

Competency, Quality Assurance and Problem Solving



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Quality Management System



- **REQUIRED FOR EVERY LABORATORY UNDER CLIA**
- **GLOBAL POLICY SHOULD BE DETAILED IN A QUALITY MANUAL**
- **PARTS OF THE QUALITY MANUAL**
 - Mission Statement
 - Organizational Chart
 - Identify lab management by name and position including the quality manager
 - Provide description of the lab operation
 - Include a separate policy for each of the 23 Quality System Essentials(QSE's) that are part of the quality system.

QSE #1 Organization and Management



The lab must be a legal entity that is free of any financial or political conflicts of interest

QSE #2 Quality Management System



The Lab must:

- participate in an external proficiency testing program
- perform internal audits
- have a system for corrective action when errors occur

QSE #3 Document Control



- Each SOP should be reviewed by the Laboratory Director at least annually
- No document should be changed unless approved by the Laboratory Director or designee
- There should be a master list of documents that show which documents are currently in use, their revision number and the date of the revision

QSE #3 Document Control Revision Example



ON-THE-JOB-TRAINING

Approved by: ASW:PHV:ET

Effective Date: 05/08/96

Revision Date: 2/22/2011

Administrative: CC070.02

REVISION HISTORY

Document #	Date	Description
CC070.01	6/4/2010	Added to document training of specific procedures and a 6 month competency. Reworded how employees are released to a bench. Converted the appendix of lists of procedures contained in each bench to a checklist used to document training done.
CC070.02	2/22/2011	Training and Assessment form resequenced and revised

QSE #4 Review of Contracts



- With managed care organizations
- With the medical staff e.g. what the physicians have agreed to in terms of reflex testing, turn-around time for stat testing

QSE #5 Evaluation of Referral Labs



- The lab must have a procedure for evaluating and selecting referral labs e.g., ask for copies of the lab's PT (proficiency testing) results

QSE #6 Evaluation of Vendors



- Instrument or product should be approved or cleared by the FDA
- Vendor ISO 9000: 2005 or ISO 13485 accredited

QSE #7 Clinical Consultant Must be Available



- The lab must provide clinical interpretations as requested by clinicians

QSE #8 Resolution of Complaints



- Documentation should include:
 - The nature of the complaint
 - Date of occurrence
 - Individuals involved
 - Nature of investigation
 - Resolution of the problem

QSE#9 Control of Nonconformities (errors)



- Record the problem
- Determine the root cause
- Document corrective action e.g., using expired reagents, modifying test procedure without approval, specimen set up even though it was not transported properly

QSE #10 Corrective Action



- Document the effectiveness of corrective action over time

QSE#11 Preventive Action



- Establish a program to reduce the likelihood of nonconformance
 - Accomplished by regular review of data generated from routine QC testing of reagents and proficiency testing.

QSE #12 Continual Improvement



- Review all operational procedures at least annually with the goal of improving all SOPs as necessary

QSE #13 Quality and Technical Records



- These include:
 - Patient test requisitions
 - Patient test reports
 - Instrument printouts
 - QC records
 - Records of specimens sent to reference labs
 - Nonconformity records
 - Complaint records
 - Record of corrective action

QSE #14 Internal and External Audits



- Verify that lab is in compliance with its quality program
 - ✘ External audits usually occur every 2 years by an outside agency
 - ✘ Internal audits are performed by staff
 - May be done using checklists from each microbiology section
 - Internal audits should be discussed with lab personnel

QSE #15 Personnel



- Maintain job descriptions
 - Should include required qualifications, experience, education, training and professional certification
- Provide adequate on-the job- training
- Provide continuing education
- Assess staff competency

Why are Training and Competency so Important?



- *Medical errors in which the laboratory is involved have been attributed to:*
 - *Training not being provided*
 - *Training being ineffective*

CAP Q Probes Program



- 1996 CAP-Q Probes Program: Three part study of employee competency assessment practices by the College of American Pathologists (CAP) included:
 - Current competency assessment practices
 - Evaluation of compliance with laboratory's own practices using personnel records
 - Written appraisal of the competence of 5 specimen processors per institution

CAP Q Probes Program



Q Probes Results from 552 Institutions

- Institutions with a written competency plan 89.2%
- Institutions following their written plan in the lab 90.3%
- Institutions reviewing employee competency at least annually 98.0%
 - Through direct observation 87.5%
 - Through review of test or QC results 77.4%
 - Through review of instrument PM 60.0%
 - Through written testing (poorest indicator) 52.2%

Additional Survey Information:

- 6.4% failed to comply with their own lab's plan
- 8.6% of employees failed their competency assessment but were allowed to continue their usual work

Summary of Competency Assessment



Items That Must be Included in a Competency Assessment Program

- ❖ Direct observation of routine patient test performance
 - Description: This is the actual observation of work as it is being performed by the laboratory staff. Not limited to test performance but include all processes in which the employee is involved, including specimen collection, preparation, as well as the actual testing of the specimens.
 - Examples: Used for areas involving a higher degree of decision making or having a significant impact on patient care (e.g., new positive blood cultures, positive cerebrospinal fluid specimens, susceptibility testing, accurate interpretation of test reactions, following appropriate work instructions)

Summary of Competency Assessment



Items That Must be Included in a Competency Assessment Program

- ❖ Monitoring the recording and reporting of test results
 - Description: Review of patient results for the proper and correct recording and reporting
 - Examples: This can be accomplished by the documentation of observation of an employee writing or entering patient test results on report forms or into the computer or by review of worksheets with report forms or computer entries.

Summary of Competency Assessment



Items That Must be Included in a Competency Assessment Program

- ❖ Review of test results, QC records, proficiency testing results, and preventive maintenance records
 - Description: One must review patient results.
 - Examples: This can be accomplished by review of worksheets or computer entries for accurate recording of patient results, review of QC worksheets or printouts for acceptable results (within QC parameters) and for review of preventive maintenance records for the appropriate and timely checks and documentation.

Summary of Competency Assessment



Items That Must be Included in a Competency Assessment Program

- ❖ Direct observation of performance of instrument maintenance and function checks
 - Description: Direct observation must be used when employees are performing maintenance procedures and check of instruments.
 - Examples: One must directly observe an employee when performing maintenance procedures and function checks on instruments in the laboratory, such as the automated identification/susceptibility testing instrument, molecular diagnostic instrumentation, and blood culture instrumentation.

Summary of Competency Assessment



Items That Must be Included in a Competency Assessment Program

- ❖ Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples
 - Description: One must assess employee competence by giving them unknown samples to evaluate as they would evaluate patient samples in the laboratory.
 - Examples: This can be accomplished by split-sample analysis, previously analyzed specimens, blind internal proficiency testing, or external proficiency testing such as CAP surveys, etc.

Summary of Competency Assessment



Items That Must be Included in a Competency Assessment Program

- ❖ Assessment of problem-solving skills
 - Description: One must assess the ability of employees to solve problems that arise during their culture analysis.
 - Examples: This can be accomplished by (i) asking the employees to write up a situation where they had to solve a problem that related to an investigation they performed or (ii) giving a fictitious (or real) example of a problem encountered in the laboratory and asking the employee how he or she would handle the situation.

Training, Evaluation and Assessment Tools



- MSI Administrative Procedure CCo70
- MSI Employee Training and Assessment Record Form
- MSI employee competency Evaluation Form

Administrative Procedure CCo70: On the Job Training



ON-THE-JOB-TRAINING

Approved by: ASW:PHV:ET

Effective Date: 05/08/96

Revision Date: 10/24/08

Administrative: CCo70

I. PRINCIPLE:

To assure that all technical staff are adequately trained, an on-the-job training program (OJT) has been developed. This procedure outlines the steps involved.

II. PROCEDURE:

- A. The Laboratory Director will assess all technical employees at the time of employment for their suitability to perform clinical testing. Individuals with appropriate education and professional certification will then go through Microbiology Specialists Inc. OJT.
- B. msi® OJT consists of mastery of multiple tasks as outlined in this SOP. The program begins with the accessioning and set-up of specimens and the performance of direct exams. The entire process can take 3-5 years.
- C. Day shift jobs are divided by benches. Each bench (Bacteriology, Virology, Mycobacteriology, Mycology, Parasitology, Molecular, and Special Studies) has a general list of tasks. Because of the extensive list of procedures, trainers and trainees are referred to procedure manuals for each bench.

MSI Employee Training Record

PROCEDURE	Assessor initials	Trainee initials	Date Initial Training completed	Semi- annual Assessment	Annual Assess-ment
Technical Benches					
Bacteriology					
Clinicals					
Isolate Identifications					
Direct Microscopy					
Molecular (Gen Prob Pace 2)					
Mycobacteriology					
Mycology					
Parasitology					
Virology					
Processing					
Bacteriology					
Virology					
Miscellaneous					
Mycobacteriology					
Mycology					
Paper/Set-Up					

Detail: MSI Employee Training Record

PROCEDURE	Assessor initials	31 Trainee initials	Date Initial Training completed	Semi-annual Assessment	Annual Assessment
TECHNICAL BENCHES					
BACTERIOLOGY					
Clinicals					
Procedure manuals read and followed:					
-Bacteriology Procedures (AA)					
-Bacteriology Tests (PP)					
-Susceptibility Procedures (SU)					
-Anaerobe Procedures (FF)					
-GLC Procedure					
-Veterinary (VV)					
Perform & assess direct Gram stain					
Criteria for work up applied appropriately					
Biochemicals & stains set up					
Biochemical & stains assessment					
Kirby-Bauer set up & assess					
E test set up & assess					
Gas Liquid Chromatography set up & assessment					
Record workup & results on workcard					
Report out results					

MSI Laboratory Employee Competency Evaluation Form



Employee's Name: _____ Date of Evaluation: _____

Evaluator's Name: _____ Bench: _____

Numerical Parameters

- 1=16 errors or more for each task
- 2= 9-15 errors or more for each task
- 3= 8 errors or less for each task
- 4= 5 errors or less for each task
- 5= 2 errors or less for each task

Appearance

	Neatness					Legibility				
Workcards	1	2	3	4	5	1	2	3	4	5

MSI Laboratory Employee Competency Evaluation Form



Sample Set-Up and Transport

<u>Were samples transported at correct temperature?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were samples preserved correctly for transport?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were sample requests date stamped?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Did sample label match Requisition Form?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were samples logged correctly?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were shared, priority or special instructions noted on sample requisition?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were safety precautions for the transport and 'check-in' of samples utilized?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were all tests set-up as ordered?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were samples inoculated onto appropriate media?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were inoculated samples incubated appropriately?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were left over samples saved appropriately?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>

MSI Laboratory Employee Competency Evaluation Form



Specimen Work-Up

<u>Were work cards easy to read?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were the correct biochemicals, slides, or subcultures set up?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Did decision making processes yield proper results and follow protocols?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Was each day's work dated and initialed?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were all biochemicals, slides, or subculture results recorded?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were biochemicals inoculated properly?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Was all work completed in a timely manner?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were specimen stains read correctly?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were specimens overworked?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were safe work practices observed?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>
<u>Were priority requests done in a timely manner?</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>N/A</u>

MSI Laboratory Employee Competency Evaluation Form



Quality Control

Were check plates done when appropriate?	1	2	3	4	5	N/A
Were necessary controls performed?	1	2	3	4	5	N/A
Were periodic QC controls performed?	1	2	3	4	5	N/A

Reporting

Was confidentiality maintained?	1	2	3	4	5	N/A
Were verbal reports given and documented?	1	2	3	4	5	N/A
Were final reports correct?	1	2	3	4	5	N/A
Were reports given in a timely manner?	1	2	3	4	5	N/A
Were all reports logged out?	1	2	3	4	5	N/A
Was supervisory review appropriate?	1	2	3	4	5	N/A

MSI Laboratory Employee Competency Evaluation Form



Conclusion

Overall performance of employee at this bench (average of tasks evaluated) 1 2 3 4 5
Is retraining necessary? _____ **Yes** _____ **No**

Note: Overall satisfactory performance does not mean retraining is not necessary. Each task is evaluated individually for retraining purposes. Retraining is required on each task that has a score of less than 3.

Additional comments:

MSI Laboratory Employee Competency Evaluation Form



Acknowledgement

Employee Signature

Date

Evaluator's Signature

Date

Follow-Up

Employee Signature

Date

Evaluator's Signature

Date

Remedial Actions for Failure



- Discuss SOP with employee and determine root cause of problem.
 - Have employee produce a flow chart to help them properly perform SOP
- Have employee observe another trained and competent employee
- Have employee practice the failed procedure with known specimens.
- Have employee retest the same clinical specimens under direct observation
- If, after reeducation and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken, which, may include supervisory review of all work, reassignment of duties or other actions deemed appropriate by the Laboratory Director

Using an Internal Audit to Also Assess Employee Competence



- Audit: Are processors withdrawing the urine loop from a well mixed urine exactly perpendicular? If not, counts could be off by as much as $\pm 50\%$. Can employee training and follow-up assessment mitigate this potential problem?

Reference: Albers, A.C. and R.D. Fletcher. 1983. Accuracy of calibrated-loop transfer. *J. Clin. Microbiol.* 18: 40-42.

Using an Internal Audit to Also Assess Employee Competence



- Observe all processors setting up urine cultures
- Have all processors test the same urine 10 times
 - Difference between analyst counts should not exceed 10%
 - Difference between counts for a single analyst should not exceed 5%

Reference: Weissfeld, A. S. 2010. Estimation of uncertainty of measurement in microbiology. Clin Micro. Newsl. 32: 171-175.

QSE # 16 Management Review



- Managers should assess deviation from quality system during past 12 months, evaluate effectiveness of the quality program and make changes as necessary
 - Solicit feedback from clients
 - Review all nonconforming work
 - Review all PT results

QSE #17 Environmental Conditions



- There must be adequate space and a safe environment to perform testing.
 - Negative pressure must be maintained in the laboratory
 - Adequate ventilation should be provided
 - Work up of all infectious specimens should be performed in a biological safety cabinet
 - Adequate utilities (water, electric)
 - Appropriate disposal and removal of infectious waste
 - Compressed gases should be appropriately stored
 - Work surfaces should be nonporous
 - All electrical circuits must be properly sized and grounded

QSE #18 Laboratory Equipment



- There must be procedures that specify monitoring of instruments including calibration and preventive maintenance
 - All reports should be documented in an equipment log
- Computer software must be validated before use

QSE #19 Pre-Analytical Procedures



- Requests for testing must provide:
 - Patient id
 - Name of ordering healthcare practitioner
 - Clinician's address
 - Type of sample and anatomic site
 - Test requested
 - Patient gender
 - DOB
 - Pertinent clinical information
 - Date and time of sample collection
 - Date and time of receipt in lab

QSE #19 Pre-Analytical Procedures (Continued)



- The laboratory must maintain a record of samples received in the lab (logbook) and specimens must be transported properly

QSE #20 Analytical Procedures



- The process of analysis must be specified using verified procedures

QSE #21 Post-analytical Procedures



- Supervisory personnel should routinely examine results prior to reporting patient results

QSE #22 Assuring Quality of Analytical Procedures



- There must be a robust QC program in place
- The laboratory shall determine the uncertainty of measurement for each test performed where relevant

QSE #23 Reporting of Results



- Results must clearly identify
 - Patient's name
 - Date and time of specimen collection
 - Test performed
 - Test results
 - Name or initials of person performing test
 - Name or initials of person reviewing the report and releasing the results

HOW TO IMPLEMENT STREAMLINED QC



REVISED AS OF JUNE/15/2009

- PHASE II Deficiency: MIC. 21626
- Is each new lot number and shipment of reagents used in bacterial identification systems tested with positive and negative organisms?

HOW TO IMPLEMENT STREAMLINED QC



Streamlined QC for Commercially Available Microbial Identification System (MIS)

CSLI (2008)

- Quality Control for Commercial Microbial Identification Systems; Approved Guideline (M50-A)
 - Document suggested by CLIAC in 2006 following ASM survey which showed <0.1% failures using unmodified MISs for aerobic/anaerobic bacteria and yeasts
 - enables lab to test only key indicator microorganisms instead of running a positive and negative for each substrate

A Four Step Program to Switch to a Streamlined QC



Step 1:

The lab must already have a robust quality assurance program in place

A Four Step Program to Switch to a Streamlined QC



Step 2:

General Responsibilities

- Handle and store MIS according to manufacturer's recommendations
- Ensure personnel competency to use MIS
- Follow all manufacturers instructions for testing
- Document all MIS QC activities and any corrective action taken

A Four Step Program to Switch to a Streamlined QC



General Responsibilities

- Report any QC failures to manufacturer or distributor, as applicable
- Retain documents as required under CLIA

A Four Step Program to Switch to a Streamlined QC



Step 3

Initial Performance

- Maintain documentation of manufacturer's compliance with ISO 13485 and FDA quality system requirements
 - COA (certification of analysis)
 - COC (certification of compliance)
 - Certification statement in manufacturer's instructions for use

A Four Step Program to Switch to a Streamlined QC



Initial Performance

- Meet one of the following options
 - Perform and document MIS verification study
 - Conduct historical review of QC performance
 - Review QC performance for at least 3 consecutive lot numbers of MIS from 3 different shipments over 3 consecutive seasons
 - QC must have been performed using positive and negative controls for each reagent and/or substrate according to manufacturer's instructions (i.e., exact ATCC strains)

A Four Step Program to Switch to a Streamlined QC



Initial Performance

- Historical review
 - Performance is considered satisfactory if at least 95% of reagent/substrate results are within results specified by the manufacturer

A Four Step Program to Switch to a Streamlined QC



Step 4:

On-going Performance

- Maintain current documentation of manufacturer conformance to QSR
- Maintain documentation of results of verification study or historical QC review
- Test all key indicator strains specified in the package insert with each batch, lot number and/or shipment of MIS

A Four Step Program to Switch to a Streamlined QC



On-going Performance

- Perform testing according to manufacturer's instructions
- Use only manufacturer's reagents
- Investigate and resolve any QC failures
- Report QC failures to manufacturer and/or distributor
- Maintain all QC documentation as required

HOW TO VERIFY AN INSTRUMENT



NEW AS OF JUNE/15/2009

- PHASE I Deficiency GEN. 41850
- Is there a summary statement, signed by the laboratory director (or designee who meets CAP director qualifications), documenting review of validation studies and approval of each test for clinical use?

VERIFICATION



(CALLED VALIDATION BY CAP)

- One time process to confirm a test's expected performance
- Amount of work to be done depends upon the type of test
 - Unmodified FDA-cleared/approved
 - Modified FDA-cleared/approved
 - Laboratory developed test

VALIDATION



(CALLED VERIFICATION BY CAP)

- On-going process to ensure a test's continued performance
 - Normal daily, weekly or monthly QC
 - Proficiency testing (PT)
 - Staff competency testing
 - Instrument cleaning/calibration

CASE STUDY



**VERIFICATION OF A NEW
AUTOMATED
INSTRUMENT FOR ORGANISM IDENTIFICATION
AND ANTIMICROBIAL
SUSCEPTIBILITY TESTING**

Verification Samples



- Well characterized clinical isolates or fresh clinical isolates tested on both systems
- ATCC strains or isolates from PT surveys
- Use distribution of organisms similar to that seen in your hospital e.g.,
 - Gram-positive panel should include MRSA, D-test positive *Staphylococcus aureus*, coagulase-negative staphylococci, vancomycin-resistant enterococci
 - Gram-negative panel should include extended spectrum β -lactamase-, carbapenamase- and Amp C-producing *Enterobacteriaceae*, MDR *Pseudomonas aeruginosa* and *Acinetobacter*

Definition of Acceptability



(Reference: Cumitech 31A: Verification and Validation of Procedures in the Clinical Microbiology Laboratory)

- Identification
 - Test 30 isolates in parallel with new system and old system
 - ✓ Send to reference lab if there are any discrepancies

Definition of Acceptability



- Antimicrobial Susceptibility Testing
 - Concordance between methods means a result is within 1 doubling dilution
 - No difference in the interpretation of resistance

Unmodified FDA-Cleared Test



- In total, at least 30 isolates should be tested with each antibiotic panel/card
 - Compare to current AST system
 - Keep in mind that the new system may be better than current system.

Minor discrepancy

- ✘ one AST system is intermediate (I), the other is susceptible (S) or resistant (R)

Major discrepancy

- ✘ One result is susceptible (S), the other is resistant (R)

Essential and Categorical Agreement



- Both categorical (S, I, R) and essential should be $\geq 90\%$
- Both major and minor errors combined should be a $<10\%$
- $<5\%$ major errors
- overall essential agreement and categorical agreement of $\geq 90\%$

Caveats



- Investigate all categorical errors for all types of systems
- If specified limits are exceeded for any antibiotic, the test must be considered unverified and withdrawn from consideration or corrective action must be taken in conjunction with the manufacturer to attempt to resolve discrepancies.
- If a significant number of organisms have MICs near the breakpoint, the categorical agreement may be $< 90\%$ due to the inherent plus/minus dilution variabilities of AST system.

NEW RULES FOR DIRECT TO CONSUMER TESTING



NEW AS OF JUNE/15/2009

CAP REQUIREMENTS FOR DIRECT TO CONSUMER (DTC) TESTING – ALL PHASE II Deficiencies

- GEN. 41460: Report only in lawful jurisdictions
- GEN. 41465: Report to licensed health care practitioner if one is designated by the consumer
- GEN. 41475: Report test results, reference range, interpretation and limitations of the test in language readily understandable to a lay person.

NEW RULES FOR DIRECT TO CONSUMER TESTING



NEW AS OF JUNE/15/2009

CAP REQUIREMENTS FOR DIRECT TO CONSUMER (DTC) TESTING – ALL PHASE II Deficiencies

- GEN. 41485: Report name, phone number and e-mail address of a licensed health care practitioner who consumer can contact about clinical significance of test.
- GEN. 41495: Report any critical results ASAP
- GEN. 41497: Maintain test records for 10 years

Microbiology Tests Offered as Direct-to Consumer Testing



- HIV-1 antibody test
- STD panel (*Chlamydia trachomatis* and *Neisseria gonorrhoeae*)
- Herpes simplex types 1 and 2 IgG serologies
- Syphilis test

States Permitting DTC Testing



As of 1/24/08, Direct to Consumer Testing and its Impact on the Lab Market, Mark Terry, Washington G2 reports

- Alaska
- Arkansas
- Delaware
- District of Columbia
- Indiana
- Iowa
- Kansas
- Louisiana
- Minnesota
- Missouri
- Montana
- Nebraska
- New Mexico
- North Carolina
- North Dakota
- Ohio
- Oklahoma
- South Dakota
- Texas
- Utah
- Vermont
- Virginia
- Washington
- West Virginia
- Wisconsin

OTHER NEW QUESTIONS



NEW AS OF JUNE/15/2009

MIC. 11150 PHASE II Deficiency

- All tests for which positive results likely to represent a critical result (i.e., imminently life-threatening infection) processed on a schedule that ensures timely reporting of results?

OTHER NEW QUESTIONS



Examples of Tests with Critical Results

- Bacterial culture of blood
- Bacterial culture of CSF
- Examination of blood films for malaria

References



- From CLSI (Clinical and Laboratory Standards Institute)
 - GP26-A3: Application of a Quality Management System Model for Laboratory Services
 - HS01-A2: A Quality Management System Model for Healthcare
- From ISO (International Organization for Standardization)
 - ISO 15189

References



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QUESTIONS?



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