Example # 3

IQCP for Disk Diffusion Antimicrobial Susceptibility Testing (AST)

Test System: Disk Diffusion Antimicrobial Susceptibility Testing (Kirby Bauer) / Twelve Disk Diffusion Test using BBL Disks

Facility:

Written by:

Date:

Implementation Date: _____

This risk assessment and IQCP plan has been approved by:

_____

on _____

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Historical Quality Review

- This lab has been using the Kirby Bauer 12 disk diffusion method for detecting beta-lactamase mediated resistance mechanisms in *Enterobacteriaceae* since January 2009
- This laboratory has been following the CLSI standards (M100, M07) and performing Equivalent QC (weekly testing of QC strains following documentation of satisfactory daily QC testing for 20-30 days) since the procedure was adopted
- Quality Control: CLIA '88 and Accrediting agency require testing of QC strains daily (or each day patient's test are performed) for AST. Alternatively, an IQCP can be developed to modify frequency of QC strain testing.
- Processes to mitigate QC errors, patient testing/ reporting errors and delayed reports are addressed in this IQCP

Information Used to Conduct Risk Assessment

1. Specimen
    a. The following policies/procedures were reviewed:
        - Patient/ Specimen Identification Policy (section 2.9)
        - Specimen Identification and General Acceptability Criteria (section 2.12)
        - Quality Control Protocol & Acceptability Criteria (section 2.2)
        - Collection and Care of Microbiology Specimens (section 2.121)
2. Test System
    a. Package inserts containing testing principle and procedure, QC recommendations, and limitations from the disk manufacturer, Becton Dickinson (BD BBL)and media manufacturer Remel, were reviewed
    b. Manufacturer alerts for antibiotic disks and media were reviewed
    c. References
        - CLSI M10
        - CLSI M02
        - CLSI M07
    d. Review of QC testing on ATCC strains *Escherichia coli* ATCC25922, *Pseudomonas aeruginosa* ATCC 27853*, Klebsiella pneumoniae* ATCC 700603 conducted weekly for the following time frame: June 2014 to December 22, 2015.

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e. The following policies/procedures were reviewed:
    - Twelve Disk Diffusion Test Procedure (section 11.6)

f. Previously known as the Ten Disk Test, 30 day validation was carried out from June 3, 2008 through July 2, 2008

g. Added later, Meropenem and Cefotetan disks had 30 day QC performed from May 9,2012 to June 7,2012

3. Test Personnel
    a. The following policies/procedures were reviewed:
        - Competency Assessment for Laboratory Testing Personnel (section 2.20). Competency Assessment (CA) is performed 6 months after initial training and annually thereafter. Documentation filed in Manager's office.
        - Microbiology CAP Specimen Handling (section 2.1)
        - Training documentation is located in the Manager's office
4. Environment
    a. Review of daily temperature checks for the microbiology lab for the time period June 01, 2014 to December 22, 2015
    b. Policy for temperature Monitoring (section 2.13)
5. Reagents
    a. Maintenance/Preparation of QC Cultures Section II (section 2.4)
    b. Section III of Microbiology procedure manual: Specimen Handling, Media, Set-up
    c. Section IV of Microbiology procedure manual: Cultures, Aerobic and Anaerobic
6. Regulatory and Accreditation Requirements
    a. CAP Accreditation IQCP Requirements: See items COM.50300, COM.50400, COM.50500, COM.50600
    b. CAP Proficiency Testing (PT) surveys for 2015 for Bacteriology were reviewed. Surveys are located in the Manager's office
    c. Quality Control: CLIA '88 and Accrediting agency require testing of QC strains daily (or each day patient's test are performed) for AST. Alternatively, an IQCP can be developed to modify frequency of QC strain testing.

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Risk Assessment Summary

a. A total of 43 patient isolates were tested during time period from June 01, 2014 through December 22,2015
b. Approximately 1968 antibiotic disks were tested with QC organisms during this time period
c. There were no corrected patient reports related to the Twelve Disk Diffusion Test
d. No out of range results were found upon review of weekly disk QC results
e. Daily temperature checks for the laboratory showed no out of range values

Risk Assessment

Determination of Risk Level Scale

Probability of Harm	**Severity of Harm**			
	No risk	**Low** (not requiring medical intervention)	**High** (impairment requiring medical intervention)	**Critical** (permanent impairment requiring medical intervention)
Frequent (1/wk)	Acceptable	Not acceptable	Not acceptable	Not acceptable
Probable (1/mo)	Acceptable	Acceptable	Not acceptable	Not acceptable
Occasional (1/ 6-12 mo)	Acceptable	Acceptable	Acceptable	Not acceptable
Unlikely (once every 2/3 yrs)	Acceptable	Acceptable	Acceptable	Acceptable

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Table 1: Risk Assessment- Measures to Control Pre-Analytical Risks

Risk Factor	Possible Error	How can sources of error be reduced?	Risk Level with solutions in place
Specimen (Primary): Patient identification Collection/container/volume Transport Specimen Integrity	Improper specimen procurement/handling/ processing	Adhere to procedures 2.9, 2.12, 2.2, 2.121 addressing patient identification specimen collection by source, labeling, transport, storage Competency assessment performed	Acceptable. Specimens rejected if mislabeled or improperly handled
Specimen (Organism):			
Clinically Relevant	Clinically irrelevant organism tested	Procedure Manual Section V: Guidelines for culture Workup (section 5.0)	Acceptable. Training/ Competency testing performed
Colony Age/Viability/Sampling	Colonies on source plate >24 hrs. or less than 18 hrs. old	Emphasize organism growth requirements during initial training and competency testing	Acceptable. Training/ Competency testing performed
Pure Isolate	Mixed inoculum when setting up susceptibility may lead to erroneous results	During initial training and competency testing, emphasize proper organism selection, risks of selecting poorly isolated colonies, potential sources of contamination, impact of delayed results	Acceptable. Procedures in place to prevent mixed inoculums/ and to avoid reporting contaminated plates
Inoculum suspension	Over inoculation or under inoculation Use on nonviable colonies	Use of photometric device for inoculum standardizations Emphasize importance of proper inoculum suspensions during initial training and competency testing	Acceptable. Procedures in place to standardize inoculum suspensions Nonviable colonies would not grow on susceptibility media
Species appropriate	Testing of species not indicated for test system	During initial training and competency testing, emphasize species that can be reliably tested by test system based on manufacturer's recommendations	Acceptable. Twelve Disk Diffusion Test Procedure (section 11.6)procedures specifies acceptable organisms

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Table 2: Risk Assessment Measures to Control Analytical Risks

Risk Factor	Possible Error	How can sources of error be reduced?	
Testing Personnel:			
Training	Improper training on setting up disks can lead to inaccurate results or delays in reporting results	During initial training and competency testing, emphasize the key aspects of proper setup, AST rules, reporting	Acceptable – training is completed and competency is checked prior to tech performing and reporting patient results.
Competency	See above	See above	
Proficiency Testing	Reporting incorrect results on CAP surveys	See above	Acceptable– Review of CAP survey results shows no errors in testing for the past year.
Staffing	Staff shortage can cause: • Incorrect disks being used • Incorrect interpretations • No documentation of errors • QC not being done in timely fashion	Supervisor to annually review appropriate staffing needs Monthly review of QC results will detect errors	Acceptable. Measures in place to detect staffing issues
Reagents:			
Shipping receiving/storage	• Incorrect ordering • Depleted disk or media supply • Disk integrity compromised • Contaminated media not detected when shipment arrives	• Designated staff assigned to inventory (order/receipt) disks and media to ensure inventory properly maintained • Reagents are shipped and stored according to manufacturer's instructions	Acceptable. Products not properly shipped/ stored are discarded
Expiration Dates	Use of expired media, disks, may lead to invalid results	Educate personnel to check dates before use	Acceptable. Expired products are not used
Preparation/Use	• Disks and/or media are removed from refrigerator /freezer and not warmed to room temperature • Once disks are opened they should be placed in a tightly sealed, desiccated container	During initial training and competency assessment, emphasize: • Removal of stored disks from freezer or refrigerator with sufficient time to equilibrate to room temperature • Proper storage of opened disks • Proper preparation/inoculation/incubation of	Acceptable. Media/disks not properly handled will be discarded

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	for storage	Mueller Hinton plate	
QC strain storage/prep	• Using QC strain that is not 18-24 hrs. old • QC organisms may degrade if improperly stored, yielding inaccurate results • Using incorrect organism	Keeping QC records up to date to detect errors Monthly review of QC logs by supervisor	Acceptable. Measures in place to detect out of range results
Environment:			
Temperature/airflow/humidity/ ventilation	Results not reported due to incubation malfunction (low or increased temperature) Freezer or refrigerator malfunction	Daily temperature recording During initial training and competency assessment, emphasize importance of equipment maintenance, and notification of environmental problems to supervisor/manager	Acceptable. Measures in place to detect environmental factors
Test System:			
Inoculation of agar plate	Improper streaking of plate leading to lawn of growth that is not confluent	During initial training and competency assessment, emphasize: Adherence to procedure section 11.6 for correct inoculation of AST media, application of disks, incubation time and atmosphere	Acceptable. Training measures in place to avoid errors
Application of disks	Disks relocated after placing on plate Disks placed too close together so that zones are overlapping	See above	Acceptable. Training measures in place to avoid errors
Incubation time/atmosphere	AST plates not incubated under appropriate atmospheric conditions AST plates not incubated for the recommended time range	See above	Acceptable. Training measures in place to avoid errors
Measurements of zones of inhibition	Failure to recognize inadequate growth or contamination	During initial training and competency assessment, emphasize: • Proper measurement of zone sizes using a measuring caliper or metric ruler	Acceptable. Training measures in place to avoid errors

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		• Recognition of contaminated plate	
Interpretation of zone sizes	Incorrect interpretation of zone of inhibition leading to erroneous results Error made when documenting results on 12 disk worksheet	During initial training and competency assessment, emphasize: • Follow M02 tables for correct interpretive criteria based on organism and zone size	Acceptable. Training measures in place to avoid errors

Table 5: Risk Assessment- Measures to Control Post-Analytical Risks

Risk Factor	Possible Error	How can sources of error be reduced?	
Test Results:			
Transcription errors during LIS entry	Incorrect interpretations entered when transferring 12 disk worksheet results to Meditech	During initial training and competency assessment, emphasize: • Accuracy when entering manual results	Acceptable – training is completed and competency is checked prior to tech reporting patient results.
Review reported results	Results reported on incorrect patient	Daily review of final reports by designated tech or lead tech Supervisor maintains summary of incorrect results released	Acceptable. Measures in place to detect errors or unusual reports

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Quality Control Plan (QCP)

1. Weekly testing of ATCC QC organisms following CLSI guidelines to ensure acceptable zone sizes are achieved
2. Any out or range result is immediately investigated and corrective action performed. Repeat testing on QC organisms performed before or concurrently along with patient specimens
3. Testing of appropriate QC strains for 20 to 30 consecutive days for each new drug added to 12 Disk panel concurrently or before reporting patient isolate results
4. Patient results are reviewed daily and reporting errors are investigated and corrective action taken
5. Any out of range QC result or unusual patient result should be brought to the attention of the supervisor/lead tech for immediate investigation
6. Manufacturer alerts and bulletins will be reviewed and acted on appropriately as necessary
7. Specimen quality
    a. Clinically relevant organisms are being tested
    b. Viable colonies being used (colonies 18 – 24 hrs. old)
    c. Use of turbidity meter for proper inoculum suspension
8. Proficiency testing (PT) failures are addressed as soon as possible
9. Training and competency of testing personnel is kept up to date

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Quality Assessment: Ongoing Monitoring for QCP Effectiveness

1. Documented review of QC will be performed by supervisor or designee monthly to ensure QC is accurately performed and documented
2. Monthly review of complaints from clinicians and other healthcare providers regarding the quality of the testing to confirm the clinical efficacy of testing
3. Monthly evaluation of errors if identified
4. Monthly evaluation of corrective actions taken if identified
5. Review of staff training and competency assessments carried out according to standard laboratory protocols
6. Regular review of Proficiency Testing results
7. IQCP reviewed at least annually and revised as needed by the lab director or designee