# Example # 2

## IQCP for Antimicrobial Susceptibility Testing (AST)

## Test System: Beckman Coulter Microscan Walkaway 96

## 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 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) for over 25 years without any significant QC problems.
- Processes to mitigate QC errors, patient testing/ reporting errors and delayed reports are addressed in this IQCP
- Current Microscan Walkaway 96 plus has been in use since June 2014
- 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.

**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)
        - Guidelines for Culture Workup (section 5.0)

2. Test System
    a. The following policies/procedures were reviewed:
        - LabPro Walkaway Microscan 96 plus (section 11.0)
        - Gram Negative Susceptibilty Microscan Dried Panel (section 11.1)
        - Gram Positive Susceptibilty Microscan Dried Panel (section 11.2)
        - Microstrep plus 2 panel (section 11.4)
        - Antibiotic Reporting (section 11.5)
        - Renok System (section 11.3)

    b. Review of QC testing on ATCC strains conducted weekly, and every new lot/ shipment for time frame July 01, 2014 to December 15, 2015.

    c. Review of MicroScan Daily QC diagnostics for time frame July 01, 2014 to December 15, 2015

    d. References
        - CLSI M100
        - CLSI M02
        - CLSI M07

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e. Current panels were verified of following dates. Documentation filed in Verification and Validation of Microscan Panels binder
   i. Pos MIC panel Type 29: January 20,2015 to February 11,2015
   ii. Neg MIC Panel Type 43: January 20,2015 to February 11,2015
   iii. MicroSTREP plus 2: January 20,2015 to February 11,2015

f. Manufacturer Alerts and Bulletins were reviewed
g. Beckman Coulter Microscan package inserts ( Dried Gram Positive procedure, Dried Gram Negative procedure, MicroStrep Plus procedure) were reviewed

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
      - Microbiology CAP Specimen Handling (section 2.1)
      - Training documentation is located in the Manager's office
4. Environment
   a. Review of daily temperature/ humidity checks for the microbiology lab for the time period July 01, 2014 to December 15,2015
   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
   d. Section XI of Microbiology procedure manual: Microscan

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.

**Risk Assessment Summary**

a. QC testing was performed according to quality control sections of procedures 11.1, 11.2, 11.4S
b. Review of QC records for date range: 07/01/14 to 12/15/15, contained approximately 8496 results

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c. 27 errors out of a total of 8496 test results were found, giving us a random QC error of 0.3%.

d. In four instances, only one drug was out of range for one QC organism. In 3 instances, the QC organism had multiple drugs out of range. When the QC organisms were re-run the following day, all drugs tested within range.

e. There were 2 instances (8/25/15 and 9/01/15) where the QC organism (*S.pneumoniae*) was out of rage (too susceptible), but was not repeated the next day. The following week, on 9/08/15, the drug (penicillin) was within acceptable range.

f. There were 2 patient results using those lots of MicroStrep plus1 panels that were reported in that 2 week time frame. One on 8/28/15 and the other on 8/30/15. The organisms tested were *S.pneumoniae* and *S. constellatus*. Resistance is rare in these organisms; therefore patient impact is predicted to have been negligible.

g. Staffing shortage at the time appears to be the reason why the QC organism wasn't repeated. During this time period, the supervisor resigned and there was a vacancy. There also was an increase in patient cultures. The staff had to prioritize their work flow and at times the QC reviews may not have been done.

h. When reviewing manufacturer defined instrument function checks, our data rarely showed out of range results. Only low humidity levels were seen, which were easily identified by the daily reports and instrument alerts.

i. Beckman Coulter Microscan package inserts (Dried Gram Positive procedure, Dried Gram Negative procedure, MicroStrep Plus procedure) were reviewed with focus on system performance data, testing principles and procedure, QC recommendations, and limitations. No risks were identified after review.

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## 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<br>Collection/container/volume<br>Transport<br>Specimen Integrity | Improper specimen procurement/handling/processing<br><br>Failure to cross-check name | Adhere to procedures 2.9, 2.12, 2.2, 2.121 addressing patient identification specimen collection by source, labeling, transport, storage<br>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. old 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 or contaminated panel | • Inoculate purity plate<br>• Daily review of AST profile for aberrant results<br>• 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 detect mixed inoculum, or contaminated panels |
| Inoculum suspension | Over inoculation or under inoculation<br><br>Use on nonviable colonies | • Use of turbidity meter for inoculum standardizations<br><br>• Emphasize proper inoculum suspensions during initial training and competency testing | Acceptable. Procedures in place to standardize inoculum suspensions<br><br>Nonviable colonies would not grow on susceptibility media |
| Species indicated for test system | Testing of species not indicated for | During initial training and competency | Acceptable. Section XI of |

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| | test system | testing, emphasize species that can be reliably tested by test system based on manufacturer's recommendations | Microbiology Procedure Manual(Microscan) specifies acceptable organisms |

**Table 2: Risk Assessment- Measures to Control Analytical Risks**

| Risk Factor | Possible Error | How can sources of error be reduced? | Risk Level with solutions in place |
|---|---|---|---|
| **Testing Personnel:** | | | |
| Training/Competency | Improper training on setting up panels can lead to inappropriate panel setup technique and inaccurate results or delays in reporting results | During initial training and competency testing, emphasize the key aspects of proper panel setup, AST rules, reporting | Acceptable – training is completed and competency is checked prior to tech performing and reporting patient results. |
| 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 shortages can cause:<br>• Inadequate care taken when setting up panels and reviewing results<br>• Maintenance not being done<br>• Documentation of errors not being recorded<br>• QC not being done appropriately | Supervisor/ designee to review appropriate staffing needs daily<br><br>Monthly review of QC results will detect errors | Acceptable. Measures in place to avoid staffing issues |
| **Reagents:**<br><br>Shipping receiving/storage | Panel or diluent shipped or received outside recommended conditions leads to product degradation | Reagents are shipped and stored according to manufacturer's instructions | Acceptable. Products not properly shipped/ stored are discarded |
| Expiration Dates | Use of expired panels may lead to invalid results | Educate personnel to check dates before use | |
| Preparation/Use | Panels opened but not used that day may lead to invalid | During initial training and | |

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| | results<br><br>Cold panels or diluent may delay growth of organisms | competency testing, emphasize the key aspects of appropriate preparation and use of AST panels | |
| QC strain storage/prep | Using QC strain that is not 18-24 hrs. old<br><br>Using incorrect organism | Keeping QC(weekly, new lot) records up to date to detect errors<br><br>Monthly review of QC logs by supervisor | Acceptable. Measures in place to detect out of range results |
| **Environment:** | | | |
| Temperature/airflow/humidity/ ventilation | Elevated room temperature may lead to elevated Walkaway temperature<br><br>Low humidity may lead to drying of panels<br><br>Airflow excessive over panel setup area may lead to contamination | Instrument installed at a location following manufacturer's suggestions<br><br>Daily temperatures taken Policy for temperature Monitoring (section 2.13)<br><br>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 |
| Utilities | Incubator or Walkaway not plugged in to a dedicated electrical outlet/ UPS not installed<br>Reporting of results delayed | Have dedicated electrical outlet for instrument<br><br>Install UPS | Acceptable. Measures in place to avoid utility problems |
| Space | Inappropriate space dedicated to instrument and setup area can lead to instrument failures and waste of materials | Have sufficient space available as suggested by manufacturer | Acceptable. Instrument placed in appropriate location |
| **Test System** | | | |
| Microscan mechanical jam | Results not reported | Microscan Daily QC diagnostics printed and checked<br>Adhere to procedures outlining proper operation and | Acceptable. Measures in place to repair jam |

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| | | maintenance | |
| Software/ antimicrobial reporting rules | MICs interpreted incorrectly<br>Inappropriate drugs reported | Software (LabPro) has rules when tech review is needed<br>Daily review of results to detect inconsistencies | Acceptable. Measures in place to detect interpretation errors |
| Problem with RENOK inoculator | Correct inoculum not being delivered | RENOK delivery volumes checked monthly | Acceptable. QC being performed in RENOK |

**Table 3: Assessment- Measures to Control Post-Analytical Risks**

| Risk Factor | Possible Error | How can sources of error be reduced? | Risk Level with solutions in place |
|---|---|---|---|
| **Test Results:** | | | |
| Results reported within 5 days | Delay in reporting results beyond expected for organism | QA monitor printed and checked daily for all final cultures. Investigate cause of delay for cultures >5 days | Acceptable. Outstanding specimen report checked daily to detect delayed specimen reporting |
| Transmission of results to Electronic Health Record | Incorrect results transmitted across LabPro to the LIS interface could lead to incorrect therapy | QA monitor printed daily and checked to detect unusual results/ errors in reporting | Acceptable – Result activity report checked daily |
| Review reported results | • Inappropriate drugs reported<br>• Erroneous results reported<br>• MIC's interpreted incorrectly | See above | See above |

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**Quality Control Plan (QCP) for Microscan Walkaway**

1. Testing of appropriate QC strains on each new lot/ shipment of panels before or concurrently with placing these materials into use for testing patient isolates following the QC sections of the procedures:
    a. Gram Negative susceptibility Microscan Dried Panel (section 11.1)
    b. Gram Positive susceptibility Microscan Dried Panel (section 11.2)
    c. Microstrep plus 2 panel (section 11.4)
2. Testing of appropriate QC strains on each panel type weekly
3. Testing of appropriate QC strains on each panel type after a major system maintenance or software upgrade before or concurrently with placing the equipment back into service
4. Testing of appropriate QC strains against any new microbial agent added to the panel for 20-30 consecutive days
5. 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
6. Instrument or QC organism failures are brought to the attention of the supervisor or designee for immediate investigation
7. Patient results are reviewed daily. Reporting errors are investigated and corrective action taken
8. Proficiency testing (PT) failures are addressed as soon as possible
9. Daily monitoring of the testing environment (room temperature)
10. 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
11. Instrument maintenance checklist as outlined in LabPro Walkaway 96 Procedure Manual
12. Manufacturer alerts and bulletins will be reviewed and acted on appropriately as necessary
13. 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 at least monthly to ensure QC is accurately performed and documented
2. Documented review of equipment maintenance and function checks at least monthly by supervisor or designee
3. Monthly review of complaints from clinicians and other healthcare providers regarding the quality of the testing to confirm the clinical efficacy of testing
4. Monthly evaluation of errors if identified
5. Monthly evaluation of corrective actions taken if identified
6. Review of staff training and competency assessments carried out according to standard laboratory protocols
7. Regular review of Proficiency Testing results
8. IQCP reviewed at least annually and revised as needed by the lab director or designee