

CE-IVDR APPROVED

EasyNAT® GBS Assay

Introduction

Group B Streptococcus (GBS), or Streptococcus agalactiae, is a significant cause of neonatal and infant sepsis and meningitis globally. According to the World Health Organization (WHO), GBS can also lead to maternal sepsis, stillbirths, and preterm births. It is particularly severe in neonates and young infants up to age 3 months. The global burden of GBS is substantial, linked to over half a million preterm births annually and resulting in nearly 100,000 newborn deaths and at least 46,000 stillbirths each year .

EasyNAT GBS Assay

The assay is an automated, in vitro nucleic acid amplification test used for qualitative diagnosis of group B Streptococcus (GBS) deoxyribonucleic acid (DNA) in vaginal swab. The assay is indicated as an aid in determining GBS colonization status in antepartum and intrapartum women.



Feature

Fast
Get result within 49 minutes

Accurate
LOD: 200 copies/mL

Simple
One-step operation

Safe
All-in-one cartridge avoids potential contamination

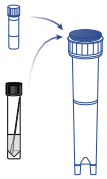
Flexibility
Independent module
Test anytime anywhere

Workflow

1 Collect sample



2 Load sample



3 Test



4 View result



Clinical Value

- **Enhance the standard of eugenics and well-being:** Group B Streptococcus (GBS) is the primary pathogen in perinatal mother-infant infections. Rapid diagnosis of GBS infection and the implementation of preventative treatment are crucial to safeguard the health of pregnant women and fetuses.
- **Early identification and diagnosis:** GBS colonization is characterized by insidious onset and atypical symptoms. Nucleic acid testing can diagnose GBS infections early, reducing the risk of neonatal infection.
- **Immediate rapid diagnosis:** Immediate molecular diagnostics can significantly reduce the turnaround time (TAT) for samples, provide rapid reporting, reduce repeat visits, and enhance the patient care experience
- **Reduce Testing costs:** POCT technology can reduce the overall cost of testing, making it suitable for widespread application in medical institutions at all levels.

Information

Product	EasyNAT GBS Assay	**Shelf life**	12 months
Sample type	vaginal swab	**Storage conditions**	2-8°C
Specification	20 tests/kit	**Transport conditions**	-25-37°C
Applicable instrument	EasyNAT Nucleic Acid Amplification and Detection Analyzer		

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