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IQCP for VITEK 2 Commercial Antimicrobial Susceptibility Testing (AST) System

Facility: EXAMPLE
Test System: Vitek 2 Commercial Antimicrobial Susceptibility Testing (AST) System
Test System Primary SOPs include: GENERAL PROCEDURES: Quality Control for AST Cards and Identification Cards located in: MICROBIOLOGY QUALITY CONTROL MANUAL – BOOK 1 CULTURE PROCEDURES: Guidelines for selecting isolates for AST testing located in: MICROBIOLOGY BACTERIOLOGY CULTURES MANUAL - BOOK 3 VITEK-2 PERFORMANCE/MAINTENANCE: located in: MICROBIOLOGY VITEK 2 PROCEDURE AND SUSCEPTIBILITY TESTING MANUAL – BOOK 5
Historical Quality Review: CLIA '88 requires testing of QC strains daily (or each day patient's tests are performed) for AST. Previously CLIA inspector guidelines recognized use of CLSI standards M100 and M07 which indicate that weekly testing of QC strains is acceptable following documentation of satisfactory daily QC testing. The laboratory has been following the CLSI standards for years without any significant QC problems. It is rare to encounter an out-of-range result with a QC strain that indicates a test system problem. Nearly all testing errors or delays in reporting occur with individual patient isolates and these errors are unrelated to testing QC strains or a problem with testing reagents or equipment. Processes to mitigate patient reporting errors and delayed reports are addressed in this IQCP.

Information Used to Conduct Risk Assessment

Regulatory and Accreditation Requirements:
Checklist from Accrediting Agency: • CAP IQCP checklist questions in the ALL COMMON and MICROBIOLOGY checklists • CMS requirements
Method verification: • Vitek 2 instrument received and test system verification completed in 2011. • Subsequent verifications performed when lab was moved to new lab 2014. • Documentation filed in Microbiology lab.
Training of personnel: • Completion of training documented in employee personnel files.
Competency Assessment: • Employees are annually accessed for current competency. Documentation filed in employee personnel files.
Proficiency Testing: • All personnel test and review results. Proficiency testing records filed in CAP SURVEY binders.
Quality Control: • CLIA '88 and CAP requirements for testing of QC strains.

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Test System Information:

Manufacturer: bioMerieux Vitek 2

- Package insert contains system performance data and describes testing principle and procedure, QC recommendations, and limitations. Package insert is located supervisor's office.
- Manufacturer alerts and bulletins are located in the Microbiology Lab.
- Operator's manual including troubleshooting guide is located the Microbiology Lab.

Scientific publications used during collection of information for RA:

- CLSI document M07-A10 and M100-S25.

Summary of in-house data from routine testing of QC strains:

- QC testing was performed according to SOP: Quality Control for AST Cards and Identification Cards located in BOOK 1.

Review of QC records for the past 12 (12/1/14 – 11/30/15) months that contained 3640 results demonstrated:

- The were 22 overall errors 0.0008% occurrence (3 incidents) of random QC errors that corrected upon repeat testing.
- 0.0052% occurrence (19 incidents) of errors caused by the Lab Tech. These errors included organisms being switched (4 incidents) and Cards not inoculated with organisms (15 incidents)

Summary of in-house data from routine instrument performance checks:

- Instrument checks were done according to SOP: VITEK-2 PERFORMANCE/MAINTENANCE: located in MICROBIOLOGY VITEK 2 PROCEDURE AND SUSCEPTIBILITY TESTING MANUAL – BOOK 5.
- Review of instrument QC records for the past 12 months and 1 report following scheduled maintenance performed by bioMerieux service engineer revealed no instrument performance problems that would impact patient results.

Summary of delayed or corrected reports and physician complaints:

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:

- There were no corrected reports or complaints by physicians regarding our reports.
- 50 delayed final reports were due to the resistance isolates being sent out to reference lab for colistin testing by the Etest method

Note: during this review of delayed or 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.

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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

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Risk Factor (Possible Sources of Error)	Frequency of occurrence	Severity of harm to patient	Risk Level
Analytical			
Testing Personnel:			
Training	probable	serious	**Not Acceptable**
Competency	probable	serious	**Not Acceptable**
Experience	probable	serious	**Not Acceptable**
Proficiency Testing	unlikely	negligible	Acceptable
Staffing	occasional	minor	Acceptable
Reagents:			
Shipping/receiving/storage	occasional	minor	Acceptable
Expiration dates	unlikely	minor	Acceptable
Preparation/use	probable	minor	**Not Acceptable**
QC strain storage/prep	occasional	negligible	Acceptable
Environment:			
Temperature/airflow/humidity/ ventilation	unlikely	negligible	Acceptable
Utilities	occasional	minor	Acceptable
Space	unlikely	negligible	Acceptable
Noise/vibration	unlikely	negligible	Acceptable
Test System:			
Mechanical/electronic stability of instrument/equipment/jam	occasional	negligible	Acceptable
Software/antimicrobial reporting rules	frequent	serious	**Not Acceptable**
Transmission of results to LIS	unlikely	serious	Acceptable
Postanalytical			
Test Results:			
Results reported within 5 days	probable	serious	**Not Acceptable**
Transmission of results to Electronic Health Record	occasional	serious	Acceptable
Review reported results	frequent	serious	**Not Acceptable**
Clinician feedback	probable	serious	**Not Acceptable**

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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 Phlebotmy.3 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 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's Guidelines for selecting isolates for AST testing located in: BOOK 3 and MICROBIOLOGY VITEK 2 PROCEDURE AND SUSCEPTIBILITY TESTING MANUAL located in: BOOK 5 • 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.

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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	• Over inoculation or under inoculation • 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 over inoculation (false R) or under inoculation (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)

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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

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		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

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		• QA monitor for time to reporting AST results
Postanalytical		
6: Test Results		• Supervisor maintains summary of incorrect results released and meets with laboratory director monthly to review this summary • QA monitor for time to reporting AST results During initial training and competency assessment, emphasize: • Need for timely results to guide therapy and identify potential multidrug resistant organisms that might require patient isolation • Reporting preliminary results (timely reporting)
Results reported within 5 days	• Results delayed beyond that expected for organism type	See above (Test Results)
Transmission of results to Electronic Health Record	• Incorrect transmission of results • Delay in transmission of results	See above (Test Results)
Review reported results	• Inappropriate drugs reported • Erroneous results reported • MICs interpreted incorrectly • Report comments missing or inappropriate for the culture	See above (Test Results and Test System) Note: results are checked at multiple steps by tech and then by supervisor
Clinician feedback	• Complaints/suggestions regarding delayed results and potential erroneous results	See above (Test Results) • Incorporate suggestions into QA plan, as appropriate.

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Final QCP for AST Vitek 2 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 for AST Cards and Identification Cards located in: MICROBIOLOGY QUALITY CONTROL MANUAL – BOOK 1 and are summarized here.
Testing of appropriate QC strains on each new lot/shipment of panels before or concurrently with placing these materials into use for testing patient's isolates.
Testing of appropriate QC strains on each panel type weekly.
Testing of appropriate QC strains on each panel type after major system maintenance or software upgrade before or concurrently with placing the equipment back into service.
Testing of appropriate QC strains against any new antimicrobial agent added to the panel at least 20 times (over a minimum of 5 days) prior to resuming weekly QC testing of the panel; accomplished during performance of verification study.
Recording and evaluating QC results according to QC acceptability criteria as defined in the SOP. 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**

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