

| PROGRAM Standard Operating Procedure – Laboratory Services | |
|--|-------------------|
| Title: MIC60080 – Xpert <i>C. difficile</i> Quality Control | Policy Number: |
| Program Name: Laboratory Services | |
| Applicable Domain: Lab, DI and Pharmacy Services | |
| Additional Domain(s): NA | |
| Effective Date: | Next Review Date: |
| Issuing Authority: Director, Laboratory and Diagnostic Imaging Services | Date Approved: |
| Accreditation Canada Applicable Standard: NA | |

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GUIDING PRINCIPLE:

Quality control is performed on Xpert *C. difficile* cartridges to ensure proper functioning on a monthly basis and to ensure new shipments have not deteriorated during shipping. Quality control should be rotated through the different modules of the instrument.

PURPOSE/RATIONALE:

This standard operating procedure describes the quality control procedures for the Xpert *C. difficile* test on the GeneXpert Dx System.

SCOPE/APPLICABILITY:

This standard operating procedure applies to Medical Laboratory Technologists (MLTs) performing quality control for the Xpert *C. difficile* test.

REAGENTS and/or MEDIA:

- ZeptoMetrix NATtrol positive and negative controls
- Xpert *C. difficile* cartridges

SUPPLIES:

- Personal protective equipment
- Dry waste container
- Sterile pipettes
- Disposable transfer pipettes

EQUIPMENT:

- GeneXpert Dx System
- Class II biosafety cabinet (BSC)
- Vortex mixer
- Refrigerator

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ENVIRONMENTAL CONTROLS:

- Store Xpert *C. difficile* assay cartridges upright between 2°C to 28°C
- Do not use a cartridge that has been damaged or leaked, dropped, or shaken
- Open a cartridge only when ready to add sample. An open cartridge must be loaded onto the GeneXpert within 30 minutes
- Cartridges are single use. Do not attempt to open or re-use a cartridge
- Cartridges and test samples stored at 4°C must be brought to room temperature before running the assay
- Do not touch the Reaction Tube, always handle the cartridge by its Body

PROCEDURE INSTRUCTIONS:

| Step | Action |
|---|--|
| Performing <i>C. difficile</i> Quality Control | |
| 1 | Xpert <i>C. difficile</i> cartridge quality control is performed monthly and upon receipt of new cartridges. |
| 2 | Perform quality control testing using ZeptoMetrix NATtrol controls. This includes a positive control and a negative control and is stored refrigerated. NOTE: Controls should be vortexed for 5 seconds prior to use |
| 3 | Quality control is rotated through the different modules of the instrument using the defined schedule. Refer to appendix below. |
| 4 | Prepare the Xpert <i>C. difficile</i> cartridge as per MIC72400-Xpert <i>C. difficile</i> substituting the patient specimen with the control solutions. Use the entire control solution in the vial. NOTE: Do not run controls with patient samples in order to prevent possible contamination from the positive control solutions |
| 5 | When creating a test run, manually enter the sample ID as Positive Control or Negative Control. |
| 6 | If all QC results are acceptable, complete MIC60081-QC Results Record-Xpert <i>C. difficile</i> . Ensure the control lot number, control expiry date, cartridge lot number, cartridge expiry date and module numbers are filled in along with the results, the performing technologist's initials, and the reason for performing (monthly, new lot or new shipment). The yearly QC Results Record is kept in the PCR Testing Completed QC Records binder under the MIC60081-QC Results Record-Xpert <i>C. difficile</i> tab. |
| 7 | If QC results are not acceptable, ensure controls were not mixed-up during loading (ex. positive control run as the negative control). After preliminary investigation, repeat testing. |
| 8 | If repeat QC testing is still not acceptable: <ul style="list-style-type: none"> • Notify the Technical Supervisor-Microbiology for resolution • Contact Cepheid to determine if issues with cartridges exist • Until the problem is resolved, patient testing may not be reported |

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APPENDIX:
***C. difficile* Quality Control Schedule for GX-XVI**

| Run | Module | Control | Run | Module | Control |
|-----|--------|----------|-----|--------|----------|
| 1 | A1 | Positive | 17 | C2 | Positive |
| 2 | A2 | Negative | 18 | C3 | Negative |
| 3 | A2 | Positive | 19 | C3 | Positive |
| 4 | A3 | Negative | 20 | C4 | Negative |
| 5 | A3 | Positive | 21 | C4 | Positive |
| 6 | A4 | Negative | 22 | D1 | Negative |
| 7 | A4 | Positive | 23 | D1 | Positive |
| 8 | B1 | Negative | 24 | D2 | Negative |
| 9 | B1 | Positive | 25 | D2 | Positive |
| 10 | B2 | Negative | 26 | D3 | Negative |
| 11 | B2 | Positive | 27 | D3 | Positive |
| 12 | B4 | Negative | 28 | D4 | Negative |
| 13 | B4 | Positive | 29 | D4 | Positive |
| 14 | C1 | Negative | 30 | A1 | Negative |
| 15 | C1 | Positive | | | |
| 16 | C2 | Negative | | | |

CROSS-REFERENCES:

- MIC60081-QC Results Record-Xpert *C. difficile*
- MIC72400-Xpert *C. difficile*

REFERENCES:

1. ZepetoMetrix. (06/17/2021). *NATtrol C. difficile External Run Controls* package insert.
2. Cepheid GeneXpert. Xpert *C. difficile* Assay Instructions for Use. 300-8023, Rev. G, October 2019
3. Cepheid GeneXpert. *Dx System User Manual*. 303-1548 Rev. A, July 2023

APPROVAL:

Date

Director, Laboratory and Diagnostic Imaging Services

REVISION HISTORY:

| REVISION | DATE | Description of Change | REQUESTED BY |
|----------|-----------|---|--------------|
| 1.0 | 30 Jan 22 | Initial Release | L. Steven |
| 2.0 | 17 Oct 22 | Procedure reviewed and updated to reflect QC run weekly as well as when new kits received | L. Steven |
| 3.0 | 16 Apr 24 | Procedure reviewed and updated to reflect QC run monthly not weekly | L. Steven |
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