Panther Fusion® GBS Assay:

Study shows faster turnaround time, less hands-on time, higher throughput than BD MAX™ GBS assay[1]

Caring for Our Most Vulnerable Patients with Confidence

GBS is the **leading cause of serious newborn infections,** and can be transmitted from mothers during delivery.[2]

Culture-based screening methods are slow and have been found to be **less sensitive** compared to NAATs (nucleic acid amplification tests).[3]

GBS detection through NAATs has the potential to **save newborn lives** through improved screening accuracy, allowing pregnant patients who are colonized to receive antibiotics.[3]

Study Design[1]

Researchers compared the workflow characteristics and assay performance of the Panther Fusion® GBS assay and the BD MAX™ GBS assay, two FDA-cleared NAATs for GBS detection.

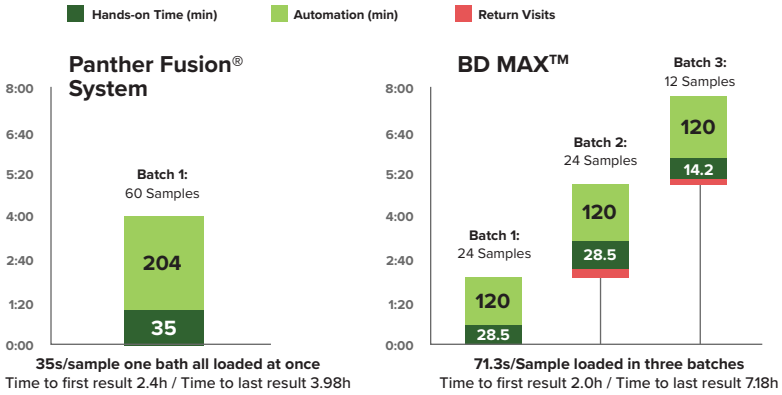
The assays were evaluated using 510 prepartum vaginal-rectal swabs with a 18 to 24 hour Lim broth enrichment. Workflow was evaluated based on a run size of 60 specimens/day.

Results[1]

Compared to the BD MAX™ GBS assay, the Panther Fusion® GBS assay demonstrated:

Invalid rates were 1.2% for BD MAX™ (6/510) and 0% for Panther Fusion® (0/510)

GBS Test Results Total (510)		True Positive	True Negative
Panther Fusion®	Positive	124	0
	Negative	0	386
BD MAX™	Positive	120	4
	Negative	1	385



Superior workflow

Shorter total turnaround time for all sample results, less preparation time and hands-on time with fewer return visits to the instrument.

Better analytical sensitivity

100% detection at the 1000 CFU/mL dilution for GBS serotype III, and 100% detection at the 300 CFU/mL dilution for GBS serotype V (vs. 80% and 70% for BD MAX™, respectively).

Strong clinical performance

Comparable clinical performance to the BD MAX™ GBS assay.

Conclusions[1]

The Panther Fusion® GBS assay exhibited **superior workflow** to the BD MAX™ in almost every respect, with additional workflow gains as sample numbers increase.

The Panther Fusion® GBS assay also demonstrated comparable clinical performance to the BD MAX™ GBS assay, with a **slightly lower limit of detection.**

Panther Fusion® system decreased labor time is achieved with less hands-on time and preparation time which can amount to $21,699/year.

- Average of 16,000 samples/year
- Estimated cost of $40/hour for a medical technologist

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1. Berry GJ, et al. Comparison of the Panther Fusion and BD MAX GBS Assays for Detection of Group B Streptococcus in Prenatal Screening Specimens. J Clin Microbiol. 2019; JCM.01034-19. **2.** Cedars-Sinai. Group B Streptococcus Infection in Babies. Cedars-Sinai.org website. Accessed April 21, 2024. https://www.cedars-sinai.org/health-library/diseases-and-conditions---pediatrics/g/group-b-streptococcus-infection-in-newborns.html. **3.** Shin JH and Pride DT. Comparison of Three Nucleic Acid Amplification Tests (NAATs) and Culture for Detection of Group B Streptococcus (GBS) from Enrichment Broth. J Clin Microbiology. 2019;57(6):e01958-18. doi:10.1128/JCM.01958-18