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

POLICY: Quality control testing that is out of range will be repeated. If result continues 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 Technologist II.
- For non-conformances related to instrumentation, notify the Technologist II and document the non-conformance on QUA40590 – Instrument Troubleshooting for the instrument involved.

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 MIC60110.
- 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-stained smear findings).
  - Re-plant all other specimens from failed jars and trays and start anaerobic incubation immediately.

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.
- A QC order will generate in TQC when a new kit is received.
- Enter results into TQC. Refer to MIC60110.
- 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.
- If QC testing results are not acceptable, refer to **non-conformances** section on page 1 and contact bioMerieux. Discard or return reagent or kit as directed and repeat quality control testing with new / replacement kit.
- The package inserts for API 20E strips and reagents are available online and in the "Package Inserts" binder in the Tech II room.

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.
- A QC order will generate in TQC when a new kit is received.
- Enter results into TQC. Refer to MIC60110.
- 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.
- If QC testing results are not acceptable, refer to **non-conformances** section on page 1 and contact bioMerieux. Discard or return reagent or kit as directed and 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 MIC60100.
- The package inserts for API NH strips and reagents are available online and in the "Package Inserts" binder in the Tech II room.

BACTEC FX blood culture instrument:

- Perform daily and monthly maintenance on the BACTEC FX instrument. Record on MIC70500.
- Annual preventative maintenance is performed by BD. File records in the "BACTEC FX Service Reports and Error Log" binder in the Tech II room.
- 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 Technologist II.
- Submit a Risk Pro.

Biological safety cabinets:

- Check airflow in the biological safety cabinets (BSC) daily and record on LSM30210. If a large difference in the reading from one day to the next is noted, notify the Technologist II.
- Before working in the BSC, turn on the blower and then:
  - Verify that the sliding view-screen is lined up with the sash level indicator arrow on the sides of the cabinet.
  - Verify that the air grills are free from obstructions.
  - Verify the IN flow FPM and DOWN flow FPM readings – record on LSM30210.
  - Disinfect all interior surfaces of the BSC with Accel TB wipes.
  - Ensure that the blower is on for 5 minutes before starting work in the cabinet.

- While working in a BSC:
  - Avoid excessive movement of hands and arms through the front access opening.
  - Keep contaminated materials to the rear of the cabinet.

- After working in the BSC:
  - Allow the BSC to run for 5 minutes with no activity.
  - Ensure all containers are closed/covered before removing from the BSC.
  - Ensure that all contaminated objects/materials are disinfected before removing from the BSC.
  - Disinfect all working areas of the BSC with Accel TB wipes while it is still in operation.

- BSCs are inspected, tested and certified annually.

Campylobacter jars:

- Include a biological control (*Campylobacter jejuni* ATCC 33291) plate in each Campylobacter jar.
- Daily, enter biological control results into TQC for each jar opened. Refer to MIC60110.
- For biological QC failure (no growth of *Campylobacter jejuni* on control plate):
  - Refer to **non-conformances** section on page 1.
  - Do not report results of Campylobacter plates from failed jars.
  - Re-plant all specimens to Campylobacter plates and re-incubate for 72 hours before reporting results.

Disinfection and decontamination procedures:

- Disinfect counter tops with Accel TB wipes at the end of the day and as required.
- Dispose of sharps (needles, glass slides, glass tubes, broken glass) in yellow plastic sharps collector. When 2/3 full, close container and place outside the microbiology laboratory in waste pickup area.
- Dispose of contaminated materials such as culture plates, Vitek cards, swabs, sticks and specimens in large cardboard biohazard waste containers. When container is full and weighs no more than 12 kg, seal plastic biohazard waste bag and close up cardboard box. Place box outside the microbiology laboratory in waste pickup area.
- Wipe the specimen processing cart with Accel TB wipes monthly.
- Wipe the specimen buckets with Accel TB wipes monthly.
- 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.
- For equipment and instrumentation decontamination, cleaning and disinfection after spills, before servicing and when decommissioning: contact the vendor and follow their recommendations.

External Quality Assurance Programs – CMPT, CAP and oneworld ACCURACY:

- The Microbiology Laboratory participates in external quality assessment programs (EQA) administered by Clinical Microbiology Proficiency Testing (CMPT), the College of American Pathologists (CAP) and oneworld ACCURACY.
- EQA specimens that are completed by MLTs will be documented on QUA30310 – Laboratory Competence Assessment Form and stored in the “Microbiology Staff Competency Assessment” binder in the Tech II room.
- Discordant EQA findings need to have an EQA Performance Investigation Form (located on the shared drive) filled out.
- Treat specimens as much as possible as patient specimens.

Freezer:

- Daily, during morning start up, check digital temperature and internal thermometer temperature of the -70 freezer and record on temperature chart QUA40491.9.
- If temperature is out of range, attempt to adjust. If temperature continues to be out of range:
  - Contact maintenance and notify the Technologist II.
  - Relocate all supplies from the faulty freezer to a functioning freezer operating at the appropriate temperature.
  - Submit a Risk Pro.
  - After freezer has been serviced, document that the temperature has been within acceptable limits for 24 hours before placing back into use.
- Thermometers are replaced and verified annually and recorded on QUA40493 – Thermometer Log.

Incubators:

- Daily, during morning start up, check digital temperature and internal thermometer temperature of all incubators. Record on temperature charts QUA40491.3, QUA40491.5, QUA40491.6, 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 Technologist II.
  - Relocate materials from the faulty incubator to a functioning incubator operating at the appropriate temperature.
  - Submit a Risk Pro.
  - 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 MIC10360– Microbiology Laboratory Equipment.
- Thermometers are replaced and verified annually and recorded on QUA40493 – Thermometer Log.
  - **a. CO_2 incubators:**
    - Check CO_2 gas gauge daily for adequate gas supply.
    - Monthly measure the % CO_2 using the FYRITE gas analyzer. Record on QUA40491.5, QUA40491.6, QUA40491.7 and QUA40491.8.
    - Result should be between 4 -10%.
    - If a CO_2 incubator alarms, identify error code. Using the manual, try to troubleshoot the problem. If cannot solve issue, phone maintenance.
  - **b. CO_2 tank change:**
    - During regular hours, call Maintenance at 4120 and request a new tank.
    - 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 QUA40491.5, QUA40491.6, QUA40491.7 and QUA40491.8. Reading 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 MIC60080 – Receiving Supplies and Stock into the Microbiology Laboratory.
- Refer to MIC60040 – Culture Media Quality Control.
- Store all media as specified by the manufacturer.
- Certificate of Analysis are available online on the Oxoid website.

Microscopes:

- Daily, check Kohler illumination.
- All microscopes receive annual preventative maintenance.
- Refer to MIC10360– Microbiology Laboratory Equipment for maintenance of microscopes.

Quality control records audit procedure:

- The Technologist II reviews completed quality control records in TQC on a weekly basis.
- Completed quality control records in TQC are kept indefinitely.

Rapid test kits:

- Includes: C.diff, Colilert 18, Simplate HPC and RSV.
- A QC order will generate in TQC when a new kit is received.
- Enter results into TQC. Refer to MIC60110.
- 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 kit to manufacturer as directed.
  - Perform quality control testing with new kit. If results are acceptable, repeat patients test and report results.
- Package inserts are available online and in the "Product Inserts" binder in the Tech II room.

Reagents:

- Do not use expired reagents or solutions.
- Record the date opened, date reconstituted and expiry date (if applicable) on each reagent.
- 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 MIC60110.
- 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 insert are available online and in the "Product Inserts" binder in the Tech II room.

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 out of range:
  - Contact maintenance and notify the Technologist II.
  - Relocate all supplies from the faulty refrigerator to a functioning refrigerator operating at the appropriate temperature.
  - Submit a Risk Pro.
  - After refrigerator 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 MIC10360 – 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.
- Patient results are withheld if quality control testing results are unacceptable.
- If held back, patient testing is repeated when quality control results are acceptable.
- 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.
- The final report must acknowledge findings from any preliminary reports. For instance, if *Staphylococcus epidermidis* was listed on a preliminary report, and was later determined to be part of commensal skin flora, this should be explained on the final report.
- Refer to MIC35000 for notification of reportable and/or communicable diseases.
- Refer to L-0910-Laboratory: Critical Values for notification of critical results.
- Refer to MIC10270 – 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 on the Biosafety and Biosecurity folder on the shared drive.
- Store lyophilized cultures in the reagent refrigerator.
- Store culture aliquots in glycerol citrate in the -70° freezer.
- Refer to MIC60070 – Stock Culture Maintenance for the handling of stock cultures; annually, monthly and weekly.
- Pathogen Safety Data Sheets (PSDSs) are technical documents produced by the Public Health Agency of Canada that describe the hazardous properties of human pathogens with recommendations for working with these agents. PSDSs are available at: http://www.phac-aspc.gc.ca/lab-bio/$_{res}$/psds-ftss/index-eng.php

Susceptibility testing:

- Store Active and Inactive E-test strips in the microbiology reagent refrigerator. Remove 1 hour before use.
- Store Active and Inactive antimicrobial disks in the microbiology reagent refrigerator. Remove 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 MIC60110.
- Verify any unusual results: repeat testing and notify the Technologist II.
- For a list of unusual results, refer to current CLSI Performance Standards for Antimicrobial Susceptibility Testing M100-S, Appendix B – Intrinsic Resistance.

Temperature and humidity monitoring:

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

	Temperature	Relative humidity
bioMerieux Vitek 2:	15˚C - 30˚C	20% - 80%
BD BACTEC FX	18˚C - 30˚C	25% - 80%

- Notify the Technologist II 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, weekly and monthly maintenance on the Vitek 2 instrument. Record on MIC70111.
- 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 - Vitek 2 Quality Control Results Record.
- 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 Technologist II.
- Submit a Risk Pro.

REFERENCES:

- 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.
- 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.
- CLSI. *Performance Standards for Antimicrobial Disk Susceptibility Tests.* 13th ed. CLSI standard M02. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.
- CLSI. *Quality Control for Commercial Microbial Identification Systems; Approved Guideline.* CLSI document M50-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.
- Vitek 2 Instrument User Manual.
- BACTEX FX Instrument User Manual.

REVISION HISTORY:

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