

Intrapartum Group B Streptococcus PCR Test

Background

Group B Streptococcal (GBS) disease remains a significant cause of morbidity and mortality among newborns in the United States. Maternal colonization of the genitourinary or gastrointestinal tracts is the most important risk factor for intrapartum transmission of GBS to the newborn. Approximately 10-30% of women will be colonized.⁸ In the 1990's implementation of prophylaxis for GBS administered during labor resulted in a decline in infections among newborns from 1.7 cases per 1,000 live births to 0.3 cases per 1,000 live births.⁶ Candidates for prophylaxis were defined by two risk categories. These groups were women with GBS identified in screening cultures collected at 35 to 37 weeks' fetal gestation and women presenting in labor with risk factors including premature delivery, rupture of membranes or fever. In 2002, following a large population-based study, the CDC recommended universal screening at 35 to 37 weeks to identify colonized women who should receive intrapartum therapy.⁷ The CDC further recommended prophylaxis for women with unknown colonization status.

The most recent CDC guidance describes sensitive methods for detection of GBS from vaginal-rectal swab specimens. All routine screening tests should include an enrichment broth step prior to detection by culture or polymerase chain reaction (PCR). However, when intrapartum testing is necessary, it is not feasible to include an enrichment broth step since it requires the broth to be incubated for 18 to 24 hours. In these cases a sensitive, direct rapid nucleic acid amplification test such as the PCR may be used, provided rapid results are available. Rapid turn-around-time is necessary to allow sufficient time for infusion of antibiotics prior to delivery.²

The Cepheid GeneXpert PCR test may be performed directly on vaginal-rectal swab specimens with results in about one hour.¹ Compared to culture from enrichment broth, the GeneXpert PCR test was shown to be 91.5 to 98.5% sensitive in several studies.³⁻⁵ Although less sensitive than PCR performed from an enrichment broth, the direct PCR method has adequate sensitivity, a rapid turn-around-time, and is simple to perform, allowing testing to be performed seven days a week on any shift.²

Clinical Indications

In 2010 the CDC published a new guideline for prevention of perinatal GBS disease.² This guideline recommends universal screening of pregnant women for GBS colonization at 35-37 weeks' fetal gestation. Those presenting in labor who have not had routine prenatal testing may be tested for GBS during labor with the Cepheid GeneXpert PCR test. However, women with risk factors including delivery prior to 37 weeks gestation, premature rupture of membranes or fever $\geq 100^{\circ}\text{F}$ ($\geq 38.0^{\circ}\text{C}$) should be given prophylaxis for GBS during labor regardless of testing for GBS.

Reporting and Interpretation

- Results are reported as:
- Negative for Group B Streptococcus by PCR.
- Positive for Group B Streptococcus by PCR.
- Invalid Result. Specimen inhibitory to amplification (*see limitations*).

Limitations of the Assay

- Intrapartum testing should not replace antepartum testing at 35–37 weeks' gestation.
- The use of collection devices other than the dual rayon swab in Stuart's liquid transport medium is not recommended. Other specimen types have not been validated with the Xpert GBS test.
- False negative results may occur if the number of organisms in the sample is below the limit of detection.
- Test results may be affected by prior antibiotic therapy.
- DNA from non-viable organisms may be detected. A positive result is presumptive for the presence of GBS.
- Results of some specimens may be reported as "invalid" due to substances in the specimen that are inhibitory to PCR amplification. Invalid results are rare (<1%) of specimens.

Methodology

The Intrapartum Group B Streptococcus test is a rapid *in vitro* diagnostic test for the direct detection of Group B Streptococcus from vaginal-rectal swabs. Developed by Cepheid and marketed as the Xpert GBS test, this FDA-approved assay uses polymerase chain reaction (PCR) methodology to amplify DNA and real-time, fluorogenic probes to detect a target within a region adjacent to the *cfb* gene of GBS. An internal control is included to verify the absence of any inhibitors that would prevent PCR amplification. Test reagents are contained within an enclosed test cartridge. No additional reagents are added. Reaction steps, including DNA extraction, PCR amplification and detection, take place within the test cartridge. All testing and analysis occur exclusively on the Cepheid™ GeneXpert instrument.¹

References

1. Package Insert: Xpert GBS. Cepheid, Sunnyvale, CA. 2011.
2. Prevention of perinatal Group B Streptococcal disease. Revised guidelines from CDC, 2010. *Mob Mortal Wkly Rep.* 2010;59:1-32.
3. Edwards RK, Novak-Weekley SM, Koty PP, Davis T, Leeds LJ, Jordan JA. Rapid group B streptococci screening using a real-time polymerase chain reaction assay. *Obstet Gynecol.* 2008;111:1335-41.
4. El Helali N, Nguyen JC, Ly A, Giovangrandi Y, Trinquart L. Diagnostic accuracy of a rapid real-time polymerase chain reaction assay for universal intrapartum group B streptococcus screening. *Clin Infect Dis.* 2009;49:417-23.
5. Gavino M, Wang E. A comparison of a new rapid real-time polymerase chain reaction system to traditional culture in determining group B streptococcus colonization. *Am J Obstet Gynecol.* 2007;197:388 e1-4.
6. Jordan HT, Farley MM, Craig A, Mohle-Boetani J, Harrison LH, Petit S, Lynfield R, Thomas A, Zansky S, Gershman K, Albanese BA, Schaffner W, Schrag SJ. Revisiting the need for vaccine prevention of late-onset neonatal group B streptococcal disease: a multistate, population-based analysis. *Pediatr Infect Dis J.* 2008;27:1057-64.
7. Schrag S, Gorwitz R, Fultz-Butts K, Schuchat A. Prevention of perinatal group B streptococcal disease. Revised guidelines from CDC. *MMWR Recomm Rep.* 2002. 51:1-22.
8. Yancey MK, Schuchat A, Brown LK, Ventura VL, Markenson GR. The accuracy of late antenatal screening cultures in predicting genital group B streptococcal colonization at delivery. *Obstet Gynecol.* 1996;88:811-5.

Test Overview

| | |
|------------------------------|--|
| Test Name | Intrapartum Group B Streptococcus PCR |
| Ordering Mnemonic | GBPCR |
| Reference Range | Negative for Group B Streptococcus |
| Specimen Requirements | Vaginal-rectal specimen collected with dual swab in Stuart's transport |
| Testing Information | Note: This test is currently ONLY available internally through Fairview and Hillcrest Hospital Laboratories. |
| Billing Codes | Fairview Hospital: LAB15222342; Hillcrest Hospital: SIM/FIM 2239 |
| CPT Code | 87653 |

Scientific Information Contact:

Susan Harrington, PhD
Main Campus & Fairview Hospital
216.445.2218
harrins2@ccf.org

Technical Information Contact:

Susan Porter, MD
Hillcrest Hospital
440.312.7991
porters@ccf.org

Mark Melaragno, MD
Fairview Hospital
216.476.7342
mamela@ccf.org