PURPOSE: To control the precision and accuracy of the antibiotic disks and E-test strips which are used to test clinical isolates.

REAGENTS:

- Oxoid antimicrobial test disks
- Liofilchem MIC Test Strips

SUPPLIES:

- Plastic Vitek tubes and caps
- 0.9% Saline
- Sterile swabs
- DensiCHEK Plus
- ATCC organisms
- Mueller-Hinton agar
- Mueller-Hinton agar with 5% sheep blood
- Haemophilus Test Medium
- Forceps
- 35° ambient air incubator and 35° CO_2 incubator
- Small, metric ruler

SPECIAL SAFETY PRECAUTIONS:

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potentially infectious materials or cultures.

- 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 to 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. Universal precautions 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 E-test 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 E-test strips which are used to test clinical isolates.
3	The stock supply and working supply of disks and E-test 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 wound bench technologist.
5	Antibiotic quality control testing agar is kept in the microbiology media refrigerator.
6	If opening a new package of antibiotic disks, E-test strips or quality control testing agar, and the package contains a yellow “NEW LOT Record #” sticker, ensure to activate new lot number and inactivate previous active lot number in TQC. Refer to MIC60100-Activating and Inactivating Lot Numbers in TQC.
7	Antibiotic quality control is be performed weekly by the Wednesday 9-5 technologist. Orders are automatically generated in TQC.
8	Refer to MIC50800-Etest and MIC51000-Disk Diffusion Test for procedure used to perform KB and E-test testing.
9	Place antimicrobial disks and E-test 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.
12	On Thursday the Urine Bench technologist will record results in TQC. Refer to 60110.
13	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.
14	If an out-of-control result is obtained and is due to an obvious error (e.g., improper disc storage, contamination, incorrect QC strain used) that is easily corrected: ➢ Enter results into TQC. Refer to MIC60110. ➢ Record reason for out-of-control result. ➢ Re-test on the same day. ➢ If the repeated result is in range, no further action is required.

15	If an out-of-control result is obtained and is NOT due to an obvious error: ➢ Enter the result into TQC. Refer to MIC60110. ➢ Test the antimicrobial agent-QC strain combination for 5 consecutive test days. ➢ Enter all results into TQC.
16	If all 5 test days are within the acceptable range, weekly testing may be resumed.
17	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).
18	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.
19	Until the problem is resolved, it may be necessary to use an alternate susceptibility testing method (i.e. refer to DynaLIFE).
20	Refer to the CLSI disk diffusion troubleshooting guide for further suggestions for corrective action and resolution of out-of-control QC issues.

REFERENCES:

- 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 Susceptibility Testing.* 29th ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.
- CLSI. *Performance Standards for Antimicrobial Disk Susceptibility Tests.* 13th ed. CLSI standard M02. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

REVISION HISTORY:

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