PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC60010 – Microbiology Quality Control	Policy Number: 15-46-V1
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s): NA	
Effective Date: 12/02/2024	Next Review Date: 12/02/2026
Issuing Authority: Director, Laboratory and Diagnostic Imaging Services	Date Approved: 12/02/2024
Accreditation Canada Applicable Standard: NA	

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GUIDING PRINCIPLE:
Quality control testing that is out of range will be repeated. If the result continues to be out of range, it is considered a non-conformance.

For all **non-conformances**:

- Take the non-conforming item out of service. Clearly label as unsatisfactory and place into segregation
- Withhold patient results obtained with the unacceptable material/equipment/instrument
- Contact the vendor for further instructions if required
- Notify patient's unit or clinician if results will be delayed and explain why
- Repeat patient testing once the material/equipment/instrument has been successfully quality controlled
- For non-conformances related to media, reagents, susceptibility testing and equipment, notify the Technical Supervisor, Microbiology
- For non-conformances related to instrumentation, notify the Technical Supervisor, Microbiology and document the non-conformance on QUA40590-Instrument Troubleshooting for the instrument involved

PURPOSE/RATIONALE:
To ensure that patient results are consistently of the highest quality, all aspects of specimen testing in the Microbiology Laboratory will be quality controlled.

SCOPE/APPLICABILITY:
This standard operating procedure applies to Medical Laboratory Technologists (MLTs) performing quality control in the microbiology laboratory.

Anaerobic jars and trays:

- Include a chemical indicator (resazurin) in all anaerobic jars and trays
- Daily, enter indicator results into TQC for each jar or tray opened
  - Refer to MIC61030-Entering Microbiology QC Results into TQC
- For chemical QC failure (pink indicator):
  - Refer to **non-conformances** section on page 1
  - Do not report results of agar plates from QC failed jars and trays (except for throat cultures positive for Group A *Streptococcus* and blood cultures growing aerobic/facultative organisms that match direct Gram stain)
  - Re-plant all other specimens from failed jars and trays

API 20E strips:

- The strips and reagents are systematically quality controlled at various stages of the manufacturing process
- Test new shipments and new lot numbers of API 20E strips on receipt using *Proteus mirabilis* ATCC 35659. Refer to MIC53100-API 20E Test
- A QC order will generate in TQC when a new kit is received
- Enter results into TQC. Refer to MIC61030-Entering Microbiology QC Results into TQC
- If quality control testing results are acceptable and kit is a new lot number, place yellow "NEW LOT Record #" sticker on the first package (of same lot number) to be used. Also, write "QC OK" with the date and your initials on the box
- If QC testing results are not acceptable, refer to **non-conformances** section on page 1. Repeat quality control testing with new/replacement kit
- Package inserts are available online and in the "Product Inserts" binder

API NH strips:

- The strips and reagents are systematically quality controlled at various stages of the manufacturing process
- Test new shipments and new lot numbers of API NH strips on receipt using *Neisseria gonorrhoeae* ATCC 31426. Refer to MIC53200-API NH Test
- A QC order will generate in TQC when a new kit is received
- Enter results into TQC. Refer to MIC61030-Entering Microbiology QC Results into TQC
- If quality control testing results are acceptable and kit is a new lot number, place yellow "NEW LOT Record #" sticker on the first package (of same lot number) to be used. Also, write "QC OK" with the date and your initials on the box
- If QC testing results are not acceptable, refer to **non-conformances** section on page 1. Repeat quality control testing with new/replacement kit
- Change reconstituted API NH James reagent monthly and ZYM B reagent every 2 weeks. Write the expiry date on reagent bottles
- If reagent is a new lot number, activate in TQC. Refer to MIC61020-Opening and Closing Lot Numbers in TQC
- Package inserts are available online and in the "Product Inserts" binder

BACTEC FX blood culture instrument:

- Perform daily and monthly maintenance on the BACTEC FX instrument. Record on MIC71110-Maintenance Record-BACTEC FX
- Annual preventative maintenance is performed by BD. File records in the "BACTEC FX Service Reports and Error Log" binder
- Record all non-conformances and issues, including UPS issues, with actions taken and resolutions on QUA40590-Instrument Troubleshooting in the "BACTEC FX Service Reports and Error Log" binder and notify the Technical Supervisor, Microbiology

BIOFIRE TORCH instrument:

- Perform daily and monthly maintenance the BIOFIRE TORCH instrument. Record on MIC73110-Maintenance Record-BIOFIRE TORCH
- Refer to MIC60110-BIOFIRE RP2.1 Quality Control for QC procedure
- Document quality control testing on MIC60111-QC Results Record-BIOFIRE RP2.1
- Record all non-conformances and issues with actions taken and resolutions on QUA40590-Instrument Troubleshooting in the "BIOFIRE TORCH Service Reports and Error Log" binder and notify the Technical Supervisor, Microbiology

Biological safety cabinets:

- Perform daily, weekly and bi-annual maintenance as required. Refer to MIC61100-Microbiology Laboratory Equipment
- BSCs are inspected, tested, and certified annually

Disinfection and decontamination procedures:

- Disinfect bench tops with Accel TB wipes at the beginning the day, at the end of the day and as required
- Dispose of sharps (needles, glass slides, glass tubes, broken glass) in yellow plastic sharps container. When 2/3 full, close container and place outside the microbiology laboratory in waste pickup area
- Dispose of contaminated materials in large cardboard biohazard waste containers. When container is full and weighs no more than 16 kg, seal plastic biohazard waste bag and close up cardboard box. Place box outside the microbiology laboratory in waste pickup area
- For biological spills or contamination, refer to the Code Brown procedure located in the code binder on the shared drive and on the laboratory safety wall

External Quality Assurance Programs-CMPT, CAP and QASI:

- The Microbiology Laboratory participates in external quality assessment programs (EQA) administered by Clinical Microbiology Proficiency Testing (CMPT) and the College of American Pathologists (CAP). Refer to MIC90300-STH Microbiology Laboratory-External Quality Assurance
- EQA specimens that are completed will be documented on QUA30310-Laboratory Competence Assessment Form for the technologist that performed the testing

Freezer:

- Daily, during morning start up, check digital temperature and internal thermometer temperature of the ultra-low freezer and record on temperature chart QUA40491.9-Temperature Log-Micro Ultra-Low Freezer
- If temperature is out of range, attempt to adjust. If temperature continues to be out of range:
  - Contact maintenance and notify the Technical Supervisor, Microbiology
  - Relocate all supplies from the faulty freezer to a functioning freezer operating at the appropriate temperature
  - Submit a RL6 incident report
  - After freezer has been serviced, document that the temperature has been within acceptable limits for 24 hours before placing back into use
- Perform monthly and bi-annual maintenance as required. Refer to MIC61100-Microbiology Laboratory Equipment
- Thermometers are replaced and verified annually and recorded on QUA40493-Thermometer Log

GeneXpert instrument:

- Perform daily and monthly maintenance on the GeneXpert instrument. Record on MIC72110-Maintenance Record-GeneXpert
- Refer to MIC60080-Xpert *C. difficile* Quality Control, MIC60090-Xpert Xpress CoV-2 plus Quality Control,MIC60100-Xpert MTB/RIF Quality Control and MIC60120-Xpert Xpress Strep A Quality Control for QC procedures
- Document quality control testing on MIC60081-QC Results Record-Xpert *C. difficile*, MIC60091-QC Results Record-Xpert Xpress CoV-2 plus, MIC60101-QC Results Record-Xpert MTB/RIF and MIC60121-QC Results Record-Xpert Xpress Strep A
- Record all non-conformances and issues with actions taken and resolutions on QUA40590-Instrument Troubleshooting in the "GeneXpert Service Reports and Error Log" binder and notify the Technical Supervisor, Microbiology

Incubators:

- Daily, during morning start up, check digital temperature and internal thermometer temperature of all incubators. Record on temperature charts QUA40491.3, QUA40491.7 and QUA40491.8
- If temperature is out of range, attempt to adjust. If temperature continues to be out of range:
  - Contact maintenance and notify the Technical Supervisor, Microbiology
  - Relocate materials from the faulty incubator to a functioning incubator
  - Submit a RL6 incident report
  - After incubator has been serviced, document that the temperature has been within acceptable limits for 24 hours before placing back into use
- Perform weekly, monthly, and bi-annual maintenance as required. Refer to MIC61100-Microbiology Laboratory Equipment
- Thermometers are replaced and verified annually and recorded on QUA40493-Thermometer Log

- CO_2 incubators:
  - Check CO_2 gas gauge daily for adequate gas supply. This is to ensure that the gas does not run out during off hours
  - Monthly measure the % CO_2 using the FYRITE gas analyzer. Record on QUA40491.7 and QUA40491.8. Result should be between 4-10%
  - If a CO_2 incubator alarms, use the manual stored on the Microbiology Shared Drive to try to troubleshoot the problem. If lab staff cannot troubleshoot the issue, contact STH maintenance
- CO_2 tank change:
  - Between 8 AM and 4 PM, Monday through Sunday, contact maintenance to request a new tank. If the tank needs to be changed after hours, keep the incubator doors closed as much as possible and leave a note for the day staff to contact maintenance as soon as possible
  - Allow 1 hour for CO_2 incubator chamber to equilibrate. Ensure that the incubator door has not been opened for 30 minutes and perform FYRITE gas analyses on CO_2 incubators
  - Record result of FYRITE analyses on QUA40491.7 and QUA40491.8. Result should be between 4-10%

Media quality control:

- Quality control of prepared media is performed in accordance with CLSI M22-A3:2004 Quality Control for Commercially Prepared Microbiological Culture Media
- Refer to MIC60040-Culture Media Quality Control
- Refer to MIC61000-Receiving Supplies in the Microbiology Laboratory
- Store all media as specified by the manufacturer
- Certificate of Analysis are available online on the Oxoid website

Microscopes:

- Daily, perform Kohler illumination
- All microscopes receive annual preventative maintenance
- Refer to MIC61100-Microbiology Laboratory Equipment for maintenance of microscopes and MIC61120-Kohler Illumination Job Aid

Quality control records audit procedure:

- The Technical Supervisor, Microbiology reviews completed quality control records in TQC on a weekly basis
- The Technical Supervisor, Microbiology reviews completed QC results records stored in accompanying QC results binder on a weekly basis
- Completed quality control records in TQC are kept indefinitely and completed manual QC results records are scanned onto the Supervisor-Microbiology shared drive

Reagents:

- Do not use expired reagents or solutions
- Perform quality control testing as per MIC60011-Microbiology QC Job Aid
- A QC order will generate in TQC when a new reagent is received, daily, weekly, or as tested depending on reagents' QC requirements. Refer to MIC60011-Microbiology Quality Control Job Aid
- Enter results into TQC. Refer to MIC61030-Entering Microbiology QC Results into TQC
- If QC testing results are not acceptable, do not report patient results
- Repeat quality control testing. If repeat testing is acceptable, repeat patients test and report results. If repeat testing is not acceptable:
  - Refer to **non-conformances** section on page 1
  - Discard or return reagent to manufacturer as directed
  - Perform quality control testing on new reagent. If results are acceptable, repeat patients test and report results
- Package inserts are available online and in the "Product Inserts" binder

Refrigerators:

- Daily, during morning start up, check digital temperature and internal thermometer temperature of all refrigerators. Record on temperature charts QUA40491.1, QUA40494.2 and QUA40491.10
- If temperature is out of range, attempt to adjust. If temperature continues to be out of range:
  - Contact maintenance and notify the Technical Supervisor, Microbiology
  - Relocate all supplies from the faulty refrigerator to a functioning refrigerator operating at the appropriate temperature
  - Submit a RL6 incident report
  - After refrigerator has been serviced, document that the temperature has been within acceptable limits for 24 hours before placing back into use
- Perform monthly and bi-annual maintenance as required. Refer to MIC61100-Microbiology Laboratory Equipment
- Thermometers are replaced and verified annually and recorded on QUA40493-Thermometer Log

Reporting results:

- Patient reports are finalized in SoftMic by MLTs performing the specimen workup
- Notify the requester of the test when examinations are delayed and the turn-around time for a test is affected to a degree that may pose clinical implications
- Gram stain results must correlate with growth in culture
- Refer to MIC36000-Reportable and Communicable Diseases Notifications for notification of reportable and/or communicable diseases
- Refer to L-0910-Laboratory: Critical Values for notification of critical results
- Refer to MIC10205-STH Microbiology Rejection Criteria for specimen rejection criteria

Stock cultures:

- Use only ATCC microorganisms for quality control testing
- A "Biosafety Risk Assessment Form for Organism Assessment" has been completed on each ATCC organism and is stored in the Biosafety and Biosecurity folder on the shared drive
- Store lyophilized cultures in the reagent refrigerator
- Store culture aliquots in glycerol citrate in the ultra-low freezer
- Refer to MIC60070-Stock Culture Maintenance for the handling of stock cultures; annually, monthly, and weekly

Susceptibility testing:

- Store Active and Inactive ETEST strips and KB disks in the microbiology reagent refrigerator. Remove individual strips 1 hour before use
- Refer to MIC60020-Antibiotic Quality Control for QC procedure
- Perform quality control testing as directed on MIC60021-Antibiotic Quality Control Job Aid
- The weekly susceptibility QC order will generate in TQC every Wednesday
- Enter results into TQC. Refer to MIC61030-Entering Microbiology QC Results into TQC
- Verify any unusual results, repeat testing, and notify the Technical Supervisor, Microbiology

Temperature and humidity monitoring:

- Daily, during morning start up, check temperature and humidity of the Microbiology Work Room and of the TB Work Room. Document on QUA40492.2 and QUA40492.3
- Instrumentation acceptable ranges are:

	Temperature	Relative humidity
bioMerieux VITEK 2:	15˚C to 30˚C	20%-80%
bioMerieux BIOFIRE TORCH	15˚C to 30˚C	20%-80%
BD BACTEC FX	18˚C to 30˚C	25%-80%
Cepheid GeneXpert	15˚C to 30˚C	10%-95%

- Notify the Technical Supervisor, Microbiology when readings are out of range
- Thermometers are replaced and verified annually and recorded on QUA40493-Thermometer Log

VITEK 2 identification and susceptibility testing system:

- Perform daily and monthly maintenance on the VITEK 2 instrument. Record on MIC70110-Maintenance Record-VITEK 2
- Refer to MIC60030-VITEK 2 Quality Control for QC procedure
- Perform quality control testing as directed on MIC60031-VITEK 2 Quality Control Job Aid
- Document quality control testing on MIC60032-QC Results Record-VITEK 2
- Record all non-conformances and issues, including UPS issues, with actions taken and resolutions on QUA40590-Instrument Troubleshooting in the "VITEK 2 Service Reports and Error Log" and notify the Technical Supervisor, Microbiology

CROSS-REFERENCES:

- L-0910-Laboratory: Critical Values for notification of critical results
- QUA30310-Laboratory Competence Assessment Form
- QUA40493-Thermometer Log
- QUA40491.1,.2, .3, .5, .6, .7, .8, .9, .10
- QUA40590-Instrument Troubleshooting
- MIC10205-STH Microbiology Rejection Criteria
- MIC36000-Notification of reportable and/or communicable diseases
- MIC60011-Microbiology QC Job Aid
- MIC60020-Antibiotic Quality Control
- MIC60021-Antibiotic Quality Control Job Aid
- MIC60030-VITEK 2 Quality Control
- MIC60031-VITEK 2 Quality Control Job Aid
- MIC60032-QC Results Record-VITEK 2
- MIC60040-Culture Media Quality Control
- MIC60070-Stock Culture Maintenance
- MIC60080-Xpert *C. difficile* Quality Control
- MIC60081-QC Results Record-Xpert *C. difficile*
- MIC60100-Xpert MTB/RIF Quality Control
- MIC60101-QC Results Record-Xpert MTB/RIF
- MIC60110-BIOFIRE RP2.1 Quality Control
- MIC60111-QC Results Record-BIOFIRE RP2.1
- MIC60120-Xpert Xpress Strep A Quality Control
- MIC60121-QC Results Record-Xpert Xpress Strep A
- MIC61000-Receiving Supplies in the Microbiology Laboratory
- MIC61020-Opening and Closing Lot Numbers in TQC
- MIC61030-Entering Micro QC Results into TQC
- MIC61100-Microbiology Laboratory Equipment
- MIC70111-Maintenance Record-VITEK 2
- MIC71110-Maintenance Record BACTEC FX
- MIC72110-Maintenance Record-GeneXpert
- MIC73110-Maintenance Record-BIOFIRE TORCH

REFERENCES:

1. CLSI. *Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition.* CLSI document M22-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2004.
2. CLSI. *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically.* 11th ed. CLSI standard M07. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.
3. CLSI. *Performance Standards for Antimicrobial Disk Susceptibility Tests.* 13th ed. CLSI standard M02. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.
4. CLSI. *Quality Control for Commercial Microbial Identification Systems; Approved Guideline.* CLSI document M50-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.

APPROVAL:

Feburary 12, 2024
Date

Director, Laboratory and Diagnostic Imaging Services

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	15 Sep 17	Initial Release	L. Steven
2.0	06 Oct 19	Procedure reviewed	L. Steven
3.0	05 Jul 21	Procedure reviewed and added to NTHSSA policy template	L. Steven
4.0	03 Jul 23	Procedure reviewed	L. Steven
5.0	12 Feb 24	Procedure reviewed	L. Steven