

Xpert™ GBS

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*Revolutionizing GBS testing.*



defining *on-demand* molecular diagnostics.

 **Cepheid®**  
Bring answers to life.

# Xpert™ GBS: Revolutionizing Group B *Streptococcus* Testing

Now rapid intrapartum or antepartum GBS results can be available in less than 75 minutes versus 2 days. This revolutionary *in vitro* diagnostic test is the first and only CLIA “Moderately Complex” amplified molecular test designed to be run in the clinical lab and near-patient by non-laboratory professionals such as labor and delivery nurses — 24 hours a day, 365 days a year. Xpert™ GBS is the only *in vitro* diagnostic test to fully meet the CDC criteria for rapid intrapartum GBS testing.<sup>2</sup> Cepheid’s Xpert GBS empowers clinicians to make appropriate patient management decisions at the time of delivery.

**problem:**  
In Europe and the United States, 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.<sup>1,2,3,6,7</sup>

The current standard of care for preventing neonatal GBS disease calls for the use of culture in screening expectant mothers at 35–37 weeks of gestation.<sup>2</sup> Although adequate for obtaining antepartum GBS results, this is an unacceptable solution for providing timely results for intrapartum patients whose

GBS status is unknown when they present in the hospital to deliver. Current rapid GBS testing methods provide an underwhelming sensitivity level of less than 65%.

**solution:**  
To better guide proper patient management, intrapartum GBS status must be determined quickly.<sup>4,5</sup> Introducing Cepheid’s Xpert™ GBS, the only *in vitro* diagnostic test to fully meet CDC criteria for rapid intrapartum GBS testing<sup>2</sup>. With results in less than 75 minutes, Xpert GBS delivers 91.9% sensitivity and 95.6% specificity for intrapartum testing.

## Xpert: in action

**impact:**  
The potential impact of Cepheid’s Xpert GBS assay is significant: **the prevention of early onset GBS disease in newborns** with rapid, highly accurate GBS colonization status when it matters most: at the time of delivery.

With CLIA “Moderate Complexity” designation, the Xpert GBS test can now easily be run in near patient settings by non-laboratory personnel such as labor and delivery nurses — a first for an amplified molecular test.

“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.”

Dr. Rodney K. Edwards — Assistant Professor at the University of Florida Department of Obstetrics and Gynecology.

**flexible:**  
Finally, slow batch processing is not your only option. The GeneXpert® System’s unique random access capabilities enable multiple users to start different tests at different times. Whether it’s high throughput centralized lab processing or near-patient care, the GeneXpert System offers the flexibility to accommodate any testing scenario.

**simple:**  
The Xpert GBS test, performed on Cepheid’s GeneXpert System, delivers unprecedented ease of use. It is the only CLIA “Moderately Complex” molecular *in vitro* diagnostic GBS test designed for use in the clinical lab **and** by non-laboratory professionals such as labor and delivery nurses. Now Xpert™ GBS tests can be run as needed — 24 hours a day, 365 days a year. Users simply perform four easy steps and the GeneXpert System does the rest.

## Xpert: by design

**fully controlled:**  
The fully controlled, self contained testing unit is the foundation for Cepheid’s Xpert GBS test. Each test cartridge contains a sample processing control, internal control, and probe check control to deliver accurate, reliable test results. This robust control system enhances confidence in every patient management decision.



## Sensitive and Specific:

Appropriate treatment decisions can be made at the time of delivery.

Table 1: 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%)

## Reproducible:

Confidence in your results.

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%
<b>% Agreement</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

## Continuous workflow:

Get results when and where you need them.

Batch testing is no longer your only option. The Xpert GBS test, on the GeneXpert® System, delivers rapid, fully automated real-time PCR results 24 hours a day, 7 days a week. It is the world's first fully integrated and automated molecular GBS test, delivering the power of true on-demand sample processing.

GeneXpert System	Tests/24 Hours	Annual Capacity
1 Site	19	6,935
2 Site	38	13,870
4 Site	76	27,740
16 Site	304	110,960

The GeneXpert delivers the flexibility and expandability to customize your system — from the lowest to the highest throughput testing requirements.

## Flexible:

Menu of tests for rapid, actionable results

The same GeneXpert System can also be used for the full menu of Xpert tests. Contact your Cepheid representative for more information.

## The Xpert™ GBS advantage: **Simplicity**

- First CLIA Moderately Complex *in vitro* amplified molecular diagnostic GBS test for use in clinical laboratories or point-of-care settings
- Fully automated process reduces handling time to just minutes
- Random access for flexibility and workflow optimization
- Rapid results to improve patient management
- Fully integrated sample processing control, internal control, and probe check control for accurate, reliable test results



1. Insert swab into cartridge and break at mark



2. Dispense Reagent 1 into port 1



3. Dispense Reagent 2 into port 2



Total hands-on time = 2 minutes



4. Insert cartridge and start assay.  
Results in 70 minutes.

## Ordering Information

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

### 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.
4. 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.
5. Puopolo et al. Early-Onset Group B Streptococcal Disease in the Era of Maternal Screening. *Pediatrics*. 2005; 115:1240-1246.
6. 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.
7. 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.

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This product is made using components produced and licensed by Eppendorf AG. The purchase price of this product includes limited, nontransferable rights to use only this amount of the product to practice the method for reversible inhibition of thermostable polymerase as claimed in US Patent No. 6,667,165.

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