ACM Medical Laboratory

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Technical Bulletin

Detailed information concerning methodology, specimen requirements, and reference ranges on new and specialized tests.

- **Test Names and Numbers:** **1) Group B Streptococcus Screen by PCR (3174)**
  2) Group B Streptococcus Screen by PCR with Reflex to Susceptibility (8089)
- **CPT codes:** **87081, 87653**
- **Department:** Molecular Diagnostics (476)
- **Testing Schedule:** Monday to Friday
- **Specimen Requirement:** Vaginal/Rectal Swab
- **Reference Range:** Not Detected
- **Methodology:** Real-time PCR (from Broth Enrichment)

Test Information

To provide a more sensitive, accurate and timely screen for Group B Streptococcus maternal colonization, ACM Medical Laboratory has transitioned all GBS screening to a polymerase chain reaction (PCR)-based assay that will detect Group B Streptococcus from vaginal/rectal swabs incubated in an enrichment broth. The testing will be performed using the BD MAX GBS Assay. The BD MAX GBS Assay is a qualitative in vitro diagnostic test designed to detect Group B Streptococcus (GBS) DNA in Lim Broth cultures after an incubation period of ≥ 18 hours

The benefits of the enriched PCR method are improved sensitivity and the ability to detect non-hemolytic GBS isolates that may be missed by using only a culture-based screening method. The BD MAX GBS Assay specifically detects the *cfb* gene present in all *S. agalactiae* (GBS). This is an FDA-approved method for detection of this organism with an analytical sensitivity of ~ 200 CFU/ml.

Laboratory Results

Results for the BD MAX GBS Assay are reported as follows:

Result:	Interpretation:
Negative	No Group B Streptococcus DNA detected
Positive	Group B Streptococcus DNA detected

Clinical Information

A broth enriched-PCR method, including the BD MAX GBS Assay, is one of the screening approaches recommended by the CDC for antepartum GBS colonization. The only appropriate specimen is a vaginal-rectal swab obtained from antepartum pregnant women.

Results from the BD MAX GBS Assay can be used as an aid in determining colonization status in antepartum women. The BD MAX GBS Assay does not provide susceptibility results. Susceptibility results may be obtained from by ordering Test Code 8089 which will include an automatic reflex to susceptibility testing for BD MAX GBS-positive specimen.

Questions? Call (585) 429-2300 (Client Services) or Dr. Suzanne Dale, Director of Microbiology and Molecular Diagnostics, (585) 429-2360. Additional copies of this Technical Bulletin are available at: www.acmlab.com.