

PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC60120 – Xpert Xpress Strep A 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 Xpress Strep A cartridges to ensure proper function 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 Xpress Strep A test on the GeneXpert Dx System.

SCOPE/APPLICABILITY:

This standard operating procedure applies to Medical Laboratory Technologists (MLTs) performing quality control for the Xpert Xpress Strep A test.

REAGENTS and/or MEDIA:

- ZepetoMetrix NATtrol positive and negative controls
- Xpert Xpress Strep A cartridges

SUPPLIES:

- Personal protective equipment
- Dry waste container
- Transfer pipettes provided in kit

EQUIPMENT:

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

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ENVIRONMENTAL CONTROLS:

- Store Xpert Xpress Strep A 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 Xpert Xpress Strep A Quality Control	
1	Xpert Xpress Strep A 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 Xpress Strep A cartridge as per MIC10325-Xpert Xpress Strep A 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 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 MIC60120-QC Results Record-Xpert Xpress Strep A. 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 MIC60120-QC Results Record-Xpress Strep A 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:
Xpert Xpress Strep A 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:

- MIC60121-QC Results Record-Xpert Xpress Strep A
- MIC72500-Xpert Xpress Strep A

REFERENCES:

- ZeptoMetrix. (07/27/2021). NATtrol Strep A External Run Controls package insert.
- Cepheid GeneXpert. *Xpert Xpress Strep A* Instructions for Use. 301-6574 Rev. E, July 2020
- Cepheid GeneXpert. *Dx System User Manual*. 303-1548 Rev. A, July 2023

APPROVAL:

Date

Director, Laboratory and Diagnostic Imaging Services

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REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	25 Nov 24	Initial release	L. Steven

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