The following represents one example of how you might organize your IQCP for disk diffusion susceptibility testing. 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 Disk Diffusion Antimicrobial Susceptibility Testing (AST)

Facility: Regional Medical Center
Test System: Disk Diffusion Antimicrobial Susceptibility Testing
Test System Primary SOPs include: #2.1.1 "Processing Microbiological Specimens" #5.1.9 "XYZ for Performance of Disk Diffusion 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 inspectors' guidelines recognized use of CLSI standards M100 and M02 which indicate 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. 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 Accreditation Agency Checklist items a, b, c
Method verification: Test system was deemed acceptable based on documentation presented.
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:
Disk Manufacturer: Package insert contains testing principle and procedure, QC recommendations, and limitations. Package insert is located _____. Manufacturer alerts and bulletins are located _____.
AST Media Manufacturer:

Package inserts for all disk diffusion susceptibility testing media contain testing principle and procedure, QC recommendations, and limitations. Package inserts are located _____.
Manufacturer alerts and bulletins are located _____.

Scientific publications used during collection of information for RA:
CLSI document M02-A12. 2015.
Doe, J et al. 2011. J Laboratory Testing. 51:120.

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 2080 results demonstrated:

- 0.5% occurrence of random QC errors that corrected upon repeat testing.
- 0.04% occurrence (one incident) of potential system QC errors that required corrective action. This error involved out- of-range QC results with oxacillin disk used for testing *S. pneumoniae* that was presumed to be due to drug degradation following failure to properly store the disk cartridge at -70˚C. However, the disks were subjected to QC once the storage error was noted, found to be out of range and the disks were discarded prior to use for testing patient isolates.

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:

- 52 corrected reports showed errors were due to one or more of the following:
  1) reporting inappropriate antimicrobial agents for the species/body site (n=11)
  2) erroneous interpretation due to mixed culture (n=2)
  3) erroneous interpretation due to application of inappropriate interpretive criteria (n=15)
  4) erroneous interpretation due to incorrect zone size reading (n=9)
  5) failure to add the correct reporting comment (n=6)
  6) failure to perform a susceptibility test when warranted (n=9)
- 5 formal physician complaints revealed:
  1) errors in results from two agents reported - repeat testing by a second method demonstrated initial interpretation was incorrect
  2) two failures to utilize appropriate interpretive criteria for the species
  3) one error of false resistance to one agent due to reporting results before identification of the organism was known and incorrect interpretive criteria was used
  4) delay in reporting results (CRE not reported for 5 days after culture submitted)
- 6 AST reports were not finalized within 5 days of specimen collection as because of:
  1) delay during verification of an MDR phenotype using a second method (n=5)
  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	**Frequency of occurrence**	**Severity of harm to patient**	**Risk Level**

		(maximum)	
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 and media sterility check	occasional	minor	Acceptable
Expiration dates	occasional	minor	Acceptable
Preparation/use	probable	minor	Not Acceptable
QC strain storage/prep	occasional	negligible	Acceptable
Environment:			
Incubator temperature/ humidity/atmosphere	occasional	minor	Acceptable
Utilities	occasional	minor	Acceptable
Test System:			
Inoculation of agar plate	occasional	serious	Acceptable
Application of disks	occasional	serious	Acceptable
Incubation time/atmosphere	occasional	serious	Acceptable
Measurement of zones of inhibition	probable	serious	Not Acceptable
Interpretation of zone sizes	probable	serious	Not Acceptable
Antimicrobial reporting rules	probable	serious	Not Acceptable
Transcription errors during LIS entry	occasional	critical	Not Acceptable
Risk Factor	**Frequency of occurrence**	**Severity of harm to patient (maximum)**	**Risk Level**
Post Analytical			
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*)
Pure isolate	• Mixed inoculum or contaminated AST plate	• Solicit regular feedback on streaking of primary plates (for isolated colonies)

		• 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 o Check for contaminating colonies growing inside the zone (s) of inhibition or superimposed on lawn of growth. • Impact of delayed results (if retesting needed)
Media Type	• Media for inoculum source other than that recommended is used • Disk diffusion AST plate fails to support growth of the test organism	During initial training and competency assessment, emphasize: • Appropriate media for inoculum • Species that can be reliably tested by disk diffusion test system based on CLSI recommendations
Inoculum suspension	• Overinoculation or underinoculation • Use of nonviable colonies	During initial training and competency assessment, emphasize: • Proper inoculum suspension preparation • Use of 0.5 McFarland turbidity standard (or photometric device) for inoculum standardization • 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 CLSI recommendations
Analytical		
2: Testing Personnel	• Incompletely trained • Unaware of updated recommendations for AST/reporting	During initial training and competency assessment, emphasize: • Key aspects of disk diffusion 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 AST media and disks at proper storage conditions (disks in dessicated environment) • Check expiration dates • Perform required QC
Shipping/receiving/storage and AST media sterility check	• Incorrect ordering • Depleted disk or media supply • Disk integrity compromised • Contaminated AST media (sterility check not performed prior to lot/shipment use)	• Designated staff member(s) assigned to inventory (order/receipt) AST disk and media to ensure inventory properly maintained and testing materials are handled appropriately on receipt • Staff member inoculating AST plates examines plates prior to inoculation for contamination
Preparation/use	• Disks and/or media removed from refrigerator/freezer and not warmed to room temperature (disk container must not be opened until it reaches room temperature) • AST Media surface wet	During initial training and competency assessment, emphasize: • Remove appropriately stored disks from freezer or refrigerator with sufficient time to equilibrate to room temperature. • Examining plates, and if necessary leave lids ajar to remove excess moisture
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 (equipment failure, e.g., incubator malfunction)	During initial training and competency assessment, emphasize standard rules for: • Take responsibility for any possible equipment/ environmental problem (out of the ordinary observation)(all staff) • Equipment maintenance • Temperature recording (done automatically with continuous monitoring device) and CO2 incubator atmosphere recording • Electrical supply
Incubator temperature/ humidity/atmosphere		See above (Environment)
Utilities		See above (Environment)
5: Test System		During initial training and competency assessment, emphasize standard rules for: • Adherence to the procedure in SOP 5.1.9 for

		correct inoculation of AST media, application of disks, and incubation time and atmosphere • Take responsibility for any possible test system problem (out of the ordinary observation)
Inoculation of agar plate	• Improper streaking of plate leading to lawn of growth that is not confluent	• See above (Test System)
Application of disks	• Disks relocated after placing on plate • Disks placed too close together so that zones are overlapping	• See above (Test System)
Incubation time/atmosphere	• AST plates not incubated under the appropriate atmospheric conditions based on the organism • AST plates not incubated for the recommended time range based on the organism	• See above (Test System)
Measurement of zones of inhibition	• When measuring zones of inhibition: ○ Failure to recognize inadequate growth or contamination ○ Under interpreting zone sizes may lead to smaller recorded zone sizes and potential false resistance ○ Over interpreting zone sizes may lead to larger recorded zone sizes and potential false susceptibility	During initial training and competency assessment, emphasize: • Proper measurement of zone sizes using a measuring caliper or metric ruler • Adequate lawn of growth and risk of false susceptible results if inadequate • Recognition of contaminated plate
Interpretation of zone sizes	• Incorrect interpretation of zone of inhibition leading to erroneous results	During initial training and competency assessment, emphasize: • Follow M02-A12 tables for correct interpretive criteria based on the organism and zone size
Antimicrobial reporting rules	• Inappropriate drugs reported • Report comments missing or inappropriate for the culture • Failure to follow laboratory reporting rules to confirm unusual susceptibility or resistance based on M100-S25 Appendix A and B (see SOP # 5.1.4)	During initial training and competency assessment, emphasize: • LIS reporting rules address (and flag) most, but not all, potential errors • Daily supervisor (or designee) review of all reported results • Laboratory reporting rules based on unusual susceptibility or resistance for an organism/antibiotic combination

		• Results requiring follow up action (e.g. confirmation by repeat testing) • Results requiring consultation with supervisor/director
Transcription errors during LIS entry	• Incorrect zone size values and/or interpretations entered during computer entry	During initial training and competency assessment, emphasize: • Accuracy when entering manual results • Supervisory review of manually entered results prior to LIS release
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 • Zone sizes interpreted incorrectly • Report comments missing or inappropriate for the culture	See above (Test Results and Test System)
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 Disk Diffusion AST System
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 #5.1.9 XYZ for Performance of Disk Diffusion AST and are summarized here.
Testing of appropriate ATCC QC strains on each new lot/shipment of disks and appropriate AST media, before or concurrently with placing these materials into use for testing patient's isolates.
Testing of appropriate ATCC QC strains on each AST media type weekly.
Testing of appropriate ATCC QC strains against any new antimicrobial agent at least 15 times (over a minimum of 5 days) prior to initiation of weekly QC testing (for that antimicrobial agent); accomplished during performance of verification study.
Recording and evaluating QC results according to QC acceptability criteria as defined in SOP #5.1.9 XYZ for performance of disk diffusion 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 by supervisor or section 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**