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Multisite Comparison of the Great Basin Portrait GBS Assay to the BD MAX GBS and Xpert GBS LB Assays for the Detection of Group B Streptococcus from Broth-Enriched Specimens

Matthew L. Faron[1,2], J. Connolly[1,2], M. H. McCoy[3], S. Fuller[3], J. Talbott[3], W. Veros[3], D. Fuller[3], T. E. Davis[3], S. Young[4,5], N. A. Ledeboer[1,2], and B. W. Buchan[1,2]

[1]Medical College of Wisconsin, Milwaukee, WI, [2]Dynacare Laboratories, Milwaukee, WI, [3]Indiana University School of Medicine, Indianapolis, IN, [4] University of New Mexico Department of Pathology, Albuquerque, NM, [5]Tricore Reference Laboratories, Albuquerque, NM

Introduction

S. agalactiae or Group B *Streptococcus* (GBS) is a commensal organism in the female urogenital tract. Colonization can be transient and asymptomatic; however transfer of GBS to a neonate during vaginal birthing can result in life threatening infections including meningitis and septicemia. In this study, we compared the clinical performance of 3 nucleic acid amplification assays to identify GBS in broth enriched vaginal/rectal specimens.

Method

A total of 518 vaginal/rectal specimens were collected from women at 35-37 weeks gestation located at 3 geographically distinct sites. Swabs were inoculated to LIM enrichment broth and were incubated > 18 h at 35 °C prior to analysis. All enriched broth specimens were tested using the Portrait GBS assay. For comparison, 342/518 (66.0%) and 176/518 (34%) specimens were tested in parallel using the Xpert GBS LB or BD MAX GBS assays. All results were compared to broth enriched culture as gold standard to identify GBS. Broths were inoculated to a blood agar plate and incubated up to 48 h at 35 °C. GBS was identified based on characteristic morphology and biochemical analysis (Gram-stain, catalase and latex antigen typing).

Table 1. Overall performance of the three GBS assays tested

Assay	# tested	Prevalence[a]	Sensitivity (95%CI)	Specificity (95%CI)	PPV[b] (95%CI)	NPV[c] (95%CI)
Portrait	518	21.6%	98.2 (93-100)	96.1 (93-98)	87.3 (80-92)	99.5 (98-100)
Xpert	342	22.8 %	96.2 (88-99)	98.5 (96-100)	94.9 (87-98)	98.9 (96-100)
BD MAX	176	19.3%	100 (87-100)	94.4 (89-97)	81.0 (65-91)	100 (96-100)

[a] Prevalence is based on culture positivity
[b] Positive Predictive Value
[c] Negative Predictive Value

Table 2. Great Basin Portrait performance for identification of GBS

GBS		Culture Pos	Culture Neg	Culture Total
Great Basin Portrait	Pos	110	16[a]	126
	Neg	2[b]	390	392
	Total	112	406	518

[a] 10/16 FP results were positive by an alternative molecular test
[b] Both FN were positive by alternative molecular test

Table 3. BD MAX performance for identification of GBS

GBS		Culture Pos	Culture Neg	Culture Total
BD MAX	Pos	34	8[a]	42
	Neg	0	134	134
	Total	34	142	176

[a] 7/8 FP results were positive by Great Basin Portrait analysis

Table 4. Cepheid Xpert performance for identification of GBS

GBS		Culture Pos	Culture Neg	Culture Total
Cepheid Xpert	Pos	75	4[a]	79
	Neg	3[b]	260	263
	Total	78	264	342

[a] 3 of 4 FP results were positive by Great Basin Portrait analysis
[b] All 3 FN results were positive by Great Basin Portrait analysis

Conclusions

- The Great Basin Portrait GBS assay was highly sensitive and specific for detecting GBS from LIM broth enriched cultures from vaginal/rectal specimens
- The addition of two additional FDA cleared tests demonstrates that all three assays are equivalent
- Of 28 FP results across all molecular tests, 20 were confirmed by a second molecular assay indicating increased sensitivity for molecular tests compared to culture
- Great Basin Portrait had a first run invalid rate of 1.7% and all invalids were resolved upon retesting
- The Assay workflow is simple and requires less than 2 minutes of hands-on-time per specimen and results are obtained in 90 minutes