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PCR Testing Enhances the Detection of Group B Streptococcus (GBS) Colonization in Pregnant Women

Ann Robinson, Ph.D., DABMM, FAAM, Director of Microbiology and Virology

Group B streptococcus (GBS) remains a leading cause of serious neonatal infection in the United States. GBS is normal flora of the gastrointestinal tract, which is the most probable source of vaginal colonization. This colonization can be transient, chronic, or intermittent. The prevalence of GBS colonization in pregnant women varies from 15-40%, with an incidence of 0.34 cases of early on-set neonatal disease per 1000 live births in the United States in 2004. Women with prenatal colonization have been shown to be more than 25 times more likely than women with negative prenatal cultures to deliver infants with early-onset GBS disease. In 2002, CDC recommended universal prenatal culture-based screening for vaginal and rectal GBS colonization of all pregnant women at 35-37 weeks gestation. This information is used to identify candidates for intrapartum chemoprophylaxis, the most effective intervention against perinatal GBS infection. Compliance with these recommendations has decreased early on-set disease by 34%. Improved test sensitivity and more rapid availability of test results are priorities recognized by the CDC to aid in the prevention of neonatal group B streptococcal disease.

The selective broth-enhanced culture method recommended by the CDC has a turn-around-time of 1 to 3 days, depending on the quantity of GBS present in the submitted vaginal and rectal swab. A real time polymerase chain (PCR) assay for GBS from broth culture has been validated that detects 20% more true positive vaginal/rectal samples than the recommended optimal culture method, with a turn-around-time of 24 hours. This assay amplifies the *cfb* gene sequence that encodes the CAMP factor, a diffusible extracellular protein that is present in virtually all GBS isolates.

As high as 10% of the adult population has some form of penicillin allergy, and GBS has developed significant levels of resistance to the recommended alternative agents of erythromycin and clindamycin. As a result, in the case of penicillin-allergic patients, it is necessary to test the actual organism to determine its susceptibility to erythromycin and clindamycin. On request, the broth culture generated as part of the enrichment portion of the PCR protocol can be subsequently subcultured to obtain the GBS isolate for susceptibility testing, requiring an additional 48 hours to complete the testing.

To assist in the more rapid and more sensitive identification of candidates for intrapartum chemoprophylaxis for GBS, the PCR assay is offered in conjunction with a reflex to susceptibility testing in the case of penicillin-allergic patients with positive PCR results. Importantly, the PCR test has significantly greater sensitivity than the conventional optimized culture method recommended by CDC. The negative predictive value of the PCR assay is >99%, permitting the reliable identification of patients who are not colonized with GBS. Patients who are penicillin-allergic must be noted at the time of test ordering so that susceptibility testing can be performed if the sample is positive for GBS. This PCR method permits the more rapid and reliable identification of patients colonized with group B streptococcus.

Continued . . .

Quick Facts

- ▶ **Group B streptococcus (GBS) remains a leading cause of serious neonatal infection in the United States.**
- ▶ **A real time polymerase chain (PCR) assay for GBS from broth culture has been validated that detects 20% more true positive vaginal/rectal samples than the recommended optimal culture method, with a turn-around-time of 24 hours.**
- ▶ **The PCR assay is offered in conjunction with a reflex to susceptibility testing in the case of penicillin-allergic patients with positive PCR results.**
- ▶ **The negative predictive value of the PCR assay is >99%, permitting the reliable identification of patients who are not colonized with GBS.**
- ▶ **This PCR method permits the more rapid and reliable identification of patients colonized with group B streptococcus.**



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Test Information

DESCRIPTION	BETA STREP GROUP B PCR
METHOD	PCR
ORDER CODE	BSBPCR
CPT CODE	87653
SAMPLE	BD culturette Plus
SPECIMEN REQUIREMENTS	Vaginal / Rectal swab in BD culturette Plus. Minimize contact with surrounding mucosa. Store and transport refrigerated.
COMMENTS	TAT 1 - 2 days. Test schedule Sun - Sat.
RANGES	Source - Beta Strep Group B PCR Result - Beta Strep Group B PCR Report Status

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