INTENDED USE
The Cepheid® Xpert GBS LB Assay is a qualitative in vitro diagnostic test designed to detect Group B Streptococcus (GBS) DNA from enriched vaginal/rectal swab specimens, using fully automated real-time polymerase chain reaction (PCR) with fluorogenic detection of the amplified DNA. Xpert GBS LB Assay testing is indicated as an aid in determining GBS colonization status in antepartum women. The assay significantly increases the sensitivity and specificity to greater than 90% over traditional subculture.

IMPORTANT:
- The assay is used for antepartum testing on enriched Lim broth cultures of vaginal/rectal swabs after 18–24 hours of incubation.
- The assay does NOT provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.
- The test should NOT be used to determine therapeutic success, as nucleic acids may be present for 3–6 weeks after antimicrobial therapy.
- GBSPCR may be ordered on penicillin-allergic women. However, culture and sensitivity testing will be required for penicillin-allergic women who test positive by PCR.
- All positive results will be called to the ordering provider, and the ordering provider will advise the lab as to whether a culture is needed for their patient.

TEST INCLUDES
The GeneXpert® System automates and integrates sample lysis, nucleic acid purification and amplification, and detection of the target sequence in complex samples using real-time and reverse transcription Polymerase Chain Reaction (RT-PCR) and PCR assays.

METHODOLOGY
Real-time PCR and RT-PCR

SPECIMEN REQUIREMENTS

<table>
<thead>
<tr>
<th>SPECIMEN</th>
<th>VOLUME</th>
<th>CONTAINER</th>
</tr>
</thead>
<tbody>
<tr>
<td>vaginal/rectal swab</td>
<td>swab</td>
<td>REMEL Red Top Dual Swab</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Collectors (non-nutritive transport medium)</td>
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<tr>
<td></td>
<td></td>
<td>available from the lab</td>
</tr>
</tbody>
</table>

Collection
To obtain adequate specimen, follow the instructions in this section closely.
1. Using a swab in a non-nutritive transport medium, collect a vaginal/rectal swab specimen according to CDC recommendations.
2. Label the specimen with patient ID.
3. Transport swab specimen to the laboratory for Lim broth enrichment.

Storage
If the swab specimens will be processed in Lim broth for enrichment within 24 hours, store at room temperature (15–30ºC). If the swab specimens will be processed in Lim broth after 24 hours, store swabs at 2–8ºC for up to six days.

Causes for Rejection
- improper swab storage (freezing or exposing specimen to excessive heat)
- swabs older than 6 days
- wrong swab (swab in nutritive transport medium) used for collection
- specimen collected from patient who has used systemic or topical (vaginal) antibiotics in the week prior or from a patient with placenta previa
INTERFERING SUBSTANCES
Potentially interfering substances include, but are not limited to: human amniotic fluid, meconium, serum, urine, fecal material, human blood, lubricating gel, vaginal anti-itch medications, vaginal antifungal medications, anti-diarrheal medications, laxatives, stool softeners, topical hemorrhoid ointments, body oil, body powder, deodorant sprays, enema solutions, and spermicidal foam. Substances were tested at concentrations close to saturation. None of the substances tested had a statistically significant effect on the assay performance.

REFERENCE RANGE
NOT DETECTED

ADDITIONAL INFORMATION
GBS bacterial infection is associated with serious illness in newborns born to women who are colonized with the microorganism. Transmission of GBS occurs from GBS-colonized women to their newborn before birth (antepartum) or during birth (intrapartum). In the United States, GBS infection is the major cause of death in newborns who develop sepsis, pneumonia, or meningitis. Currently, the standard of care for preventing neonatal GBS disease is screening pregnant women at 35–37 weeks of gestation to determine their GBS colonization status. In November 2010, the CDC published a revised guideline recommending that in addition to culture, the vaginal/rectal specimens could be tested using a nucleic acid amplification test (NAAT) after 18–24 hours of incubation at 35–37°C in an appropriate enrichment broth medium such as Lim broth to enhance the detection of GBS for antepartum specimens.

Group B Strep (GBS) are uniformly susceptible to penicillin with no known penicillin resistance. For penicillin-allergic women who test positive for GBS, culture isolates are necessary in order to test the bacteria for antimicrobial susceptibility to erythromycin and clindamycin. GBS resistance to those agents has been documented. The laboratory will call all GBS-positive results and will order a culture on penicillin-allergic women when instructed to by the provider.

<table>
<thead>
<tr>
<th>MEDITECH CODE</th>
<th>GBSPCR</th>
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<tbody>
<tr>
<td>CPT CODES</td>
<td>87653</td>
</tr>
<tr>
<td>LABORATORY</td>
<td>Molecular Pathology Department</td>
</tr>
<tr>
<td>AVAILABILITY</td>
<td>Monday–Friday, 7:30 AM–4:00 PM</td>
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<tr>
<td>TURNAROUND TIME</td>
<td>24–36 hours (specimens received on Friday will not be resulted until Monday)</td>
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