PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC60090 – Xpert Xpress CoV-2 plus 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	

Uncontrolled When Printed

GUIDING PRINCPLE:
Quality control is performed on Xpert Xpress CoV-2 plus 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 Xpress CoV-2 plus 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 CoV-2 plus test.

REAGENTS and/or MEDIA:
- ZeptoMetrix NATtrol positive and negative controls
- Xpert Xpress CoV-2 plus cartridges
- Accel TB 1L bottle
- Accel TB wipes
- 70% isopropyl alcohol

SUPPLIES:
- Personal Protective Equipment
- Wet and dry waste containers
- Orange autoclave bags
- Spray bottle
- Transfer pipettes provided in kit

EQUIPMENT:

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

ENVIRONMENTAL CONTROLS:

- Store Xpert Xpress CoV-2 plus 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 CoV-2 plus Quality Control	
1	Xpert Xpress CoV-2 plus 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 CoV-2 plus cartridge as per MIC72200-Xpert Xpress CoV-2 plus 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 Positive Control or Negative Control.
6	If all QC results are acceptable, complete MIC60091-QC Results Record-Xpert Xpress CoV-2 plus. 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 MIC60091-QC Results Record-Xpert Xpress CoV-2 plus 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: • Notify the Technical Supervisor-Microbiology for resolution • Contact Cephid to determine if issues with cartridges exist • Until the problem is resolved, patient testing may not be reported

APPENDIX:

CoV-2 plus 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:

- MIC60091-QC Results Record-Xpert Xpress CoV-2 plus
- MIC72200-Xpert Xpress SARS-CoV-2

REFERENCES:

1. ZeptoMetrix. (09/18/24). *NATtrol SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Controls* package insert.
2. Cepheid GeneXpert. *Xpert Xpress CoV-2 plus* Instructions for Use (EUA). 302-7070, Rev B, February 2023
3. Cepheid GeneXpert. *Dx System User Manual*. 303-1548 Rev. A, July 2023
4. National Microbiology Laboratory. *Biosafety and Testing Procedures for the Xpert Xpress SARS-CoV-2 Assay and GeneXpert System*. Winnipeg, Canada. V1.0 April 8, 2020

APPROVAL:

_____
Date

_____
Director, Laboratory and Diagnostic Imaging Services

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	25 May 20	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	05 Mar 24	Updated to reflect removal of schedule for GX-IV due to discontinuation of testing done at IRH	L. Steven
4.0	16 Apr 24	Updated to reflect QC run monthly not weekly as per NML	L. Steven