



Xpert[®]
GBS

GBS result in just over 30 minutes*

 **Xpert[®] GBS**

Immediate GBS results you can trust.
They deserve it.

* For Positive Results

 **Cepheid[®]**
A better way.

“Now nurses, physicians or other providers can offer a fast, accurate GBS test at the point of care. GBS can be treated and infection to newborns prevented with proper detection—a molecular test like Xpert® GBS represents a significant advancement in GBS detection that has a direct impact on patient care.”



Rodney K. Edwards, M.D.
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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 screening of 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 (L&D) 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 delivers 91.9% sensitivity and 95.6% specificity for intrapartum testing.

- Identify GBS colonization status at the time of L&D
- 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

“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

Comparison of Xpert® GBS assay and the CDC culture technique for intrapartum testing.

		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%)

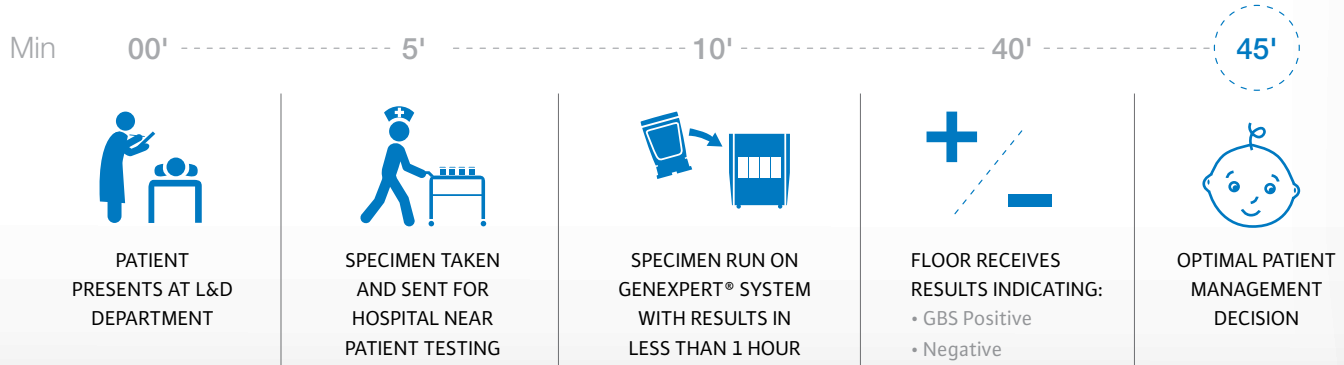
Reliable

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 x 3 x 10 days x 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%

Answer you need in 45 minutes or less

Xpert GBS provides useful and timely information to clinicians for improved patient management.



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:

1. Schrag et al. A population-based comparison of strategies to prevent early-onset group B streptococcal disease in neonates. *NEJM*. 2002; 247(4): 233-239.
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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.
4. P. Melin, G Verschraegen, L. Mahieu, G Claeys & P. De Mol. Towards a Belgian consensus for prevention of perinatal group B streptococcal disease. *Indian J Med Res*. 2004; 119: 197-200.
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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.



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