PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC81200 – Xpert Xpress SARS-CoV-2-STH	Policy Number: 29-11-V1
Program Name: Laboratory Services	
Applicable Domain: Epidemic/Pandemic	
Additional Domain(s): Lab, DI and Pharmacy Services	
Effective Date: 19/01/2021	Next Review Date: 19/01/2023
Issuing Authority: Director of Health Services	Date Approved: 19/01/2021
Accreditation Canada Applicable Standard: N/A	

GUIDING PRINCIPLE:
The Xpert Xpress SARS-CoV-2 test is a rapid, real-time PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, throat/oropharyngeal swabs or saline gargle samples collected from individuals suspected of COVID-19 by their healthcare provider.

PURPOSE/RATIONALE:
This standard operating procedure describes 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:

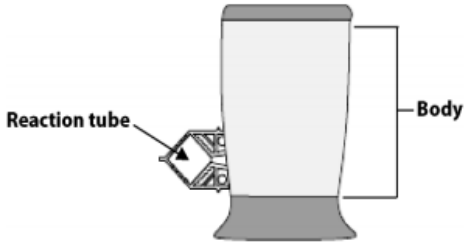
- Personal Protective Equipment
- Absorbent bench liner
- Sample rack
- Wet waste container
- Dry waste container
- Orange autoclave bag
- Spray bottles
- Transfer pipettes provided in kit
- Cartridge tray

EQUIPMENT:

- GeneXpert Dx System
- Printer
- 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



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, eye protection and Class II Biological Safety Cabinet
- 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

QUALITY CONTROL:

- AccuPlex Reference Material Kit positive and negative controls need to be performed on every new lot number and/or shipment of cartridges
- Refer to MIC81300-Xpert Xpress SARS-CoV-2 Quality Control for quality control procedure
- Record all results on MIC81310-Xpert Xpress SARS-CoV-2 QC Results Record

PROCEDURE INSTRUCTIONS:

Step	Action
Preparing the Run	
1	Order GeneXpert SARS-CoV-2 testing in the LIS: • Medipatient the order if required • In SoftMic, accession the order using the test code **PCCOV** • Add any "copies to" if required **NOTE:** Ensure copies to OCPHO (HPU1) are added if requested **NOTE:** Make sure the priority is STAT • Collect, receive and plate the order • Label the requisition with the requisition label and scan into SoftMedia • Place the sample barcode label and media barcode label in the pouch of the biohazard bag • Deliver samples to the blue bin labelled PCCOV in the microbiology specimen fridge
2	Collect accessioned samples from the microbiology specimen fridge and enter the TB work room. Don one pair of gloves and turn on the blower to the BSC. Place the biohazard bag containing the sample in the BSC on the right hand side of the working area.
3	Ensure the daily maintenance for the GeneXpert has been completed and is documented on MIC81110-Maintenance Record-GeneXpert.

4	Set up the clean BSC with the following: • Absorbent pad on working surface • Sample rack • 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 • Clean cartridge tray • Xpert Xpress SARS-CoV-2/Flu/RSV cartridge • Transfer pipette provided in kit

Step	Action
Preparing the Cartridge	
1	Don an additional pair of gloves to ensure you are double gloved before working in the BSC.
2	Open biohazard bag and discard in the dry waste container. Wipe or spray each sample with Accel TB and place in the sample rack. Once dry, label the sample with the sample label. Leave the media barcode label on the right hand side of the working area.
3	Apply the media barcode label to the right hand side of the cartridge, near the base. **NOTE:** Do not cover the barcode label on the front of the cartridge
4	Thoroughly mix the sample by inverting rapidly 5 times.
5	Open the sample carefully to avoid touching droplets on the inner lid and place upright on the absorbent pad to avoid droplets falling on the work surface.
6	Pry open the cartridge lid and open wrapper of the transfer pipette.
7	Using the transfer pipette, load 300µL of the test sample into the cartridge: • Squeeze the upper bulb firmly to ensure the pipette aspirates the full volume • Completely submerge the pipette tip in the sample liquid • Release the bulb gradually to fully aspirate sample • Keep tip fully submerged until completely full to avoid air bubbles entering the tip • Ensure the pipette is full and sample is in the reservoir bulb **NOTE:** Do not use the pipette to mix the sample
8	Dispense the sample into the cartridge along the side of the loading chamber to avoid creating bubbles in the chamber. 

9	Rinse the pipette in the wet waste container with Accel TB and allow to soak.
10	Recap the patient sample tube and move to the back of the rack.
11	Firmly snap close the lid to seal the cartridge and place in the cartridge tray on the left hand side.
12	Spray outer gloves thoroughly with isopropyl alcohol, rub together and allow to air dry. **NOTE:** Always disinfect gloves between loading of each sample
13	Repeat cartridge loading procedure for up to 16 additional samples. **NOTE:** Loaded cartridges must be processed on the GeneXpert within 30 minutes

Step	Action
Creating a Test Run	
1	Once cartridge loading is complete, spray outer gloves with isopropyl alcohol and remove.
2	Transfer the loaded cartridges in the cartridge tray to the GeneXpert bench.
3	Log into the GeneXpert software using the username **admin1** and the password **covid19**.
4	Confirm that all modules are detected by the software and ready for testing.
5	On the GeneXpert software, click **Create Test** at the top left.
6	Using the scanner, scan the sample ID barcode and the cartridge barcode. Select **Start Test**.
7	Locate the module with the blinking green light, open the module door and load the cartridge.
8	Close the module door firmly, it will latch closed.

Step	Action
Cleaning the BSC	
1	Remove gloves and don a new pair.
2	In the BSC, spray samples with Accel TB and place the sample rack on the cart.
3	Wipe the cartridge tray and "clean" area of the BSC with an Accel TB wipe.
4	Remove gloves and don a new pair. Transfer samples to the fridge.

Step	Action
Generating a Test Report	
1	A report is generated automatically upon completion of a run.
2	To view runs or reprint: Select **View Results** on the menu bar. Click **Report** → Check **Patient ID** → Click **Preview PDF** → Click **Print**

INTERPRETATION OF RESULTS:

RESULT	INTERPRETATION
NEGATIVE	• The SARS-CoV-2 target RNA is not detected • SPC: PASS; SPC has a Ct within the valid range and endpoint above the minimum setting • Probe Check: PASS; all probe check results pass
POSITIVE	• The SARS-CoV-2 target RNA is detected • The SARS-CoV-2 signal has a Ct within the valid range and endpoint above the minimum setting • SPC: NA (not applicable); SPC is ignored because SARS-CoV-2 target amplification occurred • Probe Check: PASS; all probe check results pass
NO RESULT – REPEAT TEST	• If result is NO RESULT-REPEAT TEST, retest sample • If repeat test is NO RESULT-REPEAT TEST, obtain a new specimen for testing
INSTRUMENT ERROR	• If result is INSTRUMENT ERROR , touch CLEAR ERROR and follow the on-screen instructions • When the Home screen appears, repeat the test using a new cartridge • The result could be due to a system component failure

REPORTING INSTRUCTIONS:

GX Result: SARS-CoV-2 **NEGATIVE**	• Report: **NEGATIVE**

GX Result: SARS-CoV-2 **POSITIVE** **Ct ≤38.0**	**If SARS-CoV-2 Ct is ≤38.0:** • Report: **POSITIVE** • Phone to OCPHO (HPU1) at (867) 920 8646 • Phone result to ordering location **NOTE:** If ordering location is not available, OCPHO will follow up with the patient. Document attempt in the call log • Report will automatically print to OCPHO (HPU1) • Copy report to Stanton IPAC (SIPAC) if ER or inpatient

GX Result: SARS-CoV-2 **POSITIVE** **Ct is >38.0**	• Mix sample well and repeat testing on the GeneXpert ➢ Add comment in TCOMM that testing was repeated • <u>If repeat testing is negative</u>: ➢ Report: **INDETERMINANT** ➢ From the keypad add key R to add repeat sample collection comment ➢ Phone OCPHO (HPU1) at (867) 920 8646 ○ Inform OCPHO of Ct value and that repeat testing was negative. Ct is most likely >45 ➢ Phone result to ordering location ➢ Add a copy to OCPHO (HPU1) in Order Entry ➢ Copy report to Stanton IPAC (SIPAC) if ER or inpatient

GX Result: SARS-CoV-2 **POSITIVE Ct is >38.0 con't**	• <u>If repeat testing is the positive</u>: ➢ Report: **POSITIVE** ➢ Phone to OCPHO (HPU1) at (867) 920 8646 ○ Inform OCPHO of the Ct value ➢ Phone result to ordering location ➢ Report will automatically print to OCPHO (HPU1) ➢ Copy report to Stanton IPAC (SIPAC) if ER or inpatient **NOTE:** If ordering location is not available, OCPHO will follow up with the patient. Document attempt in the call log

GX Results: SARS-CoV-2 **NO RESULT-REPEAT TEST**	• Retest the sample with a new cartridge ➢ Add comment in TCOMM that testing was repeated • If repeat testing is the same: ➢ Phone the ordering location and request a new sample be collected • Report: **NO RESULT** ➢ From the keypad add key R to add repeat sample collection comment

GX Results: SARS-CoV-2 **ERROR**	• Follow the instructions on the print out using the instrument manual • Retest the sample with a new cartridge ➢ Add comment in TCOMM that testing was repeated

NOTE: All calls are to be documented in the Call Box in SoftMic

Step	Action
Completing the Run	
1	Check the Resulting Worklist-GeneXpert.
2	In the BSC, 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	Wipe the BSC with an Accel TB wipe. Turn off the blower and lower the sash. Remove gloves and don a fresh pair.
5	Ensure all used cartridges from the GeneXpert are discarded in the biohazard waste.
6	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.

LIMITATIONS:

1. Performance of the Xpert Xpress SARS-CoV-2/Flu/RSV assay has only been established in nasopharyngeal swab specimens. Specimen types other than nasopharyngeal swabs may give inaccurate results.
2. A clinical validation done by APL/AHS demonstrated that the sensitivity of throat swabs is comparable to NP swabs for the detection of COVID-19.
3. A clinical validation done by BCCDC found that SARS-CoV-2 can be reliably detected in saline gargle compared to UTM.
4. As with any molecular test, mutations within the target regions of the Xpert Xpress SARS-CoV-2/Flu/RSV could affect primer and/or probe binding resulting in failure to detect the presence of virus.
5. This test cannot rule out diseases caused by other bacterial or vial pathogens.
6. Erroneous test results might occur from improper specimen collection; failure to follow the recommended sample collection, handling, and storage procedures; technical error; or sample mix-up. Careful compliance with the instructions in this insert is necessary to avoid erroneous results.
7. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions.
8. As the Xpert Xpress SARS-CoV-2/Flu/RSV test does not differentiate between the N2 and E gene targets, the presence of other coronaviruses in the B lineage, *Betacoronavirus* genus, including SARS-CoV-1 may cause a false positive result. None of these other coronaviruses is known to currently circulate in the human population.
9. The performance of this device has not been assessed in a population vaccinated against COVID-19.

CROSS-REFERENCES:

- MIC81110-Maintenance Record-GeneXpert
- MIC81300-Xpert Xpress SARS-CoV-2 Quality Control
- MIC81310-Xpert Xpress SARS-CoV-2 QC Results Record

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. *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	20 May 20	Initial Release	L. Steven
2.0	06 Nov 20	Updated to reflect "presumptive" removed from reporting	L. Steven
3.0	22 Dec 20	Updated to reflect positive results report to OCPHO, inform OCPHO when Ct ≥38 and record repeat testing in TCOMM	L. Steven
4.0	28 Apr 21	Updated to reflect new Xpert Xpress SARS-CoV-2/Flu/RSV cartridge	L. Steven
5.0	09 Aug 21	Updated to reflect saline gargle samples	L. Steven