PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC72200 – Xpert Xpress CoV-2 plus	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:
The Xpert Xpress CoV-2 plus assay 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.

PURPOSE/RATIONALE:
This standard operating procedure describes the Xpert Xpress CoV-2 plus test using the GeneXpert System.

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

SAMPLE INFORMATION:

Type	• Swab • Saline gargle
Source	• Nasopharyngeal • Throat/oropharyngeal • Saline gargle rinse
Collection Container	• Viral transport media (VTM) • Universal transport media (UTM) • 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 CoV-2 plus cartridge

SUPPLIES:

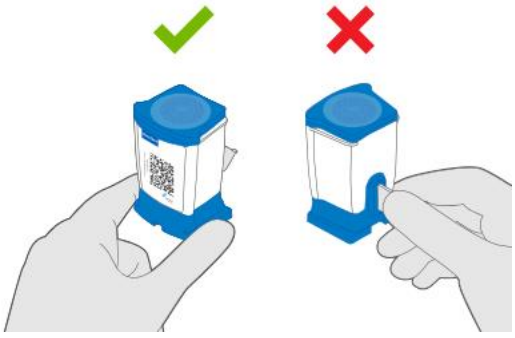
- Personal Protective Equipment
- Absorbent bench liner
- Sample rack
- Orange autoclave bag
- Spray bottles
- Wet waste container
- Dry waste container
- Accel TB 1L bottle
- Accel TB wipes
- 70% isopropyl alcohol
- Transfer pipettes provided in kit

EQUIPMENT:

- GeneXpert System
- Printer
- 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 System 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, nitrile gloves and 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
- Handle all samples and waste materials as if they were capable of transmitting infectious agents
- 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:

- Refer to MIC60090-Xpert Xpress CoV-2 plus Quality Control for quality control procedure
- Record all results on MIC60091-QC Results Record-Xpert Xpress CoV-2 plus

PROCEDURE INSTRUCTIONS:

Step	Action
Preparing the Run	
1	Order GeneXpert SARS-CoV-2 testing in the LIS: • In SoftMic, accession the order using the test code **PCCOV** • 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 • Place sample in the GeneXpert bin in the microbiology specimen fridge
2	Ensure the daily maintenance for the GeneXpert System has been completed and is documented on MIC72110-Maintenance Record-GeneXpert System.
3	Turn on the BSC and set up for SARS-CoV-2 testing with the following: • Absorbent pad on working surface • Sample rack • Wet waste container half full with Accel TB • Dry waste container containing an orange autoclave bag • Spray bottle with 70% isopropyl alcohol • Spray bottle with Accel TB • Accel TB wipes • Xpert Xpress CoV-2 plus cartridge • Transfer pipette provided in kit

Step	Action
Preparing the Cartridge	
1	In the BSC, 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.
2	Apply the COV19 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
3	Thoroughly mix the sample with the vortex mixer for 10 seconds.
4	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.
5	Pry open the cartridge lid and open wrapper of the transfer pipette.
6	Using the transfer pipette, load 300 µL 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
7	Dispense the sample into the cartridge along the side of the loading chamber to avoid creating bubbles in the chamber: 
8	Rinse the pipette in the wet waste container with Accel TB and allow to soak for at least 30 minutes.
9	Recap the patient sample tube and move to the back of the rack.
10	Firmly snap close the lid to seal the cartridge and place on the left-hand side of the BSC.
11	Spray gloves thoroughly with 70% isopropyl alcohol, rub together and allow to air dry. **NOTE:** Always disinfect gloves between the loading of each sample
12	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 gloves with 70% isopropyl alcohol and remove. Replace with new set of gloves.
2	Transfer the loaded cartridges 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 "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
NOT DETECTED	• The SARS-CoV-2 target RNA is not detected • SPC: PASS; SPC has a Ct within the valid range • Probe Check: PASS; all probe check results pass
DETECTED	• The SARS-CoV-2 target RNA is detected • The SARS-CoV-2 signal has a Ct within the valid range • SPC: NA; SPC is ignored because SARS-CoV-2 target amplification occurred • Probe Check: PASS; all probe check results pass

INVALID	• Presence or absence of SARS-CoV-2 cannot be determined. **Repeat the test** • SPC: FAIL; SPC and SARS-CoV-2 signals do not have a Ct within valid range and endpoint below minimum setting • Probe Check: PASS; all probe check results pass
ERROR	• Presence or absence of SARS-CoV-2 cannot be determined. **Repeat the test** • SARS-CoV-2: NO RESULT • SPC: NO RESULT • Probe Check: FAIL. All or one of the probe check results failed **NOTE:** If the probe check passed, the error is caused by the maximum pressure limit exceeding the acceptable range
NO RESULT	• Presence or absence of SARS-CoV-2 cannot be determined. **Repeat the test** • A NO RESULT indicates that insufficient data were collected. For example, the operator stopped a test that was in progress • SARS-CoV-2: NO RESULT • SPC: NO RESULT • Probe Check: NA

REPORTING INSTRUCTIONS:

GX Result: SARS-CoV-2 **NOT DETECTED**	• Report: **NEGATIVE**
GX Result: SARS-CoV-2 **DETECTED**	• Report: **POSITIVE** ➢ Report will automatically print to OCPHO (HPU1) ➢ Report will automatically print to Stanton IPAC (SIPAC) and Inuvik IPAC (IIPAC) if ER or inpatient ➢ Check patients home address. If from Nunavut: ○ Copy result to the applicable Nunavut CPHO • Freeze sample and log into the stored isolates log
GX Result: SARS-CoV-2 **INVALID or NO RESULT**	• Retest the sample with a new cartridge: ➢ Add comment in TCOMM that testing was repeated • If repeat testing is the same: ➢ Report: **NO RESULT** ➢ From the keypad add key R to add repeat sample collection comment
GX Result: SARS-CoV-2 **ERROR**	• Follow the instructions on the printout using the instrument manual • Retest the sample with a new cartridge ➢ Add comment in TCOMM that testing was repeated

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	Add the absorbent orange pad to the dry waste container.
4	Remove the autoclave bag from the dry waste container. Tie and wipe outside with an Accel TB wipe. Place in the biohazard waste.
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.

LIMITATIONS:

1. Performance of the Xpert Xpress CoV-2 plus Assay has only been established in nasopharyngeal (NP) 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 Xpert Xpress CoV-2 plus could affect primer and/or probe binding and result in failure to detect the presence of virus.
5. This test cannot rule out diseases caused by other bacterial or viral 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 procedure is necessary to avoid erroneous results.
7. Negative results do not preclude SARS-CoV-2 and should not be used as the sole basis for treatment or other patient management decisions.
8. The E gene targeted by the Xpert Xpress CoV-2 plus test can detect, in addition to SARS-CoV-2, other coronavirus species within the *Sarbecovirus* subgenus.
9. The performance of this device has not been assessed in a population vaccinated against COVID-19 or treated with COVID-19 therapies.

CROSS-REFERENCES:

- MIC60090-Xpert Xpress CoV-2 plus Quality Control
- MIC60091-QC Results Record-Xpert Xpress CoV-2 plus
- MIC72110-Maintenance Record-GeneXpert System

REFERENCES:

1. Cepheid GeneXpert. *Xpert Xpress CoV-2 plus* Instructions for Use (EUA). 302-7069, Rev. C, 2024-05
2. Cepheid GeneXpert. *GeneXpert 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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Director, Laboratory and Diagnostic Imaging Services

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	09 Aug 21	Updated to reflect saline gargle samples	L. Steven
4.0	17 Oct 22	Procedure reviewed and updated to reflect notification of Nunavut patients to Nunavut CPHO	L. Steven
5.0	19 Apr 23	Procedure reviewed and updated to reflect no longer calling positive results to OCPHO or ordering location	L. Steven
6.0	01 Oct 24	Procedure updated to reflect no longer sending positive samples for variant screening	L. Steven