





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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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.
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10. Balter et al. Pediatr Infect Dis J 22 (10): 853-857, 2003.
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