PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC81400 – GeneXpert Sample Pooling-STH	Policy Number:
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s):	
Effective Date:	Next Review Date:
Issuing Authority: Director of Health Services	Date Approved:
Accreditation Canada Applicable Standard: N/A	

GUIDING PRINCIPLE:
Pooling on the GeneXpert system using the Xpert Xpress SARS-CoV-2 test is used to conserve test cartridges when positive test rates are below 10%. All methods should be followed as described in the procedure MIC81200-Xpert Xpress SARS-CoV-2-STH.

PURPOSE/RATIONALE:
This standard operating procedure describes sample pooling of the Xpert Xpress SARS-CoV-2 test using the GeneXpert Dx System at Stanton Territorial Hospital.

SCOPE/APPLICABILITY:
This procedure applies to Medical Laboratory Technologists (MLTs) processing specimens for SARS-CoV-2 using the GeneXpert Dx System.

SAMPLE INFORMATION:

Type	Swab Saline gargle
Source	• Nasopharyngeal • Throat/oropharyngeal • Saline gargle rinse
Collection Container	• Viral transport media • Universal transport media • Saline gargle tube
Stability	VTM/UTM: • Room temperature up to 4 hours • Refrigerated up to 7 days Saline gargle: • Refrigerated up to 5 days

Storage Requirements	Room temperature or refrigerated
Criteria for rejection	1. Unlabeled/mislabeled samples 2. Sample container label does not match patient identification on requisition 3. Sample not in UTM/VTM or saline gargle solution 4. Sample not stored correctly

REAGENTS and/or MEDIA:

- Xpert Xpress SARS-CoV-2/Flu/RSV cartridge
- Accel TB 1L bottle
- Accel TB wipes
- 70% isopropyl alcohol

SUPPLIES:

- Personal Protective Equipment
- Absorbent bench liner
- Sample rack
- Wet waste container
- Dry waste container
- Orange autoclave bag
- Spray bottles
- Transfer pipettes provided in kit
- Cartridge tray
- Volume pipette and tips
- Clean, screwtop tubes and lids
- Alcohol-resistant marker

EQUIPMENT:

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

ENVIRONMENTAL CONTROLS:

- Store Xpert Xpress SARS-CoV-2 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

SPECIAL SAFETY PRECAUTIONS:

- Patient samples should only be opened and prepared for testing in a contained environment (i.e. certified Class II BSC)
- Personal Protective Equipment (PPE) required when working with suspect SARS-CoV-2 samples includes:
  - Lab gown, double layer nitrile gloves and Class II BSC
- The test operator and all personnel in the immediate vicinity should be wearing appropriate PPE at all times when working with suspect SARS-CoV-2 samples, in the event of a spill outside of the BSC
- Used cartridges should not be opened
- All personnel handling potential SARS-CoV-2 samples should be knowledgeable in their laboratory's biological spill clean-up protocol for infectious respiratory samples

- A dropped cartridge is unlikely to open if it has been firmly re-closed after loading. In the event that a cartridge is dropped outside of the BSC (open or closed), follow the STHA Biological Spill Control procedure

PROCEDURE INSTRUCTIONS:

Step	Action
Prepare GX Pooling Worksheet	

1	Before beginning the pooling process , prepare the pooling worksheet:
	• Enter the date on the form
	• Enter the pool name on the form:
	  ○ The name should begin with the pool number for the day and the date the pool was created
	  ○ For example, the first pool of the day on November 20, 2020 would be named: **Pool One – 20-11-20**
	• Place the extra requisition label in the "Samples in Pool" column on the worksheet. These samples will make up the sample pool
	NOTE: Each pool will consist of up to 6 samples
	NOTE: The requisition label must be used on the worksheet to ensure the form can be scanned into SoftMedia

Step	Action
Preparing the BSC	
1	Set up the designated, clean BSC in the core laboratory with the following: • Absorbent pad on working surface • Wet waste container half full with Accel TB • Dry waste container containing an autoclave bag • Spray bottle with 70% isopropyl alcohol • Spray bottle with Accel TB • Accel TB wipes • Cartridge tray • Xpert Xpress SARS-CoV-2 cartridge and pipette provided in kit • Pooling worksheet
2	The following additional supplies need to be in the BSC for pooling: • 100-1000uL volume pipette • Disposable pipette • Extended length, sterile, filtered pipette tips • Clean, screwtop tubes and lids • Alcohol-resistant marker for labelling tubes and GeneXpert cartridge

Step	Action
Preparing the Pool	
1	Place the biohazard bags containing the samples on the right hand side of the working area. Each pool will consist of up to 6 samples.
2	Don an additional pair of gloves to ensure you are double gloved before working in the BSC.

3	Open biohazard bag and discard in the dry waste container. Wipe each sample with an Accel TB wipe and place in the sample rack. Once dry, label the sample with the sample label. Save the media label, it will be needed to run samples individually if the pool is positive.
4	Label one screwtop, secondary tube with the pool name. Place the tube on the right hand side of the patient samples in the sample rack opened.
5	Thoroughly mix the first sample in the rack by inverting rapidly 5 times.
6	Refer to MIC81200-Xpert Xpress SARS-CoV-2-STH for the opening of samples for SARS-CoV-2 testing.
7	Transfer 300uL of the test specimen into the secondary tube using the volume pipette and an extended length pipette tip or a disposable pipette. **NOTE:** Do not let the sides of the pipette to come into contact with the patient sample
8	Rinse the pipette tip in the wet waste container with Accel TB and allow to soak. Wipe the pipette with an Accel TB wipe.
9	Recap the patient sample tube and move to the back of the rack.
10	Spray outer gloves thoroughly with isopropyl alcohol, rub together and allow to air dry. **NOTE:** Always disinfect gloves between the pipetting of each sample
11	Proceed to the next sample in the pool.
12	Once all samples have been pooled, tightly cap the secondary tube and invert 10 times to mix. The pool is now ready to load into the cartridge.

Step	**Action**
Preparing the Cartridge	
1	Label the cartridge on the side, near the base with the Pool ID using the alcohol-resistant marker.
2	Using the provided transfer pipette, load 300µL of the sample pool into the cartridge. Refer to MIC81200-Xpert Xpress SARS-CoV-2-STH for pipette loading instructions.
3	Dispense the sample into the cartridge. Refer to MIC81200-Xpert Xpress SARS-CoV-2-STH for cartridge loading instructions.
4	Rinse the pipette in the wet waste container with Accel TB and allow to soak. Recap the sample pool tube.
5	Firmly snap close the lid to seal the cartridge and place in the cartridge tray on the left hand side.
6	Spray outer gloves thoroughly with isopropyl alcohol, rub together and allow to air dry.
7	Once cartridge loading and decontamination is complete, spray outer gloves with isopropyl alcohol and remove.
8	Transfer the loaded cartridge to the GeneXpert bench in the TB Room.
9	Log into the GeneXpert software using the username **admin1** and the password **covid19**.

10	Confirm that all modules are detected by the software and ready for testing.
11	On the GeneXpert software, click **Create Test** at the top left.
12	In the scan sample ID barcode box manually enter the pool name. In the scan cartridge barcode box scan the cartridge barcode. Select **Start Test**.
13	Locate the module with the blinking green light, open the module door and load the cartridge. Close the module door firmly, it will latch closed.

INTERPRITATION OF RESULTS:

1. Refer to MIC81200-Xpert Xpress SARS-CoV-2-STH for the interpretation of results

REPORTING INSTRUCTIONS:

- Refer to MIC81200-Xpert Xpress SARS-CoV-2-STH for reporting of results

Step	Action
Completing the Run	
1	Check the Resulting Worklist-GeneXpert to ensure all ordered samples are complete.
2	In the BSC, with gloved hands, remove the used pipettes from the wet waste container and place into the dry waste container.
3	Remove the autoclave bag from the dry waste container. Tie and wipe outside with an Accel TB wipe. Place in the biohazard garbage.
4	Ensure supplies in BSC are stocked up.
5	Wipe the BSC with an Accel TB wipe. Turn off the blower and lower the sash. Remove gloves and don a fresh pair.
6	Ensure all used cartridges from the GeneXpert are discarded in the biohazard waste.
7	When all testing of patient samples and disinfection of surfaces is complete, remove PPE and place in the biohazard waste. Retrieve samples from the refrigerator and place in correct storage location.
8	Scan pooling worksheet into SoftMedia using the pooling template.

LIMITATIONS:

1. Refer to MIC81200-Xpert Xpress SARS-CoV-2-STH for the interpretation of results

CROSS-REFERENCES:

- MIC81200-Xpert Xpress SARS-CoV-2-STH

REFERENCES:

1. Cepheid GeneXpert. *Xpert Xpress SARS-CoV-2/Flu/RSV* Instructions for Use (EUA). 302-4419, Rev C, January 2021
2. Cepheid GeneXpert. *Dx System User Manual*. 301-0045, Rev.C, June 2012
3. National Microbiology Laboratory. *Guidelines for Sample Pooling with the Xpert Xpress SARS-CoV-2 Assay*. Winnipeg, Canada. V1.6 July 2020

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
5. Biosafety Advisory Committee. *STHA Biosafety Program Manual*. January 2016

APPROVAL:

_____
Date

_____

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	20 Nov 20	Initial Release	L. Steven
2.0	30 Apr 21	Updated to reflect new SARS-CoV-2/Flu/RSV cartridge and pool size of 6	L. Steven
3.0	20 Aug 21	Updated to reflect saline gargle samples	L. Steven