



alethia™

Group B Streptococcus

Provides physicians with accurate and reliable results, allowing for appropriate treatment decisions of mother at time of delivery, ensuring best outcome for baby

Care for Them with Certainty

The Alethia™ Platform from Meridian Bioscience helps you provide molecular accuracy when testing for GBS in expectant mothers.

Most infants who develop GBS disease are born to mothers who tested negative for Group B Strep.

- Culture sensitivity has been shown to be unreliable and is documented to be as low as 42%.
- Broth enrichment and Alethia™ Group B Strep increased detection of positives by up to 29% over culture for the detection of Group B *Streptococcus*.
- Pregnant moms and their families are hoping for a joyful birth experience. Give your labs and expectant mothers peace of mind with a definitive answer from the Alethia Group B Strep test.

If your lab currently screens for GBS with culture, the implications could be significant:

- Can you trust your negative culture and ensure your lab doesn't miss a non-hemolytic GBS strain?
- What are the implications of missing a GBS positive?

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The molecular precision of Alethia Group B Strep test ensures accurate results and timely administration of appropriate antibiotic therapy for GBS-positive patients.

Increased Confidence and Decreased Laboratory Burden

"We want to catch them all."

One Meridian Group B Strep user noted in their experience, 5% of GBS strains are non- β -hemolytic, and it was important to the staff to have this added level of sensitivity. Using Meridian's GBS test optimized their ability to maintain this level of care *and was of utmost importance* to the lab.

"It's given me so much peace."



Product Specifications

Intended Use

The Alethia Group B *Streptococcus* assay is a qualitative in vitro diagnostic for the detection of *Streptococcus agalactiae* in enriched cultures obtained from vaginal/rectal swab specimens from antepartum women.

Turnaround Time

Less than one hour, after broth enrichment

Shelf Life

18 months

Sample Type

Vaginal/rectal swab specimens, antepartum

Sample Storage

- Samples should be placed in a non-nutritive transport medium.
- Sample should be removed from the transport device and placed in culture enrichment broth (LIM Broth, TransVag Broth or Carrot Broth).
- Enriched samples may be held at room temperature for up to 6 hours prior to testing.
- Enriched samples may be held at 2–8 C for up to 7 days prior to testing.

Kit Storage

Kit should be stored at 2 - 27 C

Performance

Performance characteristics of the assay were compared to culture.

98.6% Sensitivity

93.2% Specificity

Catalog Number

Alethia™ Group B
Streptococcus - 480350

Alethia™ Group B Streptococcus
External Control - 279900

CPT Codes

87081, 87653

References

1. Department of Health and Human Services, Centers for Disease Control and Prevention. "Prevention of Perinatal Group B Streptococcal Disease, Revised Guidelines from CDC," 2010. MMWR 2010;59.
2. M. Van Dayke, PhD, et al. 2009. "Evaluation of Universal Antenatal Screening for Group B *Streptococcus*." The New England Journal of Medicine. 360: pp. 2626-2636.
3. F. Rallu, P Barriga, C. Scivo, V. Martel-Laferriere, and C. Laferriere. 2006. "Sensitivities of Antigen Detection and PCR Assays Greatly Increased Compared to that of the Standard Culture Method for Screening for Group B *Streptococcus* Carriage in Pregnant Women." Journal of Clinical Microbiology 44: pp. 725-728.

Ready to get a handle on Group B Strep testing? Let's talk.

Contact a specialist at 1-888-763-6769.
meridianbioscience.com

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LIFE DISCOVERED. LIFE DIAGNOSED.