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Multicenter Study Evaluating Performance of the Smart Group B Streptococcus (GBS) Assay Using an Enrichment Protocol for Detecting GBS Colonization in Patients in the Antepartum Period[▽]

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Group B streptococcus (GBS) remains the leading cause of infectious morbidity and mortality in infants born in the United States, especially among black infants. Because a newborn can acquire GBS during and after delivery, the Centers for Disease Control and Prevention (CDC) recommends that pregnant women be screened for rectovaginal GBS colonization during the antepartum period between weeks 35 and 37 of gestation and, if they are colonized, that intrapartum antibiotic prophylaxis be administered. A prospective investigational study was undertaken from 2 May 2006 to 14 August 2006 at three sites to establish the performance characteristics of the Smart GBS LB assay on the SmartCycler II system for detecting GBS colonization in subjects in the antepartum period from combined vaginal/rectal swab-based specimens after broth enrichment. Results were compared to broth enrichment culture and to the predicate device, the BD GeneOhm StrepB direct assay. The collected specimens were randomized for swab testing order. Each swab sample was processed simultaneously by culture, Smart GBS LB assay, and the BD GeneOhm StrepB assay. A total of 310 subjects were enrolled, with 306 subject results included in the study. Compared to enrichment culture, the Smart GBS LB assay demonstrated a sensitivity, specificity, positive predictive value, and negative predictive value of 98.6%, 90.4%, 77.1%, and 99.5%, respectively. The Smart GBS LB assay demonstrated substantially equivalent or better performance than culture or the predicate device. Screening of broth enrichment fluids by nucleic acid amplification testing requires careful handling during sample processing to avoid possible contamination.

Group B streptococcus (GBS) remains the leading cause of serious bacterial infections in the newborn infant, including neonatal sepsis, pneumonia, and/or meningitis (8, 11). Newborns can acquire GBS during gestation, delivery, or postpartum if their mothers carry GBS either vaginally and/or rectally (6). Because rectovaginal GBS colonization rates among pregnant women vary widely between socioeconomic groups and by ethnicities (<10% to >30%) and prediction of a woman's colonization status based on certain risk factors is less than accurate, universal GBS screening has been recommended for all pregnant women, with intrapartum antibiotic prophylaxis for those colonized with GBS (7). Despite the success of implementing intrapartum antibiotic prophylaxis in women colonized with GBS, where the overall incidence rates of early-onset neonatal infections were reduced from 1.7 cases per 1,000 live births in 1993 to 0.4 cases per 1,000 live births in 2006, GBS remains the most common bacterial infection in neonates (9). This is especially true among black infants, for whom the incidence rate in 2006 was 0.86 cases per 1,000 live births, compared to 0.29 cases per 1,000 live births for white infants during the same time frame (2). The 2006 rates among preterm black infants were even higher, at 1.79 cases per 1,000 live births (2).

In 2002 the Centers for Disease Control and Prevention (CDC) revised its guidelines on the prevention of perinatal group B streptococcal disease to recommend universal vaginal/rectal GBS screening cultures be performed during weeks 35 to 37 of gestation for all pregnant women unless they had a history of GBS bacteriuria during the current pregnancy or a previous infant with invasive disease (7). In these guidelines, CDC also recognized the existence of alternative testing methods to antepartum culturing and the need to validate an adequate level of sensitivity with these methods compared to the gold standard, the broth enrichment culture method, before considering their implementation. Today, alternative diagnostic choices to culture do exist and include several *in vitro* diagnostic devices (IVD) kits that have been cleared by the Food and Drug Administration (FDA).

The first IVD kit cleared by the FDA for detection of GBS from vaginal/rectal swab-based specimens in pregnant women is now referred to as the BD GeneOhm StrepB assay (Becton Dickinson, Franklin Lakes, NJ). The assay can be used to assess the vaginal/rectal GBS colonization status of women in both the antepartum and intrapartum periods. The package insert's performance characteristics of the BD GeneOhm StrepB assay for direct specimen testing (with 95% confidence intervals [CIs] in parentheses) compared to intrapartum culture are 94% (89 to 97%) sensitivity, 96% (94 to 97%) speci-

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ficity, 83.8% (77.4 to 89.1%) positive predictive value, and 98.6% (97.3 to 99.3%) negative predictive value (3). However, subsequent studies revealed somewhat lower sensitivity rates than those stated in the package insert compared to culture-based methods (1). These findings led investigators to consider performing nucleic acid amplification testing (NAAT) from enrichment broth fluid rather than from the swab directly (1). This use of the real-time PCR assay for antepartum GBS screening was considered off-label usage and required directors to validate these protocols for use in their clinical laboratories. The published reports from their efforts revealed NAAT provided improved sensitivity for broth enrichment specimens over direct swab testing, making this application feasible for antepartum GBS screening (5). However, many laboratory directors avoid use of off-label applications of FDA-cleared IVD kits in their clinical laboratories.

To this end, the present multisite prospective study was undertaken to establish the performance characteristics of the Smart GBS Lim broth enrichment (Smart GBS LB) assay (Cepheid, Sunnyvale, CA) for use with an antepartum application.

MATERIALS AND METHODS

Study design. The institutional review boards of all the participating institutions approved the study, which was conducted from 2 May 2006 through 14 August 2006. To be enrolled in the study, a subject had to be between 35 and 37 weeks gestation, have no contraindication to a vaginal examination, and provide written informed consent. Subjects who had used systemic or topical (vaginal) antibiotic treatment during the week prior and/or who presented with placenta previa were excluded from the study. Consecutive eligible and consenting subjects were enrolled, without further selection criteria, into the study. The minimum number of true culture-positive specimens needed for this study was determined with performance characteristics that included a 95% confidence interval, with an alpha of 0.05 and a power of 0.90.

Specimen collection and handling. The CDC-recommended guidelines for specimen collection were followed. A combined vaginal and rectal specimen was collected from each subject by using a rayon tip double swab collection device and liquid Stuart transport medium (catalog number 139C; Copan Diagnostics, Murrieta, CA). During the process of collecting the specimen, an attempt was made to wipe away excessive vaginal secretions by using a gauze pad before the swabs were used to collect vaginal material. The same swabs were then used to collect a specimen from the anal crypts. The double swab specimen was placed back into its protective plastic sleeve and sent to the laboratory for testing.

To minimize bias in specimen analysis the technologist receiving the research specimens was instructed to gently rub all sides of the two swabs together so as to more evenly distribute the material between the two swabs before any testing was performed. The technologists performing the nucleic acid amplification assays were different from those who performed the cultures and were blinded to those culture results.

Smart GBS LB assay. One swab from the pair was analyzed using the Smart GBS LB assay (Cepheid Inc., Sunnyvale, CA) as follows: the swab-based specimen was first placed in 5 ml of Lim broth (Todd-Hewitt broth containing 15 μg/ml nalidixic acid and 10 μg/ml colistin or 15 μg/ml nalidixic acid and 8 μg/ml gentamicin; PML Microbiologicals, Wilsonville, OR, or BBL, Sparks, MD) and incubated 18 to 24 h at 37°C before the broth was tested for GBS DNA using the Smart GBS LB assay.

Two hundred microliters of well-mixed incubated Lim broth was transferred to a tube, and the cellular material was pelleted by centrifugation (10,000 × *g* for 3 min). The resulting supernatant was removed and discarded before 750 μl of diluent reagent was added to the cell pellet. The cells were vortexed at high speed for 5 min to release the chromosomal DNA. The tubes were centrifuged briefly (5 to 7 s) in a microcentrifuge before being opened. Twenty-one microliters of diluent was added to each master mix tube, which was placed on ice while reconstituting the lyophilized, bead-based reagents. Five microliters of each prepared specimen was added to a chilled reconstituted master mix tube, recapped, and briefly vortexed (2 to 5 s) and centrifuged (>5 s) in a microcentrifuge. Twenty-five microliters from the master mix tube was added to a Smart tube, briefly centrifuged (2 to 5 s), and loaded into the SmartCycler Dx System for real-time PCR. Both a positive control (GBS) and a negative control (a non-GBS bacterium, such as *Escherichia coli*) were prepared and included in each run of specimens tested.

BD GeneOhm StrepB assay. The other swab from the pair was analyzed using the BD GeneOhm StrepB direct assay (BD Diagnostics, GeneOhm, San Diego, CA) according to the manufacturer's instructions. After the nucleic acid amplification test was performed, the swab and its remaining BD GeneOhm elution buffer containing Tris-EDTA were added to 5 ml of Lim broth, incubated for 18 to 24 h at 37°C, and cultured for GBS as described in the next section.

GBS enrichment broth culture method. The overnight Lim broths were inoculated onto a 5% sheep blood agar plate (SBA; Becton Dickinson, BBL, Sparks, MD) and an NEL GBS chromagar plate (Northeastern Laboratory Services, Winslow, ME) with the use of a sterile swab. The SBA and NEL plates were incubated for 18 to 24 h at 35 ± 2°C in 5% CO_2. If GBS was not apparent after the initial 18 to 24 h, the plates were reincubated and inspected after 48 h to identify suspicious colonies. Presumptive GBS colonies on the SBA plate were confirmed using commercially available direct agglutination reagents and GBS-specific antiserum (PathoDx; Diagnostic Products Corporation, Los Angeles, CA) or a nucleic acid probe hybridization assay (Gen-Probe, San Diego, CA) according to the manufacturer's instructions to confirm presumptive colonies of GBS on SBA plates. No additional confirmatory test was performed on the orange-colored colonies growing on the NEL chromagenic agar plates.

Statistical analysis. Two-by-two tables were established, and analytical performance characteristics with 95% confidence intervals were calculated for sensitivity, specificity, positive predictive value, and negative predictive value. Fisher's exact test was the statistical significance test used to calculate *P* values.

RESULTS

Patient accountability and demographics. A total of 310 subjects were enrolled, of which 307 were eligible, with 306 included in the overall analyses; 1 subject was enrolled twice, so the results generated from her second specimen were excluded from the data set, while 2 subjects' specimens were discarded due to inappropriate storage conditions (>6 days prior to testing) and 1 subject's specimen was missing the swabs in the transport sleeve and therefore could not be tested. Of the 306 subjects enrolled in the study, similar numbers and percentages of African Americans (92; 30.1%), Hispanics (91; 29.7%), and Caucasians (104; 34%) participated. The remaining enrollees constituted only a small percentage and were evenly divided between Asians (10; 3.3%) and others (undesignated) (9; 2.9%).

Smart GBS LB assay performance characteristics. The Smart GBS LB assay produced a valid result on the first attempt in 301/306 (98.4%) specimens tested and on the remaining 5 specimens after one repeat test. Of the 5/306 (1.6%) specimens with indeterminate results generated on the first attempt, all had been tested at one study site; 2 specimens were invalid due to internal control failures, while 3 were invalid because of an invalid negative control, which invalidated the entire run. The results from the repeat testing for these five initially invalid specimens were included in the final data set for analysis.

Comparison of the Smart GBS LB assay with broth enrichment culture. Table 1 illustrates the results of the comparison of the 306 specimens tested by the Smart GBS LB assay and by broth enrichment culture. The performance characteristics (with 95% CIs in parentheses) were calculated and found to be 98.75% (92.8% to 100%) sensitivity, 90.4% (85.8% to 93.9%) specificity, 77.1% (67.4% to 85.1%) positive predictive value, and 99.5% (97.4% to 100%) negative predictive value.

Comparison of the BD GeneOhm StrepB Direct assay with broth enrichment culture. The BD GeneOhm assay produced

TABLE 1. Comparison of the Smart GBS LB assay with broth enrichment culture[a]

Smart GBS LB result	No. of samples with indicated broth enrichment culture result		
	Positive	Negative	Total
Positive	74	22	96
Negative	1	209	210
Total	75	231	306

[a] Calculated performance characteristics (with 95% confidence intervals in parentheses) were as follows: sensitivity, 98.67% (92.79 to 99.97%); specificity, 90.48% (85.94 to 93.93%); positive predictive value, 77.08% (67.39 to 85.05%); negative predictive value, 99.52% (97.38 to 99.99%).

TABLE 3. Agreement between the Smart GBS LB assay and BD GeneOhm StrepB assay[a]

BD GeneOhm StrepB result	No. of samples with indicated Smart GBS LB result		
	Positive	Negative	Total
Positive	66	4	70
Negative	30	206	236
Total	96	210	306

[a] Positive result agreement was 68.8%, and negative result agreement was 98.1%.

a valid result on the first attempt in 296/306 (96.7%) specimens tested and on the remaining 10 specimens after one repeat test. The results from the repeat testing for these 10 initially invalid specimens were included in the final data set for analysis. Table 2 illustrates the comparison of the predicate device, the BD GeneOhm StrepB direct assay, with that of broth enrichment culture. The performance characteristics (and 95% CIs) were calculated and found to be 81.33% (70.67% to 89.4%) sensitivity, 96.1% (92.73% to 98.2%) specificity, 87.14% (76.99% to 93.95%) positive predictive value, and 94.07% (90.25% to 96.72%) negative predictive value.

Comparison of the Smart GBS LB assay with the predicate IVD device. Table 3 illustrates the comparison of the 306 specimens tested by the Smart GBS LB assay with the predicate device, the BD GeneOhm StrepB Direct assay. There was 68.8% agreement among positive results and 98.1% agreement among negative results. Discrepant analyses were performed only on specimens where the Smart GBS LB test and culture result were discordant; no discrepant analyses were conducted for the BD GeneOhm StrepB test. Table 4 illustrates the substantial equivalence analysis that was performed to compare the Smart GBS LB assay with the BD GeneOhm StrepB direct assay. The performance characteristics of sensitivity, specificity, and accuracy of the two nucleic acid amplification tests were compared for their equivalence and found to show substantial equivalence.

Preidentified substances assessed for their potential to interfere with the Smart GBS LB assay. Of the 306 specimens included in the final data set, 53 (17.3%) were observed to contain at least one of the preidentified substances that could potentially interfere with the assay. Table 5 illustrates the frequencies of the observed substances found on the swab-based specimens. After visual inspection, fecal material was the most common contaminant found on the swabs. Using the Fisher exact test, presence of these contaminants was shown not to adversely affect the sensitivity or specificity of the Smart GBS LB assay.

Discordant results analyses. Table 6 illustrates the additional testing and interpretation done for the 23/306 (7.5%) specimens with discordant results (22 false positives and 1 false negative) seen when comparing the Smart GBS LB assay with the SBA plate subcultured from its selective enrichment broth. The analysis used the results from both molecular-based assays and also the respective broth enrichment culture results as well as GBS-specific DNA probe hybridization testing, if run. The Accuprobe data were results from the standard-of-care method performed at one site.

The one specimen that initially tested negative by the Smart GBS LB assay was interpreted as a true positive, and the Smart GBS LB result was considered to be a false-negative result. Eleven of 22 (50%) specimens initially testing positive by the Smart GBS LB assay were interpreted as true positives, with their results confirmed by at least one additional testing method, while the remaining 11 of 22 (50%) were interpreted as true negatives and the Smart GBS LB results were considered to be false positive, for an overall 3.6% false-positive rate (11/306). The median threshold cycle (C_T) value for Smart GBS LB true-positive results was 20.5, while that for the Smart GBS LB false-positive results was 31.4. Table 6 also illustrates a 3.6% false-negative rate for the selective enrichment broth culture method compared to the Smart GBS LB assay when used to determine the GBS colonization status in women. This

TABLE 2. Comparison of the BD GeneOhm StrepB assay with broth enrichment culture[a]

BD GenOhm StrepB result	No. of samples with indicated broth enrichment culture result		
	Positive	Negative	Total
Positive	61	9	70
Negative	14	222	236
Total	75	231	306

[a] Calculated performance characteristics (with 95% confidence intervals in parentheses) were as follows: sensitivity, 81.33% (70.67 to 89.40%); specificity, 96.10% (92.73 to 98.20%); positive predictive value, 87.14% (76.99 to 93.95%); negative predictive value, 94.07% (90.25 to 96.72%).

TABLE 4. Substantial equivalence assessment

Performance characteristic[a]	Smart GBS result[b]	BD GeneOhm GBS result[c]	Delta value	Substantial equivalence?[d]
Sensitivity (%)	93.83	71.33	22.50	Yes
Specificity (%)	86.68	86.10	0.58	Yes
Accuracy[e] (%)	89.52	82.48	7.04	Yes

[a] Sensitivity, specificity, and accuracy results were defined as the lower one-sided 95% CI from Fisher's exact test.

[b] The Smart GBS result shown is the low 95% CI based on a one-sided Fisher's exact test.

[c] The BD GeneOhm GBS result shown in the estimate minus 0.1.

[d] Substantial equivalence was reported when the BD GeneOhm result minus 0.1 was greater than or equal to the Smart GBS LB lower 95% CI value.

[e] Accuracy was determined by the equation [(number of true positives) + (number of true negatives)]/total number of specimens.

TABLE 5. Results for specimens with interfering substances

Interfering substance	No. of specimens[a]	Sensitivity (%)[b]	Specificity (%)[b]	*P* value[c]	
				Sensitivity	Specificity
Feces	41	100.0	85.19	1.000	0.330
Blood	8	100.0	100.0	1.000	1.000
Mucus	6	100.0	100.0	1.000	1.000
Lubricant	1	NA[d]	100.0	NA	1.000
Total	53	100.0	88.9	1.000	0.7628

[a] Some specimens contained more than one of the above interfering substances.
[b] Performance characteristics of the specimens containing potentially interfering substances.
[c] Based on Fisher's exact test.
[d] NA, not applicable.

was comparable to the 4% rate described by Scicchitano and Bourbeau (10).

Table 7 illustrates the additional molecular testing and interpretation for the 23/306 (7.5%) specimens with discordant results (14 false negatives and 9 false positives) that were seen when comparing results with the BD GeneOhm StrepB assay and the SBA plate subcultured from selective enrichment broth. Fourteen of 14 (100%) specimens with initial false-negative results were confirmed to be false negatives, while 9/9 (100%) specimens with initial false-positive results were determined to be true positives. Table 7 also illustrates a 2.9% false-negative rate for the selective enrichment broth method compared to the BD GeneOhm StrepB direct assay, which is comparable to that described by Scicchitano and Bourbeau (10).

TABLE 6. Interpretation and results of additional testing performed on specimens with discordant Smart GBS LB and paired culture results[a]

Subject no.	Smart GBS LB[b]	SBA, NEL Cx[b]	BD GeneOhm StrepB[c]	SBA, NEL Cx[c]	Accuprobe[b]	Interpretation of discordant Smart GBS LB and Cx results
01503	P	N, P	N	N, P	N	TP
01518	P	N, P	N	P, P	ND	TP
01552	P	N, N	P	N, N	N	TP
01576	P	N, N	N	N, N	ND	FP
14722	P	N, N	N	N, N	P	TP
14740	P	N, N	N	N, N	N	FP
14749	P	N, N	N	N, N	P	TP
14762	P	N, N	N	N, N	N	FP
14772	P	N, N	P	N, N	P	TP
14775	P	N, N	N	N, N	N	FP
14784	P	N, N	N	N, N	P	TP
14786	P	N, N	N	N, N	N	FP
14811	P	N, N	N	N, N	N	FP
14818	P	N, N	P	N, N	P	TP
14821	P	N, N	N	N, N	N	FP
14825	P	N, N	N	N, N	N	FP
14827	P	N, N	N	N, N	N	FP
14854	P	N, N	N	N, N	N	FP
14856	P	N, N	N	N, N	N	FP
15508	P	N, P	N	P, P	ND	TP
15559	P	N, P	P	P, P	ND	TP
15567	P	N, N	P	N, P	ND	TP
01506	N	P, N	N	N, P	N	FN

[a] Abbreviations: Cx, enrichment culture; ND, not done; NEL, chromogenic agar plate; P, positive; N, negative; TP, true positive; FP, false positive; FN, false negative.
[b] Results of the swab (from each pair) tested by Smart GBS LB assay and culture.
[c] Results of the swab (from each pair) tested by BD GeneOhm assay and culture.

TABLE 7. Interpretation and results of additional testing performed on specimens with discordant BD GeneOhm StrepB and culture results[a]

Subject no.	BD GeneOhm StrepB[c]	SBA, NEL Cx[c]	Smart GBS LB[b]	SBA, NEL Cx[b]	Accuprobe[b]	Interpretation of discordant BD GeneOhm StrepB and Cx results
01518	N	P, P	P	P, P	ND	FN
15508	N	P, P	P	P, P	ND	FN
01511	N	P, P	P	N, P	ND	FN
01512	N	P, P	P	P, P	ND	FN
01530	N	P, P	P	P, P	ND	FN
01575	N	P, P	P	P, P	ND	FN
14729	N	P, P	P	P, P	ND	FN
14735	N	P, P	P	P, P	N	FN
14742	N	P, P	P	P, P	ND	FN
14798	N	P, P	P	P, P	ND	FN
14801	N	P, P	P	P, P	ND	FN
14820	N	P, P	P	P, P	ND	FN
14826	N	P, P	P	N, P	ND	FN
15536	N	P, P	P	P, P	ND	FN
01552	P	N, P	P	P, P	ND	TP
14772	P	N, N	P	P, P	ND	TP
14818	P	N, N	P	N, N	N	TP?
15567	P	N, N	P	N, N	P	TP
01517	P	N, N	P	P, P	ND	TP
01545	P	N, N	P	N, N	P	TP
14792	P	N, P	P	P, P	ND	TP
15545	P	N, P	P	P, P	ND	TP
15548	P	N, P	P	N, N	ND	TP

[a] Abbreviations: Cx, enrichment culture; ND, not done; NEL, chromogenic agar plate; P, positive; N, negative; TP, true positive; FP, false positive; FN, false negative.
[b] Results of the swab (from each pair) tested by Smart GBS LB assay and culture.
[c] Results of the swab (from each pair) tested by BD GeneOhm assay and culture.

DISCUSSION

The first FDA-cleared real-time PCR assays utilized swab-based specimens directly to test for GBS colonization in pregnant women. Since then, many studies have been published on patients in the antepartum period, with some studies showing lower levels of sensitivity than that reported in the packet inserts of these kits. These findings led some investigators to consider incorporating a broth enrichment step prior to real-time PCR testing. These studies showed that broth enrichment methods demonstrate a higher sensitivity than direct testing.

These reports led to a desire for an FDA-cleared product, which led to this well-controlled multicenter study. In this study properly collected rectovaginal specimens from patients in the antepartum period between 35 and 37 weeks of gestation were analyzed using the Smart GBS LB assay in conjunction with selective enrichment broths, and the results were compared to those with selective enrichment broth-based culture

alone and to those with the predicate device (BD GeneOhm StrepB assay).

Overall, the findings of this study illustrated that the Smart GBS LB assay had excellent performance characteristics compared to broth-based culture and was found to be substantially equivalent or better than the BD Genome StrepB direct assay based on sensitivity, specificity, and accuracy. The data from this multicenter study were pooled prior to calculating the analytical performance characteristics of the assay, because all sites, all races, and all potentially interfering substances were homogeneous compared to each other. In both cases, the Fisher's exact test for both of these statistical analyses produced a *P* value greater than 0.05. No false-negative results occurred in any of the specimens containing a potentially interfering substance(s).

Compared to the results from selective broth enrichment culture alone, broth-based enrichment used in conjunction with real-time PCR analysis may improve the ability to detect nonhemolytic GBS strains present in a specimen or to detect low levels of beta-hemolytic strains in a background of bacterial overgrowth (e.g., swarming *Proteus* species). These situations make it difficult for even the most experienced laboratory technologist to detect GBS on culture plates.

Another argument for using broth-based enrichment in conjunction with real-time PCR rather than using selective enrichment broth alone is the fact that false-negative results are known to occur with enrichment broth culture alone. This may, in part, be due to the inhibitory effect that a moderate to heavy growth of enterococci can have on the growth of GBS within a specimen (4, 10). In this study the selective enrichment broth method was found to have false-negative rates of 3.6% and 2.9% compared to the Smart GBS LB assay and BD GeneOhm StrepB assay, respectively.

A challenge identified during this study was the potential for increased false-positive results. A false-positive rate of 3.6% was seen for the Smart GBS LB test and may have been due in part to cross-contamination occurring from handling samples with high bacterial counts, such as those found in broth enrichment tubes. This suggestion was substantiated by comparing C_T values of the specimens with true-positive results compared to values of specimens with false-positive results. The difference in the median C_T values seen for the specimens with true-positive results compared to that seen for specimens with false-positive results was 10.9, a value that corresponds to a difference in GBS levels of approximately 3 logs.

It is important that individuals in laboratories involved in such testing be aware of the potential risk and the importance of strict adherence to good laboratory practice for ensuring accurate results. This practice should include using aerosol-resistant pipette tips, frequent glove changes, and minimizing aerosols when opening and closing tubes. It is also critical to track the laboratory's positivity rate whenever a new technology is implemented in the lab, so as to be proactive in identifying potential contamination events before results are reported.

The cost and technical time must also be considered when determining whether to implement a new test in the laboratory for antepartum GBS screening. The cost of the reagents needed to perform broth enrichment culture will undoubtedly be less expensive than those used to do molecular testing. However, unlike a molecular test, where most specimens can be evaluated after the initial analysis unless the test is invalid, culture methods require that all GBS-negative specimens be reincubated and reread by the technologist after an additional 24 h before sending out the final result. It is important to take factors affecting work flow into consideration as well. Because the turnaround time needed for finalizing results from antepartum samples from patients is less critical than that needed for patients in the intrapartum period being screened for GBS colonization, the addition of an enrichment step to the protocol could improve the ability to detect GBS from vaginal/rectal swab-based specimens without negatively impacting the turnaround time for the patient.

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