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Individualized Quality Control Plan (IQCP) PowerPoint® Template

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

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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.

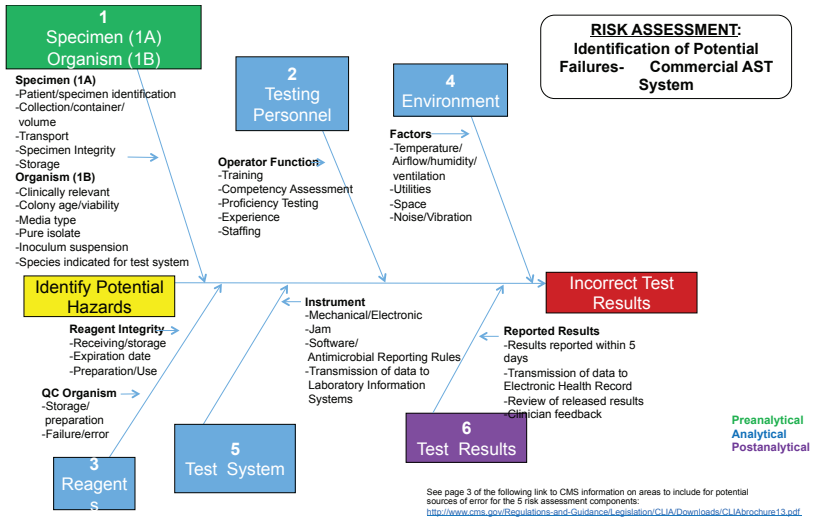
Risk Assessment

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

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