PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC60020 – Antibiotic Quality Control	Policy Number:
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s):	
Effective Date:	Next Review Date:
Issuing Authority: Director, Health Services	Date Approved:
Accreditation Canada Applicable Standard: N/A	

GUIDING PRINCIPLE:
To control the precision and accuracy of the antibiotic disks and Etest strips which are used to test clinical isolates, they need to be tested weekly on the Wednesday QC bench.

PURPOSE/RATIONALE:
To standardize the weekly quality control of antibiotic disks and Etest strips.

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

REAGENTS and/or MEDIA:
- Oxoid antimicrobial test disks
- Biomerieux ETEST reagent strips
- ATCC organisms
- Mueller-Hinton agar
- Mueller-Hinton agar with 5% sheep blood
- Haemophilus Test Medium

SUPPLIES:
- Plastic Vitek tubes and caps
- 0.9% Saline
- Sterile swabs
- Forceps
- Small, metric ruler

EQUIPMENT:
- DensiCHEK Plus
- 35° ambient air incubator and 35° CO_2 incubator

SPECIAL SAFETY PRECAUTIONS:

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potential 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.

PROCEDURE INSTRUCTIONS:

Step	Action
Performing quality control of antibiotic disks and Etest strips	
1	Refer to MIC60070-Stock Culture Maintenance for the maintenance of ATCC QC organisms that are needed for antibiotic quality control.
2	Test the control organisms using the antimicrobial disks and Etest strips which are used to test clinical isolates.
3	The stock supply and working supply of disks and Etest strips are stored in the microbiology reagent refrigerator.
4	The working supply of antibiotic disks is changed monthly, on the first Monday of the month by the assigned bench technologist.
5	Antibiotic quality control testing agar is kept in the microbiology media refrigerator.
6	If opening a new package of antibiotic disks or E-7test strips and the package contains a yellow "NEW LOT Record #" sticker, ensure to activate new lot number and inactivate previous lot number in TQC. Refer to MIC61020-Opening and Closing Microbiology Lot Numbers in TQC.
7	Antibiotic quality control is to be performed weekly by the Wednesday QC technologist. Orders are automatically generated in TQC.
8	Refer to MIC52600-Etest Strips and MIC52100-Disk Diffusion Test for procedure used to perform KB and Etest testing.
9	Place antimicrobial disks and Etest strips on plates as per MIC60021-Antibiotic Quality Control Job Aid.
10	Incubate Mueller Hinton agar in the O_2 incubator for 18 to 24 hours.
11	Incubate Mueller Hinton agar with 5% sheep blood and Haemophilus Test media in the CO_2 incubator for 18 to 24 hours.

INTERPRETATION OF RESULTS:

1	On Thursday, the Urine Bench technologist will record results in TQC. Refer to MIC61030-Entering Microbiology QC Results into TQC.
2	The maximum and minimum zone diameters, based on CLSI M100, are stored in TQC to ensure zone diameters obtained from QC testing are within acceptable limits.
3	If an out-of-control result is obtained and is due to an obvious error (e.g., improper disk storage, contamination, incorrect QC strain used): • Enter results into TQC. Refer to MIC61030-Entering Microbiology QC Results into TQC • Record reason for out-of-control result • Re-test on the same day • Do not report patient results with disk/Etest until resolved • If the repeated result is in range, no further action is required
4	If an out-of-control result is obtained and is NOT due to an obvious error: • Enter the result into TQC. Refer to MIC61030-Entering Microbiology QC Results into TQC • Take the disk or Etest strips out of service to prevent being used for patient results • Test the antimicrobial agent-QC strain combination for 5 consecutive test days • Enter all results into TQC
5	If all 5 test days are within the acceptable range, weekly testing may be resumed.
6	If all 5 test days are NOT within the acceptable QC range, continue daily testing until the problem is resolved. Investigate possible procedural problems (e.g., measurement of zones, storage and expiration dates of reagents, equipment, and maintenance of QC organism).
7	Once the problem is resolved, weekly testing cannot resume until satisfactory performance is demonstrated using the "20 to 30 day plan". 1. Perform QC daily with the antimicrobial agent-QC strain combination until results from 20 consecutive days have been obtained 2. Proficiency in performing QC testing is confirmed if no more than 1 of 20 results is outside the acceptable range 3. Weekly QC testing can then be resumed 4. If 2 or 3 of the 20 results are out-of-control, continue testing for a total of 30 days 5. If no more than 3 of 30 results are outside the acceptable range, proficiency is demonstrated and weekly testing can be initiated 6. If ≥4 results are out-of-control, proficiency is not demonstrated and daily QC testing must be continued until the "30 day plan" is acceptable
8	Until the problem is resolved, it may be necessary to use an alternate susceptibility testing method (i.e. refer to *Dyna*LIFE).
9	Refer to the CLSI disk diffusion troubleshooting guide for further suggestions for corrective action and resolution of out-of-control QC issues.

LIMITATIONS:

1. Before using the Etest strips from an unopened package, visually inspect to ensure the package is intact. Do not use if the package has been damaged.
2. When removed from the refrigerator, allow the Single Pack or Multi-Pack cartridge to reach room temperature before opening (approx. 15 minutes if stored at +4°C or approx. 30 minutes if stored at -20°C) and remove the strip from the package just before use.
3. Ensure that moisture condensing on the outer surface has evaporated completely before opening the package.
4. Do not touch the surface of the strip that contains the gradient (the side opposite the MIC scale.
5. When handling Etest strips manually with forceps or a similar device, only grip the handle of the strip (the area containing the 2-or 3-letter code).
6. Numerous factors can affect results, including inoculum size, rate of growth, formulation and pH of media, incubation environment and length of incubation, disk content and drug diffusion rate, and measurement of endpoints. Strict adherence to the procedure is required to ensure reliable results.

CROSS-REFERENCES:

- MIC52100-Disk Diffusion Test
- MIC52600-Etest Strips
- MIC60021-Antibiotic Quality Control Job Aid
- MIC60070-Stock Culture Maintenance
- MIC61020-Opening and Closing Lot Numbers in TQC
- MIC61030-Entering Microbiology QC Results into TQC

REFERENCES:

1. 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
2. CLSI. *Performance Standards for Antimicrobial Susceptibility Testing.* 29th ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2019
3. CLSI. *Performance Standards for Antimicrobial Disk Susceptibility Tests.* 13th ed. CLSI standard M02. Wayne, PA: Clinical and Laboratory Standards Institute; 2018
4. Oxoid. (2018). *Antimicrobial Test Disks* package insert

APPROVAL:

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Date

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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