: Photo

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