## Sample Test

The following represents one example of how you might organize your IQCP for a commercial antimicrobial susceptibility testing system. This is based in part on information included in CLSI EP23-A "Laboratory Quality Control Based on Risk Management" and CDC/CMS "Developing an IQCP, A Step-by-Step Guide". *Please note that some references to protocols, publications, performance data etc. are fictitious.*

### IQCP for Commercial Antimicrobial Susceptibility Testing (AST) System XYZ

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| **Facility:**<br>Regional Medical Center |
| **Test System:**<br>Commercial Antimicrobial Susceptibility Testing (AST) System XYZ |
| **Test System Primary SOPs include:**<br>#2.1.1 "Processing Microbiological Specimens"<br>#5.1.8 "XYZ for Performance of AST"<br>#5.1.3 "Guidelines for Selecting Isolates for AST" |
| **Historical Quality Review:**<br>CLIA '88 requires testing of QC strains daily (or each day patient's tests are performed) for AST. Previously CLIA inspector guidelines recognized use of CLSI standards M100 and M07 which indicate that weekly testing of QC strains is acceptable following documentation of satisfactory daily QC testing. This laboratory has been following the CLSI standards for over 25 years without any significant QC problems. It is rare to encounter an out-of-range result with a QC strain that indicates a test system problem. Nearly all testing errors or delays in reporting occur with individual patient isolates and these errors are unrelated to testing QC strains or a problem with testing reagents or equipment.<br>Processes to mitigate patient reporting errors and delayed reports are addressed in this IQCP. |

**Information Used to Conduct Risk Assessment**

| **Regulatory and Accreditation Requirements:** |
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| **Checklist from Accrediting Agency:**<br>Checklist items a, b, c |
| **Method verification:**<br>Instrument received and test system verification completed in year____. Subsequent verifications performed when new drugs were added (dates_____. Documentation filed in_____. |
| **Training of personnel:**<br>Completion of training documented in_____. |
| **Competency Assessment:**<br>New employees 6 months after initial training and annually thereafter. Documentation filed in_____. |
| **Proficiency Testing:**<br>Rotate personnel; all personnel review results. Proficiency testing records filed in_____. |
| **Quality Control:**<br>CLIA '88 and Accrediting Agency require testing of QC strains daily (or each day patient's tests are performed) for AST. Alternatively, an IQCP can be developed to modify frequency of testing QC strains. |

**Test System Information:**

**Manufacturer:**
Package insert contains system performance data and describes testing principle and procedure, QC recommendations, and limitations. Package insert is located _____.
Manufacturer alerts and bulletins are located _____.
Operator's manual including troubleshooting guide is located _____.

**Scientific publications used during collection of information for RA:**
Smith et al. 2012. J Laboratory Testing. 52:109.
Jones and Cartwright. 2015. Microbiology Today. 18:1821.
CLSI document M07-A10. 2015.

**Summary of in-house data from routine testing of QC strains**:
QC testing was performed according to SOP _____.
Review of QC records for the past 12 months that contained approximately 3500 results demonstrated:

- 0.8% occurrence of random QC errors that corrected upon repeat testing.
- 0.02% occurrence (one incident) of potential system QC errors that required corrective action. This error involved out-of-range QC results with imipenem that was presumed to be due to drug degradation following failure to properly store one box of panels at 2-8˚C. However, the panels were subjected to QC once the storage error was noted, found to be out-of-range and panels were discarded prior to use for testing patient isolates.

**Summary of in-house data from routine instrument performance checks**:
Instrument checks were done according to SOP _____.
Review of instrument QC records for the past 12 months that contained approximately 55 routine checks of instrument XYZ and 1 report following scheduled maintenance performed by the company's service engineer revealed no instrument performance problems that would impact patient results.

**Summary of corrected reports and physician complaints:**
Documentation located _____.
Review of reporting errors identified prior to report release, corrected reports and physician complaints and significantly delayed reports (> 5 days after specimen collection) for the past 12 months revealed:

- 38 corrected reports showed errors were due to one or more of the following:
  1) reporting inappropriate antimicrobial agents for the species/body site (n=14)
  2) erroneous MIC or interpretation due to mixed culture (n=6)
  3) erroneous MIC or interpretation due to application of inappropriate interpretive criteria (n=5)
  4) failure to add the correct reporting comment (n=9)
  5) failure to perform a susceptibility test when warranted (n=4)
- 3 formal physician complaints revealed:
  1) results erroneous for two agents reported on a single *S. aureus* isolate - repeat testing by a second method demonstrated initial MIC results and interpretations were incorrect
  2) failure to utilize appropriate interpretive criteria for the species (oxacillin/S. lugdunensis)
  3) delay in reporting results (CRE not reported for 5 days after culture submitted)
- 5 AST reports were not finalized within 5 days of specimen collection because of:
  1) delay during verification of an MDR phenotype using a second method (n=4)
  2) failure of the operator to "finalize" the report (n=1)

**Note: during this review of corrected reports and physician complaints, none of the errors could have been avoided by any changes in protocol for testing of QC strains including frequency of testing QC strains.**

**Risk Assessment and Determination of Risk Level**

| **Frequency of occurrence:** | **Severity of harm to patient:** |
|---|---|
| Unlikely (once every 2-3 years) | Negligible (temporary discomfort) |
| Occasional (once per year) | Minor (temporary injury; not requiring medical intervention) |
| Probable (once per month) | Serious (impairment requiring medical intervention) |
| Frequent (once a week) | Critical (life threatening consequences) |

**Risk Level:**
Risk level for any Risk Factor that is "Not Acceptable" must be addressed in the IQCP.
Risk level for any Risk Factor that is "Acceptable" may be included in the IQCP at the discretion of the Laboratory Director.

**Note:** Patient response plays a significant role in addition to AST results in guiding antimicrobial therapy and provides a limited safeguard for preventing harm in patients for which erroneous AST results are reported or results are delayed.

**Risk Acceptability Matrix**

| Probability of Harm | Negligible | Minor | Serious | Critical |
|---|---|---|---|---|
| Frequent | Not Acceptable | Not Acceptable | Not Acceptable | Not Acceptable |
| Probable | Acceptable | Not Acceptable | Not Acceptable | Not Acceptable |
| Occasional | Acceptable | Acceptable | Acceptable | Not Acceptable |
| Unlikely | Acceptable | Acceptable | Acceptable | Acceptable |

**Risk Acceptability Assignment**

| **Risk Factor (Possible Sources of Error)** | **Frequency of occurrence** | **Severity of harm to patient** | **Risk Level** |
|---|---|---|---|
| **Preanalytical** | | | |
| **Specimen (Primary):** | | | |
| Patient identification | probable | minor | Not Acceptable |
| Collection/container/volume | frequent | negligible | Not Acceptable |
| Integrity | frequent | negligible | Not Acceptable |
| Transport | frequent | negligible | Not Acceptable |
| Storage | probable | negligible | Acceptable |
| **Specimen (Organism):** | | | |
| Clinically relevant | probable | minor | Not Acceptable |
| Colony age/viability/sampling | frequent | minor | Not Acceptable |
| Media type | unlikely | minor | Acceptable |
| Pure isolate | frequent | serious | Not Acceptable |
| Inoculum suspension preparation | occasional | minor | Acceptable |

| Risk Factor (Possible Sources of Error) | Frequency of occurrence | Severity of harm to patient | Risk Level |
|---|---|---|---|
| **Analytical** | | | |
| **Testing Personnel:** | | | |
| Training | probable | serious | Not Acceptable |
| Competency | probable | serious | Not Acceptable |
| Experience | probable | serious | Not Acceptable |
| Proficiency Testing | unlikely | negligible | Acceptable |
| Staffing | occasional | minor | Acceptable |
| **Reagents:** | | | |
| Shipping/receiving/storage | occasional | minor | Acceptable |
| Expiration dates | unlikely | minor | Acceptable |
| Preparation/use | probable | minor | Not Acceptable |
| QC strain storage/prep | occasional | negligible | Acceptable |
| **Environment:** | | | |
| Temperature/airflow/humidity/ ventilation | unlikely | negligible | Acceptable |
| Utilities | occasional | minor | Acceptable |
| Space | unlikely | negligible | Acceptable |
| Noise/vibration | unlikely | negligible | Acceptable |
| **Test System:** | | | |
| Mechanical/electronic stability of instrument/equipment/jam | occasional | negligible | Acceptable |
| Software/antimicrobial reporting rules | frequent | serious | Not Acceptable |
| Transmission of results to LIS | unlikely | serious | Acceptable |
| **Postanalytical** | | | |
| **Test Results:** | | | |
| Results reported within 5 days | probable | serious | Not Acceptable |
| Transmission of results to Electronic Health Record | occasional | serious | Acceptable |
| Review reported results | frequent | serious | Not Acceptable |
| Clinician feedback | probable | serious | Not Acceptable |

**Risk Assessment**

| Possible Sources of Error | | How can identified sources of error be reduced? |
|---|---|---|
| **Risk Factor** | **Possible Error** | |
| | **Preanalytical** | |
| **1A: Specimen - Biological** | • Improper specimen procurement/ handling/processing | • Adhere to procedures in SOP #2.1.1 that addresses patient identification and specimen collection, labeling, transport, storage and remedial actions to control improperly handled specimens or delayed specimens.<br>• Annually review representative specimen processing errors (N=10 to 15) with all staff involved with patient specimens.<br>During initial training and competency assessment, emphasize:<br>• Proper specimen handling/processing is the most critical part of any test<br>• Failure to streak correctly (no isolated colonies) and delayed incubation may result in delayed AST reports |
| Patient/specimen identification | | See above (Specimen) |
| Collection/container/ volume | | See above (Specimen) |
| Integrity | | See above (Specimen) |
| Transport | | See above (Specimen) |
| Storage | | See above (Specimen) |
| **1B: Specimen - Organism** | | |
| Clinically relevant | • Clinically irrelevant organisms tested<br>• Additional species may be significant in select patient types (e.g., immunosuppressed)<br>• Physicians may request testing of isolates that are not clinically relevant; requests may be inappropriate and results misleading | • SOP 5.1.3 describes selecting organisms to test for AST based on organism ID, specimen source and quantity<br>• Physicians can request additional testing in select patients; comment added to final report indicating name of physician initiating special request. Supervisor/director discusses with requesting physician those requests that may be inappropriate. |
| Old or less viable | • Colonies on source plate > 1 day old | During initial training and competency assessment, emphasize:<br>• Organism growth requirements (especially S. pneumoniae) |
| Media type | • Media for inoculum source other than that recommended is used<br>• Panel fails to support growth of test organism | During initial training and competency assessment, emphasize:<br>• Appropriate media for inoculum<br>• Species that can be reliably tested by test system based on manufacturer's recommendations |
| Pure isolate | • Mixed inoculum or contaminated panel | • Solicit regular feedback on streaking of primary plates (for isolated colonies)<br>• Inoculate purity plate<br>• Daily review of AST profiles for aberrant results possibly due to mix/contamination<br>During initial training and competency assessment, emphasize:<br>• Proper organism selection for inoculum preparation<br>• Risks of selecting "young" colonies or poorly isolated colonies<br>• Potential sources of contamination during testing process<br>• Impact of delayed results (if retesting needed) |
| Inoculum suspension | • Overinoculation or underinoculation<br>• Use of nonviable colonies | • Turbidity meter for inoculum standardization<br>• Monthly colony counts of representative QC strains<br>During initial training and competency assessment, emphasize:<br>• Proper inoculum suspension preparation<br>• Impact of overinoculation (false R) or underinoculation (false S) |
| Species appropriate | • Testing of species not indicated for test system | During initial training and competency assessment, emphasize:<br>• Species that can be reliably tested by test system based on manufacturer's recommendations |

| Analytical | | |
|---|---|---|
| **2: Testing Personnel** | • Incompletely trained<br>• Unaware of updated recommendations for AST/reporting | During initial training and competency assessment, emphasize:<br>• Key aspects of AST to include those described in this IQCP<br>• Supervisor annually review any changes in AST recommendations described by accrediting agencies or standards organizations |
| Training | | See above (Testing Personnel) |
| Competency | | See above (Testing Personnel) |
| Experience | | • Supervisor review AST reports generated by new employees prior to release for the first two months of their employment |
| Proficiency Testing | | • All staff read (and sign off) on PT sample critiques |
| Staffing | Inadequate to perform testing without errors | • Supervisor to annually review appropriate staffing needs for AST and schedule staff accordingly |
| **3: Reagents** | | During initial training and competency assessment, emphasize standard rules to always:<br>• Take responsibility for reagents/supplies (all staff)<br>• Maintain reagents at proper storage conditions<br>• Check expiration dates<br>• Perform required QC |
| Receiving/storage | • Incorrect ordering<br>• Depleted reagent supply<br>• Reagent integrity compromised | • Designated staff member(s) assigned to inventory (order/receipt) AST reagents to ensure inventory properly maintained and testing materials are handled appropriately on receipt |
| Expiration dates | | See above (Reagents) |
| Preparation/use | • Use incorrect panel/card for select organism | • Use color codes on boxes of panels |
| QC strain storage/prep | • QC out of control due to improper QC strain maintenance | During initial training and competency assessment, emphasize:<br>• Proper maintenance of QC strains (limited number of subcultures)<br>• Potential sources of QC failures<br>• QC troubleshooting<br>• QC frequency<br>• Role of QC strains versus other QA measures to ensure reliable reporting of patient results |
| **4: Environment** | • Results not reported (ancillary equipment failure, e.g., incubator malfunction) | • Instrument installed at a location following manufacturer's suggestions.<br>During initial training and competency assessment, emphasize standard rules for:<br>• Take responsibility for any possible instrument/ environmental problem (out of the ordinary observation)(all staff)<br>• Equipment maintenance<br>• Temperature recording (done automatically with continuous monitoring device)<br>• Electrical supply |
| Temperature/airflow/humidity/ ventilation | | See above (Environment) |
| Utilities | | See above (Environment) |
| Space | | N/A (sufficient space available) |
| Noise/vibration | | See above (Environment) |

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| **5: Test System** | | During initial training and competency assessment, emphasize standard rules for:<br>• Take responsibility for any possible instrument/test system problem (out of the ordinary observation) |
| Mechanical/electronic/jam | Results not reported (e.g., instrument malfunction and/or aborted test) | • Perform preventive maintenance according to recommended schedule<br>During initial training and competency assessment, emphasize:<br>• How to avoid and resolve jams |
| Software/antimicrobial reporting rules | • Inappropriate drugs reported<br>• MICs interpreted incorrectly<br>• Erroneous results reported<br>• Report comments missing or inappropriate for the culture | • Software rules address (and flag) most (but not all) potential errors to be checked by tech; sometimes note for tech follow up action printed on internal report<br>• Software flags unusual results requiring supervisor review<br>• Daily supervisor (or supervisor designee) review of reported results<br>During initial training and competency assessment, emphasize:<br>• Intrinsic resistance patterns of commonly encountered species<br>• Results requiring follow up action (e.g., confirmation by repeat testing)<br>• Results requiring consultation with supervisor/director |
| Transmission of results to LIS | • Incorrect transmission of results<br>• Delay in transmission of results | • Daily supervisor (or supervisor designee) review of reported results<br>• Annual check of test system- LIS computer interface<br>• QA monitor for time to reporting AST results |
| **Postanalytical** | | |
| **6: Test Results** | | • Supervisor maintains summary of incorrect results released and meets with laboratory director monthly to review this summary<br>• QA monitor for time to reporting AST results<br>During initial training and competency assessment, emphasize:<br>• Need for timely results to guide therapy and identify potential multidrug resistant organisms that might require patient isolation<br>• Reporting preliminary results (timely reporting) |
| Results reported within 5 days | • Results delayed beyond that expected for organism type | See above (Test Results) |
| Transmission of results to Electronic Health Record | • Incorrect transmission of results<br>• Delay in transmission of results | See above (Test Results) |
| Review reported results | • Inappropriate drugs reported<br>• Erroneous results reported<br>• MICs interpreted incorrectly<br>• Report comments missing or inappropriate for the culture | See above (Test Results and Test System)<br>Note: results are checked at multiple steps by tech and then by supervisor |
| Clinician feedback | • Complaints/suggestions regarding delayed results and potential erroneous results | See above (Test Results)<br>• Incorporate suggestions into QA plan, as appropriate. |

| **Final QCP for AST System XYZ** |
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| Based on our risk assessment and Quality Assessment, the QCP consists of following the instructions that are provided in explicit detail in Quality Control Section II of SOP #5.1.8 XYZ for Performance of AST and are summarized here. |
| Testing of appropriate QC strains on each new lot/shipment of panels before or concurrently with placing these materials into use for testing patient's isolates. |
| Testing of appropriate QC strains on each panel type weekly. |
| Testing of appropriate QC strains on each panel type after major system maintenance or software upgrade before or concurrently with placing the equipment back into service. |
| Testing of appropriate QC strains against any new antimicrobial agent added to the panel at least 15 times (over a minimum of 5 days) prior to resuming weekly QC testing of the panel; accomplished during performance of verification study. |
| Recording and evaluating QC results according to QC acceptability criteria as defined in SOP #5.1.8 XYZ for Performance of AST. Any out-of-range result is immediately investigated and corrective action performed prior to releasing any patient results. |

| **Quality Assessment: Ongoing Monitoring for QCP Effectiveness (Performed by supervisor and/or section head)** | | |
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| Reasons for QC failures, PT failures, and patient isolate reporting errors will be examined and addressed as needed in a new/updated risk assessment: 1) Has a new risk factor been identified? 2) Does this change the frequency of risk? 3) Does the risk factor change the potential severity of harm to patient? | | |
| Daily review of patient results for reporting errors and clinician complaints. Take corrective action and revise QCP as needed. | | |
| Monthly review of QC results head. Take corrective action and revise QCP when unexpected QC failures indicate adjustment to the QC plan defined herein is needed. | | |
| Monthly review of length of time from specimen collection to AST result reporting to determine incidence of reports delayed beyond 5 days. Take corrective action and revise QCP when number of delayed reports exceeds acceptable limit as established by the laboratory director. | | |
| Regular review of Proficiency Testing results. Take corrective action and revise QCP if necessary when PT results are not acceptable. | | |
| Monthly review of all equipment maintenance/monitoring logs according to standard laboratory protocols. Take corrective action and revise QCP as needed. | | |
| Regular training and competency assessment according to standard laboratory protocols. Modify training and revise QCP as needed. | | |
| Continual participation in this institution's quality program that addresses specimen handling and erroneous specimen labeling. Take corrective action and revise QCP as needed. | | |
| **This QCP has been reviewed and is approved by the laboratory director (as named on the CLIA license).** | **Signature** | **Date** |