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| **St. Anthony**  **Regional Hospital**  POLICY/PROCEDURE | Lab Director |  |
| Lab Manager |  |
| Laboratory | Department: PCR | |
| **Title: SOP.PCR.003 Cepheid Xpert GBS Assay 20220905** | | |

# Intended Use

The Cepheid Xpert GBS is a qualitative *in vitro* diagnostic test designed to detect Group B Streptococcus (GBS) DNA from vaginal/rectal swab specimens, using fully automated real-time polymerase chain reaction (PCR) with fluorogenic detection of the amplified DNA. Xpert GBS Assay testing is indicated for rapid identification of antepartum and intrapartum GBS colonization.

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.

**Materials Required**

* GBS Assay cartridge
* Collection Swab (red cap)
* Disposable, sterile transfer pipette (for retest only)

**Specimen Collection and Transport**

To obtain adequate specimen, follow the instructions in this section closely.

Using the Cepheid Collection Swab, collect specimens according to CDC recommendations. The following procedure should be used:

1. Wipe away excessive amounts of secretion or discharge.
2. Remove both marked swabs from the transport container.
3. Carefully insert both marked swabs into the patient's vagina. Sample secretions from the mucosa of the lower one-third part of the vagina. Rotate the swabs three times to ensure uniform sample on both swabs.
4. Using the same marked swabs, carefully insert both swabs approximately 2.5 cm beyond the anal sphincter, and gently rotate to sample anal crypts.
5. Place both marked swabs in the transport container.
6. If the specimens will be processed within 24 hours, store at room temperature. If the specimens will be tested after 24 hours, refrigerate until testing is performed. Specimens stored at 2–8º C are stable for up to six days.

**Procedure**

**Important: Start the test within 15 minutes of adding the sample to the cartridge**

**Note: Only one swab is required. The second swab is extra and can be used for susceptibility testing. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women. Do not add 2 swabs to any one cartridge.**

To add the sample into the cartridge (Xpert GBS):

1. Remove the cartridge from the package.
2. Open the cartridge lid.
3. Remove the marked swabs from the container. Gently brush the two swabs together using a twirling motion so that equal amount of sample is on each swab.
4. Insert one of the swabs into the Xpert GBS cartridge chamber S

* Do not insert both swabs into the cartridge
* Return the second swab into the collection/transport tube for subsequent antimicrobial susceptibility testing by the microbiology laboratory for GBS positive patients. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

1. Raise the swab so that the score mark is centered in the notch.
2. Break the swab by snapping the shaft to the right.
3. Close the cartridge lid.

**Starting the Test**

1. Click on the *create test* icon located at the top left hand corner of the screen.
2. Scan/type the sample ID (Meditech barcode label).
3. Scan the cartridge barcode.
4. Type the patient lastname,firstname in the patient ID box.
5. Use designated user ID/password to start the test.
6. Open module door with the blinking green light and load the cartridge.
7. Close the module door completely to start the test.

**Finished Testing**

1. Result will print when finished and module door will open.
2. Place Meditech barcode label on the result page.
3. Result in Meditech using the Cepheid analyzer batch.
   * Ancillary > Laboratory > Laboratory > Analyzers > Analyzer Desktop > Cepheid
4. Compare the name in the analyzer batch with the name on the result page from the analyzer.
5. Click on the patient you are resulting, and hit the *enter results* button.
6. **Positive results will need to be called to the ordering provider’s office and documented behind the result in Meditech.**
   * In addition to calling the result, include the canned text GBSPEN.
     + Contact lab within 72 hours to request susceptibility study if patient is allergic to penicillin.
7. Final/Verify results in Meditech- sign and date results page.
8. Place results page in the binder labeled *Cepheid Reports.*
9. Place swab from patient in marked
10. Dispose of used cartridge in the sharps container.

**Reasons to repeat assay**

Repeat the test or initiate alternate procedures if one of the following test results occurs:

* **Error-** The test was aborted because a system component failed, the maximum pressure was reached, or the probe check failed.
* **Invalid-**The SPC and/or the IC failed when GBS is negative. An invalid result can also be caused by air bubbles in the reaction tube.
* **NO RESULT-** The operator stopped the test, a power failure occurred during the test, or problems were detected in the cartridge.

**For retest**

If there is fluid in the cartridge sample chamber, use a transfer pipette to transfer all the fluid to the sample chamber of a new cartridge, and then rerun the test. If there is no fluid, use sterile tweezers to transfer the swab to a new cartridge, and then rerun the test. Alternatively, prepare a new cartridge using the second swab, and then rerun the test.

**References**

* GBS package insert. Please refer to this for more information/questions