

Panther Fusion® GBS Assay

Excellent performance and automation.

The Panther Fusion® GBS assay detects Group B *Streptococcus* (GBS), a serious and sometimes fatal infection that poses a distinct threat to newborns born to infected mothers.

- Approximately 1 in 4 pregnant women carry or are colonised with GBS bacteria.[1]
- GBS can affect babies before and up to 6 months after birth.[2]

Accurate detection and treatment are essential to timely prevention

All pregnant women who test positive for GBS should receive intravenous intrapartum antibiotic prophylaxis unless a prelabor caesarean birth is performed.[3]

With antibiotics
1 in 4,000 chance of a baby developing GBS[1]

Without antibiotics
1 in 200 chance of a baby developing GBS[1]

Fully automate your GBS testing with sample to result processing

A real-time PCR test for antepartum testing with vaginal and rectal swabs following 18-24 hour incubation in selective enrichment Lim or Carrot Broth.[4]



Incubate selective enrichment broth

Transfer into Aptima® Specimen Transfer Tube

Fully automated sample to result processing

Result interpretation and reporting in 2.4 hours[5]

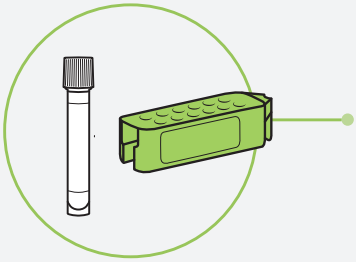
- Process 335 Panther Fusion tests or combine Aptima and Panther Fusion assays for up to 500 tests in 8hrs[5]
- Consolidate your GBS testing along with other Panther Fusion and Aptima assays for virology, respiratory, cervical and sexual health[4]
- Eliminate manual assay preparation with ready-to-use GBS reagents
- Reduce waste with unit dose assay format and 60-day onboard stability[4]

PANTHER FUSION® GBS Assay

Performance you can trust

The Panther Fusion® GBS assay provides excellent, accurate results expectant mothers and their providers can rely on.[4]

In the clinical study, the Panther Fusion GBS assay demonstrated 100% sensitivity and 96.5% specificity. Results from the test provide information to accuratley identify mothers that would benefit from intrapartum antibiotics to reduce the incidence of vertical transmission of GBS, which can ultimately save an infant's life.[4]

Panther Fusion GBS Assay		Lim Broth	Carrot Broth
 PANTHER FUSION® GBS Assay	**Sensitivity**	120/120 = 100% (95% CI: 96.9% – 100%)	83/83 = 100% (95% CI: 95.6% – 100%)
	Specificity	507/523 = 96.9% (95% CI: 95.1% – 98.1%)	211/221 = 95.5% (95% CI: 91.9% – 97.5%)

Dual Target assay targeting SIP and Cfb genes with internal control to deliver confidence in results.[4]

Automation
Sample to result automation

Efficiency
Random and Continuous access

Performance
Excellent assay performance

Ordering information

	Product Description	Kit Quantity	Catalogue Number
Panther Fusion GBS assay	Panther Fusion GBS assay cartridges	96 Tests	PRD-04484
	Panther Fusion GBS assay controls	5 Sets	PRD-04485

RUN ON PANTHER FUSION®



CE 2797 EC REP Hologic BV, Da Vincilaan 5, 1930 Zaventem, Belgium. NB Number wherever applicable.

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References: 1. CDC. Group B Strep (GBS) Fast Facts. Available at: https://www.cdc.gov/groupbstrep/about/fast-facts.html. Accessed 03rd March 2023. **2.** What is Group B Strep?. Available at: https://www.groupbstrepinternational.org/what-is-group-b-strep.html. Accessed 18th May 2023 **3.** ACOG Committee Opinion. Prevention of Group B Streptococcal Early-Onset Disease in Newborns. Obstet. Gyne-col.2020.135(2) e51-e72. **4.** Panther Fusion GBS Assay [Package Insert]. AW- 23714-001, Rev 001, San Diego, CA, Hologic Inc, 2022. **5.** Panther / Panther Fusion System Operator's Manual. AW-26055-001, Rev 001.

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