



\*\*\*\*CLIENT UPDATE \*\*\*  
New Assay for Pre-natal Group B Strep  
Testing by Real-Time PCR

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## New Assay for Pre-natal Group B Strep Testing by Real-Time PCR

*Effective January 20, 2006*

PathGroup Labs is offering a new technology for the detection of Group B streptococcus (GBS) infection using molecular (DNA) testing. The MGBS assay is a highly sensitive real-time PCR assay designed to detect GBS infection in pregnant women. This technology provides improved sensitivity, specificity and more rapid results than conventional culture methods.

GBS is a leading cause of neonatal morbidity and mortality. Up to 40% of pregnant women are colonized with GBS, which can be transmitted to the newborn. The guidelines for prevention of prenatal GBS disease revised in 2002 by the US Centers for Disease Control and Prevention recommend universal prenatal culture-based screening for GBS colonization in all pregnant women at 35-37 weeks gestation. Current literature indicates recovery of GBS from properly collected samples may be significantly improved by molecular test methods, including PCR.

The MGBS assay is designed for use on the LightCycler® instrument which can provide test results faster than the standard method of culture testing which can take up to 72 hours for results. The MGBS assay is a PCR based non-culture test that meets or exceeds the performance criteria recommended by the CDC guidelines. It provides a more rapid, accurate detection of GBS colonization in pregnant women.

PathGroup Labs recently completed a validation study of the MGBS assay on recto-vaginal specimens from pregnant women demonstrating 98.9 % sensitivity and 95 % specificity.

Specimen collection for this assay is identical to that currently used for culture. One or two swabs collected from the from the lower vagina and rectum, should be submitted together in a BBL CultureSwab™ or a BBL CultureSwab Plus™ transport system (available through PathGroup labs). If susceptibility testing is indicated for penicillin-allergic patients, two swabs should be collected. M4 (viral transport media) can also be used for PCR but susceptibility testing can not be performed on M4.

PathGroup will continue to offer both culture and molecular assay for our clients; however, we encourage use of the GBS molecular testing. We are working hard to provide the highest quality clinical laboratory services, which consistently exceed the expectations of our clients, physicians, employees, payers, and most importantly, our patients. If you have any questions concerning this memo, please feel free to call our Client Services Department at 615-234-0781 or 1-888-474-5227 or the clinical laboratory at 615-687-7900.

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