

PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC60100 – Xpert MTB/RIF Ultra 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 Xpress MTB/RIF Ultra 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 procedure for the Xpert MTB/RIF Ultra test on the GeneXpert Dx System.

SCOPE/APPLICABILITY:

This standard operating procedure applies to Medical Laboratory Technologists (MLTs) performing quality control for the Xpert MTB/RIF Ultra test.

REAGENTS and/or MEDIA:

- INTROL TB QC panel
- Xpert MTB/RIF Ultra cartridges
- Sample reagent bottles
- Accel TB 1L bottle
- Accel TB wipes
- 70% isopropyl alcohol

SUPPLIES:

- Personal Protective Equipment
- Sample rack
- Wet waste container
- Dry waste container
- Orange autoclave bag
- Spray bottle
- Transfer pipettes provided in kit
- Disposable, graduated pipettes
- Mechanical pipette and tips
- 50 mL conical tubes

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EQUIPMENT:

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

ENVIRONMENTAL CONTROLS:

- Store Xpert MTB/RIF Ultra 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 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 Xpert MTB/RIF Ultra Quality Control	
1	Xpert MTB/RIF Ultra cartridge quality control is performed monthly and upon receipt of new cartridges.
2	Perform quality control testing using INTROL TB QC panel. The kit includes <ul style="list-style-type: none">• 1 control-MTB positive and RIF resistant (red top-TBMDR1-04)• 1 control-MTB positive and RIF sensitive (green top-TBWT-04)• 1 control-MTB negative (white top-TBNEG) 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 MTB/RIF Ultra cartridge as per MIC72400-Xpert MTB/RIF substituting the patient specimen with the control solutions. NOTE: Do not run controls with patient samples in order to prevent possible contamination from the positive control solution
5	When creating a test run, manually enter the sample ID as MTB Positive/RIF Resistant Control, MTB Positive/RIF Sensitive Control or Negative Control.
6	If all QC results are acceptable, complete MIC60101-QC Results Record-Xpert MTB/RIF Ultra. 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 MIC60100-QC Results Record-Xpert MTB-RIF 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:
MTB/RIF Quality Control Schedule for GX-XVI

Run	Module	Control	Run	Module	Control
1	A1	+/R	24	C3	-
2	A2	+/S	25	C2	+/R
3	A3	-	26	C3	+/S
4	A2	+/R	27	C4	-
5	A3	+/S	28	C3	+/R
6	A4	-	20	C4	+/S
7	A3	+/R	30	D1	-
8	A4	+/S	31	C4	+/R
9	B1	-	32	D1	+/S
10	A4	+/R	33	D2	-
11	B1	+/S	34	D1	+/R
12	B2	-	35	D2	+/S
13	B1	+/R	36	D3	-
14	B2	+/S	37	D2	+/R
15	B4	-	38	D3	+/S
16	B2	+/R	39	D4	-
17	B4	+/S	40	D3	+/R
18	C1	-	41	D4	+/S
19	B4	+/R	42	A1	-
20	C1	+/S	43	D4	+/R
21	C2	-	44	A1	+/S
22	C1	+/R	45	A2	-
23	C2	+/S			

CROSS-REFERENCES:

- MIC60101-QC Results Record-Xpert MTB/RIF Ultra
- MIC72400-Xpert MTB/RIF

REFERENCES:

1. MMQCI. (October 19, 2021). *INTROL TB Control Panel* package insert
2. Cepheid GeneXpert. *Xpert MTB/RIF Ultra* package insert. 301-5987, Rev J, August 2020
3. Cepheid GeneXpert. *Dx System User Manual*. 303-1548 Rev. A 2023-07

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APPROVAL:

Date

Director, Laboratory and Diagnostic Imaging Services

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	15 Dec 22	Initial Release	L. Steven
3.0	16 Apr 24	Procedure reviewed and updated to reflect QC run monthly not weekly	L. Steven

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