Clinical evaluation of the Portrait GBS assay in detecting Streptococcus agalactiae in enriched LIM broth cultures of rectovaginal swabs from pregnant women

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INTRODUCTION

Streptococcus agalactiae ( Lancefield group B Streptococcus, GBS) is an important cause of early and late-onset neonatal sepsis and meningitis, and may be prevented through the screening and treatment of pregnant women. To evaluate the clinical performance of the Portrait GBS assay (Great Basin Scientific, Inc.) for detection of GBS in enriched LIM broth cultures of rectovaginal swabs from pregnant women, Portrait GBS results were compared to both enriched culture and two FDA cleared molecular assays.

Methods:
The Portrait GBS assay utilizes biotinylated primers to amplify a conserved region of the GBS tuf gene using biotin-labeled primers with subsequent hybridization and detection steps. All testing is performed in a closed-system, single-use cartridges (Figure 1). On the reverse side of the cartridge is a modified chip that contains multiple test zones for the Portrait GBS assay, and one control zone for the BD MAX™ GBS assay (Great Basin Scientific, Inc.).

RESULTS

A total of 318 rectovaginal swabs were enrolled in the study with a GBS prevalence of 21.6% (112/518) based on culture data. Using standard microbiological techniques to define true positives and negatives, we obtained 98.5% (95% confidence interval CI 95, 95.5-99.5%) sensitivity and 97.1% (95% CI 95, 95.1-98.5%) specificity for the Portrait GBS assay with a positive predictive value (PPV) of 98.3% (95% CI 97.1-99.0%) and negative predictive value (NPV) of 96.2% (95% CI 95.1-97.5%). The Portrait GBS assay was equivalent to the BD MAX™ GBS assay (95% CI, 95.1-98.6%) and performed better than the Cepheid Xpert® GBS LB assay (95% CI, 93.1-97.8%) at a site-3.

CONCLUSIONS

The Portrait GBS assay is a convenient, walk-away assay for the detection of GBS in enriched LIM broth cultures of rectovaginal swabs from pregnant women. It performed well in this clinical evaluation and compared favorably in sensitivity to both FDA cleared molecular assays with a specificity statistically equivalent to other commercially available GBS molecular detection methods tested.

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