FDA clears NeuMoDx 288 system, GBS assay

September 2018—NeuMoDx Molecular announced it has received FDA 510(k) clearance for its NeuMoDx 288 Molecular System and NeuMoDx GBS Assay. The fully automated NeuMoDx 288 is a scalable platform that integrates the diagnostic process, from extraction to detection, in approximately one hour. The analyzer can load up to 288 patient samples in a continuous random-access mode and features a walkaway time of more than six hours.

The dry format reagents do not require refrigeration and have an onboard stability of more than 60 days and an ambient temperature storage shelf life of more than one year. The unitized format of the dry reagents aims to increase operating efficiency while minimizing the waste associated with systems requiring manual reconstitution or use of bulk format lyophilized reagents.

The NeuMoDx GBS Assay is a qualitative in vitro diagnostic test designed to detect group B *Streptococcus* DNA from antepartum pregnant women. The assay incorporates sample lysis and automated DNA extraction to isolate nucleic acid from the specimen and real-time polymerase chain reaction to detect an 88 bp region of the pcsB gene sequence in the *Streptococcus agalactiae* chromosome. In a multicenter clinical performance study, the NeuMoDx GBS Assay results yielded a sensitivity of 96.9 percent and specificity of 96 percent, when compared with the gold standard culture method.

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