Please note that some references to protocol, publications, performance data etc. are fictitious in this EXAMPLE. Please use your own DATA for your IQCP.

The following represents one example of how you might organize your IQCP for streamlined QC of a commercial identification test system. Please note:

1) ***This example is based on a commercial identification test system that might be used in one laboratory.***
2) ***Depending on requirements of a particular accreditation organization, the format and content of this example may or may not be acceptable for an IQCP.***
3) ***A practical strategy would be to review this example together with materials provided by your manufacturer, your accreditation organization, and CMS when developing your IQCP for streamlined QC for a commercial identification test system.***

IQCP for Streamlined QC of Commercial Identification System XYZ

Facility: ABC Hospital
Test System: Commercial Identification System XYZ
Test System Primary SOPs include: #2.1.1 "Processing Microbiological Specimens" #5.1.7 "XYZ System for Performance of Microbial Identification" #10.2.2 "Quality Control of XYZ Microbial Identification System"
Historical Quality Review: CLIA '88 regulations require testing QC strains on each new lot/shipment of identification panels (that utilize two or more substrates) to verify positive and negative reactivity for each substrate and/or reagent. In 2008, CMS amended the regulations referencing the CLSI M50-A document, allowing laboratories to use quality control guidelines for reduced or "streamlined" QC as described in CLSI document M50-A "Quality Control for Commercial Microbial Identification Systems", 2008.[1] A streamlined QC scheme is permitted as long as the manufacturer has designated "key indicator strains" in their product material. The 2008 CMS announcement letter Ref: S&C-09-06 may be found on the CMS website as indicated below under References.[2] Since recent CMS regulations have removed all references to CLSI documents, including the M50A, an IQCP is required to continue streamlined QC of commercial identification system XYZ. This laboratory has been following CLSI M50-A and manufacturer's streamlined QC recommendations for over 6 years without any significant identification QC problems. Any problem related to commercial identification performance has involved: • random and infrequent unsatisfactory QC of identification substrate(s) which corrected upon repeat testing Processes to mitigate patient reporting errors based on use of unacceptable identification substrates are addressed in this IQCP.

Information Used to Conduct Risk Assessment

Regulatory and Accreditation Requirements:
Checklist from Accrediting Agency: Checklist items _____

Method verification:
Instrument received and test system verification completed in year _____. Streamlined microbial identification was verified in year _____(documented QC performance for 3 consecutive lot numbers of gram positive and gram negative panels from 3 different shipments that spanned 3 consecutive seasons). 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 regulations require testing of QC strains on each new lot/shipment of commercial identification systems (utilizing two or more substrates) to verify positive and negative reactivity for each substrate and/or reagent. Alternatively, an IQCP can be developed for streamlined QC of microbial identification.

Test System Information:

Manufacturer:

- Package insert contains system performance data and describes testing principle and procedure, QC recommendations (including streamlined QC), and limitations. Package insert (PI) is located _____.
- Manufacturer's alerts and bulletins are located_____.
- Operator's manual including troubleshooting guide is located_____.

References used during collection of information for RA:

[1] CLSI: *Quality Control for Commercial Microbial Identification Systems; Approved Guideline.* Document M50-A. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA. 2008.

[2] CMS letter, Streamlined QC Ref: S&C-09-06. 2008

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter09-06.pdf

Summary of in-house data from streamlined QC testing:
Streamlined QC testing was performed according to SOP _____.
Review of QC records for the past 12 months that contained approximately 200 results demonstrated:

- x % occurrence of random QC errors that corrected upon repeat testing.

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 corrected reports for the last 12 months indicated:
10 corrected reports with erroneous identification performed on Test System XYZ due to mixed inoculum suspensions (primarily urine cultures). (Note: none of these errors could have been avoided by performing comprehensive microbial identification QC, rather than streamlined).
There were no physician complaints as a result of unsatisfactory microbial identification.

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.

Risk Acceptability Matrix

Freq./Severity 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	occasional	negligible	Acceptable
Colony age/viability/sampling	occasional	minor	Acceptable
Media type	unlikely	minor	Acceptable
Pure isolate	unlikely	minor	Acceptable
Inoculum suspension preparation	occasional	minor	Acceptable
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	occasional	minor	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	unlikely	negligible	Acceptable
Transmission of results to LIS	unlikely	serious	Acceptable
Postanalytical			
Test Results:			
Results reported within 5 days	occasional	minor	Acceptable
Transmission of results to Electronic Health Record	occasional	serious	Acceptable
Review reported results	frequent	serious	Not Acceptable
Clinician feedback	unlikely	serious	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 inoculate/streak correctly (no isolated colonies) and delayed incubation may result in delayed microbiology 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	During initial training and competency assessment, emphasize differentiation of organisms included in normal flora group vs. potential pathogens requiring identification
Colony age/viability/sampling	• Organism non-viable (or beyond maximum age for identification testing as described by the manufacturer)	During initial training and competency assessment, emphasize: • Lengths of time various organisms generally remain viable on various media • Proper age of colony for identification testing
Media	• Media for inoculum source other than that recommended is used	During initial training and competency assessment, emphasize: • Appropriate media for inoculum preparation

		• Species that can be reliably identified by the test system based on manufacturer's recommendations
Pure isolate	• Mixed inoculum	During initial training and competency assessment, emphasize: • Proper selection of colonies for inoculum preparation • Hazards of picking from plates not incubated for sufficient time ("young" colonies) or poorly isolated colonies • Potential sources of contamination during testing process • Use of purity plates • Impact of delayed results if retesting needed
Inoculum suspension preparation	• Over- or under-inoculation • Use of nonviable colonies • Inoculum suspension sets too long before inoculating the identification panel	During initial training and competency assessment, emphasize: • Proper use of turbidity meter for inoculum standardization • Proper inoculum suspension preparation
Analytical		
2: Testing Personnel	• Incompletely trained • Unaware of updated protocols	During initial training and competency assessment, emphasize: • Key aspects of microbial identification • Supervisor annual review of any changes in microbial identification recommendations by accrediting agencies or manufacturer
Training		See above (Testing Personnel)
Competency		See above (Testing Personnel)
Experience		See above (Testing Personnel)
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 identification testing 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	• Designated staff member(s) assigned to inventory (order/receipt) microbial identification materials to ensure

	• Reagent integrity compromised	supply is properly maintained and testing materials are handled appropriately on receipt
Expiration dates		See above (Reagents)
Preparation/use	• Use incorrect panel 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)	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) (staff trained on test system)
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 jams
Software	• Erroneous results reported	• Daily supervisor (or supervisor designee) review of reported results • Software flags unusual results requiring supervisor review (e.g. organism identification is not consistent with associated AST results) During initial training and competency assessment, emphasize: • Results requiring follow up action (e.g., confirmation by repeat testing) • Atypical results requiring consultation with supervisor
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
Postanalytical		
6: Test Results		• Supervisor maintains summary of incorrect results released and meets with laboratory director monthly to review this summary • During initial training and competency assessment, emphasize timely reporting of both preliminary results and final reports
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	• Erroneous results reported	See above (Test Results)
Clinician feedback	• Complaints/suggestions regarding delayed or potential erroneous results	See above (Test Results) • Incorporate suggestions into QA plan, as appropriate.

Final QCP for Streamlined QC of Commercial Identification System XYZ
Based on our risk assessment and Quality Assessment, the QCP consists of following the instructions that are provided in explicit detail in SOP #5.1.7 "XYZ System for Performance of Microbial Identification".
Testing of appropriate QC strains for streamlined QC 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 after major system maintenance or software upgrade before or concurrently with placing the equipment back into service.
Recording and evaluating QC results according to QC acceptability criteria as defined in #10.2.2 "Quality Control of XYZ Microbial Identification System". Any abnormal result is immediately investigated.

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 microbial identification 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.		
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**