

Panther Fusion[®] GBS Assay:

A Leading Dallas Gynecologic Pathology Laboratory's Screening Technology of Choice

PathAdvantage[®] explored the possibility of implementing Nucleic Acid Amplification Tests (NAATs) for Group B *Streptococcus* (GBS) screening in pregnant patients. After conducting significant research, the practice ultimately chose to implement the Hologic Panther Fusion[®] GBS Assay because of its short turnaround times and high level of sensitivity compared to culture-based tests and alternative NAATs.

GBS: A Critical Health Concern



Naturally present in about 25% of pregnant patients in the US, and can cause serious or deadly infections in newborns when transmitted during delivery.¹



Highly treatable with antibiotics, potentially saving newborn lives when accurately detected before birth.¹



Only 57% of births are full-term,² making accurate detection before labor occurs a time-sensitive challenge.

Striving for Clinical and Workflow Excellence

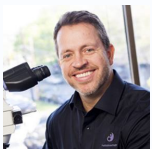
PathAdvantage[®] is a leading clinical laboratory in Dallas TX, dedicated to providing clinicians with a **24-hour results turnaround**.

Drs. Gillespie and Hopley were seeking a GBS testing method with a **fast turnaround time** and **high level of sensitivity**, which is what motivated them to explore NAATs (nucleic acid amplification tests).

The laboratory chose to focus on the **Panther Fusion[®] GBS assay from Hologic** because of its strong workflow benefits compared to alternative assays.³



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Panther Fusion[®] GBS Assay: A Verified Choice⁴

Study 1: Precision study using negative samples and GBS-spiked positive samples, testing three replicates over three days.

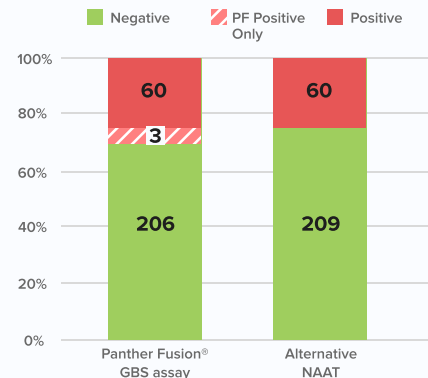
Results: The Panther Fusion[®] GBS assay demonstrated 100% precision.

Study 2: Accuracy study using Hologic-provided verification panels and patient samples, tested against PathAdvantage[®]'s prior NAAT in-house test.

Results: The Panther Fusion[®] GBS assay demonstrated 100% correlation using Hologic's verification panels and 98.9% correlation with the prior testing method.

Panther Fusion[®] GBS assay demonstrates greater sensitivity than alternative NAAT at PathAdvantage[®]⁴

3 of the 269 samples used in the accuracy study tested positive on the Panther Fusion[®] GBS assay while being negative on the previous testing method, implying a slightly greater sensitivity of the Panther Fusion[®] GBS assay.⁴ This increased sensitivity was consistent with findings described in published literature.¹



The Premium Choice for PathAdvantage[®]

PathAdvantage[®] chose to implement the Panther Fusion[®] GBS Assay for GBS testing because of its:

- Fast set-up time and hands-on time (per specimen) of under 1 minute.
- Turnaround time of <1 day for 96% of samples, allowing the lab to maintain their fast turnaround promise.
- Ease of use and reliability.

“[NAAT’s] speed, accuracy, and streamlined workflow translate to faster results, improved patient care, and a more efficient laboratory. The Hologic Panther[®] system offers significant advantages in cost-effectiveness, ease of use, and reliability.”

-Dr. Richard Hopley

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. Martin JA, Hamilton BE, Osterman MJK, Driscoll AK, Drake P. Births: Final data for 2017. National Vital Statistics Reports; vol 67 no 8. Hyattsville, MD: National Center for Health Statistics. 2018. https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_08-508.pdf. 3. 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. 4. Data on file