



Client Communication

Group B *Streptococcus* by PCR Testing

Clinical Pathology Laboratories has validated a new qualitative method for detection of Group B *Streptococcus* (GBS), *Streptococcus agalactiae*, by Real-Time Polymerase Chain Reaction (PCR) to improve sensitivity and timeliness over culture-based test methods.

The American College of Obstetricians and Gynecologists (ACOG) curates guidelines for prophylaxis and treatment of GBS maternal colonization and neonatal disease and the American Society for Microbiology (ASM) maintains guidelines for laboratory practices related to detection of GBS. The ACOG and ASM guidelines note:^{1,2}

- GBS is the leading cause of newborn infection.
- Maternal colonization of genitourinary and gastrointestinal tracts is the primary risk factor for neonatal GBS disease.
- All pregnant women should be screened for GBS colonization between 36 0/7 and 37 6/7 weeks gestation.
- A single swab should be used to sample lower vagina and then rectum without use of a speculum.
- Swabs should be submitted to the laboratory within 24 hours of collection.

While culture-based methods are considered the historical standard, ASM and CDC include provisions for using PCR/NAAT for GBS screening. After broth enrichment, PCR has sensitivity given as >96%. Recent studies report variable sensitivities for culture, but this may be as low as 53 to 70%. Additionally, PCR-based testing has shorter turnaround time (TAT), 36-48 hours including enrichment.^{3,4}

GBS Test Offering

Effective October 9, 2023, two orderable test codes for GBS detection by PCR are offered by CPL. GBS by PCR reflex to antimicrobial sensitivity testing should be limited to use in penicillin-allergic patients only. These tests are considered replacements for GBS screening by culture.

GBS by PCR Assays		Equivalent GBS by Culture Assays	
Order Code	Name	Order Code	Name
3151	GROUP B STREP SCREEN BY PCR	6079	CULTURE, STREP B - PREGNANCY
7708	GBS-PCR, PEN ALLERGIC, REFLEX SENSI	6085	CULTURE, GROUP B, PEN ALLERGIC



Key Notes

- GBS by PCR TAT is 36-48 hours vs. 2-3 days for culture-based screening.
- The sample type and collection devices remain the same with a single vaginal/rectal swab submitted in transport media.
- Swabs are inoculated in LIM enrichment broth and incubated 18-24 hours as required by ASM guidelines.²
- The CPL assay includes an internal control to prevent false-negative results.
- This is a custom designed TaqMan real-time PCR assay on the ThermoFisher Quantstudio platform validated by CPL.

References

1. Prevention of Group B Streptococcal Early-Onset Disease in Newborns. Committee Opinion No. 797. American College of Obstetricians and Gynecologists. *Obstetrics and Gynecology* 2020 Feb;135(2):e51-72.
2. Filkins L et al. for ASM. Guidelines for Detection and Identification of Group B Streptococcus. *J Clin Microbiol.* 2020 Dec 17;59(1):e01230-20.
3. Shin JH, Pride DT. 2019. Comparison of three nucleic acid amplification tests and culture for detection of group B Streptococcus from enrichment broth. *J Clin Microbiol* 57:e01958-18. <https://doi.org/10.1128/JCM.01958-18>.
4. H. Dele Davies, Mark A. Miller, Sebastian Faro, Dan Gregson, Sue C. Kehl, Jeanne A. Jordan, Multicenter Study of a Rapid Molecular-Based Assay for the Diagnosis of Group B Streptococcus Colonization in Pregnant Women, *Clinical Infectious Diseases*, Volume 39, Issue 8, 15 October 2004, Pages 1129–1135, <https://doi.org/10.1086/424518>.