PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC72500 – Xpert Xpress Strep A	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	

Uncontrolled When Printed

GUIDING PRINCIPLE:
The Xpert Xpress Strep A assay is a rapid, qualitative in vitro diagnostic test for the detection of *Streptococcus pyogenes* (Group A β-hemolytic Streptococcus, Strep A) in throat swab specimens from patients with signs and symptoms of pharyngitis.

PURPOSE/RATIONALE:
This standard operating procedure describes the Xpert Xpress Strep A test using the GeneXpert System.

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

SAMPLE INFORMATION:

Type	Swab • Amie's with or without charcoal
Source	• Throat
Stability	• Room temperature up to 48 hours • Refrigerated up to 6 days
Storage Requirements	Room temperature
Criteria for rejection	1. Unlabeled/mislabeled swab 2. Specimen container label does not match patient identification on requisition 3. Duplicate specimens obtained with same collection method within 24 hours

REAGENTS and/or MEDIA:

- Xpert Xpress Strep A cartridge

SUPPLIES:

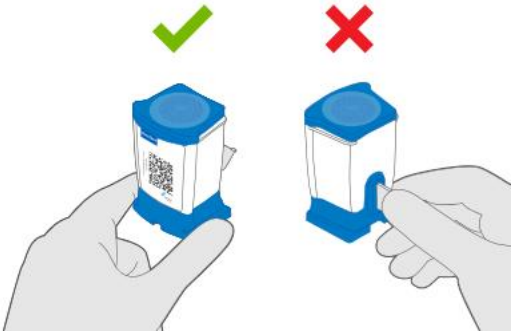
- Personal protective equipment
- Absorbent bench liner
- Orange autoclave bag
- Wet waste container
- Dry waste container
- Accel TB 1L bottle
- Accel TB wipes
- 0.45% Saline
- Plastic VITEK tubes
- Test tube rack
- Transfer pipettes provided in kit

EQUIPMENT:

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

ENVIRONMENTAL CONTROLS:

- Store Xpert Xpress Strep A 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:

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potentially infectious materials or cultures:

- Ensure that appropriate hand hygiene practices be used
- Lab gown must be worn when performing activities with potential pathogens
- Gloves must be worn when direct skin contact with infected materials is unavoidable
- Eye protection must be used when there is a known or potential risk of exposure of splashes
- All procedures that may produce aerosols, or involve high concentrations or large volumes should be conducted in a biological safety cabinet (BSC)
- The use of needles, syringes and other sharp objects should be strictly limited

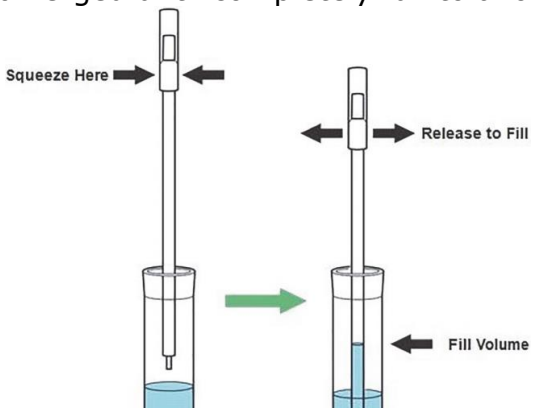
All patient specimens are assumed to be potentially infectious. Routine Practices must be followed. Since viable micro-organisms are used, all cultures must be handled with appropriate precautions. All equipment in contact with cultures should be decontaminated by appropriate methods.

QUALITY CONTROL:

- Refer to MIC60120-Xpert Xpress Strep A Quality Control for quality control procedure
- Record all results on MIC60121-QC Results Record-Xpert Xpress Strep A

PROCEDURE INSTRUCTIONS:

Step	Action
Preparing the Run	
1	Order GeneXpert Strep A testing in the LIS: • In SoftMic, accession the order using the test code **PCGAS** • Collect, receive and plate the order • If the requisition includes clinical history that indicates history of penicillin allergy/β lactam allergy, recurrent pharyngitis/tonsillitis, failure of therapy, current therapy with erythromycin or clindamycin or susceptibility testing is requested by physician: ➢ Select "Media/Due D&T" ➢ In the Media Screen dialogue box, select "Add Media" ➢ Add the media BA-2 and select "OK" • Place the sample barcode label and media barcode labels in the pouch of the biohazard bag • Place samples in the GeneXpert bin in the microbiology specimen fridge
2	Ensure the daily maintenance for the GeneXpert has been completed and is documented on MIC72110-Maintenance Record-GeneXpert.
	Turn on the BSC and set up for Strep A testing with the following: • Absorbent pad on working surface • Wet waste container half full with Accel TB • Dry waste container containing an orange autoclave bag • Accel TB wipes • Xpert Xpress Strep A cartridge • Transfer pipettes provided in kit
3	On the TB Workroom bench, place the number of plastic tubes needed for the run in the test tube rack. Using the GAS dispensette, add 1 mL of sterile saline to each tube. Place the rack in the BSC once the saline is added.
4	If susceptibility testing is indicated on the requisition, the swab will need to be plated to BA before the PCR testing is performed. Use the BA-2 label that was added in order entry and place the labelled agar plate in the BSC. **NOTE:** Plating of the sample to BA must be completed before PCR testing is performed as once processed for PCR, microorganisms in the sample will be rendered non-viable

Step	Action
Preparing the Cartridge	
1	In the BSC, open the biohazard bag and discard in the dry waste container. Label the sample with the sample label. Leave the media barcode labels on the right-hand side of the working area.
2	Label the saline tube with the GASST media barcode label.
3	If the sample needs to be plated to the BA-2 media: • Inoculate BA with the swab • Ensure all surfaces of the swab make contact with the agar • Streak for isolated growth using a disposable inoculation needle
4	After sample is plated to BA, if required, scrape off any excess gel from the swab into the C&S tube. Place the swab into the saline tube and elute it in the saline by vigorously rubbing on the tube walls and bottom for 15 seconds. Allow the swab to soak in the saline for 1 minute. **NOTE:** Excess gel should be removed from the swab before placed into the saline tube
5	While removing the swab, gently squeeze its sides against the test tube to extract as much liquid as possible. Then, place the swab back into the C&S tube and close.
6	Apply the GAS 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
7	Pry open the cartridge lid and open wrapper of the transfer pipette provided in the kit.
8	Using the transfer pipette, load 300 µL of the test sample into the cartridge: • Squeeze the bulb of the transfer pipette firmly to ensure the pipette aspirates the full volume • Completely submerge the pipette tip into the saline tube • Release the bulb gradually to fully aspirate the sample • Keep tip fully submerged until completely full to avoid air bubbles:  **NOTE:** The bulb of the pipette needs to be fully squeezed before placing the tip of the pipette into the saline tube as there is no fill line on the pipette

9	Dispense the sample into the cartridge along the side of the loading chamber to avoid creating bubbles in the chamber: 
10	Rinse the pipette in the wet waste container with Accel TB and allow to soak for at least 30 minutes.
11	Firmly snap close the lid to seal the cartridge and place on the left hand side of the BSC.
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	Transfer the loaded cartridges to the GeneXpert bench.
2	Log into the GeneXpert software using the username **admin1** and the password **covid19**.
3	Confirm that all modules are detected by the software and ready for testing.
4	On the GeneXpert software, click **Create Test** at the top left.
5	Using the scanner, scan the sample ID barcode and the cartridge barcode. Select **Start Test**.
6	Locate the module with the blinking green light, open the module door and load the cartridge.
7	Close the module door firmly, it will latch closed.

Step	Action
Cleaning the BSC	
1	Remove gloves and don a new pair.
2	Wipe the "clean" area of the BSC with an Accel TB wipe.
3	Remove gloves and don a new pair. Transfer saline tubes to the fridge and discard the C&S swabs.

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	• Strep A target DNA is not detected • SPC: PASS; SPC has a Ct within the valid range and endpoint above the threshold setting • PCC: PASS; all probe check results pass
DETECTED	• Strep A target DNA is detected • Strep A: Ct is within the valid range • SPC: NA; SPC signal is not part of the result interpretation algorithm if Strep A is detected since SPC signal may be suppressed due to competition with Strep A • PCC: PASS; all probe check results pass
INVALID	• Presence or absence of Strep A cannot be determined. **Repeat the test** • Strep A: INVALID • SPC: does not meet acceptance criteria • PCC: PASS; all probe check results pass
ERROR	• Presence or absence of Strep A cannot be determined. **Repeat the test** • Strep A: 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 Strep A cannot be determined. **Repeat the test** • NO RESULT indicates that insufficient data were collected. For example, cartridge integrity test failed, the operator stopped a test that was in progress or a power failure occurred • Strep A: NO RESULT • SPC: NO RESULT • PCC: NA

REPORTING INSTRUCTIONS:

GX Result: Strep A **NOT DETECTED**	• Report: **NEGATIVE** • If BA-2 agar was inoculated, discard the plate

GX Result: Strep A **DETECTED** Susceptibility Not Required	• Report: **POSITIVE**

GX Result: Strep A **DETECTED** Susceptibility Required	• Report: **POSITIVE** • Do NOT Prelim or Final the report • Place the inoculated BA in the CO_2 incubator in throat rack to be set up in anaerobic jar by evening technologist • Refer to MIC31300-Throat Culture for processing BA plate

GX Result: Strep A **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: Strep A **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	Remove the autoclave bag from the dry waste container. Tie and wipe outside with an Accel TB wipe. Place in the biohazard waste.
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 saline tubes from the refrigerator and discard in the sharps container.

LIMITATIONS:

1. Additional follow-up testing by culture is required if the Xpert Xpress Strep A test result is negative and clinical symptoms persist, or there is an outbreak of acute rheumatic fever (ARF).
2. Because the detection of *Streptococcus pyogenes* is dependent on the organism's DNA present in the sample, reliable results are dependent on proper sample collection, handling, and storage.

3. The Xpert Xpress Strep A test provides qualitative results and does not provide the quantitative value of the organism detected in the specimen.
4. The Xpert Xpress Strep A test has been validated only with Copan Liquid Amies Elution Swab (ESwab) Collection Kit.
5. A clinical validation done by BCCDC found that Strep A can be reliably detected in Amies C&S swabs compared to Amies Elution Swab (ESwab).
6. Mutations or nucleotide polymorphisms in primer or probe binding regions may affect detection of new or unknown *Streptococcus pyogenes* strains resulting in a false negative result.
7. A negative test result does not exclude the possibility of infection because the test result may be affected by improper specimen collection, technical error, sample mix-up, or because the number of organisms in the sample is below the limit of detection of the test.
8. The Xpert Xpress Strep A test does not differentiate asymptomatic carriers of Group A Streptococci from those exhibiting streptococcal infection. The results from the Xpert Xpress Strep A test should be interpreted in conjunction with other laboratory and clinical data available to the clinician.
9. This test has not been evaluated for patients without signs and symptoms of pharyngitis.
10. This test cannot rule out pharyngitis caused by other bacterial or viral pathogens besides Group A Streptococci.

CROSS-REFERENCES:

- MIC60120-Xpert Xpress Strep A Quality Control
- MIC60121-QC Results Record-Xpert Xpress Strep A
- MIC72110-Maintenance Record-GeneXpert

REFERENCES:

1. Cepheid GeneXpert. Xpert Xpress Strep A Instructions for Use. 302-2294, Rev. B February 2022
2. Cepheid GeneXpert. *Dx System User Manual*. 303-1548 Rev. A, July 2023

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	02 Jan 25	Initial Release	L. Steven