FDA clears Simplexa group B strep assay

Nov. 27, 2018—DiaSorin Molecular announced that the FDA has cleared its 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* 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.

“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,” Michelle Tabb, chief scientific officer at DiaSorin Molecular, said in a statement. “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.”

This is the ninth assay for infectious disease to obtain FDA 510(k) clearance on the company’s PCR platform.