



revogene®

GBS LB

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

Up to 40% of pregnant women carry Group B Strep (GBS), the leading infectious cause of sepsis and meningitis in newborns in the first week of life. And despite universal screening at 36-37 weeks, as many as 50% of women who are GBS carriers have false-negative culture results, putting the infants at risk of developing disease.^{1,2}

Revogene® directly impacts patient care by providing healthcare systems an opportunity to detect GBS with the accuracy of molecular.

- Reduce the risk of missing a true positive as culture sensitivity has been shown to be unreliable and is documented to be as low as 42%³
- Actionable results enable physicians to make informed decisions about patient management and treatment resulting in improved outcomes for newborns
- Give your expectant mothers piece of mind with a definitive answer from the Revogene® GBS LB test

Improve outcomes for babies

- What are the implications of missing a GBS positive?
- How would an accurate, easy-to-use molecular platform with just 3 steps help you improve outcomes and satisfaction among patients and physicians?

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Results that Matter

- Revogene® GBS LB ensures accurate results and timely administration of appropriate antibiotic therapy for GBS-positive patients
- The use of molecular for GBS detection offers a reasonable and more sensitive alternative to culture for antepartum testing²

Improve Efficiency, Deliver Standardization

- Improve overall lab efficiency with Revogene®'s simplified sample prep and 2 minutes hands-on-time
- Revogene®'s small footprint enables networks to standardize testing across the entire system improving overall clinical and operational efficiency

Revogene® GBS LB Procedure Steps

Sample to Result in 3 Steps

Less than 2 minutes hands on time



LIM Broth enrichment sample



1 Discharge Sample



2 Load Sample into the PIE



3 Place PIE into instrument and start

Product Specifications

Intended Use

The Revogene® GBS LB assay is a qualitative in vitro diagnostic test to detect Group B *Streptococcus* (GBS) DNA from 18-24 hour LIM broth enrichments of vaginal/rectal specimen swabs obtained from pregnant women.

Turnaround Time

70 minutes for positive and negative samples

Sample Type

Vaginal/rectal swabs that have been enriched in LIM broth for 18-24 hours

Sample Storage

- Vaginal/rectal swab specimens should be stored according to established guidelines
- Enriched LIM broth can be kept at 25 C for up to 2 days, or at 2-8 C for up to 3 days

Kit Storage

24 individual pouches (DTT, test cartridge (PIE) and SBT) per kit

Store at 2°-25°C until expiration date indicated on kit label and on each pouch

Performance*

95.9% Sensitivity

95.5% Specificity

Catalog Number

Revogene® GBS LB — 410200

CPT Codes

Revogene® GBS LB — 87653

Broth Culture — 87081

References

1. Paolucci, Michela et al. "How can the microbiologist help in diagnosing neonatal sepsis?." International journal of pediatrics vol. 2012 (2012): 120139. doi:10.1155/2012/120139
2. Obstetrics & Gynecology: July 2019 - Volume 134 - Issue 1 - p 206-210
3. Montague et al., J Clin Micro 2008;46:3470-3472

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

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

meridianbioscience.com/contact-us

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LIFE DISCOVERED. LIFE DIAGNOSED.