Introduction to AST IQCP

The "Individualized Quality Control Plan" (IQCP) is the Clinical Laboratory Improvement Amendments (CLIA) Quality Control (QC) policy that will become effective as an alternative QC option for all laboratory tests on January 1, 2016. What does this mean for antimicrobial susceptibility testing (AST) in your laboratory?

- You can either develop an IQCP or perform daily QC as described in current CLIA regulations.
- It will no longer be acceptable for your laboratory to follow CLSI AST guidelines alone for converting from daily to weekly testing of QC strains.
- Your laboratory will be required to develop an IQCP (or perform CLIA mandated QC) regardless of when weekly QC of AST was implemented in your laboratory.
- As you develop an AST IQCP for your laboratory, you must take into consideration all the activities that are in place to ensure quality AST results for your patients.
- Your IQCP may demonstrate that daily QC is not necessary and less frequent QC (e.g., weekly QC) is sufficient to ensure quality AST results for your patients.
- Although there are certain elements that must be included in each IQCP as defined by CMS (www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html), CMS is not prescriptive and each laboratory director must customize their own AST IQCP according to test method, patient population, environment, and personnel competency.
- The QCP (Quality Control Plan) developed in your IQCP may not be less than that required by the manufacturer.

Representatives from American Society for Microbiology (ASM), College of American Pathologists (CAP), and Clinical and Laboratory Standards Institute (CLSI) have jointly prepared materials you can use as a guide in development of an AST IQCP in your laboratory for a commercial automated AST system. Specifically, the following are available on each organization's website:

- Template (PowerPoint®) that describes the components that should be included in an IQCP for a commercial MIC AST system
- Example of a completed IQCP (tabular format)
- Listing of Q&A's

Additional materials will be developed to help you address IQCP for other tests in your clinical microbiology laboratory. Please be sure and check the CMS website (link shown above) to obtain additional information about the IQCP program.

Please note that a 'frequency of occurrence' table and a 'severity of harm' table are included in these materials.

Although it is not mandated by CMS, once the laboratory has identified sources of potential failures, it may be helpful to define and include a 'frequency of occurrence' table and a 'severity of harm' table to link the process of the Risk Assessment to the Quality Control Plan. Including this process will address what CMS does mandate, "the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error."

Reference: S&C: 13-54-CLIA A August 16, 2013 letter

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

Facility: Regional Medical Center
Test System: Commercial Antimicrobial Susceptibility Testing (AST) System XYZ
Test System Primary SOPs include: #2.1.1 "Processing Microbiological Specimens" #5.1.8 "XYZ for Performance of AST" #5.1.3 "Guidelines for Selecting Isolates for AST"
Historical Quality Review: 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. Processes to mitigate patient reporting errors and delayed reports are addressed in this IQCP.

Information Used to Conduct Risk Assessment

Regulatory and Accreditation Requirements:
Checklist from Accrediting Agency: Checklist items a, b, c
Method verification: Instrument received and test system verification completed in year____. Subsequent verifications performed when new drugs were added (dates_____. Documentation filed in_____.
Training of personnel: Completion of training documented in_____.
Competency Assessment: New employees 6 months after initial training and annually thereafter. Documentation filed in_____.
Proficiency Testing: Rotate personnel; all personnel review results. Proficiency testing records filed in_____.
Quality Control: 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. • Annually review representative specimen processing errors (N=10 to 15) with all staff involved with patient specimens. During initial training and competency assessment, emphasize: • Proper specimen handling/processing is the most critical part of any test • 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 • Additional species may be significant in select patient types (e.g., immunosuppressed) • 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 • 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: • Organism growth requirements (especially S. pneumoniae)
Media type	• Media for inoculum source other than that recommended is used • Panel fails to support growth of test organism	During initial training and competency assessment, emphasize: • Appropriate media for inoculum • 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) • Inoculate purity plate • Daily review of AST profiles for aberrant results possibly due to mix/contamination During initial training and competency assessment, emphasize: • Proper organism selection for inoculum preparation • Risks of selecting "young" colonies or poorly isolated colonies • Potential sources of contamination during testing process • Impact of delayed results (if retesting needed)
Inoculum suspension	• Overinoculation or underinoculation • Use of nonviable colonies	• Turbidity meter for inoculum standardization • Monthly colony counts of representative QC strains During initial training and competency assessment, emphasize: • Proper inoculum suspension preparation • 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: • Species that can be reliably tested by test system based on manufacturer's recommendations

Analytical		
2: Testing Personnel	• Incompletely trained • Unaware of updated recommendations for AST/reporting	During initial training and competency assessment, emphasize: • Key aspects of AST to include those described in this IQCP • 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: • Take responsibility for reagents/supplies (all staff) • Maintain reagents at proper storage conditions • Check expiration dates • Perform required QC
Receiving/storage	• Incorrect ordering • Depleted reagent supply • 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: • Proper maintenance of QC strains (limited number of subcultures) • Potential sources of QC failures • QC troubleshooting • QC frequency • 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. During initial training and competency assessment, emphasize standard rules for: • Take responsibility for any possible instrument/ environmental problem (out of the ordinary observation)(all staff) • Equipment maintenance • Temperature recording (done automatically with continuous monitoring device) • Electrical supply
Temperature/airflow/humidity/ ventilation		See above (Environment)
Utilities		See above (Environment)
Space		N/A (sufficient space available)
Noise/vibration		See above (Environment)

5: Test System		During initial training and competency assessment, emphasize standard rules for: • 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 During initial training and competency assessment, emphasize: • How to avoid and resolve jams
Software/antimicrobial reporting rules	• Inappropriate drugs reported • MICs interpreted incorrectly • Erroneous results reported • 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 • Software flags unusual results requiring supervisor review • Daily supervisor (or supervisor designee) review of reported results During initial training and competency assessment, emphasize: • Intrinsic resistance patterns of commonly encountered species • Results requiring follow up action (e.g., confirmation by repeat testing) • Results requiring consultation with supervisor/director
Transmission of results to LIS	• Incorrect transmission of results • Delay in transmission of results	• Daily supervisor (or supervisor designee) review of reported results • Annual check of test system- LIS computer interface • 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 • QA monitor for time to reporting AST results During initial training and competency assessment, emphasize: • Need for timely results to guide therapy and identify potential multidrug resistant organisms that might require patient isolation • 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 • Delay in transmission of results	See above (Test Results)
Review reported results	• Inappropriate drugs reported • Erroneous results reported • MICs interpreted incorrectly • Report comments missing or inappropriate for the culture	See above (Test Results and Test System) 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) • Incorporate suggestions into QA plan, as appropriate.

Final QCP for AST System XYZ
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)		
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**

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Individualized Quality Control Plan (IQCP) PowerPoint® Template

Template for use with Commercial MIC Antimicrobial Susceptibility Testing (AST) Systems

To download PowerPoint® template, please visit **http://clinmicro.asm.org/iqcp**

Individualized Quality Control Plan (IQCP)

Template for use with Commercial MIC Antimicrobial Susceptibility Testing (AST) Systems

IQCP includes the following and each will be addressed separately:

- Risk assessment (RA) of the AST System
- Quality Control Plan (QCP) for the AST System
- Quality Assessment (QA) for the AST System

Risk Assessment

Consists of two parts:

- Collect Information/Data:
  - Identify areas (i.e. risk factors) where errors or failures could occur in the entire testing process (preanalytical, analytical, and postanalytical)
- Determine the frequency of occurrence and potential for harm to the patient for each identified risk factor.

Risk Assessment
Collect Information/Data

- Manufacturer instructions: Look specifically at the 'Limitations' section to identify possible risks. Note manufacturer's recommended QC (QC defined in your IQCP may not be less stringent than that recommended by the manufacturer). Include a copy of your manufacturer's package insert (PI) in your IQCP materials.
- Manufacturer performance data: Look for any risks associated with this system that have been identified in the manufacturer's performance data (located in the PI). Also review any manufacturer alerts or bulletins for associated risks. Include copy of the PI, alert, bulletin, etc. in your IQCP materials.
- Literature published on assay: Look for any risks associated with this system that have been identified in the literature. Be sure to consider the version of the system reported in the literature as related to the version of the system/software used in your laboratory. Include copies of pertinent articles in your IQCP materials.
- Accreditation/Regulatory requirements: Ensure that your IQCP will be in compliance with any accreditation or regulatory requirements. Include copies of these requirements in your IQCP materials.
- In-house laboratory data: Review your initial verification studies (and any subsequent studies) and historical QC data to help define your IQCP. Include these data in your IQCP materials, or identify where these reports can be found in the laboratory. Include a summary of corrected reports and physician complaints. See following page for additional details on historical QC data review.

Summary of Historical In-house AST QC data

- QC data for the past [XX] months (1/1/XX - 12/31/XX) were reviewed. Testing was performed as outlined in the QC section of SOP.xxxx.
- When testing CLSI recommended QC strains using the same procedures as for testing patient's isolates, our data showed:
  - [XX]% occurrence of random QC errors which corrected upon repeat testing, and
  - [XX]% occurrence of potential system QC errors that required corrective action beyond simple repeat testing.
- When performing/reviewing manufacturer or laboratory defined instrument records and functions checks, our data showed that there were [XX]% out-of-control observations.

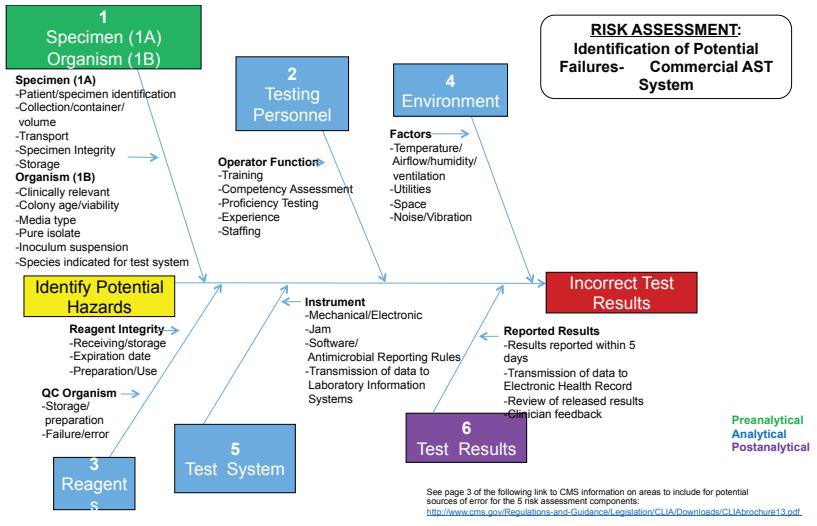
Risk Assessment

As required by CMS, evaluate at least the following five components in your Risk Assessment:

1) Specimen (also include organism for AST)
2) Testing Personnel
3) Reagents
4) Environment
5) Test System

Risk Assessment (cont'd)

- Identify where, along the testing process, risk of errors might occur.
- Determine the frequency of occurrence of the error and the possible severity of harm if an error would occur.
- See the Fishbone diagram example on the next page that lists all of the risk factors in each of the required risk assessment components



Risk Assessment Tables

Build tables to include all of the risk factors identified in your fishbone diagram (formats other than fishbone diagrams may be used).

- Determine the "Frequency of occurrence" and the possible "Severity of harm" for each risk factor identified.
- Evaluate whether the identified risk factor is "Acceptable" or "Not Acceptable"
- All risks identified as "Not acceptable" must be included in your QCP. Those identified as "Acceptable" may be included in your IQCP at the discretion of the laboratory director.

Each laboratory is unique and may have differing potential sources of error or risk factors.

Example:
Determine "Frequency of occurrence" of an error (what is the likelihood of this error occurring?)

Frequency of Occurrence
Unlikely (once every 2-3 yrs)
Occasional (1/yr)
Probable (1/mo)
Frequent (1/wk)

Example:
Determine "Severity of harm" due to this error (if this error occurs, what is the possible severity of harm to the patient as a result?)

Severity of Harm
Negligible (temporary discomfort)
Minor (temporary injury; not requiring medical intervention)
Serious (impairment requiring medical intervention)
Critical (permanent impairment requiring medical intervention)

Example of How to Determine Risk Level

Evaluate whether the risk level is “Acceptable” or “Not Acceptable”. Those that are “Not Acceptable” must be addressed in the IQCP.

- Risk Acceptability Matrix:

	Severity of Harm			
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 Assessment

- Complete your Risk Assessment: Determine which of the identified risk factors needs to be monitored or controlled regularly in the testing process or if they may already be addressed by the manufacturer in the design of the test system or monitored as part of another QA/QC protocol in your laboratory. This information will help you in developing your QCP.
  - The risk factors considered “Not Acceptable” should be monitored. The laboratory director (or designee) must determine if those considered “Acceptable” need to be specifically addressed in the QCP.
- Indicate the measures you have in place to mitigate or reduce these risks/errors (you may wish to include where to find these measures in your procedures, reports, logs, etc.).

Example: Monitoring Risk Table 1A –Specimen

Risk Factor	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Patient/ specimen identification	Occasional	Minor	Patient identification criteria defined; acceptability defined; competency assessment performed	SOP.xxxx SOP.xxxx SOP.xxxx
Collection/ Container/ Volume	Frequent	Negligible	Collection and container criteria defined per source; acceptability defined; competency assessment performed	SOP.xxxx SOP.xxxx SOP.xxxx
Transport	Frequent	Negligible	Transport criteria defined per source; acceptability defined; competency assessment performed	SOP.xxxx SOP.xxxx SOP.xxxx
Specimen Integrity	Occasional	Negligible	Specimen integrity defined per source: acceptability defined; competency assessment performed	SOP.xxxx SOP.xxxx SOP.xxxx
Storage	Occasional	Negligible	Storage criteria defined per source; acceptability defined; competency assessment performed	SOP.xxxx SOP.xxxx SOP.xxxx

Example: Monitoring Risk Table 1B – Organism

Risk Factor	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Clinically relevant	Probable	Minor	Selection criteria defined in training; competency assessment performed. Documentation of physician requests for additional testing.	SOP.xxxx SOP.xxxx
Colony Age / viability	Frequent	Minor	Selection criteria defined in training; competency assessment performed	SOP.xxxx SOP.xxxx
Media type	Unlikely	Minor	Selection criteria defined in training; competency assessment performed	SOP.xxxx SOP.xxxx
Pure isolate	Frequent	Serious	Selection criteria defined in training; competency assessment performed	SOP.xxxx SOP.xxxx
Inoculum suspension	Occasional	Minor	Preparation criteria defined in training; competency assessment performed	SOP.xxxx SOP.xxxx
Species indicated for test system	Occasional	Minor	Species indicated for testing with the test system as defined by manufacturer	SOP.xxxx

Example: Monitoring Risk Table 2 – Testing Personnel

Risk Factor	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Training	Occasional	Serious	All testing personnel have had appropriate training	SOP.xxxx (training documentation, etc.)
Competency Assessment	Occasional	Serious	All personnel have appropriate CA performed	SOP.xxxx
Proficiency Testing	Unlikely	Negligible	All PT failures addressed with corrective action	SOP.xxxx
Experience	Probable	Serious	Resulting by new, less experienced employees is peer-reviewed for a designated time.	SOP.xxxx
Staffing	Occasional	Minor	Adequate staffing to support test menu and turn-around-times on all shifts	SOP.xxxx

Example: Monitoring Risk Table 3 – Reagents

Risk Factor	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Receiving /Storage	Occasional	Minor	Reagents are shipped and stored according to manufacturer's instructions.	SOP.xxxx
Expiration dates	Unlikely	Minor	Reagents are used within expiration dates.	SOP.xxxx
Preparation/Use	Occasional	Minor	All reagents are prepared/used according to manufacturer's instructions.	SOP.xxxx
QC organism storage/ preparation	Occasional	Negligible	Results for all QC organisms are within acceptable limits. Storage and preparation of QC strains are defined.	SOP.xxxx SOP.xxxx
QC organism failure/ error	Unlikely	Negligible	AST QC log and corrective action logs	SOP.xxxx

Example: Monitoring Risk Table 4 – Environment

Risk Factor	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Temperature/ Airflow/ Humidity/ Ventilation	Unlikely	Negligible	Appropriate environmental conditions are maintained in the laboratory	SOP.xxxx
Utilities	Unlikely	Negligible	Appropriate utilities are employed in the laboratory to serve the instrumentation	SOP.xxxx
Space	Unlikely	Negligible	Appropriate space is available in the laboratory to serve the instrumentation	SOP.xxxx
Noise/Vibration	Unlikely	Negligible	Appropriate parameters are in place to serve the instrumentation	SOP.xxxx

Example: Monitoring Risk Table 5 – Test System

Risk Factor	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Mechanical/ electronic failure of instrument	Occasional	Negligible	AST Instrument Maintenance log; alternate AST procedure used during downtime of instrument	SOP.xxxx SOP.xxxx
Jam	Occasional	Negligible	Training and procedures &/or instrument operation manual is provided to resolve jams and evaluate test results after resolution.	SOP.xxxx SOP.xxxx
Software/ Antimicrobial reporting rules	Frequent	Serious	All testing personnel have had appropriate training . Regular supervisor review of reported results. Regular competency assessment.	SOP.xxxx
Transmission of data to LIS	Unlikely	Minor	Measures are in place to verify appropriate transmission of data.	SOP.xxxx

Example: Monitoring Risk Table 6 – Test Results

Risk Factor	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Results reported within 5 days	Probable	Serious	Timely transport to laboratory and processing of cultures in a timely manner. Test knowledge of timely reporting after initial training and competency.	SOP.xxxx SOP.xxxx
Transmission of results to Electronic Health Record	Occasional	Minor	Periodic review of released results to HIS.	
Review of released results	Frequent	Serious	Electronic/tech review of AST results prior to reporting. Monitor and investigate all reporting errors and inform all staff.	SOP.xxxx SOP.xxxx
Clinician feedback	Probable	Serious	Appropriate investigation for all clinician feedback, issues, complaints.	SOP.xxxx

Quality Control Plan (QCP)

Now that you have completed the risk assessment including:

- preanalytic
- analytic
- postanalytic phases

and covered the CMS mandatory 5 risk components of:

- specimen (including organism for AST)
- testing personnel
- reagents
- environment
- test system

You are now ready to develop your Quality Control Plan (QCP).

For your QCP - determine if current quality practices are adequate to detect and control failures/errors or if improvements should be implemented.

Quality Control Plan (QCP)

At a minimum, your QCP must define:

- The number, type and frequency of QC testing, which must be supported by data provided in your Risk Assessment
- Criteria for QC acceptability

NOTE: QC testing must be no less than that specified in the manufacturer's instructions

QCP cont'd

- QC for Commercial AST will consist of (for example):
  - Testing of ATCC QC organism(s) (specify organisms) per each lot /shipment on each type of AST panel before or concurrently with placing these materials into service.
  - Thereafter, weekly (or a time frame supported by your QCP) testing with ATCC QC organism(s) (specify organisms) on each type of AST panel.
  - Testing ATCC QC organism(s) (specify organisms) on each type of AST panel after each major system maintenance or software upgrade before or concurrently with placing the instrument 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) in addition to performing verification studies.
- QC Acceptability Criteria is defined in SOP.xxxx. QC results are recorded and evaluated according to acceptability guidelines. All out of range results are investigated.

Quality Assessment

The Post-Implementation Monitoring Process

Develop a "Post-Implementation Monitoring Process" that will allow you to identify when a process is in need of review/revision. These may include the review and monitoring of the following:

Staff training in specimen requirements,
test organism selection/preparation
See SOP.xxxx, SOP.xxxx
Competency assessment
See SOP.xxxx
Proficiency Testing
See SOP.xxxx
Quality Control/Instrument Function
See SOP.xxxx, SOP.xxxx
Unexpected Errors
See SOP.xxxx
Laboratory error investigation/remediation
See SOP.xxxx
Complaint investigation/remediation
See SOP.xxxx

Preanalytical
Analytical
Postanalytical

Monitoring of the Post-Implementation Process may include:

- Instrument or QC organism failures are brought to the attention of the supervisor or designee immediately for investigation (see SOP.xxxx).
- Documented review of QC will be performed by supervisor or designee weekly and by supervisor monthly to ensure QC is accurately performed and documented (see SOP.xxxx).
- PT (proficiency testing) failures are addressed as soon as possible (see SOP.xxxx).
- Patient results are reviewed daily and reporting errors are investigated and corrective action taken (see SOP.xxxx).
- Monthly review of length of time from specimen collection until reporting will be monitored for unacceptable delays (see SOP.xxxx).
- Complaint investigations are carried out in a timely manner (see SOP.xxxx).

Monitoring of the Post-Implementation Process may include: (cont'd)

- For all QC failures, PT failures, laboratory reporting errors, complaints, etc., a reassessment of risk will be performed and adjustments made to the QCP as necessary.
- The reason for failure will be identified and addressed in a new/updated risk assessment answering the following:
  - Has a new risk been identified?
  - Does this change the frequency of risk?
  - Does this risk factor change the severity of harm?
- Additional control measures will be implemented if necessary as determined by the new risk assessment.

Laboratory Director Signature

Include a signed statement by your laboratory director indicating that the IQCP/QCP has been reviewed and is acceptable. For example:

This IQCP/QCP has been reviewed and is approved by the laboratory director (as named on the CLIA license).

*Name of AST System*_____
*Name and Address of Laboratory*_____
*CLIA number*_____

Laboratory Director signature_____
Date_____

References

- CLSI. Laboratory Quality Control Based on Risk Management: Approved Guideline. CLSI document EP-23A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.
- CLIA. Individualized Quality Control Plan; Considerations When Deciding to Develop an IQCP, Brochure #12. November 2014.
  http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure12.pdf
- CLIA. Individualized Quality Control Plan; What is an IQCP?, Brochure #13. November 2014
  http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure13.pdf
- CLIA. Developing an IQCP. A Step by Step Guide. May 2015. http://wwwn.cdc.gov/CLIA/Documents/IQCP%20Layout.pdf

Antimicrobial Susceptibility Testing IQCP Questions and Answers

Test System

Q. What constitutes a "test system"?

A. Test System means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results. (Note: EP-23A uses the terminology "measuring system" for test system)

Source of Answer: CLIA 493.2 and CLSI document EP-23A

Q. When performing AST and identification on a commercial automated MIC system, do you need a separate IQCP for the AST component vs. the ID component?

A. CMS is not prescriptive on this topic. It is at the discretion of the laboratory director whether or not to have separate IQCPs for AST and identification methods done on the same instrument.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

Q. Is it acceptable to develop one IQCP to address both MIC and disk diffusion testing?

A. No. MIC and disk diffusion tests represent unique test systems despite the fact that several steps are common to each of these AST systems.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

Q. We have both a MicroScan and a Vitek 2 instrument. Can we do one AST IQCP for both?

A. No. While MicroScan and Vitek may be similar procedures, they are different make and model. You would need one IQCP for MicroScan and another IQCP for Vitek 2 since they are different instruments with differing potential risks.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

Q. We have three Vitek instruments in our laboratory. Can we do a single IQCP for all three?

A. If laboratories have multiple identical devices, one IQCP can be developed for the test system taking into consideration any unique environment or testing personnel, etc. However, there must be documentation that each instrument had a separate verification process at the time it was put into use. If the instruments are located in different locations in the healthcare facility, the QCP must be developed for each one.

Source of Answer: CMS letter Ref:S&C 13-54-CLIA, Aug. 16, 2013. FAQs.

Specimen

Q. For susceptibility testing, what is the "specimen" evaluated in the risk assessment? Is it the primary clinical specimen or the organism isolated in culture?

A. CMS is not prescriptive on this topic. The specimen must be addressed, however, it is up to the laboratory director to determine what constitutes the specimen for an AST IQCP.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

QC Frequency

Q. Will IQCP reduce the amount of QC testing that I have to perform with my laboratory testing?

A. It is possible that your IQCP will demonstrate that less QC than previously performed may be acceptable for your AST system. However, appropriate documentation must be provided to justify any QC testing schedule. For many laboratories, historical records will likely justify your current QC testing schedule and additional data would be required to support a reduced QC testing schedule.

Source of Answer: CMS letter Ref:S&C 13-54-CLIA, Aug. 16, 2013. FAQs.

Q. What is the minimum amount of QC testing allowed with AST IQCP?

A. CMS does not set a minimum QC requirement. QC cannot be less than that recommended by the manufacturer, and must be supported by the risk assessment and QC data.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

General

Q. Can I use CLSI EP-23A "Laboratory Quality Control Based on Risk Management" (2011) to prepare my IQCP?

A. CMS guidelines are based on the general principles found in EP23-A. It may be helpful to review CMS IQCP guidelines and ensure that your laboratory QCP is based on risk management. The CMS IQCP was based on principles contained in EP23-A, but the two are not 100 percent identical.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

Q. Who is qualified to prepare the IQCP?

A. The laboratory director (individual whose name is on the CLIA certificate) has the ultimate responsibility to review, sign and date the IQCP. The laboratory director may assign, in writing, specific duties for the IQCP to qualified individuals.

Source of Answer: CLIA IQCP Brochure #13 Nov. 2014

Q. Does the risk assessment need to be done with a "Fishbone" type diagram?

A. No. CMS does not mandate any specific method for performing the risk assessment. There are many methods available for risk analysis.

Source of Answer: CMS letter Ref:S&C 13-54-CLIA, Aug. 16, 2013. FAQs.

Q. What if the inspector does not agree with the IQCP approved by the laboratory director?

A. Surveyors will use the Outcome Oriented Survey Process for compliance. This means that he/she will review your IQCP to determine if your risk assessment includes all of the requirements, if the identified risks were evaluated, if the QCP includes any risk(s) that the laboratory director has determined needs to be mitigated, and that quality assessment is occurring and ongoing. If these requirements are not met, the laboratory may be cited for deficiencies.

Source of Answer: CMS letter Ref:S&C 13-54-CLIA, Aug. 16, 2013. FAQs.

Q. When is the deadline for implementation of IQCP?

A. After the IQCP Education and Transition Period ends on December 31, 2015, laboratories have two options; 1) follow CLIA regulations, or 2) implement IQCP by January 1, 2016.

Source of Answer: CMS letter Ref:S&C 13-54-CLIA, Aug. 16, 2013.