revogene®

GBS DS

Provides physicians with rapid, 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. Since 2013, the European guidelines recommend intrapartum antimicrobial prophylaxis based on a universal intrapartum GBS screening strategy using a rapid real time PCR testing.[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 DS 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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LIFE DISCOVERED. LIFE DIAGNOSED.

revogene®
GBS DS

Results that Matter

- It has been demonstrated that intrapartum PCR assay performs better than the antepartum culture for identification of GBS vaginal carriers during labor.[4]
- Revogene® GBS DS ensures accurate results and timely administration of appropriate antibiotic therapy for GBS-positive patients

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

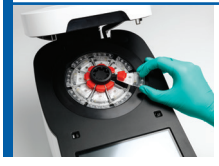
Revogene® GBS DS Procedure Steps

Sample to Result in 3 Steps
Less than 2 minutes hands on time

Vaginal/rectal swab sample

1 Discharge Sample

2 Load Sample into the PIE



3 Place PIE into intrument and start

Product Specifications

Intended Use

The Revogene® GBS DS assay is a qualitative in vitro diagnostic test to detect Group B *Streptococcus* (GBS) DNA

Turnaround Time

< 70 minutes, with as early as 40 minutes for positive specimens with ePro - early call feature

Sample Type

Vaginal/rectal swabs

Sample Storage

Vaginal/rectal swab specimens should be stored according to established guidelines

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

96% Sensitivity

90% Specificity

Catalog Number

Revogene® GBS DS — 410100

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. G. C. Di Renzo et al., Intrapartum GBS screening and antibiotic prophylaxis: a European consensus conference. J Matern Fetal Neonatal Med, 2015; 28(7): 766—782
3. Montague et al., J Clin Micro 2008;46:3470-3472
4. M. R. Khali et al., PLoS One. 2017;12(7):e0180262 10.1371/journal.pone.0180262

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

Contact a specialist at info@meridianbioscience.eu
meridianbioscience.com/contact-us

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