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Introduction

The Cepheid Xpert *C. difficile* Assay, performed on the Cepheid GeneXpert® Dx System, 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 *Clostridioides difficile* infection (CDI). The test utilizes automated real-time polymerase chain reaction (PCR) to detect toxin gene sequences associated with toxin producing *C. difficile*. The Xpert *C. difficile* Assay is intended as an aid in the diagnosis of CDI. Concomitant culture is necessary only if further typing or organism recovery is required.
Cepheid Xpert *C. difficile* Assay is not used for routine testing in this lab. It is used to identify NAP1 strains of *C. difficile* when requested by Infection Control.

Specimen Collection, Transport & Storage

Collect unformed stool specimen in a clean Starplex container, and send to the Virology laboratory as soon as possible. Stool collected in Enteric Transport Medium, or in SAF is not suitable for this assay. The specimen is stable for up to 5 days when stored at 2–8°C. Alternatively, specimens can be kept at room temperature (20 – 30 °C) for up to 24 hours. Eswab rectal samples may be used for testing for Infection Control purposes upon request by Infection Control Practioners.

Materials & Equipment

- GeneXpert Dx System
- Vortex mixer
- Dry swab for transfer of the specimen, such as the swab found in the Cepheid Sample Collection Device 900-0370 (Copan Venturi Transystem® Culture) or the Copan Dual Swab and Transport System.
- Disposable transfer pipettes.
- Xpert *C. difficile* kit – each kit contains 10 or 120 Xpert *C. difficile* cartridges and buffer

Each Xpert *C. difficile* Assay Cartridge with integrated reaction tubes contain:

Bead 1 (freeze-dried)

- Polymerase
- dNTPs
- BSA (bovine serum albumin)
- Probe

Bead 2 (freeze-dried)

- Primers
- Probes
- BSA

Bead 3 (freeze-dried)

- Sample Processing Control (SPC) non-infectious sample preparation control spores

Reagent 1 (Sodium Hydroxide)

Reagent 2 (Tris Buffer, EDTA, surfactants)

Xpert *C. difficile* reagent pouch

- Sample Reagent (Guanidinium thiocyanate, surfactants)

Procedure

GeneXpert Cartridge Preparation

1. The disposable single-use GeneXpert DX cartridge holds the samples and reagents that you want to process in the GeneXpert DX System. Do not reuse spent cartridges.

2. Store new GeneXpert DX cartridge at 2 – 28 °C. The cartridge and reagents are stable for up to 7 days after the package has been opened.

3. The test must be started within 30 minutes of adding reagents to the cartridge.

4. Use one cartridge and one sample reagent vial for each stool sample that needs to be tested. Label the cartridge with the corresponding sample ID barcode. Do not hold the cartridge from the reaction tube.

5. Place a dry swab which came with the Cepheid Sample Collection Device into the unformed stool sample. The swab does not need to be completely saturated.

6. Insert the swab into the elution vial containing the Sample Reagent.
   Note: Use sterile gauze to minimize the risk of contamination.
7. Hold the swab by the stem near the rim of the vial, lift the swab a few millimeters from the bottom of the tube and push the stem against the edge of the vial to break it. Make sure the swab is short enough to allow the cap to close tightly.
8. Close the lid and vortex at high speed for 10 seconds.
9. Open the cartridge lid. Using a clean transfer pipette, transfer the entire contents of the Sample Reagent into the "S" chamber of the Xpert *C. difficile* Assay cartridge.
10. Close the cartridge lid.

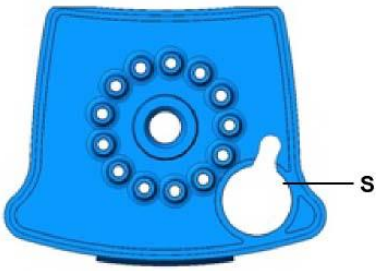

Figure 1. Xpert *C. difficile* cartridge (top view)

Assay Method:

1. Turn on the computer, and then turn on the GeneXpert Dx instrument. Log into windows using the password "cphd".
2. On the Windows® desktop, double-click the GeneXpert Dx shortcut icon.
3. Log on to the GeneXpert Dx System software using your user name and password, for example (User Name: admin1, Password: admin1).
4. The Database Management dialog box appears on top of the GeneXpert Dx System window once the system starts up. Click "**NO**" in the Database Management dialog box if you do not want to perform any database management tasks.
5. If a test archive is overdue, the Test Archive Reminder dialog box appears. If you do not want to archive click "**No**" and if you do want to archive click "**Yes**".
6. In the GeneXpert Dx System window, click **Create Test**. The Scan Sample ID Barcode dialog box appears. Scan the Sample ID barcode using the barcode scanner or you can manually enter the sample ID by clicking "Manual Entry". Type in the Sample ID into the Manually Patient ID Barcode Entry dialog box that appears.
7. Scan the barcode on the Xpert *C. difficile* Assay cartridge. The **Create Test** window appears. Using the barcode information, the software automatically fills in the boxes for the following fields: Select Assay, Reagent Lot ID, Cartridge SN, and Expiration Date.
8. Click **Start Test**. In the Create Test dialog box that appears. In the Check Status Window, the selected instrument module progress changes to Waiting.
9. Open the instrument module door with the blinking green light and load the cartridge.
10. Close the door. The test starts and the green light stops blinking.
11. When the test is complete the instrument module door unlocks and the green light turns off. Wait until the system releases the door lock before opening the module door and removing the cartridge.
12. Dispose of the used cartridge in an appropriate specimen waste container.
13. Once testing is complete the report is automatically printed. To view the result, in the GeneXpert DX System window, click **View Results** on the menu bar. The View Results window appears.

14. Click View Test. The Select Test To Be Viewed dialog box appears. Select the test of interest and click **OK**. The results of the selected test appear in the View Results window.
15. The View Results window contains three tabs: **Results**, **Errors**, and **Support**. The **Results** tab displays the information for a test such as the Patient ID, Sample ID, Assay name and the test Result. The Errors tab list the errors encountered during the test process.

Interpretation of Results

The results are interpolated by the GeneXpert Dx System from measured fluorescent signals and embedded calculation algorithms and will be shown in the **View Results** window. Possible results are:

1. **Toxigenic *C. difficile* POSITIVE**

   - Toxin producing *C. difficile* target DNA sequences are detected.
   - The toxin producing *C. difficile* target(s) have Cts within the valid range and endpoint above the minimum setting.
   - SPC — NA (not applicable); SPC is ignored since *C. difficile* target amplification may compete with this control
   - Probe Check – PASS; all probe check results pass.

2. **Toxigenic *C. difficile* NEGATIVE with no Critical Threshold (ct) or Endpoint**

   - *C. difficile* target DNA sequences are not detected.
   - Toxin producing *C. difficile* targets not detected.
   - SPC — PASS; SPC has a Ct within the valid range and endpoint above the endpoint minimum setting.
   - Probe Check — PASS; all probe check results pass.

3. **Toxigenic *C. difficile* NEGATIVE with Critical Threshold (ct) or Endpoint (INDETERMINATE)**

   - *C. difficile* target DNA sequences are detected but not sufficient to trigger a POS result.
   - The GeneXpert test report gives a non-zero numeric value under ct or >10 under EndPt for Toxin B yet the Analyte Result is NEG
   - LIS will trigger a ?END: SIG although test is “NEG” in the test result window to notify of an indeterminate result.
   - All such stools should be frozen (7 vials)

4. INVALID

- Presence or absence of *C. difficile* target DNA cannot be determined
- SPC — FAIL; SPC target result is negative and the SPC Ct is not within valid range and endpoint below minimum setting.
- Probe Check — PASS; all probe check results pass.
- The sample was not properly processed or PCR was inhibited.
- Inform Virology Charge/ Senior and repeat the test according to the following retesting procedure below.

5. ERROR

- Presence or absence of *C. difficile* cannot be determined.
- Toxin producing *C. difficile* targets — NO RESULT
- Probe Check — FAIL*; one or more of the probe check results fail.
- If the probe check passed, possible causes for the error include: the reaction tube was filled improperly; a reagent probe integrity problem was detected; or the maximum pressure limits exceeded the acceptable range.
- Inform Virology Charge/ Senior and repeat the test according to the following retesting procedure below.

6. NO RESULT

- Indicated that insufficient data were collected, the presence or absence of *C.difficile* cannot be determined.
- Possible causes include the operator stopping the test will it was in progress.
- Inform Virology Charge/ Senior and repeat the test according to the following retesting procedure below.

Retesting Procedure

The test should be repeated if an "INVALID", "ERROR" or "NO RESULT" result was obtained.

To repeat a test within 3 hours of an "INVALID/ERROR/NO RESULTS" result:

1. Transfer the remaining contents from the S Chamber of the current Xpert *C. difficile* Assay cartridge to a new Sample Reagent Vial using a disposal transfer pipette.
2. Vortex and add the entire contents of the Sample Reagent to Chamber S of a new Xpert *C. difficile* Assay cartridge.
3. Close the lid and start new test

To repeat a test after 3 hours of an "INVALID/ERROR/NO RESULTS" result:

1. Repeat the test from original stool specimen with a new diluent.
   (do **NOT** use transfer remaining contents of original Xpert *C. difficile* Assay cartridge S Chamber)

Reporting

Result	LIS Codes	Result Comments
Negative	?END: NSG ?NAP1: NEGATIVE ?CLD: NEG	**Auto resulting TEST Comment**: **}NCTB** Negative "Negative - No C difficile toxin B gene detected by Cepheid Xpert C. difficile/Epi assay. This assay has a negative likelihood ratio between 0.03-0.06. A second test does NOT significantly increase the sensitivity or change the negative likelihood ratio. (Ref: Eur J Clin Microbiol Infect Dis. 2013 Jan;32(1):97-9)
Positive	?END: SIG ?NAP1: SIG or NEG ?CLD: ?DETECTED 1. In test window, pick 'P' from keypad 2. Chose '1' or 'D' from keypad - '1' will generate: ~^clodn-; (C.diff pos, nap-1 neg) - 'D' will generate: ~^clodn+; (C.diff pos, nap-1 pos) 3. Verify Isolate, Accept "YES" Pop Up Comment Clodn+/- - ~\GXPT Clodn+/- - ~\Cdif 4. Verify, Finalize, View & Save 5. Notify ward/ICP, 6. Add media FRZ, freeze 4 vials	**ISOLATE** Comment: "C difficile toxin B gene DETECTED by PCR using Cepheid Xpert C.difficile/Epi assay. Note: Strain designation is provided for Infection control reasons only. For TGH/TWH, MSH, PMH ED and inpatient only: **ISOLATE** Comment: **\CD1** *NOTE*: If this is your patient's first episode of C.difficile infection, place orders using the C.difficile treatment order set in Power Chart at Mount Sinai Hospital or Electronic Patient Record(EPR) at University Health Network. Follow the "First Episode C difficile Infection Management Algorithm" available at http://tinyurl.com/jox5nmw for best practices associated with the management of C.difficile infection.

Indeterminate	These will print out as NEG but have a endpoint >10. ?END: SIG ?NAP1: NEGATIVE ?CLD: NEG 1. In test window, pick 'P' from keypad. 2. Chose 'I' from keypad 3. Accept "YES" Pop Up Comment cloptb - ~\Ceph cloptb - ~\Cptb cloptb - ~\Cdif 4. Verify, Finalize all tests, View & Save 5. Notify ward/ICP, freeze 7 vials	**ISOLATE** Comment: "INDETERMINATE for C.difficile toxin B gene by PCR using Cepheid Xpert C.difficile/Epi Assay. This result indicates either C. difficile toxin B gene at low concentrations or a false positive result. Clinical correlation is required. If you have any questions, please contact the Medical Microbiologist on call. For TGH/TWH, MSH, PMH ED and inpatient only: **ISOLATE** Comment: **\CD1** *NOTE*: If this is your patient's first episode of C.difficile infection, place orders using the C.difficile treatment order set in Power Chart at Mount Sinai Hospital or Electronic Patient Record(EPR) at University Health Network. Follow the "First Episode C difficile Infection Management Algorithm" available at http://tinyurl.com/jox5nmw for best practices associated with the management of C.difficile infection.

"INVALID", "ERROR" or "NO RESULT"	?END: ERROR ?NAP1: ERROR ?CLD: ERROR 1. To add repeat test media, under the CLD test, click in the CLDT media and press "R" in the keypad. This will drop "CLDRP" repeat media. 2 .**DO NOT** remove any significant flags  in Test Tab OR any results until you receive the repeat result. 3. Once the second result is available , Report accordingly 4. Should the repeat test give another Errot/Invalid/No result**, DO NOT SET UP AGAIN;** Report as: M- Not processed }Due to interfering	Upon repeat, if the second result is: NEGATIVE 1.Remove the significant flag so it will not be posted as abnormal. 2.Under all tests, **delete "ERROR".** In ?CLD Use keypad 1 }NCDB Negative. 3.Finalize all test ?END,?NAP1 and CLD. POSITIVE 1.DO NOT remove the significant flag. 2.Follow POSITIVE reporting instructions. 3.Finalize all test ?END,?NAP1 and CLD. INDETERMINATE 1.DO NOT remove the significant flag 2.Follow INDETERMINATE reporting instructions 3.Finalize all test ?END,?NAP1 and CLD. INVALID, ERROR, NO RESULT 1. Remove the significant flag. 2. Delete "ERROR" and use keypad M Not Processed} DUE to interfering 3.Finalize all test ?END,?NAP1 and CLD.

***Any ?ERROR comment in the CLD test window will trigger a "significant" flag (even after saving and finalizing result). Delete any ?ERROR left in the CLD test window before finalizing result.**

Phone positive result to ward (in-patient) or physician (Out-patient), and also phone to Infection Control Practitioner as perIsolate Notification and Freezing Table QPCMI16003.

Referred Result

Previous Result	LIS Code	TEST Comment
Negative within 7 days	**}PNEG PrevNeg**	"This patient has tested negative for C. difficile toxin B gene within the past week. This assay has a negative likelihood ratio between 0.03-0.06. A second test does NOT significantly increase the sensitivity or change the negative likelihood ratio. (Ref: Eur J Clin Microbiol Infect Dis. 2013 Jan;32(1):97-9) If your patient has NEW, ONGOING or WORSENING signs/symptoms since the last test that suggest C difficile infection, please contact the Microbiologist-on-call to arrange repeat testing."
Positive within 15 days	**}CLD+ PrevPos**	"This patient has tested positive for C. difficile toxin B gene within the past 15 days. Do not repeat C. difficile toxin testing unless the patient has received a full course of treatment (14 days) and has developed recurrent signs/symptoms of C. difficile. Repeat C. difficile toxin testing is not indicated in patients who have clinically responded to treatment."
Indeterminate within 7 days	**}IND+ PrevIND+**	"This patient has tested indeterminate for C.difficile toxin B gene within the past week. Indeterminate results indicate either detection of low levels of C.difficile toxin B gene or a false positive result. If your patient has signs/symptoms consistent with C.difficile infection, an indeterminate result most likely reflects a low level positive result and the test does not need to be repeated.If you would like repeat testing for another reason, please contact the Microbiologist-on-call."

Rejected Samples

Rejection Criteria	LIS Code	TEST Comment
Formed stool received	**Formed}FSTL**	"Not Processed. Formed stool received. Test cancelled."
Rectal swab received	**Rectal}RECT**	"Not Processed. Rectal swab received; unsuitable for testing.Please resubmit a stool sample."
Duplicate Orders received in the same day	**}DUPL ICATE**	"This is a duplicate order. This test has been cancelled."
Specimen received in SAF transport media	**}SAF received**	"Not Processed. Specimen received in SAF (fixative for parasite) and is unsuitable for C difficile toxin testing. If you have any question, please call the Microbiology lab."
Charcoal Swab received	**}CHAR coal received**	"Not Processed. Charcoal swab received is unsuitable for this test.If you have any question, please call the Microbiology lab."
Specimen received in enteric pathogen transport medium	**}CDTX ETT received**	"Not Processed. Specimen received in enteric pathogen transport medium.Unsuitable for C.difficile testing. Please repeat."
Patient's Age is less than 1 year old	**}<1y Age**	"Test not performed on patients less than one year of age."

Maintenance

Weekly Maintenance Procedure:

a. Disinfect the instrument surfaces
   1. Dampen a paper towel with 10% bleach solution and wipe the instrument surface thoroughly with the paper towel.
   2. Wait 10 minutes
   3. Dampen a paper towel with 70% alcohol solution and wipe the instrument thoroughly with the paper towel.

b. Disinfect the cartridge bay interior
   1. Dip a swab into 70% alcohol solution. Press the swab against the inside wall of the container to remove excess solution.
   2. Open the instrument module door.
   3. Wipe the surfaces inside the cartridge bay with the swab. Do not touch the slit on the I-CORE module into which the cartridge reaction tube is inserted.
   4. Close the instrument module door.

c. Disinfecting the plunger rod
   1. In the GeneXpert DX System window, click **Maintenance** on the menu bar. The **Maintenance** window appears.
   2. On the **Maintenance** menu, click **Plunger Maintenance**. The Plunger Maintenance dialog box appears.
   3. In the **Module** table, select the module you want to clean, and then click **Clean** or select **Clean All** to clean all modules simultaneously. The Plunger Cleaning dialog box then appears.
   4. Follow the directions in the Plunger Cleaning dialog box, then click **OK**. In the Plunger Maintenance dialog box, the **Clean** button changes to Move Up (if you clicked Clean All button, it changes to Move Up All). In the instrument, the plunger rod in the selected module (or all modules if you clicked Clean All button) lowers into the cartridge bay.
   5. Dip a number of swabs in the 70% alcohol solution. Press the swabs against the inside wall of the container to remove excess solution.

6. Wipe the plunger rods with the swabs. Use a fresh swab for each plunger rod.
7. In the Plunger Maintenance dialog box, click Move Up (or Move Up All). The plunger rod moves back into its resting position.
8. Click Close to dismiss the Plunger Maintenance dialog box.

d. Clean fan filters

Annual Maintenance

The GeneXpert DX instrument needs to be recalibrated annually or after 2000 test per instrument module, whichever comes first. The system monitors the number of tests since last calibration. To check whether the system requires calibration:

a. In the Maintenance window, look at the **ICORE Starts Since Cal** column. On the Maintenance menu, click Module Reports. The Module Reports dialog box appears.

b. Check the calibration date. If calibration is required contact the Cepheid Technical Support to schedule a calibration.

Assay validation

Each test includes a Sample Processing Control (SPC) and Probe Check Control (PCC):

A. Sample Processing Control (SPC) — ensures the sample was correctly processed. The SPC contains spores of *Bacillus globigii* in the form of a dry spore cake that is included in each cartridge to verify adequate processing of the sample bacteria. The SPC verifies that lysis of *C. difficile* bacteria and a spore have occurred, if the organism is present, and verifies that specimen processing is adequate. Additionally, this control detects specimen-associated inhibition of the real-time PCR assay. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria.

B. Probe Check Control (PCC) — Before the start of the PCR reaction, the GeneXpert Dx System measures the fluorescence signal from the probes to monitor bead rehydration, reaction-tube filling, probe integrity and dye stability. Probe Check passes if it meets the assigned acceptance criteria.

Quality Control

Each test includes a Sample Processing Control (SPC) and Probe Check Control (PCC). Refer to a senior technologist if control results are outside of limits or for any other problems with running or reporting the assay.

Run external control (*C. difficile* Toxin from Positive *C. difficile* culture) with each new lot, QC and instrument problems. Result filed in External Control Binder. If result is negative, the run is invalid. Inform Charge/senior technologist, and repeat testing.

CAP provides external proficiency testing.

Related Documents

Qualitative PCR External QC Log	T:\Microbiology\Virology\QC statistics\EXTERNAL QC and INVENTORY Logs\Qualitative PCR EXTERNAL QC.xls

Reference

Xpert C.difficile PCR Assay package insert

Appendix 1: Testing for C. difficile toxin from eSwab for Infection Control Purpose

Infection Control Practioners may request *C. difficile* on specimens collected in eSwab during admission screening to rule out *C. difficile* infection prior to admission.

1. From a previously collected eSwab culture, **place a new order** in the LIS and order the *C. difficile* toxin test
2. use the Cepheid instrument by the VRE bench so that automated results through the interface do not occur
3. use 100 uL of eSwab liquid transport media for testing and follow the **Procedure** above
4. **Report** results as above with additional Comment:

"Note: This specimen type is not appropriate for C. difficile testing but has been tested for infection control purposes only."

Appendix 2: *C. difficile* Toxigenic Culture and Typing Requests

Infection Control Practioners may request *C. difficile* toxigenic culture and typing to be perfomed. This test is sent to the National Microbiology Laboratory (NML).

1. Specimen Accessioning

Specimens sent for *C. difficile* toxigenic culture and typing should be ordered through EPR or Cerner.

The test can aldo be ordered though the STOOL order entry keypad:

- For UHN (EPR) code: **CDTC**
- For MSH (Cerner) code: **CDTCX**

Make note if the specimen is part of an outbreak investigation.

Accession the specimen in the LIS.

2. NML Requisition

Obtain a NML Antimicrobial Resistance and Nosocomial Infections Requistion from the website below:

https://www.cnphi-rcrsp.ca/gts/faces/public/laboratory.xhtml?labId=1001&lang=en

Ensure to indicate if the specimen being sent is an outbreak investigation samples.

- PFGE pattens and NAP designations results are included for routine specimens
- PFGE patterns, NAP designation and dendrograms are included for outbreak investigation submissions

For MSH specimens, request that NML copy results to ALL the following:

Dr. Allison McGeer by Fax # 416-586-8358
Dr. Allison McGeer by Email: amcgeer@mtsinai.on.ca
Microbiology Special Queries by email: MicrobiologySpecialQueries-MBX@mtsinai.on.ca.

For UHN specimens, request that NML copy results to Microbiology Special Queries by email: MicrobiologySpecialQueries-MBX@mtsinai.on.ca.

3. Reporting

When NML results return, enter results into the LIS system. Add the specimen NML No to the end of the result.

Negative Culture:

Toxigenic C. difficile Culture:
NO C difficile isolated.
As reported by the National Microbiology Laboratory (NML)
1015 Arlington Street, Winnipeg, MB R3E 3R2.
NML Specimen No.

Positive culture; non-toxigenic strain:

Toxigenic C. difficile Culture:
C difficile isolated
C. difficile PCR Genotype: non-toxigenic C. difficile
As reported by the National Microbiology Laboratory (NML)
1015 Arlington Street, Winnipeg, MB R3E 3R2.
NML Specimen No.

Positive Culture; toxigenic stain:

Toxigenic C. difficile Culture:
C difficile isolated
C. difficile PCR Genotype: toxigenic C. difficile
Primary PFGE Pattern:
Primary PFGE Enzyme:
Epidemic Type:
As reported by the National Microbiology Laboratory (NML)
1015 Arlington Street, Winnipeg, MB R3E 3R2.
NML Specimen No.

Record of Edited Revisions

Manual Section Name: *C difficile* toxin B gene PCR by Cepheid GeneXpert

Page Number / Item	Date of Revision	Signature of Approval
Manual Transferred from Molecular Diagnostics Manual Policy # MI/MD/v51 archived 2015.12.02	December 2, 2015	Dr. T. Mazzulli
Annual Review Added Appendix II: *C.difficile* toxigenic culture and typing	December 8, 2015	Dr. T. Mazzulli
Appendix II: *C.difficile* toxigenic culture and typing added: -For MSH email Dr. McGeer and Micro special queries -For UHN specimens, request that NML copy results to Microbiology Special Queries by email: MicrobiologySpecialQueries-MBX@mtsinai.on.ca.	January 16, 2016	Dr. T. Mazzulli
Removed use of Bleach for maintenance **inside** of Genexpert cleaning for cartridge bay cleaning and plunger rod cleaning.	February 10, 2016	Dr. T. Mazzulli
Added new MSH logo in header Clarified in Retesting Procedure section under: To repeat a test after 3 hours of an "INVALID/ERROR/NO RESULTS" result: "Changed from: Repeat the test with a new swab sample." To: "Repeat the test from original stool specimen and a new Sample Reagent Vial. (do **NOT** use transfer remaining contents of original Xpert *C. difficile* Assay cartridge S Chamber)"	April 5, 2016	Dr. T. Mazzulli
Annua Review Updated positive and indeterminate resulting with: For TGH/TWH, MSH, PMH ED and inpatient only: **ISOLATE** Comment: **\CD1** *NOTE*: If this is your patient's first episode of *C.difficile* infection, place orders using the *C.difficile* treatment order set in Power Chart at Mount	October 18, 2016	Dr. T. Mazzulli

Page Number / Item	Date of Revision	Signature of Approval
Sinai Hospital or Electronic Patient Record(EPR) at University Health Network. Follow the "First Episode *C difficile* Infection Management Algorithm" available at http://tinyurl.com/jox5nmw for best practices associated with the management of *C.difficile* infection.		
Annual Review Moved routine *C. difficile* testing to Luminex Aries. GeneXpert Assay is reserved for NAP1 identification when requested by Infection Control	October 02, 2017	Dr. T. Mazzulli
Annual Review	October 02, 2018	Dr. T. Mazzulli
Annual Review	October 30, 2019	Dr. T. Mazzulli

Full document review included in all updates. Bi-annual review conducted when no revision had been made within 2 years.

Page Number / Item	Date of Revision	Edited by:
Minor formatting change	April 11, 2021	Jessica Bourke
Removed Clostridium, nomenclature update	April 19, 2021	Wayne Chiu