

Competency Assessment: More Important than Ever



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OBJECTIVES

- To learn how to use competency assessment as a performance improvement tool
- To learn how to assess knowledge and skills
- To understand how to use competency assessment as a training opportunity

Beginnings



- 1966: 60 Minutes Exposé on “Sink Testing” : Leads to calls for reform
- 1967 : Clinical Laboratory Improvement Act (CLIA '67)
 - ❑ Applied only to laboratories engaged in Interstate Commerce (approx 12,000 or 7%)
 - ❑ Required:
 - Strict adherence to quality control standards (QC)
 - Proficiency Testing (PT)
 - Strict adherence to Standard Operating Procedures (SOPs)
 - Personnel standards

Beginnings



- ❑ HCFA : Health Care Finance Administration, (eventually the name was changed to the Center for Medicare and Medicaid Services(CMS))
- ❑ Agency of the Dept. of Health and Human Services (DHHS) , given regulatory oversight to :
 - ✦ Act as an enforcement arm for CLIA '67
 - ✦ Oversee Medicare and Medicaid Program
- 1987 Wall Street Journal : Exposé on “Pap Mills”, led to:
- 1988 Clinical Laboratory Improvement Amendments
(CLIA '88)

Components of CLIA '88



- ❑ Extended oversight to any facility performing clinical laboratory testing (approximately 170,000 labs), including physician office labs (POLs)
- ❑ The level of regulation was determined by the complexity of tests performed
- ❑ Mandated employee training and ongoing assessment of competency to ensure testing quality
- ❑ Outlined components of the Laboratory Competency Assessment Program
 - Direct observation of routine patient test performance
 - Monitoring the recording and reporting of test results
 - Review of test worksheets, and quality control (QC) records, PT results, and preventive maintenance (PM) records

Components of CLIA '88



- Direct observation of performance of instrument maintenance and function sheets
- Assessment of performance through testing previously analyzed specimens, internal blind testing samples or external PT samples
- Assessment of problem-solving skills

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

Standards for Competency Testing



- **CAP GUIDELINES**
- **THE JOINT COMMISSION STANDARDS**
- **MICROBIOLOGY CERTIFICATION REQUIREMENTS CLIA '88**

CAP Guidelines Addressing Competency Testing



- CAP # GEN. 54750

Question: For laboratories subject to U.S. federal regulations, do all testing personnel meet CLIA '88 requirements?

Answer: There must be evidence in personnel records that all testing personnel have been evaluated against CLIA '88 requirements , and that all individuals qualify.

CAP Guidelines Addressing Competency Testing



- CAP # GEN. 55200
- Question: Are there annual reviews of the performance of existing employees and an initial review of new employees within the first 6 months?
- Answer: The laboratory must conduct an annual performance review of all employees. New employees must be reviewed within 6 months of employment and annually thereafter.

CAP Guidelines Addressing Competency Testing



- CAP # GEN. 55500
- Question: Has the competency of each person to perform his/her assigned duties been assessed?
- Answer: The manual that describes training activities and evaluation must be specific for each job description. The training and assessment program must be documented and specific for each job description. Activities requiring judgment or interpretive skills must be included. The records must make it possible for the inspector to be able to determine which skills were assessed and how those skills were measured.

CAP Guidelines Addressing Competency Testing



- CAP # GEN. 55000 (cont'd)

Some elements of competency assessment include but are not limited to:

- ✦ Direct observation of routine patient test performance, including patient preparation.
- ✦ If applicable, specimen handling, processing and testing
- ✦ Monitoring the recording and reporting of test results;
- ✦ Review of intermediate test results or worksheets, QC records, proficiency testing results and preventive maintenance records
- ✦ Direct observation of performance of instrument maintenance and function checks
- ✦ Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples; and
- ✦ Evaluation of problem-solving skills

CAP Guidelines Addressing Competency Testing



- CAP # GEN. 57000
- Question: If an employee fails to demonstrate satisfactory performance on the competency assessment, does the laboratory have a plan of corrective action to retrain and reassess the employees competency?
- Answer: The laboratory should have a documented corrective-action plan to retrain and reassess employee competency when problems are identified with employee performance. If, after reeducation and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken, which, may include close supervisory review of work, reassignment of duties or other actions deemed appropriate by the Laboratory Director.

CAP Guidelines Addressing Competency Testing



- CAP # GEN. 58500
- Question: Is there documentation of retraining and reassessment for employees who initially fail to demonstrate satisfactory performance on competency assessment?
- Answer: Documentation of retraining and reassessment of employees who initially fail competency assessment should be available.

The Joint Commission Standards Regarding Competency Testing



- HR 2.10
- Standard: Orientation provides initial job training and information
- Explanation: As appropriate, each staff member, student, and volunteer is oriented and then assessed to the following:
 - ✦ The organization assesses and documents each person's ability to carry out assigned responsibilities safely, competently, and in a timely manner on completion of orientation
 - ✦ The organization documents that each person has completed orientation and has been evaluated for competency in performing required laboratory tasks as well as other parameters defined in his or her job description
 - ✦ Documentation of orientation participation includes written approval by the laboratory director or appropriate supervisor noting that the individual is capable of performing laboratory duties and confirmation by the employee that he or she feels qualified after orientation to perform the tasks required

The Joint Commission Standards Regarding Competency Testing



- HR. 2.30
- Standard: Ongoing education, including in-services, training and other activities, maintains and improves competence.
- Explanation: The following occurs for staff, students and volunteers who work in the same capacity as staff providing care, treatment, and services:
 - ✦ Training occurs when job responsibilities or duties change
 - ✦ Participation in ongoing in-services, training, or other activities occurs to increase staff, student, or volunteer knowledge of work-related issues
 - ✦ Ongoing in-services and other education and training are appropriate to the needs of the populations served and comply with law and regulation

The Joint Commission Standards Regarding Competency Testing



✦ HR. 2.30 (cont'd)

- ✦ Ongoing in-services, training, or other activities emphasize specific job-related aspects of safety and infection prevention and control
- ✦ Ongoing in-services, training or other education incorporate methods of team training, when appropriate
- ✦ Ongoing in-services, training or other education reinforce the need and ways to report unanticipated adverse events
- ✦ On-going in-services or other education is offered in response to learning needs identified through performance improvement findings and other data analysis (that is, data from staff surveys, performance evaluations, or other needs assessments)
- ✦ On-going education is documented
- ✦ At a minimum, for supervisory staff, attendance at outside workshops, institutes, and local, regional or national society meetings occurs as feasible

The Joint Commission Standards Regarding Competency Testing



- HR.3.10
- Standard: Competence to perform job responsibilities is assessed, demonstrated, and maintained
- Explanation: Competency assessment is systematic and allows for a measurable assessment of the person's ability to perform required activities. Information used as part of competency assessment may include data from performance evaluations, performance improvement and aggregate data on competency, as well as the assessment of learning needs. This standard encompasses the following:

The Joint Commission Standards Regarding Competency Testing



• HR.3.10 (cont'd)

- ✘ The laboratory director or appropriate laboratory supervisor regularly assesses the continued competency of staff on all laboratory work shifts through performance evaluations
- ✘ Staff members are evaluated for competency in performing required laboratory tasks as applicable, as well as for all other parameters defined in their job descriptions
- ✘ Supervisory staff are evaluated for performance of their job responsibilities, as defined in their job descriptions
- ✘ A job description and a completed competency assessment, an evaluation, or an appraisal tool are on file for each contracted or employed individual
- ✘ Each staff member's performance is evaluated and documented after orientation and annually thereafter
- ✘ An individual qualified to provide technical judgments about performance evaluates technical staff
- ✘ The procedures to assess and document annually the competency of technical staff include but are not limited to the following:

The Joint Commission Standards Regarding Competency Testing



✦ HR.3.10 (cont'd)

- Routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing
- The recording and reporting of test results
- QC, proficiency testing, and preventive maintenance performance
- Instrument function checks and calibration performance
- Test performance assessment as defined by laboratory policy (e.g., testing previously analyzed specimens, internal blind testing samples, and external proficiency or testing samples)
- Assessment of problem-solving skills as appropriate to the job
- ✦ If a test method or instrumentation changes or the individual's duties change, his or her performance is reevaluated to include skills in the areas of change
- ✦ Each laboratory employee performing such tests participates in the program
- ✦ Acceptable performance criteria are established
- ✦ Performance levels are documented
- ✦ When indicated, remedial action is taken and documented

The Joint Commission Standards Regarding Competency Testing



- LD.2.90

- Standard: The laboratory director is responsible for determining the qualifications and competency of laboratory staff
- Explanation: The director determines the procedures and tests that staff members are qualified and authorized to perform and is responsible for determining the competence and qualifications of laboratory staff. The director ensures that the level of supervision provided and the level of testing complexity is commensurate with the education, training, and experience of staff. The director must also require that staff demonstrate the ability to perform all duties before actually testing patient specimens and that all staff maintain competencies to perform required tasks.

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.

Microbiology Certification Requirements: CLIA '88



Test Complexity Level	Personnel	Minimum Qualifications
Moderate	Director	Physician (MD,DO,DDS,DPM) or PhD in science; must have 1 year of supervisory experience if not a board-certified pathologist or doctoral scientist or
		Baccalaureate degree in science plus 2 years of laboratory training and experience and 2 years of supervisory experience.
	Technical Consultant (responsible for technical oversight if a nurse or non-medical technologist is the laboratory director)	Baccalaureate degree in science plus 2 years of experience

Microbiology Certification Requirements: CLIA '88



Test Complexity Level	Personnel	Minimum Qualifications
Moderate (continued)	Clinical consultant (liaison between laboratory and clinicians)	Physician (MD, DO, DDS, DPM) or board certified doctoral scientist
	Testing Personnel	High school diploma plus documentation of on-the-job training.
High	Director	Physician (MD, DO, DDS, DPM) or board certified doctoral scientist
	Technical supervisor	Baccalaureate degree in science plus 4 years of laboratory experience in high complexity testing.

Microbiology Certification Requirements: CLIA '88



Test Complexity Level	Personnel	Minimum Qualifications
High (continued)	General supervisor	Associate degree in medical laboratory science plus 2 years of laboratory experience in high complexity testing.
	Clinical consultant (can be director)	Physician (MD, DO, DDS, DPM) or board certified doctoral scientist
	Testing personnel	Associate degree in medical laboratory technology or laboratory science.

Training, Evaluation and Assessment Tools



- **MSI ADMINISTRATIVE PROCEDURE MANUAL CCo70**

- CLIA '88 Personnel Evaluation Form
- MSI Employee Training Record Form
- MSI Training Standards: Technical Benches
- MSI Training Standards: Processing

- **MSI LABORATORY EMPLOYEE COMPETENCY EVALUATION FORM**

- **USE OF INTERNAL AUDIT TO ALSO ACCESS EMPLOYEE COMPETENCY**

CLIA '88 Personnel Evaluation Form



I have reviewed the training and experience of

and they meet the CLIA '88 requirements for employment as a

_____.

Alice S. Weissfeld, Ph.D.
Director

Date

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*

Administrative Procedure CCo70: On the Job Training



ON-THE-JOB-TRAINING

05/08/96

Approved by: ASW:PHV:ET

Effective Date:

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 Administrative Procedure CCo70: On the Job Training



- D. When both trainers and trainees feel that the trainees are ready to do a bench themselves, the trainees will have their work reviewed closely by supervisory personnel, including reviewing culture plates, slides, etc.
- E. When trainees have 2-3 months of experience on a bench, they are given a competency evaluation to assess their abilities. In all cases, all employees who have been at work for six months will have a competency evaluation.
- F. Individuals with favorable competency ratings are checked off as having learned that bench on the “Employee Training Assessment” form.
- G. After training on a bench and after favorable competency has been assessed, the employee will sign the front of the appropriate procedure manual acknowledging their competency with that SOP.
 - 1. All subsequent additions and revisions to each SOP are reviewed and initialed by the laboratory director, each technologist and all supervisors.
- H. Annual Assessment of Employee competency:
 - 1. After initial training and competency evaluation, technical employees will be evaluated yearly thereafter.
 - 2. Competency records are kept in the employee’s personnel file.
 - 3. Employees failing their annual competency evaluation will have documented re-training and re-testing in areas found to be lacking.

MSI Employee Training Record



Employee's Name: _____

PROCEDURE	ANALYST	TRAINER	DIRECTOR
Technical Benches			
Bacteriology			
Anaerobes			
Clinicals			
Aerobic IDs			
Virology			
Mycology			
Mycobacteriology			
AFB 1			
AFB 2			
Parasitology			

MSI Employee Training Record



PROCEDURE	ANALYST	TRAINER	DIRECTOR
Molecular			
Gen-Probe Pace 2			
Miscellaneous (AM)			
Quality Control			
Processing			
Bacteriology			
Virology			
AFB/Mycology			
Paper/Set-Up			

Employee Signature

Date

Lab Director

Date

MSI OJT Training Standards: Technical Benches



• BACTERIOLOGY

Clinicals:

- All clinical procedures are outlined in the Bacteriology Procedure Manual
- Set-up / assess susceptibilities by following methodology:
 - MICs
 - Kirby-Bauer susceptibilities
 - ϵ -test
- Prepare and inoculate standard biochemicals and assess their reactions

Anaerobes:

- All anaerobe procedures are outlined in the Anaerobic Procedure Manual
- Set-up / assess susceptibilities by MIC methodology
- Prepare and inoculate standard biochemicals and assess their reactions
- Process and assess Gas Liquid Chromatography (GLC) patterns

MSI OJT Training Standards: Technical Benches



• BACTERIOLOGY (cont'd)

Aerobic Identifications:

- All aerobic identification procedures and corresponding identification charts are outlined in the Aerobic Identification Manual
- Prepare and inoculate standard biochemicals and assess their reactions
- Set-up / assess susceptibilities by the following methodologies:
 - MICs
 - Kirby-Bauer
 - ϵ -test
- Use of selected charts containing biochemical reactions to identify human pathogenic organisms

The following Procedure Manuals have been referenced above:
Bacteriology Procedure Manual
Anaerobe Procedure Manual
Aerobic Identification Procedure Manual
Bacti Test Procedures
Susceptibility Test Procedures
King charts

MSI OJT Training Standards: Technical Benches



• VIROLOGY

All virology procedures are outlined in the Virology Procedure Manual.

- Reading tissue culture cell tubes (dailies and weeklies)**
- Prepare, fix, stain and assess direct/indirect fluorescent antibody (DFA)/IFA stains for viral confirmation**
- Hemadsorption Test Procedure**
- Acid-Test Procedure**
- Reporting of test results**

The following procedure manual has been referenced above:

Virology Procedure Manual

MSI OJT Training Standards: Technical Benches



• MYCOLOGY

All mycology procedures are outlined in the Mycology Procedure Manual.

- Prepare / assess Calcaflour white (CFW) stains
- Special stains:
 - Kinyoun's stain
 - Q-stain
 - Potassium hydroxide prep (KOH)
 - Lactophenol aniline prep
- API 20Cs
- Biochemical identification tests for moulds and yeasts
- Macroscopic and microscopic identification of moulds

The following procedure manual has been referenced above.

Mycology Procedure Manual

MSI OJT Training Standards: Technical Benches



• MYCOBACTERIOLOGY

All mycobacteria procedures are outlined in the Mycobacteriology Procedure Manual.

- Bactec procedure methods
- Identification tests for mycobacteria
- DNA probes for mycobacteria identification
- Standard and special susceptibilities for mycobacteria
- Auramine – rhodamine stain
- Ziehl – Neelsen stain

The following procedure manual has been referenced above:

Mycobacteriology Procedure Manual

MSI OJT Training Standards: Technical Benches



• PARASITOLOGY

All parasitology procedures are outlined in the Parasitology Procedure Manual

- Collection and use of preservative transports
- Microscopic examination:
 - Formalin concentrate
 - Trichrome stain
- Special stains:
 - Giardia/Cryptosporidium* fluorescent stain
 - Microsporidia
 - Modified acid-fast
- Detection of blood parasites

The following procedure manual has been referenced above.

Parasitology Procedure Manual

MSI OJT Training Standards: Technical Benches



• MOLECULAR

Non-amplified tests:

-Gen-Probe Pace 2

The following procedure manuals have been referenced above:

Molecular Procedure Manual
Individual Manufacturer's Procedure and Equipment Manuals

MSI OJT Training Standards: Technical Benches



• MISCELLANEOUS STAINS

Direct Microscopy

- Viral DFA or IFA
- Calcafluor white
- Auramine – rhodamine
- Ziehl-Neelsen
- Gram stain
- Kinyoun's stain
- Q stain
- Legionella* stain

The following procedure manuals have been referenced above:

Bacti Test Procedure Manual
Virology Procedure Manual
Mycology Procedure Manual
Mycobacteriology Procedure Manual

MSI OJT Training Standards: Technical Benches



• QUALITY CONTROL (QC)

All QC procedures are outlined in the Quality Control Manual and in the Equipment Quality Control Manual

- Performance of by-lot QC
- Performance of daily periodic QC
- Performance of weekly periodic QC
- Performance of monthly periodic QC
- Performance of equipment QC

The following procedure manuals have been referenced above:

Quality Control Procedure Manual
Equipment Quality Control Procedure Manual

MSI OJT Training Standards: Processing



- **Bacteriology:**

- Homogenization of tissue
- Use of appropriate media for culture (as outlined in laboratory Bacteriology Manual)

- **Serotyping:**

- E.coli* O157
- Salmonella / Shigella
- Streptex

- **Virology:**

- Preparation and inoculation of tissue culture cells
- Preparation of direct exam slides
- Preparation and inoculation of shell vials (Rapid culture technique)
- Preparation of special PMK refeed medium

MSI OJT Training Standards: Processing



- **Miscellaneous:**

- Bacti Notes:

- Gram stains
- Catalase
- Oxidase
- LAP
- PYR
- Susceptibilities (set up)
 - Kirby-Bauer
 - ε-test

- Inoculation including:

- Andrades sugars
- OF sugars
- TSI
- LIA
- Urea
- MIO

MSI OJT Training Standards: Processing



- **Miscellaneous: (cont'd)**

- Direct fluorescent microscopy:

- Herpes simplex type 1 & 2
- Varicella-zoster
- Respiratory Syncytial Virus
- Influenza A&B
- Legionella*

- Non-amplified DNA probes:

- Chlamydia
- Neisseria gonorrhoea (GC)
- Chlamydia/GC Probe competition assay
- India Ink exams (CSF /urine)
- Clostridium difficile* Cytotoxin Assay (set-up)

MSI OJT Training Standards: Processing



- **AFB/Mycology:**

- AFB

- Preparation / Digestion
- Preparation of direct exam slides
- Inoculation of appropriate culture media

- Mycology

- Preparation /Digestion-Homogenization/Mincing
- Preparation of direct exam slides
- Inoculation of appropriate culture media
- Tease mounts/Scotch-tape preparations
- API 20Cs (preparation/inoculation)

MSI OJT Training Standards: Processing



-Paper / Set-Up

- Accessioning of patient specimens
- Labeling of patient specimens
- Work card attachment
- Tissue culture cell quality assessment
- Set-up of appropriate tissue culture cell lines on viral cultures
- Mail
- Epidemiology reports
- Distribution of computer reports
- Check calendar

The following procedure manuals have been referenced above:

Bacteriology Procedure Manual
Virology Procedure Manual
Mycobacteriology Procedure Manual
Mycology Procedure Manual
Parasitology Procedure Manual
Paper work Procedure Manual
Administrative Procedure Manual
Bacti Test Procedure Manual

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

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



- Title: Urine Cultures, Pre-analytical, Analytical, and Post-analytical Review
- Purpose:
 - ✘ To assess whether contaminated urine samples were being submitted by clients
 - ✘ To review whether technologists were adhering to specimen work-up and reporting guidelines for urine cultures
- Design:
 - ✘ Evaluated all urine culture submitted between January-March 1993
- Data:
 - ✘ 233 specimens were submitted for urine culture:
 - 23.6% were positive for significant organisms
 - 45.5% were sterile
 - 34.3% contained one or more organisms of contaminating flora

Analysis of Urine Samples Submitted



CLIENT	TOTAL NO. OF SPECIMENS	STERILE CULTURES	POSITIVE CULTURES WITH NO CONTAMINATING FLORA	POSITIVE CULTURES WITH CONTAMINATING FLORA PRESENT	% POSITIVE	CULTURES WITH A SINGLE CONTAMINANT	CULTURES WITH MIXED CONTAMINANTS	PERCENT OF CULTURES SHOWING CONTAMINATION
1	123	60	27	6	26.8	18	12	29.3
2	54	9	13	4	31.5	15	12	57.4
3	1	0	1	0	0	0	0	0
4	25	19	3	0	13	1	2	12
5	24	15	0	0	0	6	3	37.5
6	1	0	0	0	0	0	1	100
7	3	3	0	0	0	0	0	0
8	1	0	1	0	0	0	0	0
9	1	0	0	0	0	1	0	100
TOTAL	233	106	45	10	-	41	29	-

Using an Internal Audit to Also Assess Employee Competence



• REASONS FOR CONTAMINATION

• PRE-ANALYTICAL

• Specimen collection by Clients

- There were too many contaminated urine specimens submitted for work up. Client #1 submitted 29.3% contaminated specimens, Client #4 had 12%, and Client #5 had 37.5% contaminated specimens.
- The requisition forms were not filled out with adequate information in the clinical syndrome category. More patient information (i.e., symptoms) would be useful in deciding if low colony counts are significant.

Using an Internal Audit to Also Assess Employee Competence



- ANALYTICAL

- Technologist Errors

- Twelve cultures should have been held an additional 24 hrs. due to the presence of 4+ enteric gram-negative rods, gram-positive cocci in clusters or yeast seen on direct exam. None of these organisms were noted on the culture after 24 hours of incubation. Therefore, the direct exam did not agree with the culture results that were reported.
 - Four cultures were reported out as contaminated with 2-3 different organisms. Each isolate was $>10^2$ organisms/ml with none being predominant. Enteric gram-negative rods or *S. saprophyticus* should have been pursued if the patient was symptomatic. The client should have been called to ascertain this information.

Using an Internal Audit to Also Assess Employee Competence



• Technologist Errors (cont'd)

- In three instances, a report of a single isolate of $<10^4$ organisms/ml of a gram-negative rod was not called to the client to inquire if the patient was symptomatic.
- Twenty-seven times, a report of a single isolate of a gram-positive cocci at $<10^4$ organisms/ml was not called to the client to inquire if the patient was symptomatic. *S. saprophyticus* should have been pursued if the client had symptoms of a UTI.
- Eleven instances where 2 organisms were isolated at least one being a catalase-positive gram-positive cocci, in approximately equal numbers at a level of $>10^2$ organisms/ml of urine. The client should have been called to see if *S. saprophyticus* needed to be ruled out.

Using an Internal Audit to Also Assess Employee Competence



- POST-ANALYTICAL
 - Supervisory Review Errors
 - None of the errors listed above were caught by review of the report before it went out.

Using an Internal Audit to Also Assess Employee Competence



- Clerical Errors

- One report was filed without organism identification
- One report had a susceptibility performed and reported, but the final report did not note “Susceptibility attached”

Using an Internal Audit to Assess Employee Competence



• Conclusions/Recommendations

- The urine culture procedure should be revised to include more precise instructions for specimen work-up. Included will be a category for cultures that should be incubated an additional 24 hours and which cultures should be called to the client to determine if the specimen was from a symptomatic patient.
- Clients submitting more than 10% contaminated urine specimens will be sent a letter re-emphasizing the correct technique for collecting a urine specimen. Ask that more patient information (especially if the patient has symptoms of a UTI) be filled out on the test requisition. Give a brief description of “Acute Urethral Syndrome” and let the clients know that the lab will be calling about cultures that fit the criteria of AUS (i.e. the presence of low numbers of enteric gram-negative rods or possible *S. saprophyticus*) unless adequate patient information is given on the test requisition.

Using an Internal Audit to Assess Employee Competence



• Conclusions/Recommendations

- More information needs to be included on the direct exam workcard. Include descriptions of gram positive rods– are they chaining or beaded? Are they attached to epithelial cells? Are gram-positive cocci chaining or in clusters. The Fifth edition of the *Manual of Clinical Microbiology* reports that *C. pseudodiphtheriticum*, Group JK and Group D-2 can cause UTI. Group E has been implicated in cases of pyelonephritis and “*C. genitalium*” may cause urethritis. Be aware that all gram positive rods in urine are not *Lactobacillus* or *G. vaginalis*.
- All technologists and supervisors should review the revised urine culture procedure and read the attached information on “Acute urethral Syndrome”.

References



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