

R262

Publication Only

Molecular biology, including diagnostics: Molecular bacteriology

Clinical evaluation of the Xpert GBS assay (Cepheid) for intrapartum GBS colonisation screening

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**Objectives:** Group B streptococcus (GBS) is the leading cause of infectious neonatal morbidity and mortality. The majority of early-onset GBS disease can be prevented using antibiotic prophylaxis during labor. Enrichment culture performed at 35-37 weeks' gestation is the gold standard for the GBS colonization screening. However, culture results are not available until 24-72h and colonization can occur after the time of screening. Novel rapid molecular assays aim to address this issue. The aim of our study was to evaluate the Xpert GBS real-time PCR (Cepheid) for the determination of GBS status at the time of delivery.

**Methods:** We tested 54 consecutive women presenting for labor in a large tertiary care perinatal facility. Recto-vaginal specimens were collected using double swab (Copan Transystem) and transported immediately to the microbiology laboratory. One swab was used for the Xpert GBS assay and the second swab was used for the enrichment culture. The swab for the Xpert GBS assay was processed using the GeneXpert system (Cepheid) in accordance to the manufacturer's instructions. The swab for enrichment culture was inoculated into the selective broth medium (Todd-Hewitt broth supplemented with colistin and nalidixic acid) and chromogenic agar chromID StreptoB (bioMérieux), followed after 24h by subculture on chromID StreptoB.

**Results:** The prevalence of GBS carriage in our sample as determined by the enrichment culture was 24.1% (n=13). 12 samples were positive by both methods, 1 sample was positive by enrichment culture only and 41 samples were negative by both methods. Sensitivity, specificity, positive predictive value and negative predictive value of the Xpert GBS assay as compared to the enrichment culture (gold standard) were 92.3%, 100%, 100% and 97.7%. The one discrepant sample (positive by enrichment culture and negative by Xpert GBS) had low concentration of GBS in the specimen, as it was culture positive only after the enrichment. The mean turnaround time for Xpert GBS assay was 30 minutes for positive samples and 50 minutes for negative samples.

**Conclusion:** The Xpert GBS real-time PCR assay is a rapid (<1h turnaround time) and accurate method (92.3% sensitivity and 97.7% negative predictive value) for the detection of maternal GBS colonization status. The assay is especially valuable in a clinical setting where results of screening with culture are not available either due to preterm labor or because the test was not performed during pregnancy. The Xpert GBS enables targeted and more effective intrapartum antibiotic prophylaxis.