

PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC10310 – Xpert <i>C.difficile</i> Quality Control	Policy Number:
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s):	
Effective Date:	Next Review Date:
Issuing Authority: Director, Health Services	Date Approved:
Accreditation Canada Applicable Standard: N/A	

GUIDING PRINCIPLE:

Quality control is performed on Xpert *C.difficile* cartridges to ensure proper functioning on a weekly 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 procedure applies to Medical Laboratory Technologists (MLTs) and Medical Laboratory Assistants (MLAs) performing quality control for the Xpert *C.difficile* test.

REAGENTS and/or MEDIA:

- ZeptoMetrix NATrol positive and negative controls
- Xpert *C.difficile* cartridge

SUPPLIES:

- Personal protective equipment
- Dry waste container
- Sterile, dry swabs
- Disposable transfer pipettes

EQUIPMENT:

- GeneXpert Dx System
- Printer
- 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 open a cartridge lid until you are ready to perform testing
- 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 weekly by the Monday Specimen Receiving Bench technologist and upon receipt of new cartridges.
2	Perform quality control testing using ZeptoMetrix NATrol positive and negative controls.
3	Quality control is rotated through the different modules of the instrument using the defined schedule. Refer to appendix below.
4	Vortex the NATrol control vigorously for 5 seconds.
5	Remove the cartridge and reagent from the package.
6	On the right hand side of the cartridge, write with a marker which control is being run; positive or negative.
7	Briefly place a swab in the control solution.
8	Insert the swab into the vial containing the Sample Reagent.
9	Hold the swab by the stem near the rim of the vial and push the stem against the edge of the vial to break it. NOTE: Make sure the swab is short enough to allow the cap to close
10	Close the lid and vortex at high speed for 10 seconds.
11	Pry open the cartridge lid and open wrapper of the transfer pipette.
12	Transfer the entire contents of the Sample Reagent to the Sample Chamber of the cartridge.
13	Firmly snap close the lid to seal the cartridge.
14	Load the cartridge as per MIC10300-Xpert <i>C.difficile</i> . Manually enter the sample ID as Positive Control or Negative Control.
15	If all QC results are acceptable, complete MIC10320-Xpert <i>C.difficile</i> QC Results Record. 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 (weekly or new shipment). Place the current monthly sheet in the GeneXpert PCR Testing Quality Control Results binder.
16	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.
17	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-IV**

Run	Module	Control	Run	Module	Control
1	A1	Positive	5	A3	Positive
2	A2	Negative	6	A4	Negative
3	A2	Positive	7	A4	Positive
4	A3	Negative	8	A1	Negative

CROSS-REFERENCES:

- MIC10300-Xpert *C.difficile*
- MIC10320-Xpert *C.difficile* QC Results Record

REFERENCES:

1. ZeptoMetrix. (06/17/2021). *NATtrol C. difficile External Run Controls* package insert.
2. Cepheid GeneXpert. *Xpert C. difficile Assay Instructions for Use*. 300-9680 Rev. F, March 2016
3. Cepheid GeneXpert. *Dx System User Manual*. 301-0045, Rev.C, June 2012

APPROVAL:

 Date

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

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