PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC81300 – Xpert Xpress SARS-CoV-2 Quality Control	Policy Number: 29-13-V1
Program Name: Laboratory Services	
Applicable Domain: Epidemic/Pandemic	
Additional Domain(s): Lab, DI and Pharmacy Services	
Effective Date:	Next Review Date:
Issuing Authority: Director of Health Services	Date Approved:
Accreditation Canada Applicable Standard: N/A	

GUIDING PRINCPLE:
Quality control is performed on every new lot number and/or shipment of Xpert Xpress SARS-CoV-2 cartridges to ensure proper function and to ensure cartridges have not deteriorated during shipping. Quality control should be rotated through the different modules of the instrument.

PURPOSE/RATIONALE:
This standard operating procedure describes quality control for the Xpert Xpress SARS-CoV-2 test on the GeneXpert Dx System.

SCOPE/APPLICABILITY:
This procedure applies to Medical Laboratory Technologists (MLTs) processing specimens using the GeneXpert Dx System.

REAGENTS and/or MEDIA:
- AccuPlex Reference Material Kit
- Xpert Xpress SARS-CoV-2/Flu/RSV cartridge
- Transfer pipettes provided in kit
- Accel TB 1L bottle
- Accel TB wipes
- 70% isopropyl alcohol

SUPPLIES:
- Personal Protective Equipment
- Absorbent bench liner
- Wet waste container
- Dry waste container
- Orange autoclave bags
- Spray bottle
- Cart

EQUIPMENT

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

ENVIRONMENTAL CONTROLS:

- Store Xpert Xpress SARS-CoV-2/Flu/RSV 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 SARS-CoV-2 Quality Control	
1	Xpert Xpress SARS-CoV-2 quality control is performed on every new lot number and/or shipment of cartridges.
2	Enter cartridge information into TQC. Refer to MIC60090-Entering New Media and Reagents into TQC.
3	Perform quality control testing using AccuPlex SARS-CoV-2 Reference Material Kit. The kit includes a positive and a negative control solution.
4	Quality control is rotated through the different modules of the instrument using the defined schedule. Refer to appendix below.
5	Prepare the Xpert Xpress SARS-CoV-2/Flu/RSV cartridge as per MIC81200-Xpert Xpress SARS-CoV-2 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
6	When creating a test run, manually enter the sample ID as Positive Control or Negative Control.
7	If QC results are acceptable, complete MIC81310-Xpert Xpress SARS-CoV-2 QC Results Record. Ensure the control lot number, control expiry date, cartridge lot number, cartridge expiry date, cartridge receipt date and module numbers are filled in along with the results and the performing technologist's initials. Place the current monthly sheet in the GeneXpert PCR Testing Quality Control Results binder.
8	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.
9	If repeat QC testing is still not acceptable: • Notify the Technical Supervisor-Microbiology for resolution • Contact Inter-Medico to determine if issues with cartridges exist • Until the problem is resolved, patient testing may not be reported

APPENDIX:

SARS-CoV-2 Quality Control Schedule for GX-XVI

Run	Module	Control	Run	Module	Control
1	A1	Positive	17	C1	Positive
2	A2	Negative	18	C2	Negative
3	A2	Positive	19	C2	Positive
4	A3	Negative	20	C3	Negative
5	A3	Positive	21	C3	Positive
6	A4	Negative	22	C4	Negative
7	A4	Positive	23	C4	Positive
8	A1	Negative	24	C1	Negative
9	B1	Positive	25	D1	Positive
10	B2	Negative	26	D2	Negative
11	B2	Positive	27	D2	Positive
12	B3	Negative	28	D3	Negative
13	B3	Positive	29	D3	Positive
14	B4	Negative	30	D4	Negative
15	B4	Positive	31	D4	Positive
16	B1	Negative	32	D1	Negative

SARS-CoV-2 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:

- MIC60090-Entering New Media and Reagents into TQC
- MIC81200-Xpert Xpress SARS-CoV-2
- MIC81310-Xpert Xpress SARS-CoV-2 QC Results Record

REFERENCES:

1. AccuPlex. (Mar 20, 2020). *SARS-CoV-2 Reference Material* package insert.
2. Cepheid GeneXpert. *Xpert Xpress SARS-CoV-2/Flu/RSV* Instructions for Use (EUA). 302-4419, Rev C, January 2021
3. 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
4. Biosafety Advisory Committee. *STHA Biosafety Program Manual*. January 2016

APPROVAL:

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Date

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REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	25 May 20	Initial Release	L. Steven