Xpert® GBS LB XC & Xpert® GBS

A Complete GBS Testing Solution

The only solution able to fully meet CDC criteria
for both antenatal and intrapartum testing

US-IVD. *In Vitro* Diagnostic Medical Device.

Cepheid®
A better way.

The Need

In the U.S., Group B *Streptococcus* (GBS) remains a leading cause of early onset neonatal sepsis. Rates of maternal colonization have not changed, but universal antenatal screening at 35–37 weeks along with the use of intrapartum antibiotic prophylaxis (IAP) has resulted in a decrease of early onset disease.[1,2]

Challenges remain:

- CDC and ACOG Practice guidelines recommend universal antepartum screening along with intrapartum where indicated based on risk
- Risk based IAP exposes 65–85% of GBS-negative women with risk factors to antibiotics. This has been linked to emergence of resistant strains[3]
- Up to 50% false negatives when testing with agar alone[4]

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.
Assistant Professor at the University of Florida
Department of Obstetrics and Gynecology

The Solution

Cepheid's GeneXpert® system, with both Xpert® GBS LB XC and Xpert® GBS, is the only solution able to fully meet CDC criteria for both antenatal and intrapartum testing, with positive results in approximately 40 minutes.

On-demand molecular testing — an ideal solution:

- System designed with Early Assay Termination (EAT) with positive samples reported STAT
  - As soon as positive sample is confirmed, software concludes test and reports immediately
- Moderately complex testing with minimal hands-on time
  - STAT intrapartum specimens can be performed by lab, or by labor and delivery staff
  - Reduces lab's work for antenatal screening
  - Random access ensures any test on the menu can be run anytime, without the need to batch

Coverage, plus
Accuracy, plus
Peace of mind

That's the **PCR***plus* advantage.
From Cepheid.

The Impact

Xpert® GBS LB XC

for antepartum screening

The Xpert GBS LB XC test, performed on Cepheid's GeneXpert® systems, delivers an elegant, simple and streamlined solution. A molecular *in vitro* diagnostic, Xpert GBS LB XC is designed for use in the clinical lab **allowing users to perform three simple steps while the GeneXpert does the rest.**

- Easy-to-use screening test
- Delivers results on positive LIM broth samples in 27* minutes
- Fast accurate NAAT results
- Moderate complexity

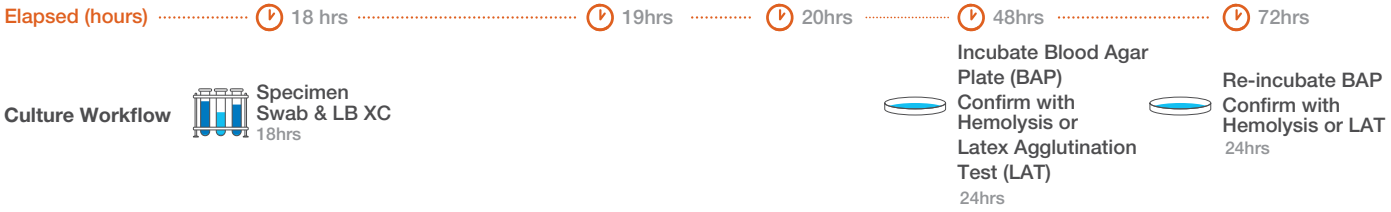
Performance

Sensitivity 99.3% (95% CI: 96.1–99.9)
Specificity 98.7% (95% CI: 97.3–99.4)
PPV 95.9% (95% CI: 91.4–98.1)
NPV 99.8% (95% CI: 98.8–100.0)

The overall LoD for the assay is 333 CFU/mL.

Impact on Patient Pathway

Antepartum



* Xpert GBS LB XC test includes an Early Assay Termination feature, returning results in 27 minutes for high titer samples. With GBS negative samples, the test returns results in approximately 43 minutes

The Impact

Xpert® GBS

for direct intrapartum screening in labor/delivery

Rapid intrapartum GBS results can be available to assess GBS colonization of low risk women at term with unknown colonization status. Xpert GBS is the first and only 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.**

- Easy to use direct test
- Rapid results for patients with unknown GBS status
- Delivers results on positive samples in 40 minutes
- Moderate complexity

Performance

Sensitivity	91.9% (95% CI = 84.7–96.5%)
Specificity	91.9% (95% CI = 84.7–96.5%)
PPV	86.7% (95% CI = 78.6–92.5%)
NPV	97.4% (95% CI = 95.0–98.9%)

Impact on Patient Pathway

Intrapartum

Elapsed (hours) ····· 1hr

No Rapid Testing

- **Status Unknown** — Assess Risk Factors
- **Status Unknown** — Risk-based Treatment
- **Status Unknown** — Risk-based Patient Management

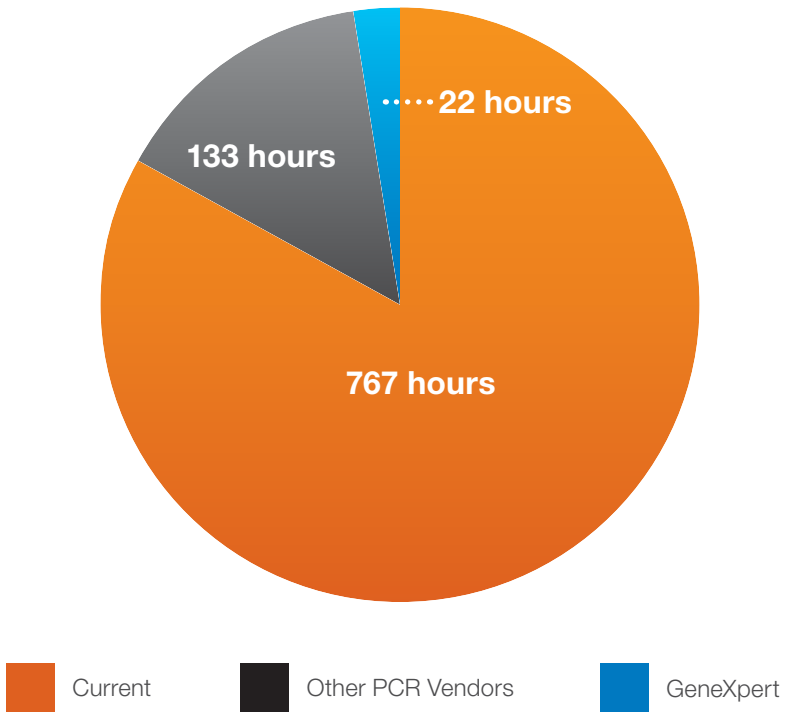
Xpert GBS

- **Status Unknown** — Specimen Collection 2mins
- **Status Known** — Test & Results 35–55mins
- **Status Known** — Evidence-based Patient Management

The GeneXpert® system's extensive menu, combined with random access, on-demand testing flexibility, has been proven to increase laboratory level of service.

GBS Hands-On Labor Comparison*

GBS Annual Hands-On Labor – 2000 GBS Samples*



* All data from leading U.S. clinic serving over a million patients.

Workflow

Xpert® GBS LB XC

3 Easy Steps

1

Dip swab in LIM broth

2

Insert the swab into the chamber S

3

Insert cartridge and start test

Xpert® GBS

2 Easy Steps

1

Insert the swab into the chamber S

2

Insert cartridge and start test

ORDERING INFORMATION		CATALOG INFORMATION	PATIENT COLLECTION DEVICE	ASSAY SWABS
Xpert® GBS LB XC	10 tests	GXGBSLBXC-10	900-0370	SDF-120
	120 tests	GXGBSLBXC-120		
Xpert® GBS	10 tests	GXGBS-10	900-0370	

References:

1 CDC. Prevention of Perinatal Group B *Streptococcal* Disease: Revised Guidelines from CDC, 2010. Nov 19, 2010 / 59(RR10);1-32.
2 ACOG Committee Opinion No. 485: Prevention of early-onset group B *streptococcal* disease in newborns. Obstet Gynecol. 2011 Apr;117(4):1019-27.
3 Alfa MJ, et al. Real-time PCR assay provides reliable assessment of intrapartum carriage of group B *Streptococcus*. J Clin Microbiol. 2010 Sep;48(9):3095-9.
4 Paolucci M, et al. How can the microbiologist help in diagnosing neonatal sepsis? Int J Pediatr. 2012;2012:120139

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