

Xpert®
GBS LB

Xpert®
GBS



A complete GBS testing solution



Xpert® GBS LB & Xpert® GBS

Only molecular system with moderately complex antepartum and intrapartum tests on a single platform

 **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.

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



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 strains³
- Up to 50% false negatives when testing with agar alone⁴



THE SOLUTION

Cepheid’s GeneXpert® System, with Xpert® GBS LB and Xpert GBS is the only solution able to fully meet CDC criteria for both antenatal and intrapartum testing, with positive results in just over 35 minutes.

On-demand molecular testing — an ideal solution:

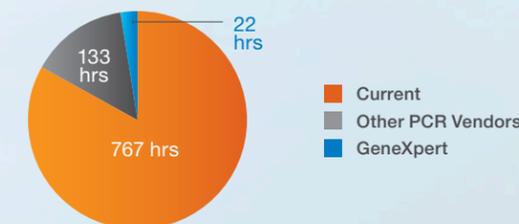
- System designed with Early Assay Termination (EAT) with positive samples reported STAT
 - As soon as positive sample is confirmed, software concludes test and reports immediately
- Moderately complex testing with < 1 minute hands-on time
 - STAT intrapartum specimens can be performed by lab, or by 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



The GeneXpert® System’s extensive menu, including GBS, GBS LB, MRSA, C. difficile, Flu, FII/FV 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.



THE IMPACT



Xpert® GBS LB for antepartum screening

The Xpert GBS LB test, performed on Cepheid's GeneXpert® Systems, delivers an elegant simple and streamlined solution. A molecular *in vitro* diagnostic, Xpert GBS LB is designed for use in the clinical lab. It allows users to simply perform ONE easy step and the GeneXpert System does the rest.

- Easy to use screening test
- Delivers results on positive Lim broth samples in 35 minutes
- Fast accurate NAAT results
- Moderate complexity

PERFORMANCE

Sensitivity: 99.0% (95% CI = 96.3–99.9)
 Specificity: 92.4% (95% CI = 90.1–94.4)
 PPV: 79.7% (95% CI = 74.1–84.7)
 NPV: 99.7% (95% CI = 98.8–100.0)

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



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
- NAAT results in 35-55 minutes
- Moderate complexity

PERFORMANCE

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%)



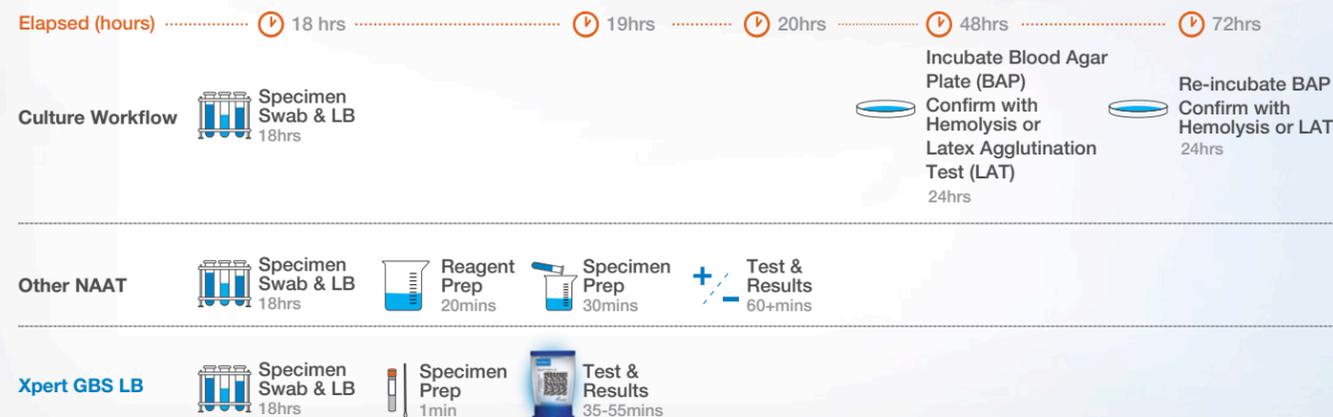
Clinical usefulness in intrapartum GBS screening would consist of a simple bedside kit that enables labor and delivery staff to perform a test, have a turn-around time of **<30 minutes**, and have a sensitivity and specificity of $\geq 90\%$.

Prevention of Perinatal Group B Streptococcal Disease. MMWR 2010 Nov 19; 59 (10)



IMPACT ON PATIENT PATHWAY

Antepartum



IMPACT ON PATIENT PATHWAY

Intrapartum





IMPACT ON LABORATORY

	GBS	GBS LB	Flu	MRSA	<i>C. difficile</i>	CT/NG
GeneXpert®						
Gen-Probe	—			—		
BD			—			
Meridian	—		—	—		—



IMPACT OF AUTOMATION

- Automation facilitates:
 - Reduction in resources
 - Easy implementation
 - Highly reproducible results
- 3 Automated quality controls in EACH cartridge:
 - Probe check control checks integrity of probes (PCC)
 - Internal control for enzyme integrity and PCR inhibition (IC)
 - Sample processing control monitors sample processing (SPC)



GeneXpert I

GeneXpert II

GeneXpert IV



GeneXpert XVI



GeneXpert Infinity-80



WORKFLOW:

Xpert® GBS LB

3 EASY STEPS

Total hands-on time:
<1 Minute

Ordering Information

CATALOG INFORMATION

GXGBSLB-10 (10 tests with reagents)

PATIENT COLLECTION DEVICE

900-0370

ASSAY SWABS

SDPS-120

1

Dip swab in LIM broth



2

Insert the swab into the chamber S



3

Insert cartridge and start assay



Xpert® GBS

2 EASY STEPS

Total hands-on time:
<1 Minute

Ordering Information

CATALOG INFORMATION

GXGBS-10 (10 tests with reagents)

PATIENT COLLECTION DEVICE

900-0370

1

Insert the swab into the chamber S



2

Insert cartridge and start assay



References:

1. CDC. (2010). Prevention of Perinatal Group B Streptococcal Disease, Revised Guidelines. Morbidity and Mortality Weekly Report, Vol.59.
2. ACOG, A.C. (2011). Prevention of Early-Onset Group B Streptococcal Disease in Newborns. Committee Opinion, 1.
3. Alfa, M. J. (Sept. 2010). Real-Time PCR Assay provides reliable assessment of intrapartum carriage of group B streptococcus. Journal of Clinical Microbiology, 3095-3099.
4. Paolucci, M. E. (2012). How can the microbiologist help in diagnosing neonatal sepsis? International Journal of Pediatrics, 14.

For In Vitro Diagnostic Use.

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