Individualized Quality Control Plan
IQCP Examples

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(No disclosures)

KAISER PERMANENTE®

3 Examples

- Cepheid Xpert MRSA Assay
- Vitek-2 Commercial AST
- Remel Exempt Media

Cepheid Xpert MRSA Assay

Cepheid Xpert MRSA Assay

Package insert (PI) contains system performance data and describes testing principle and procedure, QC recommendations, and limitations.

- This PI is located in the microbiology laboratory's PI files.
- No specific limitations were noted in the PI that would affect the use of this test for our patient population; and no risks were identified upon review of the PI.
- No manufacturer recommendations are given for external QC
  - *"External controls may be used in accordance with local, state, and federal accrediting organizations, as applicable."*

Manufacturer alerts and bulletins are located with the microbiology laboratory's PI files.

- No risks were identified upon review of any alert/bulletin.

Literature

- *J Clin Microbiol*. Oct 2008; 46(10): 3285–3290. **Evaluation of the Xpert Methicillin-Resistant *Staphylococcus aureus* (MRSA) Assay Using the GeneXpert Real-Time PCR Platform for Rapid Detection of MRSA from Screening Specimens.** Angela S. Rossney, Celine M. Herra, Gráinne I. Brennan, Pamela M. Morgan, and Brian O'Connell.

- *J. Clin. Microbiol.* March 2009 vol. 47 no. 3 758-764. **Multicenter Evaluation of the Cepheid Xpert Methicillin-Resistant *Staphylococcus aureus* (MRSA) Test as a Rapid Screening Method for Detection of MRSA in Nares.** D. M. Wolk, et al.

The above pertinent published studies have been reviewed and no risk factors were identified that would affect the performance of this assay in our laboratory.

Copies of these articles, along with our initial verification testing documentation, are located in the microbiology supervisor's Xpert verification files.

CAP IQCP Accreditation Requirements

This IQCP is in compliance with all CAP Checklist Requirements

See Common Checklist items:

- COM.50200 (IQCP test list)
- COM.50300 (RA)
- COM.50400 (QCP approval)
- COM.50500 (QCP defined)
- COM.50600 (QA monitoring)

Historical QC data - Summary

Historically, QC has been performed as outlined in the most current version of SOP.1234. Briefly, 1 positive and 3 negative external controls are utilized for all QC testing (unless indicated otherwise below):

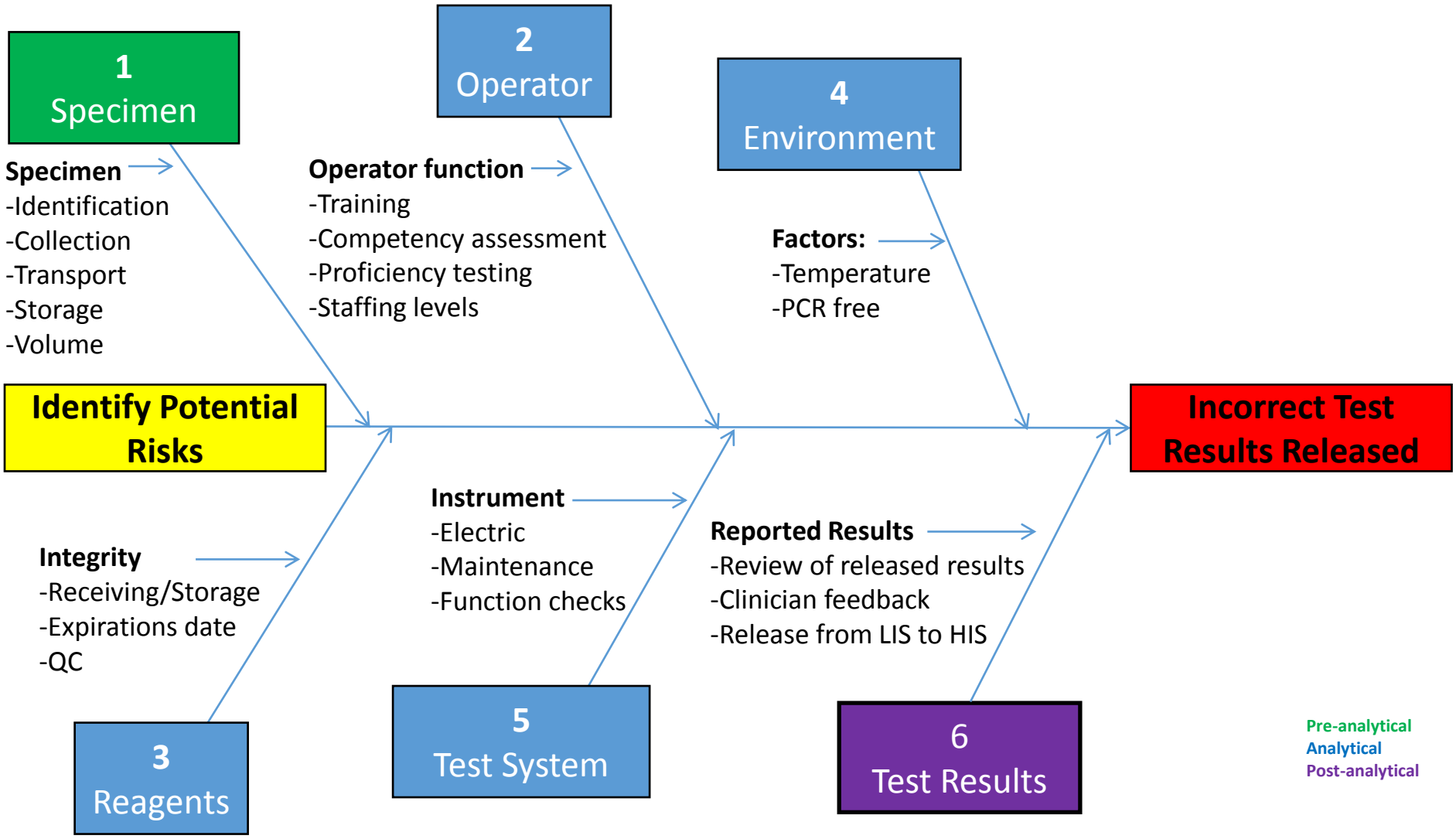
Review of data for the past 12 months (4/1/14 - 3/31/15) using -

- New Lot and/or shipment QC (performed for 6 lot/shipment checks)*
- Major maintenance (performed twice during the time period)
- Software upgrades (performed once during time period)
- Bi-weekly QC using 1 positive and 1 negative control - rotating the negative controls (24 QC cycles using 1 positive and 1 negative control)*
- < 2% (1.8%) failures of external QC* (which were within limits upon repeat testing).

No external QC failures were noted after system maintenance or software upgrades.

No internal QC failures were noted when testing patient samples (327 days).

RISK ASSESSMENT: Identification of Potential Risks - Cepheid Xpert MRSA Assay



Risk Assessment Tables

1 Sample - Preanalytical

Xpert MRSA assay

1 SAMPLE	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP - Documentation
Identification	Occasional	Critical	Specimen identification criteria are defined. Training (TR) completed. Competency assessment (CA) performed.	SOP.xxxx TR.xxxx CA.xxxx
Collection	Occasional	Negligible – Minor	Collection criteria are defined. Training completed. CA performed.	SOP.xxxx TR.xxxx CA.xxxx
Transport	Occasional	Negligible – Minor	Transport criteria are defined. Training completed. CA performed.	SOP.xxxx TR.xxxx CA.xxxx
Storage	Occasional	Negligible – Minor	Storage criteria are defined. Training completed. CA performed.	SOP.xxxx TR.xxxx CA.xxxx
Volume	Occasional	Negligible	Rejection criteria are defined. Training completed. CA performed.	SOP.xxxx TR.xxxx CA.xxxx

2 Operator - Analytical

Xpert MRSA assay

2 Operator	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP - Documentation
Training	Occasional	Minor – Critical	All testing personnel have had appropriate training before performing this assay.	SOP.xxxx TR.xxxx
Competency Assessment	Occasional	Minor – Critical	All personnel have appropriate competency assessment (CA) performed on this assay.	SOP.xxxx CA.xxxx
Proficiency Testing	Unlikely	Minor	All staff participate in PT and review all final critiques. All PT failures with this assay are addressed with corrective action.	SOP.xxxx
Staffing	Occasional	Minor – Critical	Adequate staffing to support this test and turn-around-times is available on all shifts.	SOP.xxxx

3 Reagents - Analytical

Xpert MRSA assay

3 Reagents	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP - Documentation
Receiving/ Storage	Occasional	Minor – Critical	Reagents for the Xpert MRSA assay are stored according to manufacturer's instructions.	SOP.xxxx
Expiration dates	Unlikely	Minor	All reagents used in the Xpert MRSA are used within expiration dates.	SOP.xxxx
QC	Unlikely	Negligible	All QC results for the Xpert MRSA assay are within parameters prior to releasing patient results. All specimen-specific QC parameters are controlled within the cartridge; if there is a failure, the assay will not deliver a patient result. The result will be an "error" or an "invalid".	SOP.xxxx manufacturer's package insert

4 Environment - Analytical

Xpert MRSA assay

4 Environment	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP - Documentation
Temperature	Unlikely	Negligible	Appropriate environmental conditions are maintained in the laboratory.	SOP.xxxx
PCR free	Unlikely	Negligible	Benches are bleached prior to performing testing; gloves are used for testing; procedures for reducing cross-contamination are used. Also, the test cartridges for the Xpert MRSA assay are self-contained - amplicons cannot escape unless the cartridge integrity is damaged. Proper discarding and decontamination protocols are followed for disposal of all cartridges.	SOP.xxxx manufacturer's package insert

5 Test System - Analytical

Xpert MRSA assay

5 Test System	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP - Documentation
Electric	Unlikely	Negligible	Appropriate utilities are employed in the laboratory to serve the Xpert MRSA instrumentation.	SOP.xxxx
Maintenance	Unlikely	Negligible	Criteria are defined to address Xpert MRSA instrument maintenance.	SOP.xxxx QC-FORM.xxxx
Function checks	Unlikely	Negligible	Criteria are defined to address failures associated with the Xpert MRSA system/instrument.	SOP.xxxx QC-FORM.xxxx

6 Test Result - Postanalytical

Xpert MRSA assay

6 Test Result	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP - Documentation
Review of released results	Occasional	Minor – Critical	Criteria are defined to address review of released results and investigate any errors detected related to the Xpert MRSA assay.	SOP.xxxx
Clinician feedback	Unlikely	Minor – Critical	Criteria are defined to address clinician feedback and investigate concerns with the Xpert MRSA assay.	SOP.xxxx
Release from LIS to HIS	Unlikely	Negligible – Minor	Criteria are defined for periodic review of results transfer related the Xpert MRSA assay.	SOP.xxxx

Quality Control Plan for Xpert MRSA assay

QCP for the Xpert MRSA screening assay will consist of following instructions in SOP.xxxx and recording results on QC-FORM.A (external controls) and QC-FORM.B (internal controls).

QC will include:

- External QC (1 positive and 1 negative) performed per lot/shipment (rotating the negative targets).
- External QC (1 positive and 1 negative) performed the second week of each month (rotating the negative targets).
- The Internal Controls are to be acceptable and documented each day patient samples are tested.

Acceptable QC is defined in SOP.xxxx.

Post-implementation Quality Assessment monitoring process will include all of the following:

- **Specimen collection/acceptability guidelines reviewed annually**
  - **See SOP.xxxx**
- **Staff Training updated annually as necessary**
  - **See SOP.xxxx**
- **Competency assessment performed semi-annually and annually as required**
  - **See SOP.xxxx**
- **Proficiency Testing results review and mediated ASAP as required**
  - **See SOP.xxxx**
- **QC/Instrument Function checks reviewed and mediated ASAP as required**
  - **See SOP.xxxx, SOP.xxxx. QC-FORM.xxxx, QC-FORM.xxxx**
- **Unexpected Errors investigated ASAP and remediated**
  - **See SOP.xxxx**
- **Laboratory error investigation/remediation performed ASAP**
  - **See SOP.xxxx**
- **Complaint investigation/remediation performed ASAP**
  - **See SOP.xxxx**

For errors/ failures/ concerns a reassessment of risk will be performed.

- The reason for failure will be identified and related to a new/updated risk.
- Additional control measures will be implemented if necessary as determined by the new risk assessment.

Pre-analytical
Analytical
Post-analytical

IQCP for Xpert MRSA assay

This IQCP/QCP has been reviewed and is approved by the CLIA laboratory director:

_____(director signature)

_____(date)

Vitek-2 Commercial AST System

IQCP for Vitek-2 Antimicrobial Susceptibility Testing (AST) System

Our Regional Medical Center

Test System Primary SOPs include:

SOP.111 "Processing Microbiological Specimens"
SOP.222 "Vitek-2 Performance/Maintenance"
SOP.333 "Guidelines for Selecting Isolates for AST"

Historical Quality Review:

CLIA '88/CMS requires testing of QC strains daily (or each day patient's tests are performed) for AST.

Previously CLIA 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.

- **Our laboratory has been following the CLSI standards for over 20 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 and are also unrelated to a problem with the Vitek-2.**

Processes to mitigate patient reporting errors and delayed reports as well as QC are addressed in this IQCP.

Information Used to Conduct Risk Assessment

Regulatory and Accreditation Requirements:
See CAP IQCP checklist questions in the CAP COMMON checklist.
NOTE: Our IQCP is in compliance with CMS and CAP requirements. Copies of these requirements are located in our Compliance Department.

Method verification:
Instrument received and test system verification completed in year 2012. Subsequent verifications performed when new drugs were added (1/12/14 and 4/14/15). This documentation is filed in Vitek-2 verification files. All verifications were deemed acceptable by the Laboratory Director.

Training of personnel:
Completion of training documented in Compliance Department office.

Competency Assessment:
New employees 6 months after initial training and annually thereafter. Documentation filed in Compliance Department office.

Proficiency Testing:
All personnel will test and review results. Proficiency testing records filed in supervisor's office.

VITEK-2 Information

Manufacturer:
Package insert contains system performance data and describes testing principle and procedure, QC recommendations, and limitations. Package insert is located in the supervisor's office.
Manufacturer alerts and bulletins are located the supervisor's office.

NOTE: No risks were identified when looking at the PI for this system. Both the Limitations and Performance data sections were closely reviewed to identify possible risks associated with the system and none were found.

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

NOTE: Upon review of these articles no risk factors were identified.

VITEK-2 Data

Summary of in-house QC data from routine testing of QC strains.
Review period from 3-14-14 to 3-13-15.
QC testing was performed according to SOP.2222.

Review of QC records for 1 year of ~ 3500 results demonstrated:

- **0.8% occurrence of random QC errors (corrected upon repeat testing)**
- **0.02% occurrence (one incident) of potential system QC error that required corrective action.**

- **This involved an out-of-range QC results with imipenem that was presumed to be due to drug degradation following improper storage of 1 box of panels.**
- **Additional panels from this box were QC'd and found to be out-of-range; panels were discarded, none were used for patient testing.**

Vitek-2 Instrument Information:

Summary of in-house data from routine instrument maintenance and performance checks (done according to SOP.2222):

- Review of instrument QC records for the past 12 months (3-14-14 to 3-13-15) included approximately 55 routine checks of instrument A and 55 routine checks of instrument B.

- There was 1 scheduled maintenance performed by the company's service engineer (8-1-14).

NOTE: None of these reviews showed any performance problems with the Vitek-2 that would impact patient results.

Laboratory Data:

Summary of corrected reports and physician complaints (documentation located in supervisor's office):

Review of reporting errors (corrected reports), physician complaints, and delayed reports (> 5 days after specimen collection) for these 12 months showed…

38 corrected reports showed errors were due to one or more of the following:

1. **inappropriate antimicrobial agent reported for the species/body site (n=17)**
2. **incorrect result released due to mixed culture (n=9)**
3. **incorrect result released due to use of inappropriate MIC interpretation (n=8)**
4. **failure to perform a susceptibility test when warranted (n=4)**

2 formal physician complaints revealed:

1. **question of a result for *S.aureus* isolate - repeat testing = initial results were incorrect**
2. **delay in reporting results for a CRE due to the need to confirm results**

5 AST reports delayed > 5 days were due to:

1. **verification of an MDR phenotype needing confirmatory testing (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 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	frequent	minor	Not Acceptable
Media type	unlikely	minor	Acceptable
Pure isolate	frequent	serious	Not Acceptable
Inoculum suspension	occasional	minor	Acceptable
Analytical			
Testing Personnel:			
Training and Competency	probable	serious	Not Acceptable
Proficiency Testing	unlikely	negligible	Acceptable
Staffing	occasional	minor	Acceptable
Reagents:			
Receiving/storage/expirations dates	occasional	minor	Acceptable
Preparation/use	probable	minor	Not Acceptable
QC strain storage/prep	occasional	negligible	Acceptable
Environment:			
Conditions - temperature/airflow/humidity/ventilation/utilities/noise/ vibration	unlikely	negligible	Acceptable
Test System:			
Mechanical/electronic/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 from LIS to HIS	unlikely	serious	Acceptable
Review reported results	frequent	serious	Not Acceptable
Clinician feedback	probable	serious	Not Acceptable

Risk Factor (Possible Sources of Error)	Frequency of occurrence	Severity of harm to patient	Risk Level
Preanalytical			
Specimen (Primary):			
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Inoculum suspension	occasional	minor	Acceptable

Risk Factor (Possible Sources of Error)	Frequency of occurrence	Severity of harm to patient	Risk Level
Analytical			
Testing Personnel:			
Training and Competency	probable	serious	Not Acceptable
Proficiency Testing	unlikely	negligible	Acceptable
Staffing	occasional	minor	Acceptable
Reagents:			
Receiving/storage/expirations dates	occasional	minor	Acceptable
Preparation/use	probable	minor	Not Acceptable
QC strain storage/prep	occasional	negligible	Acceptable
Environment:			
Conditions - temperature/airflow/humidity/ventilation/utilities/ noise/ vibration	unlikely	negligible	Acceptable
Test System:			
Mechanical/electronic/jam	occasional	negligible	Acceptable
Software/antimicrobial reporting rules	frequent	serious	Not Acceptable
Transmission of results to LIS	unlikely	serious	Acceptable

Risk Factor (Possible Sources of Error)	Frequency of occurrence	Severity of harm to patient	Risk Level
Postanalytical			
Test Results:			
Results reported within 5 days	probable	serious	Not Acceptable
Transmission of results from LIS to HIS	unlikely	serious	Acceptable
Review reported results	frequent	serious	Not Acceptable
Clinician feedback	probable	serious	Not Acceptable

Risk Acceptability Assignment

Risk Factor	Possible Sources of Error: Possible Error	How can identified sources of error be reduced?
Preanalytical		
1A: Specimen - Biological		
Patient/specimen identification **Collection/container/ volume** **Transport** **Storage** **1B: Specimen - Organism**	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
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		
Results reported within 5 days	• Results delayed beyond that expected for organism type	• 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)
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.

Risk Acceptability Assignment

Possible Sources of Error		How can identified sources of error be reduced?
Risk Factors	**Possible Errors**	
Preanalytical		
1A: Specimen (patient)		
Patient identification **Collection/container/ volume** **Transport** **Storage**	• Improper specimen procurement/ handling/processing	• Adhere to procedures in SOP.1111 that addresses patient identification and specimen collection, labeling, transport, storage and remedial actions to control improperly handled specimens or delayed specimens. • Annually review of selected specimen processing errors (N=10 to 15) with all staff involved with patient specimens. During initial training and competency assessment emphasize: > Proper specimen handling and processing is a very critical part of any patient testing > Failure to streak plates correctly (= no isolated colonies) can lead to a delay in reporting AST for patients

Risk Acceptability Assignment

Possible Sources of Error		How can identified sources of error be reduced?
Risk Factors	**Possible Errors**	
Preanalytical		
1B: Specimen (organism)		
Clinically relevant	-Clinically irrelevant organisms tested -Physicians may request testing of non-significant isolates; requests may be inappropriate.	-SOP.333 describes selecting organisms to test based on organism ID, specimen source and quantity -Supervisor/director discusses with requesting physician those requests that may be inappropriate.
Colony age	Colonies > 1 day old	During initial training and competency assessment emphasize: -Organism growth requirements (especially S. pneumoniae)
Media type	Incorrect media used for inoculum	During initial training and competency assessment emphasize: -Appropriate media for inoculum
Pure isolate	Mixed inoculum	-Inoculate purity plate -Daily review of results for errors due to mixed inoculum During initial training and competency assessment emphasize: -Proper organism selection for inoculum preparation -Risks of selecting “young” colonies or poorly isolated colonies -Impact of delayed results (if retesting needed)
Inoculum suspension	-Overinoculation or underinoculation	Turbidity meter for inoculum standardization During initial training and competency assessment emphasize: -Impact of overinoculation (false R) or underinoculation (false S)

Risk Acceptability Assignment

Possible Sources of Error		How can identified sources of error be reduced?
Risk Factors	**Possible Errors**	
Analytical		
2: Testing Personnel		
Training and Competency	• Incompletely trained • Unaware of updated recommendations for AST/reporting	During initial training and competency assessment emphasize: • Key aspects of AST • Supervisor annually review any changes in AST recommendations described by CLSI/FDA
Proficiency Testing	Errors in PT performance	• All staff perform and review all PT sample critiques
Staffing	Inadequate to perform testing without errors	• Supervisor to annually review appropriate staffing needs for AST and schedule staff accordingly

Risk Acceptability Assignment

Possible Sources of Error		How can identified sources of error be reduced?
Risk Factors	**Possible Errors**	
Analytical		
3: Reagents		
Receiving/storage **Expiration dates**	• Incorrect ordering • Depleted reagent supply • Reagent integrity compromised • Reagents used past expiration date	During initial training and competency assessment emphasize: • Take responsibility for reagents/supplies (all staff) • Maintain reagents at proper storage conditions • Check expiration dates prior to use • Perform required QC
Preparation/use	• Incorrect AST card used for 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 • Potential sources of QC failures • QC troubleshooting • QC frequency

Risk Acceptability Assignment

Possible Sources of Error		How can identified sources of error be reduced?
Risk Factors	**Possible Errors**	
Analytical		
4: Environment		
Conditions: **-temperature** **-airflow** **-humidity** **-ventilation** **-utilities** **-noise** **-vibration**	• Results not reported/delayed	During initial training and competency assessment emphasize: • Take responsibility for any possible instrument/environmental problem/out of the ordinary observation (all staff) • Equipment maintenance • Temperature recording

Risk Acceptability Assignment

Possible Sources of Error		How can identified sources of error be reduced?
Risk Factors	**Possible Errors**	
Analytical		
5: 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 and resolve jams
Software/antimicrobial reporting rules	• Inappropriate drugs reported • MICs interpreted incorrectly • Incorrect results reported	• Software rules address (and flag) most (but not all) potential errors – results to be checked by tech During initial training and competency assessment emphasize: • The intrinsic resistance patterns of some common species • Some results require follow up action (e.g., confirmation by repeat testing) • Some 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

Risk Acceptability Assignment

Possible Sources of Error		How can identified sources of error be reduced?
Risk Factors	**Possible Errors**	
Postanalytical		
6: Test Results		
Results reported within 5 days	• Results delayed beyond 5 days	• Supervisor maintains summary of incorrect/delayed results and takes corrective action During initial training and competency assessment emphasize: • Timely reporting preliminary results for initial therapy • Need for timely results to guide therapy and identify potential MDR organisms that might require patient isolation
Transmission of results from LIS to HIS	• Incorrect transmission of results • Delay in transmission of results	Supervisor maintains summary of incorrect/delayed results due to transmission errors and takes corrective action
Review of reported results	• Inappropriate drugs reported • Incorrect results reported • MICs interpreted incorrectly	Results are checked at multiple steps by tech and then by supervisor
Clinician feedback	• Complaints/suggestions regarding delayed results and potential erroneous results	Supervisor investigates and incorporates new risks into QA plan, as appropriate.

Final Quality Control Plan (QCP) for the Vitek-2 AST System

Based on our Risk Assessment and Quality Assessment, the QCP consists of following the in Quality Control Section of SOP.2222 for Performance of AST. This is summarized below:

- **Testing of appropriate QC strains on each new lot/shipment of panels before or concurrently with placing these materials into use for patient testing 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 upgrades before or concurrently with placing the equipment back into service.**
- **Testing of appropriate QC strains against any new antimicrobial agent added to the panel with the 3x5 plan (over 5 days) prior to weekly QC testing of the panel.**
- **Recording and evaluating QC results according to QC acceptability criteria as defined in SOP.2222. 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

QC failures, PT failures, and patient isolate reporting errors will be investigated and addressed as needed in a new/updated risk assessment and the QCP revised as needed.
Daily review of patient results looking for reporting errors. Clinician complaints are investigated ASAP. Take corrective action and revise QCP as needed.
Monthly review of QC results performed. Take corrective action and revise QCP as needed.
Monthly review of results delayed beyond 5 days. Take corrective action for all, and the QCP will be revised as needed when number of delayed reports exceeds acceptable limit (more than 2%).
Review Proficiency Testing results. Take corrective action and revise QCP as necessary when PT results are not acceptable.
Monthly review of all equipment maintenance/monitoring logs. Take corrective action and revise QCP as needed.
Perform training and competency assessment. Modify training/CA 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.	Signature	Date

Remel Commercially prepared CLSI-exempt media

Our CLSI-exempt media consists of the following Remel products:

- Blood agar
- MacConkey agar
- PEA agar
- CNA agar
- Mannitol salt agar
- Blood/SXT agar
- CIN agar
- PC agar
- Brucella agar
- Middlebrook agar
- Lowenstein-Jensen agar
- IMA
- Saboaraud's dextrose agar
- LIM broth
- Selenite broth
- Thioglycolate broth
- TSI agar
- Urease agar

Information Review

College of American Pathologists:

NOTE: *The components of the QCP (quality control plan) must meet:*

- *Regulatory requirement (e.g.; CMS),*
- *CAP accreditation requirements, and*
- *Be in compliance w/ manufacturer instructions/recommendations*

Information Review

College of American Pathologists:

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CMS guidelines:

CMS's FAQ for IQCP, revised April 2015, Question 42 – states in part:

"For example, laboratory documentation showing visual quality checks of media are acceptable in-house data. The laboratory may also include manufacturer's quality certificates as part of the information considered in its risk assessment."

Reference

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/FAQs-IQCP.pdf

Information Review

College of American Pathologists:

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- *CAP accreditation requirements, and*
- *Be in compliance w/ the manufacturer instructions/recommendations*

Per CAP - Commercially prepared media must have IQCP.

- *Microbiology media, and reagents used for microbial identification and susceptibility testing may implement an IQCP as defined in the checklist.*
  - See Common Checklist items: COM.50200 (IQCP test list), COM.50300 (RA), COM.50400 (QCP approval), COM.50500 (QCP defined), and COM.50600 (QA monitoring).

Reference

http://www.cap.org/ShowProperty?nodePath=/UCMCon/Contribution%20Folders/WebContent/pdf/proposed-cap-checklist-requirements-iqcp.pdf&msource=477002

Information Review

College of American Pathologists:

NOTE: *The components of the QCP (quality control plan) must meet:*

- *Regulatory requirement (e.g.; CMS),*
- *CAP accreditation requirements, and*
- *Be in compliance w/ manufacturer instructions/recommendations*

Manufacturer information:

- Remel's "Certificates of Quality" certify that specific lot numbers of exempt media have met all performance and QC criteria for the product. See link: http://www.remel.com/IFUs/TM93.pdf
- No additional risks were identified from review of the Remel's IFU (Instructions For Use), alerts or bulletins associated with these media products.
  - IFU for these media can be found at the below link: http://www.remel.com/Support/SearchDocument.aspx
  - All alerts and bulletins pertaining to these media can be found in the microbiology laboratory's media QC files.
- Remel has no recommendation for end-user QC of CLSI exempt media. See link: http://www.remel.com/IFUs/TM93.pdf

Summary of Historical In-house data for Remel commercially prepared CLSI-exempt media

Media quality data were reviewed for 12 months (4/1/14 - 3/31/15).

When evaluating commercially prepared CLSI-exempt media we undergo a visual inspection looking for:[1]

- change in expected color of media
- agar detached from the plates
- frozen or melted agar
- unequal filling of plates
- insufficient agar in the plates
- hemolysis of blood containing media
- cracked or damaged plates
- excessive bubbles or rough surfaces
- excessive moisture or dehydration
- obvious contamination
- presence of precipitates

In addition:

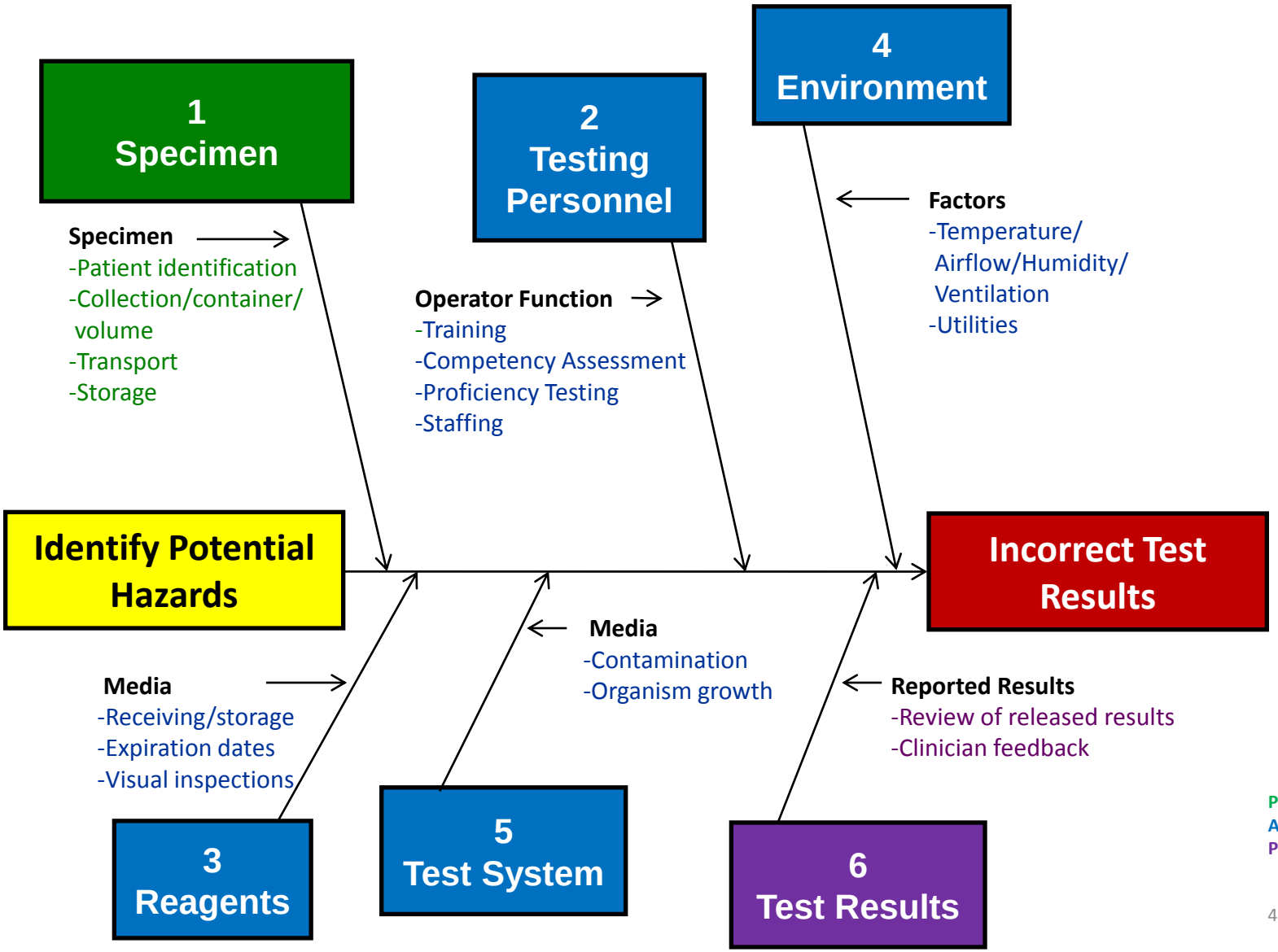
- ❖ Media is checked for contamination immediately before inoculation with specimens.
- ❖ Look for organisms growing on a piece of media and not on others when reading cultures.

When using the above parameters:

- 0.2% occurrence of unacceptable quality was noted. These plates were not used for patient care but were discarded. This was not associated with any one particular media type. (We consider anything less than 0.5% acceptable[1]).
- At no time when using media was plate contamination suspected upon review of culture results.

1. reference: NCCLS document M22-A3

RISK ASSESSMENT: Identification of Potential Failures - Commercially Prepared Remel CLSI-Exempt Media



Pre-analytical
Analytical
Post-analytical

Risk Assessment Tables

1 Sample – Preanalytical

Commercially prepared Remel CLSI-exempt media

1 Specimen*	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Patient identification	Occasional	Minor	Patient identification criteria defined; acceptability defined; competency assessment performed	SOP.xxxx SOP.xxxx SOP.xxxx
Collection/ Container/ Volume	Occasional	Minor	Collection and container criteria defined per source; acceptability defined; competency assessment performed	SOP.xxxx SOP.xxxx SOP.xxxx
Transport	Occasional	Minor	Transport criteria defined per source; acceptability defined; competency assessment performed	SOP.xxxx SOP.xxxx SOP.xxxx
Storage	Occasional	Minor	Storage criteria defined per source; acceptability defined; competency assessment performed	SOP.xxxx SOP.xxxx SOP.xxxx

***NOTE: Specimen collection has little to do with media quality.**

2 Testing Personnel –Analytical

Commercially prepared Remel CLSI-exempt media

2 Testing Personnel	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP - documents
Training	Occasional	Minor-Critical	All testing personnel have had appropriate training in appropriate utilization of media and media quality parameters.	SOP.xxxx Training documentation
Competency Assessment	Occasional	Minor-Critical	All personnel have appropriate CA performed regarding appropriate utilization of media and media quality parameters.	SOP.xxxx Competency documentation
Proficiency Testing	Occasional	Negligible-Minor	All PT failures are addressed with corrective action; media quality is always investigated as deemed necessary.	SOP.xxxx Proficiency Testing documentation
Staffing	Occasional	Minor-Critical	Adequate staffing to support appropriate evaluation of media upon arrival and prior to use.	SOP.xxxx

3 Reagents (media) – Preanalytical

Commercially prepared Remel CLSI-exempt media

3 Reagents (media)	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP - documents
Receiving / storage	Occasional	Minor	Media are received and stored according to manufacturer's recommendations.	SOP.xxxx Manufacturer PI
Expiration dates	Occasional	Minor	Media are used within expiration dates; no expired media are ever used for any reason.	SOP.xxxx
Visual Inspections	Unlikely	Negligible	Training and procedures are provided for appropriate visual inspections of media upon receipt. Competency assessment is performed.	SOP.xxxx Competency documentation

4 Environment – Analytical

Commercially prepared Remel CLSI-exempt media

4 Environment	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Temperature/ Airflow/ Humidity/ Ventilation	Unlikely	Negligible – Minor	Appropriate environmental conditions are maintained in the laboratory for proper storage and incubation of media as specified by the manufacturer.	SOP.xxxx
Utilities	Unlikely	Negligible – Minor	Appropriate utilities are employed in the laboratory for appropriate storage and incubation of media as specified by the manufacturer.	SOP.xxxx

5 Test System –Analytical

Commercially prepared Remel CLSI-exempt media

5 Test System (media)	Frequency Of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Contamination	Unlikely	Negligible – Minor	Training and procedures are provided to check for contamination prior to plating patient specimens. Competency assessment is performed.	SOP.xxxx Competency documentation
Organism growth	Unlikely	Negligible – Minor	Training and procedures are provided to check for inconsistencies in organism growth on media types. All discrepant cultures are reviewed with the supervisor.	SOP.xxxx

6 Testing Results – Postanalytical

Commercially prepared Remel CLSI-exempt media

6 Test Results	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Review of released results	Unlikely	Negligible – Minor	Review of all released results. Appropriate investigation for all reporting errors is undertaken including media quality review as necessary.	SOP.xxxx
Clinician feedback	Unlikely	Minor – Critical	Appropriate investigation is undertaken for all clinician feedback, issues, complaints including media quality review as necessary.	SOP.xxxx

Quality Control Plan (QCP)

- ❖Upon receipt of exempt media visual inspection will be performed as outlined in the CLSI-M22. Failed media will be brought to the attention of the supervisor or lead technologist and addressed immediately.

- ❖Media will be checked for contamination immediately before inoculation with patient specimens. Contaminated media will be brought to the attention of the supervisor or lead technologist and addressed immediately.

- ❖Suspected media contamination when reviewing cultures will be brought to the attention of the supervisor or lead technologist and addressed immediately.

- ❖Remel QC alerts and bulletins will be reviewed and acted on appropriately as necessary.

QC Acceptability Criteria is defined in SOP.xxxx

Our post-implementation Quality Assessment (QA) monitoring process will include all of the following:

- Media receipt and storage guidelines are reviewed and updated annually as necessary
  See SOP.xxxx
- Staff training documents are reviewed and updated annually as necessary
  See SOP.xxxx
- Competency assessment performed semi-annually and annually as required
  See SOP.xxxx
- Proficiency testing results review and mediated ASAP as required
  See SOP.xxxx
- Media quality information is reviewed and mediated ASAP as required
  See SOP.xxxx, SOP.xxxx. QC-FORM.xxxx, QC-FORM.xxxx
- Unexpected errors investigated ASAP and remediated
  See SOP.xxxx
- Laboratory error investigation/remediation performed ASAP
  See SOP.xxxx
- Complaint investigation/remediation performed ASAP
  See SOP.xxxx

Pre-analytical
Analytical
Post-analytical

For errors/failures/concerns in QC, PT, CA, QCP, etc., a reassessment of risk will be performed:

- The reason for failure will be identified and investigated.
- Additional control measures will be implemented if necessary as determined by the new risk assessment.

Commercially prepared Remel CLSI-exempt media

This IQCP/QCP has been reviewed and is approved by the CLIA laboratory director.

_____ _____

(CLIA Laboratory Director signature) (date)

http://clinmicro.asm.org/iqcp

ASM/CAP/CLSI effort for IQCP on AST