PROGRAM Standard Operating Procedure – Laboratory Services			
Title: MIC10300 – Xpert <i>C.difficile</i>	Policy Number: 15-148-V1		
Program Name: Laboratory Services			
Applicable Domain: Lab, DI and Pharmacy Services			
Additional Domain(s): NA			
Effective Date: 18/03/2024 Next Review Date: 18/03/202			
Issuing Authority: Director, Laboratory and Diagnostic Imaging Services	Date Approved: 18/03/2024		
Accreditation Canada Applicable Standard: NA			

### Uncontrolled When Printed

### **GUIDING PRINCIPLE:**

The Xpert *C.difficile* assay is a qualitative *in vitro* diagnostic test for rapid detection of toxin B gene sequences from unformed (liquid or soft) stool specimens collected from patients suspected of having *Clostridium difficile* infection (CDI). The test utilizes automated real time polymerase chain reaction (PCR) to detect toxin gene sequences associated with toxin producing *C.difficile*.

### **PURPOSE/RATIONALE:**

This standard operating procedure describes the Xpert *C.difficile* test using the GeneXpert Dx System.

### **SCOPE/APPLICABILITY:**

This standard operating procedure applies to Medical Laboratory Technologists (MLTs) processing specimens for *C.difficile* using the GeneXpert Dx System.

Туре	Stool (Unformed)	
Collection Container	Orange top, sterile container	
Stability	<ul><li>Room temperature up to 24 hours</li><li>Refrigerated up to 5 days</li></ul>	
Storage Requirements	Room temperature or refrigerated	
	1. Unlabeled/mislabeled samples	
Criteria for	2. Sample container label does not match patient	
rejection	identification on requisition	
	3. Sample not in sterile container	

### SAMPLE INFORMATION:

4.	Sample not stored correctly
5.	Repeat testing on positive samples will not be performed
	within 7 days (Cancellation code:  XCDP)
6.	Repeat testing on negative samples will not be
	performed within 7 days (Cancellation code: IXCDN)
7.	Testing will not be performed on patients <12months old
	(Cancellation code:  XCD1)
8.	Testing for <i>C. difficile</i> Toxin is not performed on formed
	stools (Cancellation code: IXCDT)

#### **REAGENTS and/or MEDIA:**

- Xpert *C.difficile* cartridge
- Sample reagent

#### SUPPLIES:

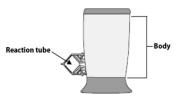
- Personal protective equipment
- Dry waste container
- Sterile, dry swabs
- Disposable transfer pipettes

#### **EQUIPMENT:**

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

### **ENVIRONMENTAL CONTROLS:**

- Store Xpert *C.difficile* 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 MIC60080-Xpert *C.difficile* Quality Control for quality control procedure
- Record all results on MIC60081-QC Results Record-Xpert C.difficile

### **PROCEDURE INSTRUCTIONS:**

(	ring the Run Order GeneXpert <i>C.difficile</i> testing in the LIS: • Medipatient the order if required	
•		
1	<ul> <li>In SoftMic, accession the order using the test code PCCDI</li> <li>Add any "copies to" if required</li> <li>Collect, receive and plate the order</li> <li>Label the requisition with the requisition label and scan into SoftMedia</li> <li>Place the sample barcode label on the sample and the barcode label in the pouch of the biohazard bag for when the sample is being processed</li> </ul>	
	Ensure the daily maintenance for the GeneXpert has been completed and is documented on MIC72110-Maintenance Record-GeneXpert.	

Step	Action	
Preparing the Cartridge		
1	Remove the cartridge and reagent from the package. Acquire a swab and a pipette for each sample being tested.	
2	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	

3	The test must be started within 30 minutes of adding reagents to the cartridge.		
4	Vortex the sample for 10 seconds to ensure it is evenly mixed.		
5	Briefly place a swab in the unformed stool sample. The swab does not need to be completely saturated: Too little sample Correct amount of sample Too much sample		
6	Insert the swab into the vial containing the Sample Reagent.		
7	Hold the swab by the stem near the rim of the vial and push the stem against the edge of the vial to break it. NOTE: Make sure the swab is short enough to allow the cap to close		
8	Close the lid and vortex at high speed for 10 seconds.		
9	Pry open the cartridge lid and open wrapper of the transfer pipette.		
10	Transfer the entire contents of the Sample Reagent to the Sample Chamber of the cartridge:		
11	Firmly snap close the lid to seal the cartridge and place in the cartridge tray.		

Step	Action		
Creat	Creating a Test Run		
1	Transfer the loaded cartridges in the cartridge tray to the GeneXpert bench.		
2	Log into the GeneXpert software using the username <b>admin1</b> and the password <b>covid19</b> .		
3	Confirm that all modules are detected by the software and ready for testing.		
4	On the GeneXpert software, click <b>Create Test</b> at the top left.		
5	Using the scanner, scan the sample ID barcode and the cartridge barcode. Select <b>Start Test</b> .		
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		
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 $\rightarrow$ Check Patient ID $\rightarrow$ Click Preview PDF $\rightarrow$ Click Print		

#### **INTERPRETATION OF RESULTS:**

RESULT	INTERPRETATION
<ul> <li>• C.difficile target DNA sequences are not detected</li> <li>• Toxins producing C.difficile targets not detected</li> </ul>	
POSITIVE	<ul> <li><i>C.difficile</i> target DNA sequences are detected</li> <li>The toxin producing <i>C.difficile</i> target(s) have Cts within the valid range</li> </ul>
NO RESULT	Presence or absence of <i>C.difficile</i> target DNA cannot be determined
ERROR/ INVALID	<ul> <li>Presence or absence of <i>C.difficile</i> cannot be determined</li> <li>Toxin producing <i>C.difficile</i> targets-NO RESULT</li> <li>Probe Check: FAIL; one or more probe checks have failed</li> </ul>

#### **REPORTING INSTRUCTIONS:**

Toxigenic <i>C.difficile</i> <b>NEGATIVE</b>	• Report: <b>NEGATIVE</b>
Toxigenic <i>C.difficile</i> <b>POSITIVE</b>	<ul> <li>Report: <b>POSITIVE</b></li> <li>Phone results to patient location</li> <li>Document call in the Call Box in SoftMic</li> <li>Report will automatically print to OCPHO (HPU1)</li> <li>Report will automatically print to Stanton IPAC (SIPAC) and Inuvik IPAC (IIPAC) if ER or inpatient</li> </ul>
Toxigenic <i>C.difficile</i> <b>NO RESULT</b>	<ul> <li>Retest the sample with a new cartridge         <ul> <li>Add comment in TCOMM that testing was repeated</li> </ul> </li> <li>If repeat testing is the same:         <ul> <li>Phone the ordering location and request a new sample be collected</li> <li>Report: NO RESULT - Presence of C.diff toxin cannot be determined</li> <li>From the keypad add key R to add repeat sample collection comment</li> </ul> </li> </ul>

# LIMITATIONS:

- 1. This test detects but does not differentiate the NAP1 (Ribotype 027) strain from other toxigenic strains of *C.difficile*.
- 2. This test targets the *tcdB* gene for Toxin B production. This test will not detect strains of *C.difficile* that do not contain the *tcdB* gene.
- 3. Positive results observed with immunocompromised pediatric patients may reflect asymptomatic carriage of *C.difficile*.
- 4. Results from the Xpert *C.difficile* Assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician.
- 5. Erroneous test results might occur from improper specimen collection, failure to follow the recommended sample collection, handling and storage procedures, technical error, sample mix-up, or because the number of organisms in the specimen is too low to be detected by the test.
- 6. Inhibition of the Xpert *C.difficile* Assay has been observed in the presence of the following substances: Zinc oxide paste and Vagisil cream.
- 7. False negative results may occur when the infecting organism has genomic mutations, insertions, deletions or rearrangements or when performed early in the course of illness.

# **CROSS-REFERENCES:**

- MIC60080-Xpert C. difficile Quality Control
- MIC60081-QC Results Record-Xpert C. difficile QC
- MIC72110-Maintenance Record-GeneXpert

# **REFERENCES:**

- 1. Cepheid GeneXpert. Xpert *C. difficile* Assay Instructions for Use. 300-9680 Rev. F, March 2016
- 2. Cepheid GeneXpert. *Dx System User Manual*. 301-0045, Rev.C, June 2012

# **APPROVAL:**

March 18, 2024

Date

Director, Laboratory and Diagnostic Imaging Services

### **REVISION HISTORY:**

REVISION	DATE	Description of Change	REQUESTED BY
1.0	30 Jan 22	Initial Release	L. Steven
2.0	14 Feb 24	Procedure reviewed	L. Steven

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