A complete GBS testing solution

**Xpert® GBS LB & Xpert® GBS**

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

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.9

Rodney K. Edwards, M.D.
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Department of Obstetrics and Gynecology

The GeneXpert® System’s extensive menu, including GBS, GBS LB, MRSA, C. difficile, Flu, FI/FV combined with random access, on-demand testing flexibility has been proven to increase laboratory level of service.

GBS Hands-On Labor Comparison*

<table>
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<th>GBS Annual Hands-On Labor — 2000 GBS Samples</th>
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<tr>
<td>Current</td>
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<td>133 hrs</td>
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* All data from leading U.S. clinic serving over a million patients.
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

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.

**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 ≥90%.

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

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<thead>
<tr>
<th></th>
<th>GBS</th>
<th>GBS LB</th>
<th>Flu</th>
<th>MRSA</th>
<th>C. difficile</th>
<th>CT/NG</th>
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**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)
**WORKFLOW:**

**Xpert® GBS LB**

**3 EASY STEPS**

*Total hands-on time: <1 Minute*

1. Dip swab in LIM broth
2. Insert the swab into the chamber S
3. Insert cartridge and start assay

**Ordering Information**

**CATALOG INFORMATION**
GXGBSLB-10 (10 tests with reagents)

**PATIENT COLLECTION DEVICE**
900-0370

**ASSAY SWABS**
SDPS-120

**Xpert® GBS**

**2 EASY STEPS**

*Total hands-on time: <1 Minute*

1. Insert the swab into the chamber S
2. Insert cartridge and start assay

**Ordering Information**

**CATALOG INFORMATION**
GXGBS-10 (10 tests with reagents)

**PATIENT COLLECTION DEVICE**
900-0370

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**References:**


For In Vitro Diagnostic Use.