

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): NA	
Effective Date:	Next Review Date:
Issuing Authority: Director, Laboratory and Diagnostic Imaging Services	Date Approved:
Accreditation Canada Applicable Standard: NA	

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**GUIDING PRINCIPLE:**

To control the precision and accuracy of the KB disks and ETEST strips which are used to test clinical isolates, they need to be tested weekly on the Wednesday QC bench.

**PURPOSE/RATIONALE:**

This standard operating procedure describes the weekly quality control of KB disks and ETEST strips.

**SCOPE/APPLICABILITY:**

This standard operating procedure applies to Medical Laboratory Technologists (MLTs) performing KB disk and ETEST strip quality control.

**REAGENTS and/or MEDIA:**

- Oxoid KB disks
- bioMerieux ETEST strips
- ATCC organisms
- Mueller-Hinton agar
- Mueller-Hinton agar with 5% sheep blood
- Haemophilus Test Medium

**SUPPLIES:**

- Plastic VITEK tubes and caps
- 0.45% Saline
- Sterile swabs
- Forceps
- Small, metric ruler

**EQUIPMENT:**

- VITEK DENSICHEK
- 35° ambient air incubator and 35° CO<sub>2</sub> incubator

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### **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.

### **PROCEDURE INSTRUCTIONS:**

Step	Action
<b>Performing quality control of KB disks and ETEST strips</b>	
<b>1</b>	Refer to MIC60070-Stock Culture Maintenance for the maintenance of ATCC QC organisms that are needed for antibiotic quality control.
<b>2</b>	Test the control organisms using the KB disks and ETEST strips which are used to test clinical isolates.
<b>3</b>	The stock supply and working supply of KB disks and ETEST strips are stored in the microbiology reagent refrigerator.
<b>4</b>	The working supply of KB disks is changed monthly, on the first Monday of the month by the assigned bench technologist.
<b>5</b>	Antibiotic quality control testing agar is kept in the microbiology media refrigerator.
<b>6</b>	If opening a new package of KB disks or ETEST 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.
<b>7</b>	Antibiotic quality control is to be performed weekly by the Wednesday QC technologist. Orders are automatically generated in TQC.
<b>8</b>	Refer to MIC52100-KB Disks and MIC52600-ETEST Strips for procedure used to perform KB and ETEST testing.
<b>9</b>	Place KB disks and ETEST strips on plates as per MIC60021-Antibiotic Quality Control Job Aid.
<b>10</b>	Incubate Mueller Hinton agar in the O <sub>2</sub> incubator for 18 to 24 hours.
<b>11</b>	Incubate Mueller Hinton agar with 5% sheep blood and Haemophilus Test media in the CO <sub>2</sub> incubator for 18 to 24 hours.

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## INTERPRETATION OF RESULTS:

Step	Action
<b>1</b>	On Thursday, the antibiotic quality control results will be entered into TQC. Refer to MIC61030-Entering Microbiology QC Results into TQC.
<b>2</b>	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.
<b>3</b>	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): <ul style="list-style-type: none"> <li>• Enter results into TQC. Refer to MIC61030-Entering Microbiology QC Results into TQC</li> <li>• Record reason for out-of-control result</li> <li>• Re-test on the same day</li> <li>• Do not report patient results with KB disk/ETEST strip until resolved</li> <li>• If the repeated result is in range, no further action is required</li> </ul>
<b>4</b>	If an out-of-control result is obtained and is NOT due to an obvious error: <ul style="list-style-type: none"> <li>• Enter the result into TQC. Refer to MIC61030-Entering Microbiology QC Results into TQC</li> <li>• Take the KB disk or ETEST strip out of service to prevent being used for patient results</li> <li>• Test the antimicrobial agent-QC strain combination for 5 consecutive test days</li> <li>• Enter all results into TQC</li> </ul>
<b>5</b>	If all 5 test days are within the acceptable range, weekly testing may be resumed.
<b>6</b>	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).
<b>7</b>	Once the problem is resolved, weekly testing cannot resume until satisfactory performance is demonstrated using the "20 to 30 day plan": <ol style="list-style-type: none"> <li>1. Perform QC daily with the antimicrobial agent-QC strain combination until results from 20 consecutive days have been obtained</li> <li>2. Proficiency in performing QC testing is confirmed if no more than 1 of 20 results is outside the acceptable range</li> <li>3. Weekly QC testing can then be resumed</li> <li>4. If 2 or 3 of the 20 results are out-of-control, continue testing for a total of 30 days</li> <li>5. If no more than 3 of 30 results are outside the acceptable range, proficiency is demonstrated, and weekly testing can be initiated</li> <li>6. If <math>\geq 4</math> results are out-of-control, proficiency is not demonstrated, and daily QC testing must be continued until the "30 day plan" is acceptable</li> </ol>
<b>8</b>	Until the problem is resolved, it may be necessary to use an alternate susceptibility testing method (i.e. refer to APL).
<b>9</b>	Refer to the CLSI disk diffusion troubleshooting guide for further suggestions for corrective action and resolution of out-of-control QC issues.

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### **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 KB disks 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 ETEST 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-KB Disks
- 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*. 12th ed. CLSI standard M07. Clinical and Laboratory Standards Institute; 2024.
2. CLSI. *Performance Standards for Antimicrobial Susceptibility Testing*. 35th ed. CLSI supplement M100. Clinical and Laboratory Standards Institute; 2025.
3. CLSI. *Performance Standards for Antimicrobial Disk Susceptibility Tests*. 14th ed. CLSI standard M02. Clinical and Laboratory Standards Institute; 2024.
4. Oxoid. (2023). *Antimicrobial Test Disks* package inserts.
5. bioMérieux. (2021). *ETEST Strips* package inserts.

### **APPROVAL:**

\_\_\_\_\_  
Date

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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	02 Jun 25	Procedure reviewed	L. Steven

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