



NEWS RELEASE

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DiaSorin Molecular Secures FDA Clearance for Group B Strep Assay

Simplexa™ GBS Direct molecular assay enables in vitro detection of Group B Streptococcus

Cypress, Calif. (November 26, 2018) – DiaSorin Molecular LLC announced today that the FDA has cleared its new Simplexa™ GBS Direct assay for diagnostic use. Designed for use on the LIAISON® MDX instrument, the highly sensitive assay enables qualitative detection of Group B *Streptococcus* (GBS) nucleic acid from 18- to 24-hour Lim broth enrichments of vaginal/rectal specimen swabs obtained from antepartum women. Assay results can be used as an aid in determining the colonization status of antepartum women. The new assay can replace traditional culture testing methods and features an efficient, fast workflow. This is the ninth assay for infectious disease on DiaSorin Molecular's PCR platform to obtain FDA 510(k) clearance.

GBS infection is a significant challenge in the health management of newborns and is a leading cause of early-onset neonatal sepsis. An estimated one in four pregnant women is colonized by GBS bacteria, which is a major, yet preventable, cause of infant infection. 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. In order to prevent transmission, pregnant women are screened for GBS colonization at 35 to 37 weeks gestation. Those that test positive are given intrapartum antibiotic prophylaxis, which substantially decreases the risk of GBS transmission to the newborn, thus reducing the occurrence of EOD.

“Our new GBS assay simplifies GBS testing and allows for the detection of non-beta-hemolytic strains that can be missed with typical culture methods,” said Michelle Tabb,

chief scientific officer at DiaSorin Molecular. “We are pleased to enter the women’s health testing market with this assay. Our company strives to meet the needs of clinical labs around the world with high-quality molecular assays that are easy to use and deliver actionable results.”

About DiaSorin Molecular

DiaSorin Molecular LLC is part of the DiaSorin Group and 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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