PROGRAM Standard Operating Procedure – Laboratory Services	
Title: **MIC70800 – Xpert® Xpress SARS-CoV-2 Assay**	Policy Number: **DRAFT**
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:

The Xpert Xpress SARS-CoV-2 test is a rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal or throat/oropharyngeal swabs collected from individuals suspected of COVID-19 by their healthcare provider. The Xpert Xpress SARS-CoV-2 test is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis of SARS-CoV-2 and is based on widely used nucleic acid amplification technology. The Xpert Xpress SARS-CoV-2 test contains primers, probes and internal controls used in RT-PCR for the *in vitro* qualitative detection of SARS-CoV-2 RNA in swab specimens.

PURPOSE/RATIONALE:

This standard operating procedure describes the method for performing SARS-CoV-2 testing using the GeneXpert Dx Instrument System.

SCOPE/APPLICABILITY:

This procedure applies to Medical Laboratory Technologists processing specimens using the GeneXpert Dx System.

SAMPLE INFORMATION:

Type	Swab
Source	Nasopharyngeal or throat/oropharyngeal
Collection Container	• UTM (Universal Transport Media) • ESwab (Elution Swab)
Volume	UTM = 3 mL, ESwab = 1 mL
Stability	UTM: • Room temperature for up to 8 hours • Refrigerated up to 7 days ESwab: • Room temperature for up to 48 hours • Refrigerated up to 7 days
Storage Requirements	Room temperature or refrigerated
Criteria for rejection and follow up action	1. Unlabeled/mislabeled swabs 2. Specimen container label does not match patient identification on requisition 3. Specimen not in UTM or ESwab 4. Specimen not stored correctly

REAGENTS and/or MEDIA:

- Xpert Xpress SARS-CoV-2 cartridge
- SerraCare AccuPlex™ Reference Material Kit
- Accel TB wipes
- 70% isopropyl alcohol

SUPPLIES:

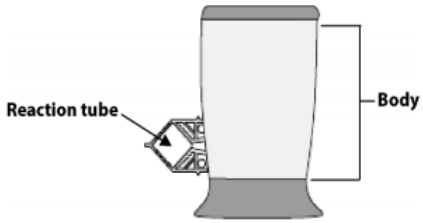
- Personal Protective Equipment
- Absorbent bench liner
- Wet waste container
- Dry waste container
- Orange autoclave bags
- Spray bottle
- Transfer pipettes provided in kit
- Specimen racks

EQUIPMENT

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

ENVIRONMENTAL CONTROLS:

- Store Xpert Xpress SARS-CoV-2 cartridges upright between 2°C -28°C
- Do not use a cartridge that has been damaged or leaked, dropped or shaken
- Open a cartridge only when ready to add specimen. 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 specimens 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:

- Handle patient specimens in a class II biosafety cabinet (BSC)
- Personal Protective Equipment (PPE) required when working with suspect SARS-CoV-2 specimens includes:
  - Lab gown, double layer nitrile gloves, eye protection and N95 mask
- Full PPE is recommended for all personnel in the lab during the test procedure, in the event of a spill outside of the BSC
- Used cartridges should not be opened
- All items in the BSC must be sprayed with isopropyl alcohol or wiped with Accel TB and allowed to disinfect for 5 minutes prior to removal
- All personnel handling potential SARS-CoV-2 specimens 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.

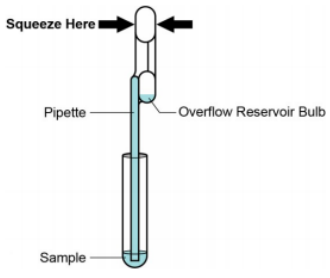
QUALITY CONTROL:

- SerraCare AccuPlex Reference Material Kit positive and negative controls need to be run on every new lot number and/or shipment of cartridges

PROCEDURE INSTRUCTIONS:

Step	Action
Preparing the BSC	
1	Perform daily maintenance for the GeneXpert instrument. Document on MIC70711, MIC70712, MIC70713 and MIC70714 – Maintenance Record – GeneXpert.
2	At the TB bench, working with gloved hands and the specimens still in the biohazard bag, remove the requisition from the outer pouch. Read the requisition, checking for patient information and clinical history.
3	Refer to MIC70810-LIS Ordering of Respiratory Viral Samples to determine if testing is to be performed at Stanton using the GeneXpert.
4	If GeneXpert testing is required: • Use the test code **PCCOV** for GeneXpert testing performed at Stanton • A copy to HPU1 is automatically added to test • Add next order to add confirmation test code **NP19** and **VIRC** if indicated on requisition Label the requisition and place the specimen and media barcode labels in the pouch of the biohazard bag. Place bags in the BSC, up to 4 at one time.
5	Set up the clean BSC with the following: • Absorbent pad on working surface • Wet waste container containing Accel TB • Dry waste container containing orange autoclave bag • Spray bottle with Accel TB • Accel TB wipes container opened • 4 Xpert Xpress SARS-CoV-2 cartridges and 4 pipettes provided in kit • Empty specimen rack

Step	Action
Prepare the GeneXpert	
1	Turn ON the power to the GeneXpert.
2	Power up the laptop. The password on the computer is **covid19**.
3	The software for the GeneXpert Dx System automatically opens. Enter the username **admin1** and the password **covid19**.
4	The message "Do you want to perform Database Management tasks?" appears. Select **No** and then click **OK** to log on.

Step	Action
Preparing the cartridge	
1	In the BSC, open biohazard bags and label specimens. Place into the specimen rack when complete. Allow specimens to come to room temperature prior to testing.
2	Separate the media barcode labels and place on the left hand side of the working area.
3	Thoroughly mix the specimen by inverting rapidly 5 times.
4	Label a cartridge with the media barcode label on the right hand side of the cartridge, near the base. Do not place the label on the lid or obscure the digital matrix code on the front of the cartridge.
5	Remove the transfer pipette from the wrapper and open the cartridge lid.
6	Open the specimen and hold in your left hand. Squeeze the top bulb of the transfer pipette completely and then place the pipette tip into the specimen transport tube to fill the entire pipette:  **NOTE:** Do not use the pipette to mix the specimen.

7	Release the top bulb of the pipette to fill before removing from the tube. After filling, excess sample will be seen in the overflow reservoir bulb. Check that the pipette does not contain bubbles.
8	Dispense the sample along the side of the loading chamber of the cartridge to avoid creating bubbles:  **NOTE:** Do not mix the sample in the loading chamber.
9	Rinse the pipette in the wet waste container with Accel TB and then discard in the dry waste.
10	Recap the patient sample tube and move to the back of the sample rack.
11	Firmly snap close the lid to seal the cartridge and move to the right hand side of the BSC.
12	Spray outer gloves thoroughly with isopropyl alcohol, rub together and allow to air dry.
13	Repeat cartridge loading procedure for up to 3 additional specimens. **NOTE:** No more than 4 cartridges should be prepped at one time. **NOTE:** Loaded cartridges must be processed on the GeneXpert within 30 minutes.
14	Once all cartridge loading is complete, spray outer gloves with isopropyl alcohol and remove. Discard in the dry waste bin.
15	Use an Accel TB wipe to carefully wipe down the outer surface of each cartridge. **NOTE:** Take caution to avoid touching the reaction tube.
16	Place the cartridge on a silver tray to be transferred to instrument.
17	Discard the orange bench liner and wipe the work area with an Accel TB wipe.
18	Place specimen rack in the fridge while testing is completed.
19	Transfer the tray of loaded cartridges to the GeneXpert bench. Remain in PPE until the cartridges are securely transferred and loaded on to the GeneXpert.

Step	Action
Create a test run	
1	While still wearing gloves, open all module doors on the GeneXpert.
2	Remove and discard gloves. Don a fresh clean pair of gloves.
3	In the GeneXpert System window, click **Create Test** at the top left of the screen. Pick up the first cartridge to be loaded onto the instrument.
4	The Scan Cartridge barcode dialogue box opens. Scan the barcode on the Xpert Xpress SARS-CoV-2 cartridge to populate the Select Assay field. Using the barcode information, the software automatically fills in the boxes for the following fields: Reagent Lot ID, Cartridge SN, Expiration Date and Selected Assay.
5	In the Sample ID field, scan the media label barcode.
6	Click **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. The test starts and the green light stops blinking.
9	Remove and discard gloves. Don a fresh clean pair of gloves.
10	Another test run can be created immediately after the cartridge is loaded. Each test takes approximately 50 minutes to complete. Ensure gloves are changed during the loading of each cartridge.
11	When complete, the module door automatically unlatches and the green light turns off.

Step	Action
View Results	
1	In the GeneXpert Dx System window, click **View Results** on the menu bar. The View Results window appears.
2	To select a test, click **View Test**. The Select Tests To Be Viewed dialog box appears.
3	The selected test result will be displayed on the **Test Result** tab.

INTERPRETATION OF RESULTS:

Result	Interpretation
SARS-CoV-2 POSITIVE	The SARS-CoV-2 target nucleic acids are detected. • The SARS-CoV-2 signal for the N2 nucleic acid target or signals for both nucleic acid targets (N2 and E) have a Ct within the valid range and endpoint above the minimum setting • SPC:NA; SPC is ignored because coronavirus target amplification occurred • Probe Check: PASS; all probe check results pass
SARS-CoV-2 PRESUMPTIVE POSITIVE	The SARS-CoV-2 nucleic acids may be present. Sample should be retested. Additional confirmatory testing should be done. • The SARS-CoV-2 signal for only the E nucleic acid target has a Ct within the valid range and endpoint above the minimum setting • SPC: NA; SPC is ignored because a target amplification has occurred • Probe Check: PASS; all probe check results pass
SARS-CoV-2 NEGATIVE	The SARS-CoV-2 target nucleic acids are not detected. • The SARS-CoV-2 signals for two nucleic acid targets (N2 and E) do not have a Ct within the valid range and endpoint above the minimum setting • SPC: PASS; SPC has a Ct within the valid range and endpoint above the minimum setting • Probe Check: PASS; all probe check results pass
INVALID	SPC does not meet acceptance criteria. Presence or absence of the SARS-CoV-2 nucleic acids cannot be determined. Repeat test as per the repeat procedure in the troubleshooting section. • 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
NO RESULT	Presence or absence of the SARS-CoV-2 nucleic acids cannot be determined. Repeat test as per the repeat procedure in the troubleshooting section. 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 (not applicable)

REPORTING INSTRUCTIONS:

IF	THEN
SARS-CoV-2 NEGATIVE	• Report: **SARS-CoV-2 NEGATIVE** • A test comment is automatically added to state: **"This rRT-PCR testing was performed on the GeneXpert Dx System"** • A test comment is automatically added to state: **"Sent to Alberta Precision Laboratories for confirmation"**
SARS-CoV-2 POSITIVE	• Report: **SARS-CoV-2 POSITIVE** ➢ Phone results to OCPHO (HPU1) at (867) 920 8646 • A test comment is automatically added to state: "**This rRT-PCR testing was performed on the GeneXpert Dx System"** • A test comment is automatically added to state: **"Sent to Alberta Precision Laboratories for confirmation"**
SARS-CoV-2 INVALID	• Report: **SARS-CoV-2 INVALID** • A test comment is automatically added to state: **"This rRT-PCR testing was performed on the GeneXpert Dx System"** • A test comment is automatically added to state: **"Sent to Alberta Precision Laboratories for confirmation"**

NOTE: All samples need to be sent to Alberta Precision Laboratories for confirmation. On the Alberta requisition, ensure the Healthcare Provider ID is present. Also, add a copy to Submitter ID 11122.

NOTE: If rapid respiratory panel is ordered, same sample and requisition can be sent to Alberta for RPP testing as well as COVID19 confirmation. Ensure a copy to Submitter ID 11122 is added.

NOTE: After GeneXpert testing is complete, place sample with corresponding requisition into a biohazard bag and deliver to the core lab specimen processing area to be packaged and sent to Alberta Precision Laboratories for testing.

TROUBLESHOOTING:

If any of the test results mentioned below occur, repeat the test once:

- A **PRESUMPTIVE POSITIVE** indicates the SARS-CoV-2 nucleic acids may be present.
- An **INVALID** result indicates that the control SPC failed. The sample was not properly processed, PCR is inhibited or the sample was not properly collected.
- An **ERROR** result could be due to, but not limited to, Probe Check Control failure, system component failure, or the maximum pressure limits were exceeded.
- A **NO RESULT** indicates that insufficient data were collected. For example, cartridge failed integrity test, the operator stopped a test that was in progress or a power failure occurred.

INTERFERENCES AND SOURCES OF VARIATION:

- Performance of the Xpert Xpress SARS-CoV-2 has only been established in nasopharyngeal swab specimens. Specimen types other than nasopharyngeal swabs may give inaccurate results.
- 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
- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may occur if inadequate numbers of organisms are present in the specimen.
- As with any molecular test, mutations within the target regions of the Xpert Xpress SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- This test cannot rule out diseases caused by other bacterial or vial pathogens.

REFERENCES:

- Cepheid GeneXpert. *Xpert Xpress SARS-CoV-2* package insert. 302-3562, Rev A, May 2020
- 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:

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Date

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REVISION HISTORY:

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