Laboratory Accreditation

Competency Assessment

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Objectives

- Describe how Competency became an important part of Lab Accreditation
- Discuss the differences between training and competency
- Recognize overconfidence
- Differentiate between Waived and Non Waived Testing and how it relates to competency assessment
- List 6 levels of Competency
- Explain what makes a competency assessment meaningful

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CLIA

Clinical Laboratory Improvements Amendment

Competency Standard Beginnings….

- **1967 Congress passes 1st CLIA Law**
  - Established when Medicare was introduced
  - To regulate costs
  - Ensure high quality of health care
  - To make sure system was not abused financially
  - Ensure quality of laboratory results
  - Only required hospitals and large clinical laboratory
  - Labs were required to adhere to strict standards
    - Quality Control
    - Proficiency Testing
    - Performance and Personnel Standards
      - Competency

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CLIA
Clinical Laboratory Improvements Amendment
Competency becomes a reality…

- **1988 Congress passes 2nd CLIA Law**
  - Pap Mills turning out inaccurate results were the impetus for new law
  - 1987 Series of articles which appeared in Wall Street Journal
  - Response of the public furor from one or more deaths due to
  - False-Negative PAP smear reporting
- CLIA '88 purpose is to ensure that all laboratory testing is done accurately and according to quality standards

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CLIA 88

- **CLIA 88 Law**
  - **Requires employee training and competency**
  - **Must assess the competency of all testing personnel who handle human specimens**
  - Established the requirements for performance and documentation of initial training and on going competency

Clinical Laboratory Improvement Amendments

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CLIA
Clinical Laboratory Improvements Amendment

CLIA regulations place overall responsibility on the **LABORATORY DIRECTOR**

- CLIA Regulates all testing on humans for health purposes, diagnosis and treatment of disease
- CLIA '88 regulations are based on **complexity** of the testing the more complex the test the more stringent the standards for quality
  - Ensures accurate and reliable testing regardless of the lab and its location
- VA labs, research labs and forensic labs are exempted
- **1992** Centers for Medicare and Medicaid Services (CMS), published regulations to enforce the CLIA law
- CMS enforces CLIA

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CMS

Centers for Medicare and Medicaid Services

- Federal Agency with the US department of Health and Human Services (DHHS) that administers Medicare
- Partially funds Medicaid
- Sets the Standards
- Supports CLIA in partnership with CDC and FDA
- Must follow CMS regulations or you cannot bill federally funded programs
- Gives deemed authority to CAP and TJC for inspecting and accrediting labs
- CMS inspects if complaint filed or randomly selects labs
  - **Validation Inspection**
  - **2% of all labs are randomly selected**
- Formally know as Health Care Financing Administration (HCFA)

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Agencies

Regulating Laboratories

- TJC – The Joint Commission
  - Established 1951
  - Inspecting labs since 1979
- CAP – College of American Pathologists
  - Established 1962
  - 1967 deemed status to do Lab Accreditations
  - Strictest interpretation of CLIA Law
- COLA – Commission of Office of Laboratory Accreditation
  - Founded in 1988 – 1993 recognized by TJC
  - Inspects Physician Offices
- OSHA – Occupational Safety and Health Administration
- FDA – Federal Food Administration
- AABB – American Association of Blood Bankers
- OIG – Office of Inspector General
  - Oversees Billing Fraud
- OCR – Office of Civil Rights
  - Enforces HIPAA

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TJC

The Joint Commission

- 1979 Started evaluating laboratories
- 1995 TJC was deemed by CMS to certify labs under Clinical Laboratory Improvements Amendments (CLIA '88) requirements
- Laboratory standard set by TJC include wide variety of labs
  - Hospitals
  - Clinics
  - Home care facilities
  - Reference labs
- Labs that are accredited by CAP do not have to be re-inspected when the hospital the lab is located in is inspected by the Joint Commission
- 2002 Joint Commission establishes the National Patient Safety Goals and Speak Up campaign™
- 2003 Universal Protocol for preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™

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Laboratory Accreditation Program
College of American Pathologists (CAP)

1962 Laboratory Accreditation Program

- Program to improve the quality of Clinical Laboratory Services
  - Voluntary participation
  - Peer Review
  - Education
  - Compliance with performance standards
- 1967 CAP was deemed by Health Care Financing Administration (HCFA) now CMS as a certifying accreditation agency which meets or exceeds CLIA standards.
- 1995 CMS started limiting accrediting agency deemed status
  - CAP was initially awarded 3 years
- 2015 CMS renewed CAP status as an accreting agency for 6 more years

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OSHA
Occupational Safety and Health Administration

Source: www.OSHA.gov

- Main federal agency which enforces workplace health and safety legislation for ALL workers
- Regulations include
  - Blood Borne Pathogen
    - 1985 introduced Universal Precautions
      - 1996 became Standard Precautions to be used on all patients
  - Chemical exposure
  - Ergonomic injuries
  - Fire and Electrical Safety
- Prompts inspection:
  - Reported imminent danger in workplace
  - Fatalities or catastrophes
  - Employee complaint
  - Referral from other agencies
  - Targeted facilities
    - High hazard industries

Criminal and Civil penalties against an organization or individuals if laws are not followed.

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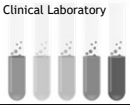
Lab Accreditations

CMS

CAP

The Joint Commission

Clinical Laboratory



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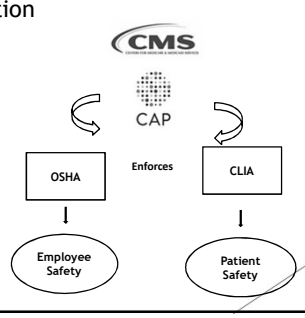
Accreditation



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University Medical Center New Orleans

Clinical Laboratory

Blood Gases
Moderately complex
Non-waived

Forensic Laboratory
High Complexity

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

Main Lab
High Complexity Testing

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Overconfidence bias...

British shipping company confident..."Unsinkable"
Titanic sets sail with not enough life boats

- Failure to think one is wrong
- Leads to insufficient thinking
- Too often people are wrong when they are certain they are right
- Allows one to make mistakes

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Overconfidence…

- "Most people rate themselves above the mean on almost every positive personal trait- including driving ability, a sense of humor, managerial risk taking, and expected longevity."

http://www.sfb504.uni-mannheim.de/glossary/overcon.htm

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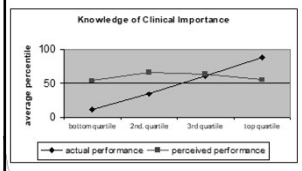
Overconfidence



"one is so sure of himself, that questions are no longer asked"

- People's tendency to exaggerate the extent of what they know is correct.
- Overconfidence may increase the likelihood of error
- Overconfidence in the clinical setting is a dangerous phenomenon
- Professional expertise does not immunize one from making fallible choices

Kissinger, JA. Overconfidence: A Concept Analysis. Nursing Forum.April-June 1998 p.18-26.

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"Epidemic of Medical Error"

"We are especially interested in innovative approaches to improving patient safety… "

Donald Berwick & Lucian L. Leape, July 1999

"Error in Medicine"

Published in 1994 JAMA
Lucian Leape, MD

To Err is Human: Building a Safer Heath System
Published 1999
Institute of Medicine

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Overconfidence repeats itself...

History

British shipping company confident...April 15, 1912

- "Unsinkable" Titanic sets sail with not enough life boats

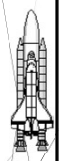
NASA managers confident...January 28, 1986

- Launched space shuttle Challenger
- Even though engineers were worried about its safety

Chernobyl operators confident..April 26, 1986

- Recently recognized for high productivity
- Routinely violated safety rules
  - without consequence
  - accepted behavior
  - increased productivity

Deep Water Horizon…2010



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Overconfidence leads to...

- Contempt for rules
  - Rules made for other people
    - ▶seat belts
    - ▶life jackets
    - ▶helmets
    - ▶latex gloves
  - Breaking rules pays off
  - Researchers of workplace accidents
    - safety violations are utterly routine

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Dunning Kruger Effect

1999

The Dunning–Kruger Effect Shows Why Some People Think They're Great Even When Their Work Is Terrible

- Cognitive Bias
- People who are incompetent at something are unable to recognize their incompetence
- Feel competent when they are actually incompetent
- Over inflated images of oneself
- Unskilled and Unaware
- "the knowledge and intelligence that are required to be good at a task are often the same qualities needed to recognize that one is not good at that task."

https://www.forbes.com/sites/markmurphy/2017/01/24/the-dunning-kruger-effect-shows-why-some-people-think-theyre-great-even-when-their-work-is-terrible/#6496dbc95d7c

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Do They Know - What They Don't Know?

Journal of Personality and Social Psychology
Kruger and Dunning 1999

Unskilled and unaware of it: how difficulties in recognizing one's own incompetence lead to inflated self-assessments.

- Unskilled and Unaware
  - Overly favorable views
    - Social and intellectual domains
- Incompetent individuals
  - Over estimate ability and performance
- Competent individuals
  - Under estimate ability and performance

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What does this mean?

- Overconfident staff
  - Unlikely to ask for help
  - Unlikely to research a problem
  - Unlikely to seek additional education

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Overconfidence

Resolutions to Help Lab Leaders Improve Quality

Micheal Astion, MD,PhD

- Study done at Medical Center of Louisiana at New Orleans 1999
- Participants rated how the personnel perceived knowledge of the job
- Assessment was given to see what they knew objectively really reflected what was preceived
- Study revealed that those who overrated their knowledge actually knew less
- Ones who preceived themselves as not knowing were the ones who actually knew the most

Haun DE, et al. Assessing the competency of specimen processing personnel. Laboratory Medicine 2000;31:633-637.

https://link.zixcentral.com/u/d2fe1326/Nm9mPtfz68GxIztoKuAQAw?u=https%3A%2F%2Fyoutu.be%2FxTvfdeKJvIg

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Specimen Processing Challenge

- Provide an objective measurement of skills
- Predict problem-solving performance
- Reveal training opportunities
- Steer improvement interventions

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Specimen Processing Challenge

Included…

- Self-Assessment and Objective Measurement
  - Knowledge of clinical relevance
  - Medical Terminology
  - Problem solving ability

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Self Assessment

Compared to my co-workers, I would rate my problem solving ability as___

10 9 8 7 6 5 4 3 2 1

superior average poor

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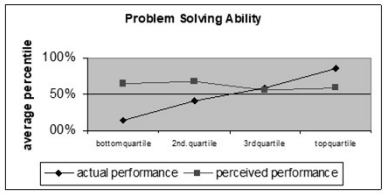
Problem Solving

A medical student brings up a blue top tube for a STAT preop PT and APTT. The student tells you that, at first, he put the blood into a red top tube but then realized the mistake and poured the blood into the blue top tube. Since the specimen is not clotted so you should ___.

a. just process the tests that are ordered.
b. reject the specimens.
c. tell the student to go get a fresh specimen.
d. call the lab for advice
e. wait for a supervisor

28 28

Can they solve difficult problems?



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Clinical relevance test

A. If the test is not immediately important (routine)

B. If the test is moderately important

C. If the test is extremely important

D. If you aren't sure or don't know

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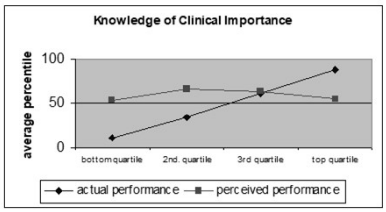
Do they know how important these test are?



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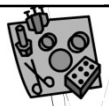
Medical terminology



___ Pericardium

___ Amniotic

___ Clean catch

___ Heparin

A. the odor of the fluid
B. a common anticoagulant
C. urine collection method
D. disease of the liver

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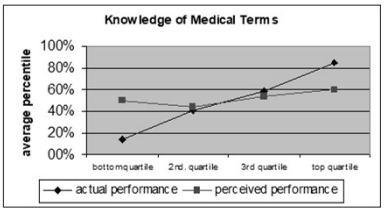
Do they know what the words mean?



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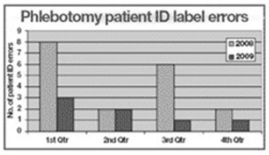
Labeling Errors

Overconfidence – Preanalyical

CAP Today April 2010



Karen Titus, Hammering away at patient ID error, CAP Today April 2010 http://www.cap.org (May 5,2010)

- Failing to check armband
  - Not properly ID patient
  - Not asking to State Name
- Multiple labels (belonging to other patients)
  - Labels from one patient intermixed with another
- Wrong labels taken off printer
  - Outpatients
  - Many labels printing at same time
- New Staff
  - Time to understand process
- Experienced Staff
  - Overconfidence
  - Complacent
  - Familiarity with patients

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Education versus Training

- Professional Education
  - Provides the theory and basic knowledge
  - Prepares learner for future job
  - Focus on skills to be developed
- Professional Training
  - Focus is on present job
  - Concentrates on skills needed for the job
  - Emphasizes responsibilities and requirements of the job

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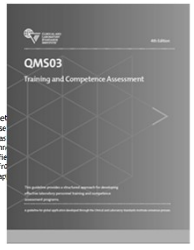
Training versus Competency



Compet
Assesse
same as
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- Verifie
skills fro
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- Initial Training
  - Staff new to the organization
  - Staff assigned different job
  - Staff who are introduced to new equipment
  - Knowledge, Skills, Behaviors to do the job – essence of the job
  - Is assessed by proving competence in new work policies and procedures
  - Assessed only once
  - Assessed before patient testing begins
  - Non-waived training -
    - Does not require all 6 levels of assessment

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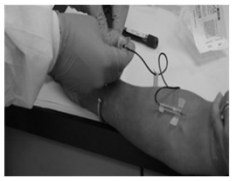
Training versus Competency

- Competency
  - Verifies continuation of the necessary knowledge, skills to perform work processes and procedures
  - Initially assessed before and again after patient testing has begun
    - Six months
    - Annually
  - Reflects ever changing nature of the job
  - High Risk job functions
  - On-going Assessment
  - Non-waived Assessment –
    - Requires all 6 levels



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Competency

Lab General Checklist

***NEW** 08/21/2017*
GEN.55499 Competency Assessment - Waived Testing **Phase II**

The competency of personnel performing waived testing is assessed at the required frequency.

***REVISED** 08/21/2017*
GEN.55500 Competency Assessment - Nonwaived Testing **Phase II**

The competency of personnel performing nonwaived testing is assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed.

NOTE: Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance as required in GEN.55450.

Competency must be assessed at the following frequency:

- *During the first year of an individual's duties, competency must be assessed at least semiannually;*
- *After an individual has performed his/her duties for one year, competency must be assessed at least annually;*
- *Retraining and reassessment of competency must also occur when problems are identified with an individual's performance.*

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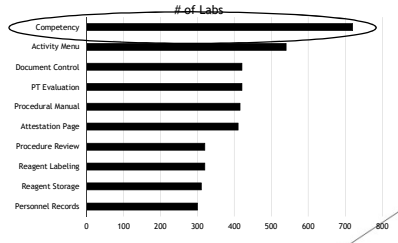
Most Commonly Cited Deficiencies

CAP 2015



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Categories of Testing

Waived and Non-waived

The more complicated the test the more stringent the CLIA regulations.

- Waived
  - Simple test with low risk for incorrect results.
  - Cleared by FDA for home use
  - Only 2 levels of competency
- Non-Waived
  - Term used to refer collectively to moderate and high complexity testing
  - Moderately complex: lab test requiring basic knowledge and training for testing personnel
  - High Complexity: lab test requiring multiple or significant steps in preparation, processing and interpretation
  - All 6 levels of competency must be assessed

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Competency – Requirements

Waived

- 2 CLIA levels of competency are assesed
  - Initial Training
  - Annually
  - Any 2 of the 6 are selected

Waived Tests can have significant impact on patient if not performed correctly

Non-Waived

- All 6 CLIA levels of competency are assessed
  - Semi-annually in first year
  - Annually thereafter
  - Method or instrument change

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Common Pitfalls of Competency

Assessments

- Required frequency
  - At 6 months during 1st year
  - Annually for the life of the employee
- Not all 6 components of competency are being assessed
  - Non Waived
- Individual performing competency does not meet the requirements

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Testing Personnel
Qualifications

Winn Dixie Houma 2005

- Waived
  - No specific requirements defined by CLIA
  - Must meet facility's minimum requirements
  - Documented Training
  - Must follow Manufacturers requirements
- Moderately Complex
  - High School Graduate
  - Documented Training
  - Laboratory Assistant Licensure
- High Complexity
  - Associate Degree – In chemical, physical, or biological science or Medical Laboratory Technician
  - Bachelor's Degree – medical technology, clinical laboratory science

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Who can assess Competency?
CLIA Regulations


Competency Assessment
Does the New CLIA Guidance Mean Big Changes?

https://www.aacc.org/publications/cln/articeles/2013/june/competency

- Waived
  - No specific requirements to assess
  - Delegated in writing by laboratory director
- Moderately Complex
  - Must be qualified as a Technical Consultant
    - At least a BS degree and 2 years of laboratory training or experience in non-waived testing
    - Must be delegated in writing by CLIA Laboratory Director
- High Complexity
  - Must be qualified as a technical supervisor
    - BS degree and 4 year training or experience in High Complex Testing
  - General Supervisor can be delegated in writing by the Technical Supervisor
    - Must have an associated degree and 2 year's of high complexity training or experience

The required qualifications of the assessor vary by the complexity of testing.

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Technical Consultant
Assessing Competency

- Nurses fall under this category if they are performing any competency assessment
- Must have a BS degree to qualify
  - Associate's degreed nurses cannot do competency evaluations
- Must have diploma or transcript on file
- Must have two years experience doing point of care testing.
- MUST be delegated by CLIA Lab Director to assess competency

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Who needs competency assessment?

- Technical Consultant
  - At least a BS degree and 2 years experience
- Technical Supervisor
  - BS degree and 4 year training or experience in High Complex Testing
- Clinical Consultant
  - MD
- General Supervisor
  - Must have at least an associated degree and 2 year's of high complexity training or experience
- Testing personnel
  - High School Graduate – Moderately Complex
  - Associate Degree – In chemical, physical, or biological science or Medical Laboratory Technican – High Complexity

- Lab director is not required to be competency assessed.
- Responsible for all personnel – CLIA defined responsibilities
- Assessment of Lab Director is performed during on-site inspection

http://www.cola.org/wp-content/uploads/2015/12/Competency-Assessment-Webinar-PowerPoint-and-Q-A-Dec-7-2015.pdf

Comprehensive Competency Program includes assessing:
1. Pathologists
2.Managers/Supervisors
3.Phlebotomists/ Receiving Personnel
4. Testing Personnel and all staff who perform any Point of Care Testing.

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Competency Model

Meaningful Assessment

Assess tech on all three levels of competency
Knowledge + Skills + Attitude = Competency

- Know
  - Knowledge to perform the task
    - Knowledge – basic level
      - Written Test
- Can
  - Ability and Training necessary to properly perform the task
  - Skills
    - Application
      - Observe the task being done
      - Checklist
- Do
  - Knowledge, ability and the integrity to perform the task in real life situations
    - Performance
      - Assess through daily work flow
      - Does a complete job
      - Patient Surveys
    - Attitude

Leach, AP, Haun, D Assessing Competence in Finding and Reporting Abnormal Morphologic Features While Scanning Peripheral Blood Smears. Clin Lab Sci 2000;13(3):160-165

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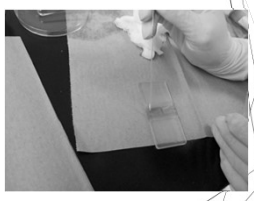
Getting Started

- Define all Test Systems
  - Each test system must be assessed annually
- Determine which component needs evaluating – Clinically Significant Steps
- Develop effective meaningful competency assessments
  - Identifies areas for improvement
- Identify methods and components to be assessed



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Testing

- Instrument Platforms
  - Any series of similar or identical analytical methods intended by their manufacturer to give identical patient results across all models

Any test which involve an additional procedure within the same testing platform must be assessed as a different test system to ensure staff are competent (ie, pretreatment, dilution)

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Testing

- Test Systems
  - The process that includes pre-analytical, analytical and post-analytical steps used to produce a test result or set of results.
  - May be manual, automated and can include all consumables required to produce results.
  - Test system may encompass multiple identical analyzers or devices.
  - Different test system may be used for the same analyte.
  - Tests performed on the same instrument or device may be defined as a single test system.

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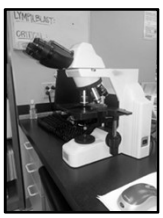
Major Categories of Competency

Test Systems



- Direct Observation
  - Patient Testing
  - Instrument Maintenance
- Results Review
  - Worksheets
  - Reporting of Results
- Assessing Competency
  - Proficiency Testing, Blind Samples, Previously analyzed
  - Written Tests

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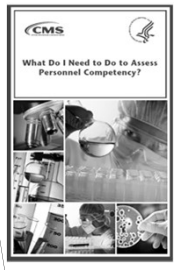
CLIA – Competency 6 levels - Introduction



- Non-waived
  - High Complexity
  - Moderately Complex
- All 6 levels of competency must be assessed annually for each test system
  - Direct Observation
  - Recording/Reporting of Results
  - Review of QC
  - Direct Observation of Instrument Maintenance
  - Testing previously analyzed samples
  - Problem Solving

Waived only assess 2 levels of competency

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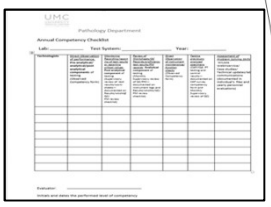
Six Levels of Competency

CLIA '88

- Direct Observation of Routine patient test performance
  - Patient identification and preparation
  - Specimen collection, handling, processing and testing
- Monitoring the recording and resulting of test results
  - Reporting of Critical Values
  - Properly filing results
- Review of intermediate test resuts or worksheets
  - QC records, Proficiency Testing results and preventive maintenance records
- Direct Observation of instrument maintenance and function checks
- Assessment of test performance
  - Using previously analyzed specimens,
  - Blind testing samples
  - External Proficiency Testing samples
- Evaluation of problem solving skills
  - Online Written Tests



All 6 levels must be assessed for each Test System a Tech is deemed Competent to perform.

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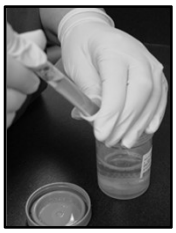
1.Direct Observation

Routine Patient Test Performance



- Pre-analytical, analytical and post analytical processess
- Specimen Preparation
  - All processes in which employee is involved
    - Collection
    - Specimen Prep for lab testing
    - Actual Testing on sample
- All procedural steps
  - All steps needed to provide an accurate result
  - Vital steps must be included in the checklist
  - Employee follows written protocol
- Focus on procedures (performed incorrectly) which have a major impact on Patient Care - High Risk
  - Processes in which there is a greater instance of employee variability
  - Steps skipped or not preformed
  - Short Cuts or workarounds
- Checklist may be used to assess this component

Sharp,SE and Elder, BL 2004. Competency Assessment in theClinical Microbiology Laboratory.2004 Clin Microbiol. Rev. 17(3):681-694

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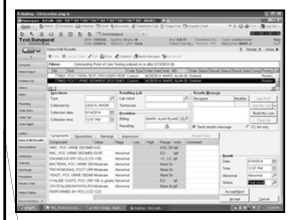
2. Monitoring of Results

Recording and Reporting



- Checklist may to used to record this assessment
- Can reveal mistakes and issues directly relating to lack of competence
- Documentation must also be provided that this process was reviewed by the technical supervisor
- Observe the employee performing the result
  - Provide documentation
  - Make a copy (remove all patient ID) and save with the checklist in employee file
  - If manual procedure save worksheet and copy computer printout which corresponds to the worksheet
    - Compare worksheet with computer printouts

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3. Review of Intermediate Test Results or Worksheets

QC Records, Proficiency Testing Results, Preventative Maintenance Records

Lack of objective evidence of competence assessments can cause citations from accreditating agencies

- Manager can directly observe a tech entering and recording preliminary patient or QC results
  - Actual QC or PT documentation must also be in Employee File
- Retrospective review of the QC, PT, patient worksheets
  - Documentation is required
  - Calculations or Dilutions
- Checklist can be used to accomplish this assessment
  - Documentation is required
  - Copy of the reviewed QC, PT or worksheet should be documented and placed in employee file (all patient info should be blacked out)

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4. Direct Observation of Instrument Maintenance

- Direct Observation must be done when the tech is actually performing the daily/weekly/monthly maintenance
- Asssessment must be for each instrument a tech is competent to operate
- Documentation must be present in employee competency file
  - Copy of maintenance with supervisor review is required

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5. Assessing Test Performance

Previously Analysed Specimens, Internal Blind Testing or External Proficiency Testing Samples

CLSI. Training and Competence Assessment 4th ed CLSI guideling QMS03. Wayne, PA: Clinical and Laboratory Standards Institute; 2016

- Each employee should be assigned at least one Proficiency Sample
  - Split samples from PT testing program
    - Must be run after results of PT has be submitted to CAP
      - According to CLIA PT Guidelines
- Blind testing is considered to be the best assessment of routine performance
  - Can identify problems within all phases of sample workflow.
  - Tech should be unaware of blind test
- Previously analyzed samples can provide accessible internal comparisons from shift to shift
- Known samples with challenging constituents or abnormalities
- Qualtiy Control material can also be used for assessing Test Performance

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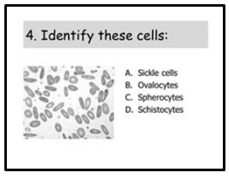
6. Problem Solving

Online Assessment



Involves critically thinking skills

- Engages the tech ability to critically think about factors which can directly affect patient outcomes and care
  - Detects overconfidence which causes personnel to perform outside of their level of knowledge and training
- Written test
  - Assess important step in procedure
  - Assess ablilty to critically think
- Case study with based on actual laboratory information
- Audits, complaints, physician or patient feedback
  - Provide information to use in written test and case study development.

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Competency Overview

6 levels identified

- Documents all competencies assessed
- All Test Systems can be included on this document
- All 6 levels are documented in one place for each tech
- Simple way
  - Observed
  - Results Review
  - Problem Solving

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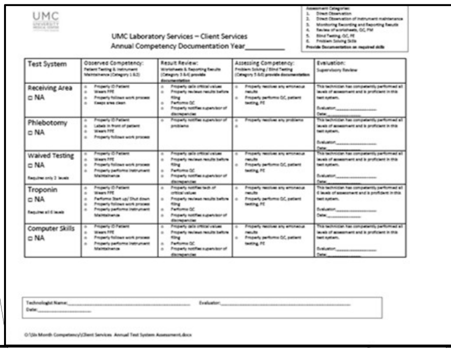
UMC Laboratory Services – Client Services
Annual Competency Documentation Year__________

Assessment Categories:
1. Direct Observation
2. Direct Observation of instrument maintenance
3. Monitoring Recording and Reporting Results
4. Review of worksheets, QC, PM
5. Blind Testing, QC, PE
6. Problem Solving Skills
Provide Documentation on required skills

Test System	Observed Competency: Patient Testing & Instrument Maintenance (Category 1 & 2)	Result Review: Worksheets & Reporting Results (Category 3 & 4) provide documentation	Assessing Competency: Problem Solving / Blind Testing (Category 5 & 6) provide documentation	Evaluation: Supervisory Review
Receiving Area ☐ NA	Properly ID Patient; Wears PPE; Properly follows work process; Keeps area clean	Properly calls critical values; Properly reviews results before filing; Performs QC; Properly notifies supervisor of discrepancies	Properly resolves any erroneous results; Properly performs QC, patient testing, PE	This technician has competently performed all levels of assessment and is proficient in this test system. Evaluator:______ Date:______
Phlebotomy ☐ NA	Properly ID Patient; Labels in front of patient; Wears PPE; Properly follows work process	Properly notifies supervisor of problems	Properly resolves any problems	This technician has competently performed all levels of assessment and is proficient in this test system. Evaluator:______ Date:______
Waived Testing ☐ NA Requires only 2 levels	Properly ID Patient; Wears PPE; Properly follows work process; Properly performs instrument Maintenance	Properly calls critical values; Properly reviews results before filing; Performs QC; Properly notifies supervisor of discrepancies	Properly resolves any erroneous results; Properly performs QC, patient testing, PE	This technician has competently performed all levels of assessment and is proficient in this test system. Evaluator:______ Date:______
Troponin ☐ NA Requires all 6 levels	Properly ID Patient; Wears PPE; Performs Start up/ Shut down; Properly follows work process; Properly performs instrument Maintenance	Properly notifies tech of critical values; Properly reviews results before filing; Performs QC; Properly notifies supervisor of discrepancies	Properly resolves any erroneous results; Properly performs QC, patient testing, PE	This technician has competently performed all 6 levels of assessment and is proficient in this test system. Evaluator:______ Date:______
Computer Skills ☐ NA	Properly ID Patient; Wears PPE; Properly follows work process; Properly performs instrument Maintenance	Properly calls critical values; Properly reviews results before filing; Performs QC; Properly notifies supervisor of discrepancies	Properly resolves any erroneous results; Properly performs QC, patient testing, PE	This technician has competently performed all levels of assessment and is proficient in this test system. Evaluator:______ Date:______

Technologist Name:______ Evaluator:______
Date:______

O:\Six Month Competency\Client Services Annual Test System Assessment.docx

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Competency Documentation

Each TEST SYSTEM

- Checklist
- Provides additional information
- Includes all necessary documentation inspector may want to see
- Utilizes the function of documentating the different levels of competence which was reviewed
  - Worksheets
  - Result Reporting
  - QC and Proficiency Testing performed

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UMC

Pathology Department

Name:______ Date:______ 90-100% Acceptable
Evaluator:______ Score:______ 75-90% Reviewed
below 70% unacceptable

CORE LABORATORY – Troponin iSTAT
Direct Observation of Instrument Maintenance, Function Checks, and Performance

PRE-ANALYTICAL PROCESSING
And SPECIMEN HANDLING

REVIEW OF TEST RESULTS, WORKSHEETS, and QC RECORDS

INSTRUMENT MAINTENANCE and FUNCTION CHECKS

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Problem Solving

Written Test

- Documents objectively the knowledge and problem solving skills of each tech
- We do online assessments which we have developed ourselves
  - We use real life situations
  - Include issues which have come up in the past

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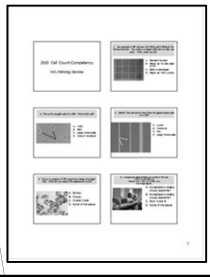
Meaningful Assessments

Measurable, Objective and Effective



- High Risk
- High Errors
- Complaints
- Taking short cuts

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Understanding Overconfidence

- Overconfidence
  - Above average effect
  - Over estimating one's ability
  - Easy Test
- Underconfidence
  - Below average effect
  - Under estimating one's ability
  - Hard Test
- Stems from the anchoring bias
  - Used in decision-making
  - Can be re-calibrated with objective information

- Anchoring or focalism is a term used in psychology to describe the common human tendency to rely too heavily, or "anchor," on one trait or piece of information when making decisions.

https://www.sciencedaily.com/terms/anchoring.htm

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Lake Wobegon Be Gone!

Justin Kruger Cornell University 1999

The Lake Wobegon effect, a natural human tendency to overestimate one's capabilities:

Easy test: Above-average effect

Difficult test: Below-average effect

Our lesson? Objective competency challenges may allow for adjustment of the egocentric anchor.

The characterization that "all the women are strong, all the men are good-looking, and all the children are above average" has been used to describe a real and pervasive human tendency to overestimate one's achievements and capabilities in relation to others.

J Pers Soc Psychol. 1999 Aug;77(2):221-32.

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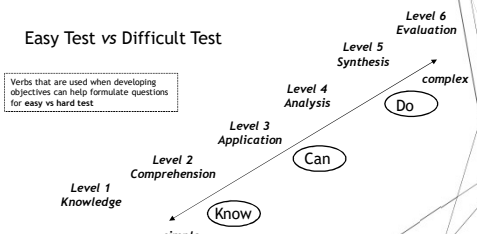
Develop Appropriate Tests

Bloom's Taxonomy of Educational Objectives

Easy Test *vs* Difficult Test

Verbs that are used when developing objectives can help formulate questions for **easy** vs **hard** test



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Develop Appropriate Tests

Bloom's Taxonomy of Educational Objectives

Bloom's Taxonomy Action Verbs:

Basic Level		Intermediate Level		Advanced Level	
Remembering	Understanding	Applying	Analyzing	Evaluating	Creating
Citing	Arrange	Adapt	Analyze	Appraise	Attach
Choose	Associate	Apply	Audit	Approve	Assemble
Define	Clarify	Calculate	Breakdown	Argue	Build
Draw	Compare	Catalogue	Certify	Assemble	Combine
Finds	Contrast	Chart	Compare	Assess	Compile
Identifies	Convert	Classify	Contrast	Conclude	Compose
Label	Demonstrate	Compute	Correlate	Confirm	Conceive
List	Describe	Construct	Criticize	Critique	Create
Locate	Diagram	Consolidate	Deduce	Debate	Design
Match	Draw	Develop	Defend	Decide	Devise
Memorize	Discuss	Employ	Detect	Judge	Discover
Name	Estimate	Extend	Diagram	Justify	Draft
Outlines	Explain	Extrapolate	Differentiate	Prioritize	Forecast
Recall	Express	Generalize	Distinguish	Prove	Formulate
Recite	Generalize	Illustrate	Examine	Rank	Generate
Recognize	Identify	Infer	Experiment	Rate	Integrate
Record	Interpret	Interpolate	Inspect	Recommend	Invent
Repeat	Locate	Interpret	Investigate	Research	Make
Reproduce	Outline	Make	Outline	Revise	Manage
Select	Paraphrase	Manipulate	Question	Support	Organize
Shows	Report	Modify	Practice	Validate	Plan
State	Relate	Order	Reason	Verify	Predict
Tell	Review	Prepare	Separate	Weigh	Prepare
Write	Sort	Produce	Solve		Propose
	Summarize	Sketch	Subdivide		Reorder
	Transfer	Solve	Survey		Reorganize
	Translate	Submit	Test		Setup
	Visualize	Tabulate	Uncover		Structure
		Transcribe	Verify		Synthesize
		Use			
		Utilize			

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Competency examples…

Developing Meaningful Assessments

1. Knowledge (recall) question:
The high limit for accepting an MCV is ___

2. Application question:
Match the following conditions with actions on the right

a. MCV >120 ____ for normal cells
b. MCV <63 ____ for hypochromic cells
c. MCV 80-96 ____ for macrocytic cells

3. Evaluation Question:
A specimen MCV's is 128, the glucose normal, there is no agglutination and the cells are
macrocytic on the smear. You should____
a. check the specimen for lipemia
b. immediately contact the physician
c. reject the specimen and recollect
d. sign-out the result

Simple = Knowledge

Difficult = Evaluation

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Point of Care

Laboratory Oversite

- Laboratory Oversees
- Must follow manufacturers instructions
- We develop Online assessments
- Keep track of everyone progress
- Document Competency
  - Observed
  - Written

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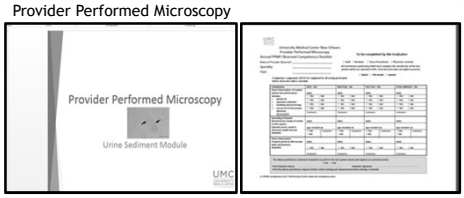
PPMP

Provider Performed Microscopy



Physicians are the most difficult group to conduct Competency Assessments.

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Corrective Action

- Retake Problem Solving ONLINE module if score below 70%
- If fall below 70% after retake a new module will be developed according to the learner's needs

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Corrective Action

GEN.57000 Competency Corrective Action **Phase II**

If testing personnel fail to demonstrate satisfactory performance on the competency assessment, the laboratory follows a plan of corrective action to retrain and reassess competency.

NOTE: If it is determined that there are gaps in the individual's knowledge, the employee should be re-educated and allowed to retake the portions of the assessment that fell below the laboratory's guidelines. If, after re-education and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken which may include, supervisory review of work, reassignment of duties, or other actions deemed appropriate by the laboratory director.

Evidence of Compliance:

- ✓ Records of corrective action to include evidence of retraining and reassessment of competency
- ✓ Written procedure for competency assessment corrective action

- Component necessary for a Clinical Laboratory to have a comprehensive competency program

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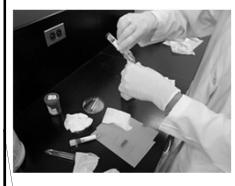
Retaining



- Re-Training should be modeled on the current training performed on new and transferred technologists
- Modified version covering all aspects of the test system tech is having difficulty with.

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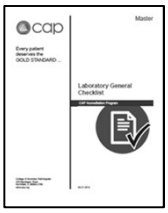
CAP General Checklist



- Operational Requirements for the Clinical Laboratory
- Personnel Requirements
  - Testing
  - Supervisors
    - Assessing
    - Evaluating
- Competency Requirements
  - Waived Testing
  - Non-Waived Testing

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Most Commonly Cited Deficiencies

on CMS radar – All Three Agencies
CAP, TJC, COLA

CAP is very strict about these categories – are high priority standards set by CMS – accreditation can be pulled if lab is not in compliance!

- Proficiency Testing
  - Stringent rules
- Competency – All Test Systems
  - High and Moderately Complex Testing
    - All 6 levels of competency
    - 6 month and Annually
  - Waived Tesing
    - 2 levels of competency
    - Annually
- Personnel Qualifications
  - Delegation
  - Continuing Ed
  - Licensure

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Personnel Qualifications

Common Deficiency

- CMS requires that every employee has documentation of all his or her education and experience on file. "If one person – and you might have a lab of 50 to 60 people – is missing something, its an automatic citation."
- CAP is less stringent, but now is under much scrutiny by CMS to make sure all labs comply with this ruling.
  - Cleveland Clinic
  - CMS Validation Inspection
- CMS requires license (for technologists only, nurses, respiratory therapist need transcript/diploma) instead of diploma/transcripts in states where licensure is a requirement
- CAP addresses this issue in the General Checklist under Personnel
- CAP requires the lab director to delegate in writing the responsibilities of each person involved in testing

Make sure your personnel file is up to date

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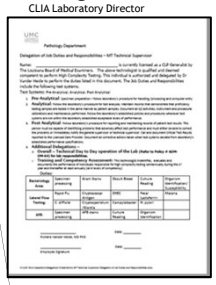
Delegations

CLIA Laboratory Director



- Laboratory Director must delegate in writing the test system each testing personnel can perform
- Personnel Must have on file competency to mirror the delegations assigned
- CAP Inspectors may compare delegations with competency assessments and test system assignments
- CLIA Lab Director must approve in writing if technologist can assess competency

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Assessing Supervisor

Managerial Competency

- All responsibilities of supervisors who evaluate competency MUST be delegated in writing by the CLIA Lab Director
  - Technical Supervisor
  - General Supervisor
    - Associate's degree
- If supervisors are performing non-waived testing they must also be assessed using all 6 elements of competency.

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Successful Competency Process

- Identify each test system
  - Extra step like manual dilution is a separate test system
- Incorporate assessment into daily practice
  - Document competency daily
- Supervisors should be familiar with the assessment and how it should be given
- Define competency expectations

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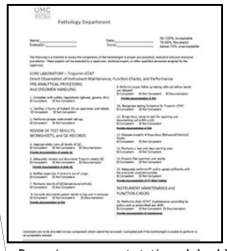
Competency is On-going


Pathology Department

- Need to reflect ever changing nature of the job
- Develop tools to evaluate performance
- Meaningful and achievable
- Focus on competencies to reflect services and patient outcomes
  - New procedures
  - Changes in procedures
  - High risk aspects
  - Problematic aspects

Dynamic process not static and should change with the current needs

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Laboratories in the news
Cleveland Clinic

- CMS validation inspection
- CMS found disparities in CAP inspection
- Using expired reagents
- Did not calibrate instruments
- No QC
- Poor procedures in Blood Bank
  - Not checking temperature of blood being returned from operating room
- Weren't following PT rules
- Lab could not document that the techs met educational requirements for their job
- Were not Documenting Competency
- **Demoted laboratory director**, closed part of testing lab, terminated lab managers and testing personnel
- Fined $769,000 for time they were out of compliance.
- Lab closed in September 2015
  - reopened in November 2015 after replacing it's operations and leadership that was in charge when violations occurred.

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Accreditation…
It's a good thing

- Internationally accepted for increasing test quality and reducing lab error
- Maintains accuracy of test results and ensure accurate patient diagnosis
- Provides improved patient care
  - Patient safety is preserved
  - Maintains employees are competent to do the job
- Protects employees and patients
- Promotes trust in laboratories and confidence in health care providers

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Could this be overconfidence?

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