Cepheid®
A better way.

Immediate GBS results you can trust,
at the right time — *as early as 30 minutes*[*]

## Xpert® Xpress GBS

[*] For Positive Results.
CE-IVD. *In Vitro* Diagnostic Medical Device. Not available in all countries.


> The benefits of this solution are extreme. Everything becomes easier for everyone. It is a team effort based on trust between laboratories, midwives, and gynecologists, all of whom must be convinced that this POC solution is useful and provides an effective response to their organisation."

**Prof. Luton,**
***Head of the Obstetrician Gynecologist Department***
***Bichat- Claude Bernard Hospital (APHP)***

## The Need

Group B *Streptococcus* (GBS) remains a leading cause of early onset neonatal sepsis. Rates of maternal colonisation 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]

**Challenges remain, including:**

- Risk of change of GBS colonisation status following screening at 35–37 weeks of gestation[2,3]
- Some women with unknown GBS status presenting at Labor & Delivery unit[4,5]
- Risk-based IAP exposes 65–85% of GBS-negative women to antibiotics[6]
- 69% sensitivity of antenatal culture for GBS detection when compared to intrapartum culture[7]

## The Solution

Cepheid's Xpert® **Xpress** GBS test is the only *in vitro* diagnostic test to fully meet the GBS European consensus criteria for rapid intrapartum GBS testing.[4] The Xpert **Xpress** GBS test delivers rapid results with 93.5% sensitivity* and 95.5% specificity.*

**On-demand molecular testing — an ideal solution:**

- Dual targets in highly conserved regions for an extended GBS strain coverage
- Test designed with Early Assay Termination (EAT) to provide positive results in approximately 30 mins
- Easy-to-use testing with 1 min hands on time
- Intrapartum rectal/vaginal swabs can be tested by trained lab, or labor and delivery staff
- Sample Adequacy Control integration to ensure correct sample incorporation into the cartridge
- Random access, enables any test in the menu to be run at anytime, without the need to batch

## The Impact

The Xpert **Xpress** GBS test can easily be run in near-patient settings by trained non-laboratory personnel. Now clinicians are able to identify GBS colonisation status when it matters most.

- Identify GBS colonisation status at the time of labor
- Fast and easy to interpret results, enables timely appropriate treatment preventing early onset of GBS disease in newborns
- Reduce unnecessary use of intrapartum antibiotic prophylaxis (IAP)
  - Reduce overall hospital cost[8]
  - Reduce length of stay[9]
  - Streamline patient management
  - Less impact on newborn intestinal flora[10]

* Sensitivity and specificity results for intrapartum vaginal/rectal.

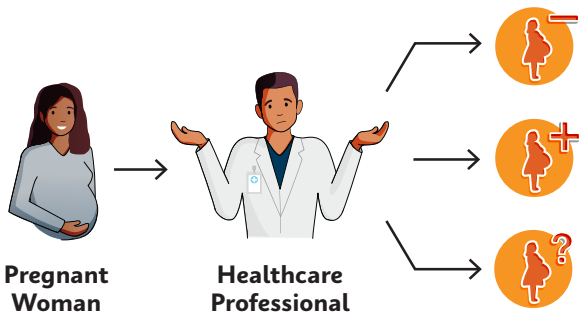
**Coverage**, plus
**Accuracy**, plus
**Peace of mind**

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

## Impact on Patient Pathway

### Challenge

Increased Threat to Newborns Due to Inaccurate Antepartum or Risk-Based GBS Screening

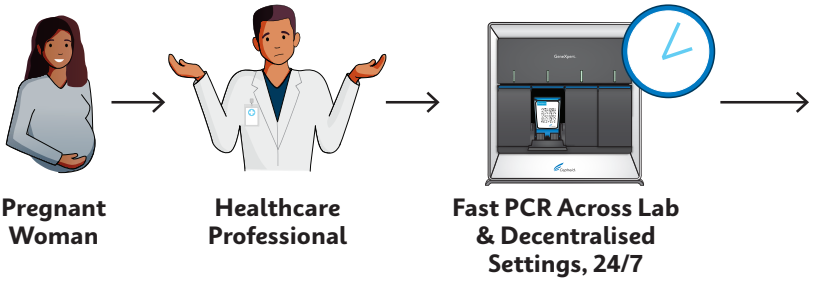



- High Risk of GBS Status Change Following Screening at 35–37 Weeks Pregnancy[2]
- Incorrect Administration of IAP^ May Result in EOD[9^] and May Impact the Correct Assemby of Neonatal Flora[10]
- Some Pregnant Women with Unknown GBS Status During Labour[4]

→ **Poor outcomes for newborn baby**

### Solution

Fast & Accurate Intrapartum PCR Testing for GBS as early as 30 minutes*




- Correct Identification of GBS Status During Delivery
- Evidence-Based IAP^ & Patient Management[7]
- Reduced Infection Risks & Overall Hospital Costs[8,9]

## Clinical Performance

Xpert **Xpress** GBS test results and estimated performance by specimen collection type.

| Specimen Collection Type | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|
| **Intrapartum vaginal/rectal** | 93.5% (85.7– 97.2) | 95.5% (93.9– 96.7) |
| **Antepartum vaginal/rectal** | 88.1% (81.1– 92.8) | 95.6% (93.5– 97.0) |

* For positive GBS results with Early Assay Termination (EAT). 42 minutes for negative GBS results.
^ IAP: Intrapartum Antibiotic Prophylaxis, EOD: Early Onset Disease, AMR: Antimicrobial Resistance.

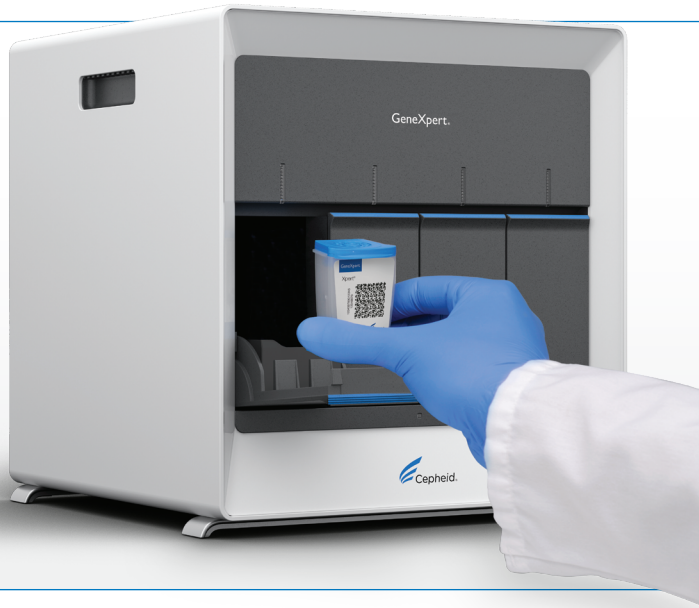
## Workflow: 2 Easy Steps

1

Insert the swab into the chamber S

2

Insert cartridge and start test




## Catalog Information

| | | |
|---|---|---|
| Xpert® **Xpress** GBS | 10 tests | XPRSGBS-CE-10 |

**References:**

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