

Group B *Streptococcus* Qualitative Test

For in vitro diagnostic use

CERNER ORDERABLE
GBBS PCR

CPT CODE
87653

CLINICAL UTILITY

Group B *Streptococcus* (GBS) causes illness in newborns, pregnant women, the elderly, and adults with other medical conditions such as diabetes and liver disease. In the United States, GBS infection is the major cause of death in newborns who develop sepsis, pneumonia, or meningitis. Currently, pregnant women are screened for GBS at 35-37 weeks of gestation to determine if intrapartum chemoprophylaxis is necessary.

However, some women may not have their GBS status at the onset of labor. IU Health Molecular Pathology lab GBS QL PCR provides a rapid determination of Group B status from vaginal/rectal swabs with an average turn-around-time of 5 hours to establish results in time to administer antibiotics before delivery if required¹.

METHODOLOGY

Qualitative PCR

SPECIMENS

FDA approved for Vaginal/Rectal swabs.

SPECIMEN STABILITY

Within 24 hours of collection room temperature, greater than 24 hours refrigerate for up to 6 days

SHIPPING

Ship specimen at room temperature or if greater than 24 hours on ice pack

CAUSES FOR REJECTION

Incorrect collection swab

SPECIFICITY and SENSITIVITY

Specificity is 96.7% and Sensitivity is 81.8%

ASSAY RANGE

Qualitative results (Detected/Not detected)

Error/Invalid and swabs with GBS not detected are sent to Microbiology for culture.

TURNAROUND TIME

7 days a week, 2-8 hours

1. Reference information can be found in the Indiana University Health Molecular Assay Procedures.