COMPLETION OF MICROBIOLOGY LABORATORY QUALITY CONTROL FORMS: *Antimicrobial Susceptibility Tests*

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General Information

- This is a review of standard forms for the documentation of antimicrobial susceptibility quality control testing.
- Quality control tests must be performed, accessed for acceptability and documented before the review and reporting of patient test results.
- **All record fields must be completed unless otherwise instructed.**

First Steps In Test Performance

- The receipt of all test supplies must be documented, the integrity of the packaging and the product accessed, and the date of receipt recorded on the product when placed into inventory.
- Quality control testing must be performed on all test material components (i.e., media, diluents, antibiotic disks/gradient strips/test systems) upon receipt by the laboratory to assess the impact of shipping conditions on the products and to ensure adequacy for patient testing.
- Materials that do not yield acceptable performance must be removed from use and the vendor notified for verification, replacement and/or credit.
- Timely testing is required, or the vendor may refuse notification and corrective action.

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Antibiotic Disk Inventory Quality Control Log: Escherichia coli ATCC 25922 **YEAR:_____**

Antibiotic Disk	Antibiotic Disk Lot#	Brand	Quantity	Unit	Receipt Date	Expiration Date	Test Date	Acceptable QC Range (mm)*	Zone Size (mm)	QC Acceptable (Yes/No)	Corrective Action	Tech/Date

*As stated in the current CLSI standard

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E-Test Strip Inventory Quality Control Log: Escherichia coli 25922 **YEAR:_____**

ANTIBIOTIC	Antibiotic Strip Lot#	QUANTITY	UNIT	Date Received	Expiration Date	Test Date	Acceptable QC Range (ug/mL)*	MIC (ug/mL)	QC Acceptable (Yes/No)	Corrective Action	Tech/Date

*As stated in the current CLSI standard

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ESBL Confirmation Test QC

- Record the date/tech setting up the test.
- Record the media lot number, expiration date, and date received
- Record the lot number and expiration date for each antibiotic disk used.
- After the required incubation period:
  - Record the date/tech recording the test results.
  - Record antibiotic disk zone sizes first to determine if testing is acceptable for the interpretation of patient tests.
  - If acceptable, record the zone sizes of the antibiotic inhibitor combination disk.
- Calculate the zone size ratio for each test. If acceptable, proceed with patient test interpretation.
- **DO NOT REPORT PATIENT TESTING** if unacceptable. Repeat quality control and patient testing with fresh, well isolated colonies.

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ESBL Confirmation Agar Disk Diffusion Susceptibility Quality Control Log

Quality Control Frequency	Perform quality control testing for each lot or shipment of antibiotic disk, and each day of patient testing

					Escherichia coli ATCC 25922		Klebsiella pneumoniae ATCC 700603	
Date/Tech	**Muellar Hinton Agar**	**Antibiotic disk**	**Disk Lot #**	**Exp. date**	**accepted**	**measured**	**accepted**	**measured**
Set Up:	**Lot #/Expiration:**	Cefotaxime/Clavulanate 30/10mcg						
Recorded:	**Date Rec'd:**	Cefotaxime 30 mcg			29-35 mm		17-25 mm	
		Zone Size Ratio			**≤2 mm**		**≥3 mm**	
		Ceftazidime/Clavulanate 30/10 mcg						
		Ceftazidime 30 mcg			25-32 mm		10-18 mm	
		Zone Size Ratio			**≤2 mm**		**≥5 mm**	
Set Up:	**Lot #/Expiration:**	Cefotaxime/Clavulanate 30/10mcg						
Recorded:	**Date Rec'd:**	Cefotaxime 30 mcg			29-35 mm		17-25 mm	
		Zone Size Ratio			**≤2 mm**		**≥3 mm**	
		Ceftazidime/Clavulanate 30/10 mcg						
		Ceftazidime 30 mcg			25-32 mm		10-18 mm	
		Zone Size Ratio			**≤2 mm**		**≥5 mm**	
Set Up:	**Lot #/Expiration:**	Cefotaxime/Clavulanate 30/10mcg						
Recorded:	**Date Rec'd:**	Cefotaxime 30 mcg			29-35 mm		17-25 mm	
		Zone Size Ratio			**≤2 mm**		**≥3 mm**	
		Ceftazidime/Clavulanate 30/10 mcg						
		Ceftazidime 30 mcg			25-32 mm		10-18 mm	
		Zone Size Ratio			**≤2 mm**		**≥5 mm**	

Do not report out drug interpretation for antibiotics that are out of control. Notify the laboratory manager or designee of all out of control results.
Note corrective action on laboratory quality assurance and quality improvement form. HIGHLIGHT NEW DISK LOTS **PLEASE RECORD ACTUAL ZONE SIZES**
Reference: Current CLSI M100- S# Standard

Kirby Bauer Disk Agar Diffusion Test QC

- Record the date/tech setting up the test.
- Record the media lot number, expiration date, and date received
- Record the lot number and expiration date for each antibiotic disk used.
- **NOTE:** ***Do not use antibiotic trade names in the record when performing miscellaneous disk testing.***
- After the required incubation period:
  - Record the date/tech recording the test results.
  - Record antibiotic disk zone sizes first to determine if testing is acceptable for the interpretation of patient tests.
  - Record the status of testing (Results acceptable (Yes/No).
- **DO NOT REPORT PATIENT TESTING** if the QC testing is unacceptable. Repeat quality control and patient testing with fresh, well isolated colonies.

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ESBL Confirmation Agar Disk Diffusion Susceptibility Quality Control Log

Quality Control Frequency	Perform quality control testing for each lot or shipment of antibiotic disk, and each day of patient testing

Date/Tech	Muellar Hinton Agar	Antibiotic disk	Disk Lot #	Exp. date	Escherichia coli ATCC 25922 accepted	Escherichia coli ATCC 25922 measured	Klebsiella pneumoniae ATCC 700603 accepted	Klebsiella pneumoniae ATCC 700603 measured
Set Up:	**Lot #/Expiration:**	Cefotaxime/Clavulanate 30/10mcg						
Recorded:	**Date Rec'd:**	Cefotaxime 30 mcg			29-35 mm		17-25 mm	
		Zone Size Ratio			**≤2 mm**		**≥3 mm**	
		Ceftazidime/Clavulanate 30/10 mcg						
		Ceftazidime 30 mcg			25-32 mm		10-18 mm	
		Zone Size Ratio			**≤2 mm**		**≥5 mm**	
Set Up:	**Lot #/Expiration:**	Cefotaxime/Clavulanate 30/10mcg						
Recorded:	**Date Rec'd:**	Cefotaxime 30 mcg			29-35 mm		17-25 mm	
		Zone Size Ratio			**≤2 mm**		**≥3 mm**	
		Ceftazidime/Clavulanate 30/10 mcg						
		Ceftazidime 30 mcg			25-32 mm		10-18 mm	
		Zone Size Ratio			**≤2 mm**		**≥5 mm**	
Set Up:	**Lot #/Expiration:**	Cefotaxime/Clavulanate 30/10mcg						
Recorded:	**Date Rec'd:**	Cefotaxime 30 mcg			29-35 mm		17-25 mm	
		Zone Size Ratio			**≤2 mm**		**≥3 mm**	
		Ceftazidime/Clavulanate 30/10 mcg						
		Ceftazidime 30 mcg			25-32 mm		10-18 mm	
		Zone Size Ratio			**≤2 mm**		**≥5 mm**	

Do not report out drug interpretation for antibiotics that are out of control. Notify the laboratory manager or designee of all out of control results.
Note corrective action on laboratory quality assurance and quality improvement form. HIGHLIGHT NEW DISK LOTS **PLEASE RECORD ACTUAL ZONE SIZES**
Reference: Current CLSI M100- S# Standard

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Antibiotic Gradient Strip Susceptibility Test QC

- **NOTE: Current supply vendors are BioMeriuex Etest and Lifochem.**
- Record the media lot number and expiration date.
- Record the date/tech setting up or processing the test.
- Record the antibiotic name, lot number and expiration date for each antibiotic gradient strip used. ***Do not use antibiotic trade names in the record.***
- Record the acceptable test range result (ug/mL) listed in the current Clinical Laboratory Standards Institute (CLSI) M-100 reference if not noted on the form.
- Record the quality control organism being tested (i.e., *Escherichia coli* ATCC 25922)
- After the required incubation period:
  - Record the date/tech recording the test results.
  - Record the antibiotic gradient strip QC test range first to determine if testing is acceptable for the interpretation of patient tests.
  - Record the status of testing (Results acceptable (Yes/No) if required by the form.
- **DO NOT REPORT PATIENT TESTING** if the QC testing is unacceptable. Repeat quality control and patient testing with fresh, well isolated colonies.

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Miscellaneous E-Test Strip Susceptibility Quality Control

Perform quality control testing with each new lot/shipment of disks, and with each test or weekly thereafter as specified by departmental procedure.

Type of Agar Media	Media Lot Number	Media Expiration Date	Processing Technologist	Date Tested	Recording Technologist	Date Results Recorded

Comment:

Organism/ATCC #	Organism/ATCC #	Organism/ATCC #

Antibiotic Gradient Strip	Lot#	Exp. date	Accepted	Measured	Accepted	Measured	Accepted	Measured

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Type of Agar Media	Media Lot Number	Media Expiration Date	Processing Technologist	Date Tested	Recording Technologist	Date Results Recorded

Comment:

Organism/ATCC #	Organism/ATCC #	Organism/ATCC #

Antibiotic Gradient Strip	Lot#	Exp. date	Accepted	Measured	Accepted	Measured	Accepted	Measured

Do not report out drug interpretation for antibiotics that are out of control. Notify the laboratory manager or designee of all out of control results.
Note corrective action on laboratory quality assurance and quality improvement form. HIGHLIGHT NEW DISK LOTS Reference: Current CLSI M100- S# Standard

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Viridans Streptococcus E-Test Susceptibility Quality Control Log

Quality Control Frequency	Perform quality control testing for each lot or shipment of antibiotic disk, and each day of patient testing
Quality Control Organism	Streptococcus pneumoniae ATCC 49619

Mueller Hinton Blood Agar	Antibiotic E-Test Strip	Lot #	Exp. date	Accepted	Measured	Corrective Action/Comments
Lot #:	Ceftriaxone			0.03 – 0.12 mcg/ml		
Expiration Date:	Clindamycin			0.03 – 0.12 mcg/ml		
Receipt Date:	Erythromycin			0.03 – 0.12 mcg/ml		
Test Set Up Date/Tech:	Penicillin			0.25 – 1.0 mcg/ml		
Results Recorded Date/Tech:	Vancomycin			0.12 – 0.5 mcg/ml		
Results Acceptable? Circle Yes No						
Lot #:	Ceftriaxone			0.03 – 0.12 mcg/ml		
Expiration Date:	Clindamycin			0.03 – 0.12 mcg/ml		
Receipt Date:	Erythromycin			0.03 – 0.12 mcg/ml		
Test Set Up Date/Tech:	Penicillin			0.25 – 1.0 mcg/ml		
Results Recorded Date/Tech:	Vancomycin			0.12 – 0.5 mcg/ml		
Results Acceptable? Circle Yes No						
Lot #:	Ceftriaxone			0.03 – 0.12 mcg/ml		
Expiration Date:	Clindamycin			0.03 – 0.12 mcg/ml		
Receipt Date:	Erythromycin			0.03 – 0.12 mcg/ml		
Test Set Up Date/Tech:	Penicillin			0.25 – 1.0 mcg/ml		
Results Recorded Date/Tech:	Vancomycin			0.12 – 0.5 mcg/ml		
Results Acceptable? Circle Yes No						

Shaded areas (   ) = Not tested   *Shaded areas with values (1-2 mm) = Not routinely tested*

Do not report out drug interpretation for antibiotics that are out of control. Notify the laboratory manager or designee of all out of control results.

Note corrective action on laboratory quality assurance and quality improvement form. HIGHLIGHT NEW DISK LOTS   Reference: Current CLSI M100- S# Standard

Antibiotic Susceptibility Rapid Detection Test QC

- Record the test (i.e., PBP2, Carba5, etc.) or selective media (i.e., Remel Spectra MRSA) lot number, receipt date and expiration date for the date that the testing is performed or set up.
- After the performance of the rapid test or required incubation period for the selective media:
  - Result the test by answering the result questions Yes (Y) or No (N).
    NOTE: Recording results using answers other than those listed is the same as not recording the result.
  - Record your initials in the technologist initials column.
- **DO NOT PERFORM/REPORT PATIENT TESTING** if the QC testing is unacceptable. Repeat quality control and patient testing with fresh, well isolated colonies.
- Mark the appropriate column and enter your initials once you determine that no patient testing has been performed on the date.

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PBP2 TEST

Quality Control Frequency	Perform external control testing for each lot, shipment, and each day of patient testing or every 30 days if the test is performed less frequently
Expected Results	Methicillin **Resistant** *Staphylococcus aureus* (**MRSA**) = **Positive** (Pink - Purple control line **AND** Pink-Purple sample line) Methicillin Sensitive *Staphylococcus aureus* (MSSA) = Negative (Pink - Purple control line only) ***(See test procedure for interpretation of test results)***
Results	**Yes (Y)** **No (N)** **Test Kit Not Available For Testing (NA)**

Test Date	Individualized Quality Control Plan Implemented	Patient Testing Not Performed	Lot #	Receipt Date	Expiration Date	*Staphylococcus aureus* MRSA = Positive?	*Staphylococcus aureus* MSSA = Negative?	Technologist Initials
1	☐	☐						
2	☐	☐						
3	☐	☐						
4	☐	☐						
5	☐	☐						
6	☐	☐						
7	☐	☐						
8	☐	☐						
9	☐	☐						
10	☐	☐						
11	☐	☐						
12	☐	☐						
13	☐	☐						
14	☐	☐						
15	☐	☐						
16	☐	☐						
17	☐	☐						

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REMEL SPECTRA MRSA

Quality Control Frequency	Perform external control testing for each lot, shipment, and each day of patient testing or every 30 days if the test is performed less frequently
Expected Results	*Staphylococcus aureus* **ATCC 43300** = Denim blue colonies *Staphylococcus aureus* **ATCC 29213** = No Growth *(See test procedure for interpretation of test results)*
Results	**Yes (Y) No (N) Media Not Available For Testing (NA)**

Test Date	Patient Testing Not Performed	Lot #	Receipt Date	Expiration Date	*Staphylococcus aureus* ATCC 29213 = No Growth?	*Staphylococcus aureus* ATCC 43300 = Denim blue colonies?	Technologist
1	☐						
2	☐						
3	☐						
4	☐						
5	☐						
6	☐						
7	☐						
8	☐						
9	☐						
10	☐						
11	☐						
12	☐						
13	☐						
14	☐						
15	☐						
16	☐						