



## Panther Fusion® GBS Assay:

### Highly Sensitive PCR NAATs are the Preferred Method for Prenatal GBS Screening<sup>1</sup>

Group B Streptococcus (GBS) bacteria is present in ~25% of pregnant women in the US and is a **critical health concern**.<sup>1</sup> When passed to newborns during delivery, infections are a **leading cause of infant fatalities** through Early Onset Disease (EOD).<sup>1</sup>



## Can we do more to protect our youngest patients?

Culture-based testing is a widespread method for GBS testing during pregnancy. However, a large percentage (81%) of newborns who develop EOD are born from mothers with a negative GBS screening test<sup>2</sup>. This suggests **potentially inadequate sensitivity of culture-based screening tests** leading to false negative results.<sup>1,2,3</sup>

## Study Design<sup>1</sup>

This study evaluated the performance of 3 FDA-cleared GBS NAATs (Nucleic Acid Amplification Tests) compared to conventional GBS culture.



Panther Fusion® GBS Assay, ARIES® M1 GBS Assay, GeneXpert® IV GBS Assay, and standard culture test.



500 pregnant women at 35 to 37 weeks of gestation.



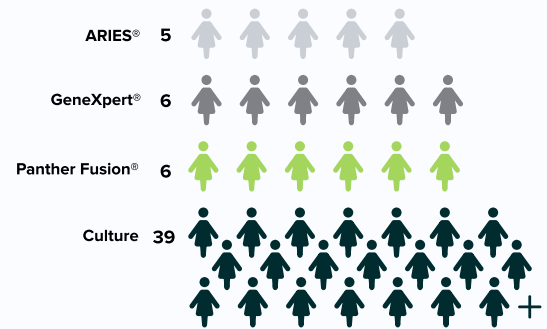
Specimens directly inoculated into Lim enrichment broth and incubated for 18 to 24 hours.

## Key Results<sup>1</sup>

The NAATs demonstrated **increased sensitivity** and resulted in **fewer false negatives** than culture. Specifically, the Panther Fusion® GBS assay detected **31% more positives** than culture.

### False Negative Results:

The Panther Fusion® GBS assay demonstrated the lowest limit of detection across NAATs, and had the greatest sample throughput.



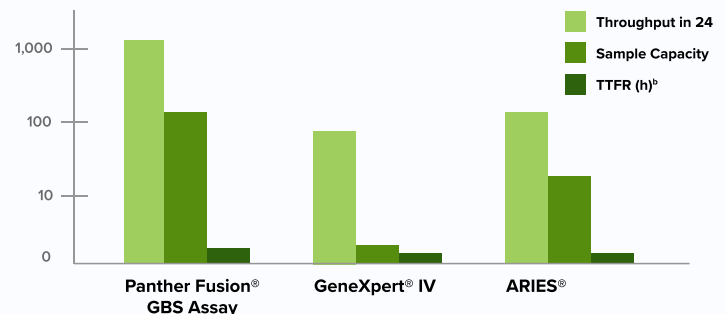
PCR NAATs are highly sensitive and should be considered the **preferred method for GBS screening** in the prenatal period.<sup>1</sup>

Study findings suggest that compared to standard culture, NAATs have the potential to:<sup>1</sup>

- Significantly **reduce newborn morbidity and mortality** associated with EOD due to false negatives from culture-based tests.
- **Increase the overall sensitivity of GBS screening** by reducing the number of false negatives.
- Optimize workload, including **reducing the time to obtain results**.

## Workflow of Automated Systems<sup>1</sup>

### Clinical Sensitivity (95% CI)



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1. 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 Microbiol JCM.01958-18; DOI: 10.1128/JCM.01958-18. 2. Stoll BJ, Hansen NI, Sanchez PJ, Faix RG, Poindexter BB, Van Meurs KP, Bizzarro MJ, Goldberg RN, Frantz ID, 3rd, Hale EC, Shankaran S, Kennedy K, Carlo WA, Watterberg KL, Bell EF, Walsh MC, Schibler K, Laptook AR, Shane AL, Schrag SJ, Das A, Higgins RD. 2011. Early onset neonatal sepsis: the burden of group B streptococcal and E. coli disease continues. Pediatrics 127:817– 826. <https://doi.org/10.1542/peds.2010-2217>. 3. Miller SA, Deak E, Humphries R. 2015. Comparison of the AmpliVue, BD Max System, and illumigene molecular assays for detection of group B Streptococcus in antenatal screening specimens. J Clin Microbiol 53: 1938 –1941. <https://doi.org/10.1128/JCM.00261-15>.

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