



## Real-Time PCR and Cultural Tests for the Detection of Group B Streptococci in Vaginal/Rectal Samples for Routine Prenatal Screening

Effective December 17, 2007, the Microbiology Department of Laboratory Alliance of Central New York began offering two different tests, a molecular-based PCR assay and a conventional culture method, for the detection of vaginal/rectal carriers of Group B Streptococci (GBS) in pregnant women as part of routine prenatal screening. The real-time PCR amplification assay is intended for screening maternal carriers of GBS who do not have a history of penicillin allergy whereas the cultural method is recommended for the penicillin allergic patient for which a bacterial isolate is needed to perform an antimicrobial susceptibility test to erythromycin and clindamycin. As indicated below, **separate test codes are used to order each of these tests**, based upon the patient's history of penicillin allergy.

### **Clinical Significance:**

The gastrointestinal tract serves as the natural reservoir for GBS and is the likely source of vaginal colonization. Vaginal colonization is unusual in childhood but becomes more common in late adolescence (1). Approximately 10 to 30% of pregnant women are colonized with GBS in the vagina and/or rectum and this colonization can be transient, chronic, or intermittent (2). Maternal intrapartum GBS colonization is a risk factor for early-onset disease in infants with vertical transmission of GBS from mother to fetus primarily occurring after the onset of labor or membrane rupture. However, colonization early in pregnancy is not predictive of neonatal sepsis (3). Screening of both the vagina and rectum for GBS late in gestation during prenatal care can detect women who are likely to be colonized with GBS at the time of delivery and, thus, at higher risk of perinatal transmission of the organism (4).

Collection of specimens between 35 and 37 weeks gestation is recommended to improve the sensitivity and specificity of detecting women who remain colonized at the time of delivery (4,5). Swabbing both the lower vagina and rectum through the anal sphincter increases the yield substantially compared to sampling the vagina alone (6). As such, sampling both sites is recommended using a blue cap dual-swab collection device swabbing the lower vagina and then the rectum. Alternatively, two separate blue cap swab collection devices can be used for separate collection. Both swabs will be combined and processed as one specimen type because the anatomic site of colonization is not important for clinical management (7).

Physicians are reminded that confirmed GBS resistance to penicillin or ampicillin has not been reported to date (7). Penicillin remains the agent of choice for intrapartum antibiotic prophylaxis in the non-penicillin allergic patient. Ampicillin is an acceptable alternative but penicillin is preferred because it has a narrower spectrum of activity and is less likely to select for bacterial resistance. For penicillin-allergic women at risk for anaphylaxis, cefazolin, clindamycin, or erythromycin are possible therapeutic options. While there is no reported resistance to cefazolin, between 40 to 50 % of the GBS vaginal/rectal isolates recovered from specimens submitted to Laboratory Alliance are resistant to erythromycin and clindamycin. Vancomycin is recommended in the penicillin-allergic patient with GBS resistant to clindamycin or erythromycin or when the susceptibility of the isolate is unknown. There is no reported resistance to vancomycin. The laboratory will perform GBS susceptibility testing against erythromycin and clindamycin when a susceptibility is requested.

**Test Name:** Grp B Strep PCR (no penicillin allergy)

**Test Code:** BSBP (For Group B Strep by PCR only i.e. no patient history of penicillin allergy).

<b>Test Name:</b>	<b>Grp B Strep with sensitivity</b> (penicillin allergy)
<b>Test Code:</b>	<b>BSBS</b> (For Group B Strep culture with susceptibility, i.e. penicillin allergic patient).
<b>Method:</b>	Real-time PCR following Lim broth enrichment for test code BSBP.  Culture following Lim broth enrichment for test code BSBS.
<b>Specimen Requirements:</b>	Vaginal and/or rectal sample, preferably both, collected either with one dual-swab or on separate swabs (a separate swab for each site) using the blue cap collection device with Amies semi-solid transport medium. Swabbing both the lower vagina and rectum through the anal sphincter increases the yield substantially compared to sampling the vagina alone. If collecting on separate swabs, both swabs will be combined and processed as one specimen type that will have only one laboratory charge.
<b>Unacceptable Conditions:</b>	Freezing or exposing the specimen to excessive heat.
<b>Storage and Transport:</b>	2 to 30°C during specimen transport. Specimen may be stored for the first 24 hours at room temperature then 2 to 8°C for up to 6 days.
<b>Stability:</b>	72 hours at room temperature, 7 days at 2 to 8°C.
<b>Schedule of Testing:</b>	Monday – Saturday
<b>CPT Code:</b>	87798 (for real-time PCR test) 87081 (for GBS culture screen)
<b>Billing Code:</b>	3010323 3010333 (Note: Additional billing code(s) will be added for positive specimens requiring susceptibility testing.)

**For more information:**

Please do not hesitate to contact Mr. Russell Rawling, Microbiology Manager at 315-410-7060 if you have any questions regarding this upgrade in laboratory service.

**References:**

1. Hammerschlag MR, et al. Colonization with group B streptococci in girls under 12 years of age. *Pediatrics* 1977;60:473-6.
2. Regan JA, et al. Vaginal Infections and Prematurity Study Group. The epidemiology of group B streptococcal colonization in pregnancy. *Obstet Gynecol* 1991;77:604-608.
3. Regan JA, et al. Colonization with group B streptococci in pregnancy with adverse outcome. *Am J Obstet Gynecol* 1996;174:1354-60.
4. Boyer KM, et al. Selective intrapartum chemoprophylaxis of neonatal group B streptococcal early-onset disease. II. Predictive value of prenatal cultures. *J Infect. Dis* 1983;148:802-9.
5. Yancy MK, et al. The accuracy of late antenatal screening cultures in predicting genital group B streptococcal colonization at delivery. *Obstet Gynecol.* 1996;88:811-5.
6. Badri MS, et al. Rectal colonization with group B streptococcus: relation to vaginal colonization of pregnant women. *J Infect Dis* 1977;135:308-12.
7. Schrag S, et al. Prevention of perinatal group B streptococcal disease *MMWR*, Aug. 2002, 51(RR11);1-22.