Xpert® __C.difficile_BT__ Hands On Checklist

Note to instructor: Check or initial box(es) upon correct demonstration of skills/ written answers in the spaces provided.

Name of Trainee: _____ Date:_____

- ## Overview of GeneXpert®
  - Log onto system using windows password: ___cphd.
  - What is the GeneXpert instrument serial number: _____.
    Serial Number is located on the back side of the instrument, the Tech Support business card on the side of the instrument, and the header of each test report.

- ## Good Laboratory Practices
  - Clean work surfaces with 1:10 dilution of household chlorine bleach followed by 70% ethanol or denatured ethanol.

    Regardless of the household bleach concentration in your country, the final Active Chlorine concentration should be 0.5%.

  - When should you change your gloves?
    Change gloves between samples.
    Change or remove gloves before using the computer.

- ## Specimen and Reagent Storage and Handling
  - What are the approved specimens for this assay?
    Raw, Unpreserved, Unformed or Liquid Stool.

  - What are the storage and/or transport conditions for the following:
    Kit- 2-28 °C.
    Specimen- Raw, unpreserved stools can be held at 20-30 °C for up to 24 hours. If they cannot be processed within 24 hours, samples are stable at 2-8 °C for up to 5 days.

  - Describe the importance of the storage and transport conditions:
    Failure to store or transport either the kits or specimen under the required conditions may result in a negative effect to test results.

- ## Preparation of Xpert cartridge
  - Where can you find the procedure for preparing the cartridge?

The package insert located on the CD that is shipped with each kit.

- Describe the procedure for preparing the cartridge.

1. Remove the cartridge and Sample Reagent from the package.
2. Briefly place a swab in the unformed stool sample. The swab does not need to be completely saturated.
3. Insert the swab into the tube containing the Sample Reagent.

Note: Use sterile gauze to minimize risks of contamination.

4. Hold the swab by the stem near the rim of the tube, lift the swab a few millimeters from the bottom of the tube and push the stem against the edge of the tube to break it. Make sure the swab is short enough to allow the cap to close tightly.
5. Close the lid and vortex at high speed for 10 seconds.
6. Open the cartridge lid. Using a clean transfer pipette (not supplied), transfer the entire contents of the Sample Reagent to the Sample chamber of the Xpert *C. difficile* BT cartridge.
7. Close the cartridge lid.

• Starting the Test

- Where can you find the procedure for starting the test?

  The package insert or the operator manual.

- Describe EAT (Early Assay Termination). EAT is not applicable to all tests.

  Real-time monitoring of reaction progress

  Termination of the reaction when the cycle threshold of a particular reaction is crossed

  Benefit: Positive results reported immediately saving valuable minutes for patients requiring time-critical interventions.

- Dispose of the used cartridges in the appropriate specimen waste containers, according to your local institution's standard practices.
  Describe your facilities procedure for cartridge disposal.

  Response should include, at the very least, knowledge of whom to contact to find the information or where to find a relevant procedure.

□ Xpert Results

- Create a Test Report.
- View the results under **View Results**, **View Test** and/or **Report.**

□ Retest procedure

- Describe the reasons a retest procedure would be used.

When an INVALID, NO RESULT or ERROR is the test result.

- Explain the retest procedure.
  1. Retest Procedure can be located in the package insert
  2. For retest within 3 hours of an indeterminate result, use a new cartridge (do not re-use the cartridge) and new reagents.
  3. Transfer remaining contents from Chamber S to a new Sample Reagent vial using a disposable transfer pipette.
  4. Vortex and add the entire contents of the Sample Reagent to Chamber S of the new Xpert *C.difficile* BT cartridge.
  5. Close the lid and start new test.

For retest after 3 hours of an indeterminate result, repeat the test with a new swab sample.

☐ Explain the Control Strategy

- Describe the three performance characteristics that the System Checks validate:
  Optics.
  Temperature of the module.
  Mechanical integrity of each cartridge.

- List and define the Cepheid Assay Control Strategy i.e. assay internal controls:
  Sample Processing Control (SPC) — Ensures the sample was correctly processed. The SPC contains spores of *Bacillus globigii* in the form of a dry spore cake that is included in each cartridge to verify adequate processing of the sample bacteria. The SPC verifies that lysis of *C. difficile* bacteria and spores have occurred, if the organisms are present, and verifies that specimen processing is adequate. Additionally, this control detects specimen-associated inhibition of the real-time PCR assay. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria.

  Probe Check Control (PCC) — Before the start of the PCR reaction, the GeneXpert Dx System measures the fluorescence signal from the probes to monitor bead rehydration, reaction-tube filling, probe integrity and dye stability. Probe Check passes if it meets the assigned acceptance criteria

☐ Cepheid Technical Support

- Where do you locate the contact information for Technical Support?

  Implementation Guide
  Business cards located on the side of the instrument
  Package Insert
  Operator Manual

- What information is required when contacting Technical Support?

  Instrument Serial Number
  Name
  Contact Information
  Short description of the reason for calling