





Xpert®
GBS

GBS result in just over 30 minutes*

 **Xpert® GBS**

Immediate GBS results you can trust.
They deserve it.

* For Positive Results

  In Vitro Diagnostic Medical Device

 **Cepheid®**
A better way.

“For term deliveries, GBS screening at the time of labor and delivery, empowers clinicians to accurately assess the patient status and the need for intrapartum antibiotic prophylaxis. Xpert® GBS is easy to use and returns results, if positive, in just over 30 minutes. It helps clinicians to reduce neonatal Early-Onset GBS disease, therefore decreases the hospitalization of newborns.”



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The Need

Group B Streptococcus (GBS) is a leading cause of infant mortality and serious neonatal infections such as sepsis, pneumonia and meningitis. Transmission of GBS occurs from GBS-colonized women to their babies during childbirth.^{1,2,3,4,5}

The current standard of care for preventing neonatal GBS disease calls for the use of enriched culture in screening expectant mothers at 35–37 weeks of gestation.² A study published in 2009 found that 61.4% of full-term infants born with GBS disease were born to women who had previously screened negative during their 35–37 week of gestation.⁶

Why Rapid Intrapartum Testing?

- High Risk of GBS status change following screening at 35–37 weeks of gestation^{7,8}
- High incidence of patients with unknown GBS status presenting at Labor & Delivery unit⁹
- Reduce unnecessary use of intrapartum antibiotic prophylaxis (IAP)
- Longer length of stay for infants whose mother received maternal IAP¹⁰

The Solution

Cepheid’s Xpert GBS is the only *in vitro* diagnostic test to fully meet CDC criteria for rapid and accurate intrapartum GBS testing.² With positive results in just over 30 minutes, Xpert GBS is capable of On-Demand intrapartum testing to make a clinical difference.

“Rapid, PCR-based testing at admission for delivery may improve the accuracy of screening by identifying colonization status at the time of labor and delivery.”

Van Dyke et al.,
Evaluation of Universal Antenatal Screening for Group B
Streptococcus,
N Eng J Med 2009; 360: 2626-36

Sensitive and Specific

Comparison of Xpert® GBS assay (intrapartum specimen) against the CDC culture method

		Culture		
		+	-	TOTALS
Xpert GBS	+	91	14	105
	-	8	302	310
		99	316	415

SENSITIVITY: **91.9%** (95% CI = 84.7–96.5%)
SPECIFICITY: **95.6%** (95% CI = 92.7–97.6%)
PPV: **86.7%** (95% CI = 78.6–92.5%)
NPV: **97.4%** (95% CI = 95.0–98.9%)

Reliable

A panel of four simulated specimens with varying concentrations of GBS was tested in triplicate on 10 different days at each of the three sites (4 specimens × 3 × 10 days × 3 sites). One lot of reagent was used for the study.

Sample (Ct Range)	Site 1	Site 2	Site 3	Total Agreement	Total % Agreement
GBS Negative (0 or >42)	30/30	30/30	30/30	30/30	100%
GBS Low Positive (31 to 41)	30/30	30/30	30/30	30/30	100%
GBS Moderate Positive (27 to 37)	30/30	30/30	30/30	30/30	100%
GBS High Positive (19 to 29)	30/30	30/30	30/30	30/30	100%
Total Agreement	120/120	120/120	120/120	120/120	100%
% Agreement	100%	100%	100%	100%	100%

The Impact

With CLIA “Moderate Complexity” designation, Xpert GBS can easily be run in near patient settings by non-laboratory personnel. Now clinicians are able to obtain GBS colonization status when it matters most.

- Identify GBS colonization status at the time of labor and delivery
- Decrease neonatal Early-Onset GBS infection
- Prevent early onset GBS disease in newborns
- Limits intrapartum antibiotic prophylaxis to only those patients who are in need
 - Reduce overall hospital cost¹¹
 - Reduce Length of Stay¹¹
 - Streamline patient management protocol
 - Provide the most accurate patient status

WORKFLOW:

2 Easy Steps

Total hands-on time: <1 Minute



TOTAL HANDS-ON TIME <1 MINUTE
POSITIVE RESULTS IN ABOUT 30 MINUTES

ORDERING INFORMATION

Xpert® GBS (10 Cartridges with reagents) Catalog No. GXGBS-100N-10

References:

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3. Schuchat A. Epidemiology of Group B Streptococcal Disease in the United States: Shifting Paradigms. Clin Micro Rev. 1998; 11(3): 497-513.
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5. S Hansen, N. Ulbjerg, M. Kilian & U. Sorensen. Dynamics of Streptococcus agalactiae Colonization in women during and after pregnancy and in their infants. Journal of Clinical Microbiology. 2004; 83-89.
6. Van Dyke et al., Evaluation of Universal Antenatal Screening for Group B Streptococcus, N Engl J Med 2009;360:2626-36.
7. Davis et al. Multicenter Study of a Rapid Molecular-Based Assay for the Diagnosis of Group B Streptococcus Colonization in Pregnant Women. C. Infectious Disease. 2004; 30: 1129-35.
8. Puopolo et al. Early-Onset Group B Streptococcal Disease in the Era of Maternal Screening. Pediatrics. 2005; 115:1240-1246.
9. Center for Disease Control and Prevention. Disparities in Universal Prenatal Screening for Group B Streptococcus -- North Carolina, 2002-2003, MMWR 2005; 54 (28): 700-703.
10. Balter et al. Pediatr Infect Dis J 22 (10): 853-857, 2003.
11. Najoua El Helali, poster 535, RICA1 2010



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