Excellence in Pathology and Laboratory Services

Test Revision: Group B Streptococcus by PCR

Overview March, 2009

PathGroup Labs is pleased to announce the implementation of the BD GeneOhm™ StrepB Assay. The assay is FDA-cleared for the detection of Group B Streptococcus from vaginal/rectal specimens of prepartum or intrapartum women.

Group B Streptococcus (GBS) is a leading cause of neonatal morbidity and mortality in the U.S. Up to 40% of pregnant women are colonized with GBS, which can be transmitted to the newborn (1, 2). Currently, GBS remains a frequent cause of sepsis and meningitis in newborns despite important prevention efforts. The guidelines for prevention of prenatal GBS disease recently 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 (2). Though culture is the standard method for the diagnosis of GBS, it has limitations in time and sensitivity. Moreover, the cultures are negative in some women whose infants subsequently have GBS infections. On the other hand, the use of antibiotic prophylaxis on the basis of risk assessment leads to unnecessary treatment in many women. Thus, the utilization of a rapid and sensitive real-time PCR assay will simplify the prevention practice and rationalize the use of antibiotics, particularly at the time of delivery. Penicillin is the antibiotic of choice with no reported resistant GBS so far. Susceptibility testing is only recommended for penicillin-allergic GBS positive patients.

PCR-based methods offer a great potential for the development of highly sensitive detection of GBS directly from clinical specimens. Detection of Group B Streptococcus using the LightCycler™ real-time PCR test (by Roche Diagnostics) provides a simple and rapid diagnostic tool with the highest sensitivity and specificity for screening for GBS colonization in pregnant women (3).

The test code for Group B Streptococcus will not change. However, BBL CultureSwab EZ, BBL CultureSwab EZII , and Remel M4 swabs will no longer be acceptable collection devices. The appropriate collection devices are available from PathGroup Labs.

Clinical Utility

- Detection of Group B Streptococcus (GBS) DNA in vaginal/rectal specimens from prepartum or intrapartum women to establish the GBS colonization status

Methodology: BD GeneOhm™ StrepB Assay (Real-time PCR)

Test Codes: MGBS

CPT Codes: 87798

Specimen Collection: For optimal recovery, collection from both the vaginal and the anal areas (combined) at 35-37 weeks gestation is recommended. Specimens should come from the lower third of the vagina, and the anal swab should pass through the anal sphincter. Collect vaginal-rectal specimens with a BBL™ Culture Swab with Liquid Stuart or Amies media.

Shipping and Handling: Store and transport at room temperature.

Reference Ranges: The normal reference range is Not Detected.

Turnaround Time: Next business day (Assay performed Tue-Sat).

References:

1. Bergeron MG, Ke D, Menard C, Picard FJ, Gagnon M, Bernier M, Ouellette M, Roy PH, Marcoux S, Fraser WD. Rapid detection of Group B Streptococci in pregnant women at delivery. N Engl J Med. 2000 Jul 20;343(3):175-9.
2. Schrag S, Gorwitz R, Fultz-Butts K, Schuchat A. Prevention of perinatal group B streptococcal disease. Revised guidelines from CDC. MMWR Recomm Rep. 2002 Aug 16; 51(RR-11):1-22.
3. Picard FJ, Bergeron MG. Laboratory detection of Group B Streptococcus for prevention of perinatal disease. Eur J Clin Microbiol Infect Dis. 2004 Sep;23(9):665-71.