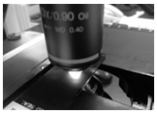


Laboratory Accreditation

An Overview

Argie P. Leach MHS,MT(ASCP)SH

Objectives

- Accrediting agencies
- CAP role in accreditation process
- CAP inspections
- Checklists
- Everyone's participation

2

History of Improved Health Care

Over 150 years ago

Ignaz Semmelweis
Pioneer of antiseptic procedures

Florence Nightingale
Founder of Modern Nursing

- 1846 – Ignaz Semmelweis
  - Assistant Professor at John Hopkins
  - Hand washing
    - required all his medical students to wash their hands with chlorine solution before doing OB exam. The students routinely switched from doing autopsy to giving birth causing 18% of women giving birth to die from puerperal fever (childbed fever).
- 1854 – Florence Nightingale
  - Public Health Pioneer saw that poor hospital sanitation resulted in a increase in fatalities among the wounded soldiers in the Crimean War
  - Developed practices which are still in existence today
    - Sanitizing surgical tools
    - Changing bed linens regularity
    - Promoter of good nutrition and clean air

Hand washing alone can prevent 40% of hospital infections!

3

Hospital Reform Timeline

- **1847** American Medical Association (AMA) – formed to standardize medical education
- **1917** American College of Surgeon (ACS) proposed the "End Result System" for the its Hospitalization Standardization Program which set minimum standards for hospitals
  - In 1918 begin implementing standards to inspect hospitals – only 89% met the minimum requirements
- **1951** The Joint Commission on Accreditation of Hospitals was formed by American College of Surgeons, American College of Physicians, the American Hospital Association, the American Medical Association and the Canadian Medical Association
- **1962** College of American Pathologist implemented a Laboratory Accreditation Program
- **1991** national attention was finally gained for hospital reform when it was reported that 98,000 people die yearly in hospitals due to preventable medical error.
  - To Err is Human: Building a Safer Health System

4

Agencies

Regulating Laboratories

- CAP – College of American Pathologists
- TJC – The Joint Commission
- COLA – Commission of Office of Laboratory Accreditation
- 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

5

CLIA

Clinical Laboratory Improvements Amendment

- 1967 Congress passes 1st CLIA Law
  - To regulate costs and quality of health care
  - Only required hospitals and large clinical laboratory
- Impetus for CLIA '88
  - Pap Mills turning out inaccurate results
  - 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 reading
  - Congress passed law 1988
  - CLIA '88 purpose is to ensure that all laboratory testing is done accurately and according to good quality standards
    - 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

6

CLIA

Clinical Laboratory Improvements Amendment
Continued

- 1992 Centers for Medicare and Medicaid Services (CMS), published regulations to enforce the CLIA law
- Regulates all testing on humans for health purposes
  - Labs which provide information for diagnosis, prevention or treatment of diseases
  - Ensures accurate and reliable testing regardless of the lab and its location
  - CLIA regulations place overall responsibility on the laboratory director
- CLIA '88 regulations are based on complexity of the testing the more complex the test the more stringent the standards for quality
- VA labs, research labs and forensic labs are exempted
- CMS enforces CLIA

7

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 compliant filed or randomly selects labs
- Formally know as Health Care Financing Administration (HCFA)

8

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™

9

Laboratory Accreditation Program

College of American Pathologist

- Inspected and accredited laboratories since 1962
- Initially only hospital and private pathology labs were inspected
- Now inspects
  - University labs
  - Commercial reference labs
  - Physicians offices

10

Laboratory Accreditation Program

College of American Pathologists (CAP)

- 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.
- Initially approved as an accrediting agency by CMS for 3 years in 1995
- 2015 CMS renewed CAP status as an accreting agency for 6 more years

11

OSHA

Occupational Safety and Health Administration

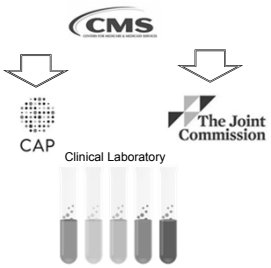
Source: www.OSHA.gov

- Main federal agency which enforces workplace health and safety legislation for 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.

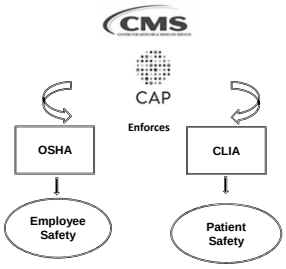
12

Lab Accreditations



13

Accreditation



14

University Medical Center New Orleans

Clinical Laboratory

Main Lab

Blood Gases

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

15

Standards for Laboratory Accreditation

College of American Pathologist

Core principles for CAP Laboratory Accreditation Program:

- **Standard I – Director and Personnel**
  - Medical Significance, Interpretation, Consultations, Correlation of Data, Quality Management, Personnel, Selection of Equipment, Delegation of functions and Implementation of a safe environment.
- **Standard II – Physical Resources**
  - Space, instrumentation, data processing, supplies, environment to permit effective performance of personnel
- **Standard III – Quality Management**
  - Performance improvement, QC, Instrument maintenance, Proficiency testing, Clinical relevance
- **Standard IV – Administrative Requirements**
  - Eligibility for participation in Laboratory Accreditation Program
  - Pathology and Clinical laboratory must submit to a complete periodic on–site inspection and self inspections
  - Laboratory and laboratory director must cooperate with the Commission on Laboratory Accreditation.
  - Each accredited lab must comply with the Terms of Accreditation listed in the official notice of accreditation sent to the lab by CAP.

Source: www.CAP.org

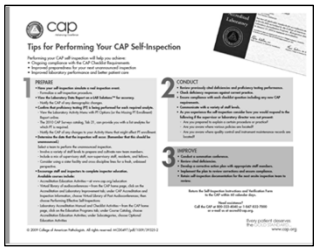
16

Inspections

- Every two years
  - Anniversary date onsite inspection
- Self inspections on the off year
  - Anniversary date
  - Administered by lab
    - Deficiencies are noted
  - Should mimic actual inspection

17

Self Inspections



- "Treat Self Inspections as a real event"
  - Mock inspection
- Identify and fix potential noncompliance which could result in deficiencies in a real inspection
- Prepare –
  - Review last inspections deficiencies and make sure the lab is doing what they say they are doing
  - Review all new checklist questions
- Conduct –
  - Should be performed in one day
  - Involve bench techs in process
- Improve –
  - Summation should also be held after the inspection is completed
  - Deficiencies should be reviewed and corrective action implemented
  - Documentation should be available for next on-site review.

Source: www.CAP.org

18

On-site Inspection Process

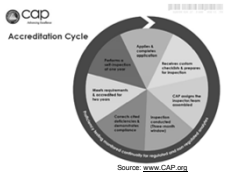
- Peer Review
- Avoid conflict of interest
  - Not having former colleagues or competitors inspect each other
- Team assigned by CAP
- Uses algorithm to match comparable labs
- CAP matches team with comparable lab
  - Test Volumes
  - University Lab Vs Reference Lab

Source: www.CAP.org

19

Ready or Not… Inspection Process begins

- **7 months** before inspection window opens
  - Welcome packet in email with application link
  - Application and Organizational Profile must be completed online within 3 months
  - Application includes the following:
    - Lab Director
    - Administration
    - Staff List
    - Blackout Dates
    - Testing volumes
    - Activity Menu
      - Testing performed by each lab
    - Travel accommodations
    - Lab specific information
- **3 months** before anniversary date
  - CAP Custom Lab Specific Checklist sent and available online
  - Lab reviews checklist
  - Lab sections are responsible for these checklists:
    - General, Common and Lab Specific Checklist
- **Inspection Unannounced** – Held within 3 months of anniversary date



Source: www.CAP.org

20

Online Application

Source: www.CAP.org

21

New CAP Roster

- Personnel to include on CAP Roster:
  - High complexity testing
  - Non waived or moderately complex testing
  - Physicians who do PPM
  - Grossing Techs
  - Pathology Staff and Residents
  - Cytotechnologists
- Personnel who do not need to be included:
  - Wavied Testing personnel
  - Phlebotomist
  - Histology Techs

Source: www.CAP.org

22

CLIA Roles

- Technical Supervisors
- General Supervisors
- Technical Consultant
- Laboratory Director
- All Staff Pathologists
- All personnel must be included in Staff List to be included in CLIA Role

Source: www.CAP.org

23

Non Laboratory Testing Personnel

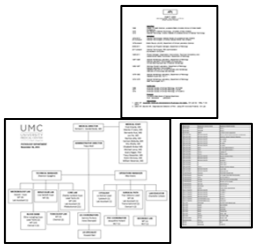
Provider Performed Microscopy - Physicians
Nurses who perform non-waived testing

- Provider Performed Microscopy
  - Physicians
- Nurses or Techs who perform non-waived test
  - Respiratory Techs
  - Nurses who do competency evaluations
  - Waived testing personnel are not required

Source: www.CAP.org

24

Online Attachments



- Equipment List
- Organizational Chart
- Laboratory Director CV
- Personnel Roster – New process 2018
  - Names of all testing personnel
  - Template can be loaded only once
    - Updated every 6 months
    - Updated online
    - After initial template loaded all other testing personnel must be entered manually
  - Level of testing complexity
  - Licensure

Source: www.CAP.org

25

CAP Profiles

- All supervisors or direct participants in the CAP inspection must create a profile on the CAP website.
- This process is a requirement even if you are faxing in application
- Personnel forms are no longer included in with the CAP application packet.

Source: www.CAP.org

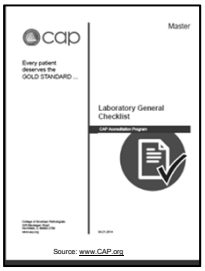
26

Laboratory Data

- Print out of all data which was entered in Organization Profile submitted to CAP
- Before submitting to CAP we are able to generate a PDF of all the data we provided.

27

CAP Checklist

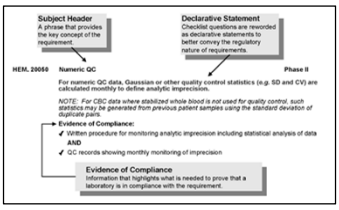


Source: www.CAP.org

- First checklist compiled in 1965
- Helps lab focus on the important criteria
- Fulfill all the requirements set by CMS
- Updated annually
- Types of Checklist
  - General
  - All Common
  - Lab Specific
- Formats for Checklist
  - PDF or EXCEL
  - Master and Custom

28

Checklist Components



- Subject Header
  - Key concept
- Declarative Statement
  - Explanation of the regulation
- Evidence of Compliance
  - Needed to prove lab is in compliance
- Notes
  - Very important to follow
  - More important than Evidence of Compliance

Source: www.CAP.org

29

Evidence of Compliance

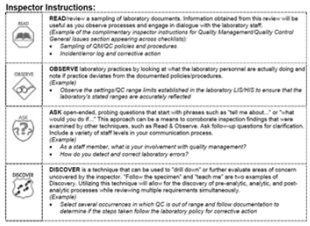
- Assist the lab in preparing for the inspection and in managing ongoing compliance
- Helps the inspector and laboratory consistently understand the requirements
- Provides examples of acceptable documentation

Source: www.CAP.org

30

Inspector Instructions

Read, Observe, Ask, Discover



Source: www.CAP.org

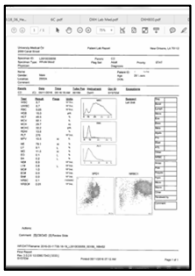
- Redesigned Accreditation Checklist in June 2010
  - Ensures compliance by making checklist easy to use with clear requirements
- CAP has established guidelines for inspectors
  - Streamlines inspections
  - Efficient, Consistent, Effective inspection process
- R·O·A·D· Inspection Techniques – enhanced approach for inspectors
  - Read
  - Observe
  - Ask
  - Discover
- Roadmaps with icons help inspectors focus on the items which are most important

Similar to Tracer Methodology used by The Joint Commission

31

Tracer Methodology

Follow the Specimen

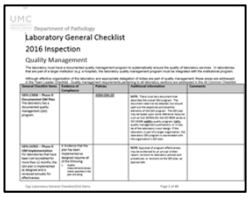


Source: www.CAP.org

- Begin tracer with test result
- Follow entire testing process
- Includes Pre-analytical, analytical, post analytical process
- Pre-analytical
  - Ordering
  - Collecting procedures
    - Identifying patient
    - Labeling in front of patient
  - Transporting of specimen
- Analytical
  - QC
  - Proficiency testing results for the analyte in question
- Post analytical
  - Computer print out
  - Reporting of panic values
- Personnel involved
  - Review Delegations
  - Review Competencies

32

CAP General Checklist



- Quality Management
- Specimen Collection, Data Handling and Reporting
- Quality of Water and Glassware
- Laboratory Computer Systems
- System Maintenance
- Personnel
- Physical Facilities
- Lab Safety
- Numbering system – GEN.00000

Laboratory Administration is responsible for the Laboratory General Checklist compliance. Lab administrators may delegate duties to other laboratory areas.

33

CAP Common Checklist

Source: www.CAP.org

Laboratory Areas must review All Common for lab specific criteria.

- Introduced 2011
- Consolidated items that were similar across disciplines
  - Proficiency Testing
  - Procedure Manual
  - Results Reporting
  - Reagents
  - Instruments and Equipment
    - Maintenance and Function Checks
    - Thermometers
    - Temperature Dependent Instruments, Equipment and Environments
  - Test Method Validation
    - Method Performance Specifications
    - Reference Intervals
  - Individualized Quality Control Plan (IQCP)
  - Numbering system – COM.00000

34

Individualized Quality Control Plan (IQCP)

Source: www.CAP.org

- It was developed for non-waived testing in which QC is not performed on a daily basis
  - Introduced in 2014 required implementation in 2016
  - Customary QC plan developed for the laboratory specific to your environment to provide reliable and accurate patient testing
  - Labs must continue to follow manufacturer's instructions for QC
    - A lab may not implement an IQCP that allows for quality control to be performed less frequently than indicated by the manufacturer
  - Does not apply to waived testing
- If a lab does not follow IQCP guidelines it must run at least two levels of external QC each day of patient testing.

35

IQCP Program

Allows continued use of Electronic Quality Control

Source: www.CAP.org

- Risk Assessment
  - Identifies and evaluates potential failures in the testing process and must address all 5 areas listed through all 3 phases of testing
    - Specimen
    - Environment
    - Reagents
    - Test system
    - Testing personnel
- Quality Control Plan
  - Ensures accuracy and reliability of test results
    - Internal Controls
    - Electronic Controls
    - Calibration
    - Training and Competency
- Quality Assessment
  - Continuous process of monitoring effectiveness of QC program
    - QC review
    - PT review
    - Compliant reports

36

Laboratory Specific Checklist

Source: www.CAP.org

Download checklist in EXCEL Format easier to concentrate on new and questions with evidence of compliance

- Collection requirements
  - Anticoagulants
  - Rejection criteria
- Procedural Manual
- Calibration Procedures
- Quality Control
- Validation Procedures
- Corrective Actions

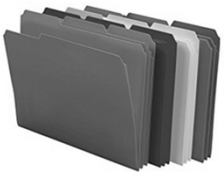
37

Day of Inspection

- Team Arrival
  - Arrival time usually 7:30-8:00
  - Team is met at information desk
- Opening Conference
  - Team leader introduces inspectors to lab
  - Lab director introduces self and all lab personnel present to team
  - Lab supervisors are paired with inspectors
  - Inspectors are given a tour of the lab which lasts 15-20 minutes
- Inspection
  - Review of lab manuals / documents requested
  - Inspector uses R O A D and interacts with lab staff
  - Refer to the lab roster to determine staff personnel files for review
  - Interacts with staff with a FOCUS on lab policies, lab safety, QC, Proficiency testing procedures, and corrective actions
  - Inspector should discuss all deficiencies as they are found with lab supervisor
- Summation
  - Team thanks the lab for hosting them
  - Present deficiencies and how to improve

38

Summation



- Team will gather all information
  - Deficiencies
  - Recommendations
- Take all recommendations and deficiencies seriously
- Address all issues

39

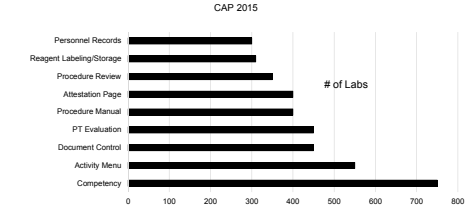
Deficiencies

Source: www.CAP.org

- Must be submitted within 30 days of inspection
- All deficiencies must be sent together
- Contact CAP if you have any questions about response or challenging
- Be vigilant and look for any responses from CAP for additional information about deficiencies responses submitted

40

Most Commonly Cited Deficiencies

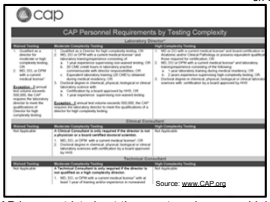


Source CAP

41

Most Commonly Cited Deficiencies

on CMS radar



Source: www.CAP.org

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

- Personnel Qualifications
  - Delegation
  - Continuing Ed
  - Licensure
- Competency
  - High Complexity Testing
    - 6 levels of competency
    - All Test Systems
  - Waived
    - 2 levels of competency
- Proficiency Testing
  - Stringent rules

42

Director Responisbilities

WHAT ARE THE RESPONSIBILITIES FOR WHICH I MUST MAINTAIN DIRECT OVERSIGHT AND CANNOT DELEGATE TO OTHERS?

As laboratory director, you must ensure that:

- testing systems in the laboratory provide quality services in all aspects of test performance, i.e., the preanalytic, analytic, and postanalytic phases of testing and are appropriate for your patient population;
- physical and environmental conditions of the laboratory are adequate and appropriate for the testing performed;
- the environment for employees is safe from physical, chemical, and biological hazards and safety and biohazard requirements are followed;
- a general supervisor (high complexity testing) is available to provide day-to-day supervision of all testing personnel and reporting of test results as well as provide on-site supervision for specific minimally qualified testing personnel when they are performing high complexity testing;
- sufficient numbers of appropriately educated, experienced, and/or trained personnel who provide appropriate consultation, properly supervise, and accurately perform tests and report test results in accordance with the written duties and responsibilities specified by you, are employed by the laboratory;
- new test procedures are reviewed, included in the procedure manual and followed by personnel; and
- each employee's responsibilities and duties are specified in writing.

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/brochure7.pdf

- Testing systems provide quality
  - Preanalytic, analytic and postanalytic phases of testing
- Physical environment
- Safety of employees
- A general supervisor is available to provide day to day supervision
- Trained personnel who can accurately perform and report out test
- New procedures are reviewed
- Each employee responsibilities and duties are specified in WRITING

43

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
- If job assignments have changed then Delegation MUST be updated to reflect the duties assigned

  Test system this tech is competent to perform must be listed in the delegation

(15) Specify, **in writing,** the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. https://www.law.cornell.edu/cfr/text/42/493.1445

44

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 requires the lab director to delegate in writing the responsibilities of each person involved in testing
- CAP addresses this issue in the General Checklist under Personnel

Pathology Personnel Checklist

Name:

Laboratory:

Date of Hire:

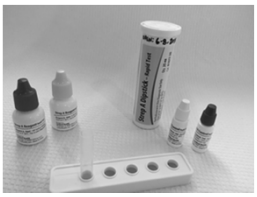
Checklist Items:	Availability:
Summary of Training and Experience	☐ Yes ☐ No
Louisiana State Board of Medical Examiners Licensure	☐ Yes ☐ No
Certification – ASCP	☐ Yes ☐ No
Job Description	☐ Yes ☐ No
Dates of Employment	☐ Yes ☐ No
Continuing Education	☐ Yes ☐ No
Delegation of Duties and Responsibilities	☐ Yes ☐ No
Department Specific Orientation	☐ Yes ☐ No
Other: Copy of Academic Degree	☐ Yes ☐ No
	☐ Yes ☐ No
	☐ Yes ☐ No

Make sure your personnel file is up to date

45

Reagent Labeling and Storage

Common Deficiency



- Properly Stored
- Properly labeled
- Temperature and Humidity Monitored
- Used within expiration dates

46

Procedure Manual

Common Deficiency

- Procedure same as practice
- All personnel have signed and it is available
- Must be reviewed biannually by director or designee
- Electronic downtime backup

47

Attestation Page

Common Deficiency

***REVISED** 08/17/2016*

COM.01400 PT Attestation Statement Phase II

The proficiency testing attestation statement is signed by the laboratory director or qualified designee and all individuals involved in the testing process.

NOTE: Physical signatures must appear on a paper version of the attestation form. A listing of typed names on the attestation statement does not meet the intent of the requirement. The signature of the laboratory director or designee need not be obtained prior to reporting results to the proficiency testing provider.

Designees must be qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing as defined in the Personnel section of the Laboratory General Checklist.

- *For high complexity testing, it may be delegated to an individual meeting the qualifications of a technical supervisor or section director (GEN.53400). For the specialties of Histocompatibility, Cytogenetics, and Transfusion Medicine, refer to specific requirements for the qualifications of section directors/technical supervisors in the associated checklists (HSC.40000, CYG.50000, and TRM.50050).*
- *For moderate complexity testing, it may be delegated to an individual meeting the qualifications of a technical consultant (GEN.53625).*

Source: www.CAP.org

Evidence of Compliance:

✓ Appropriately signed attestation statement from submitted PT result forms

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7146 [42CFR493.801(b)(1)]

48

Proficiency Testing

Common Deficiency

- Samples MUST be performed with routine laboratory workload
- Samples MUST be analyzed by personnel who routinely test patient samples
- Samples Must be rotated among all testing personnel and NOT just dedicated operators or instruments
- Samples MUST be run like patient sample
  - No duplicate testing
- Lab personnel MUST notify CMS if it receives a PT testing request from another laboratory
- Personnel are STRICTLY prohibited from communicating with other testing labs about PT samples

Source: www.CAP.org

1967 Proficiency Testing participation becomes a requirement for accreditation

49

Document Control

Common Deficiency

https://www.medialabinc.net/

- All Documents must be included
  - Forms
  - Job aids or cheat sheets
- Make sure that only current documents or forms are in use
- All current documents are properly approved

50

Activity Menu

Common Deficiency

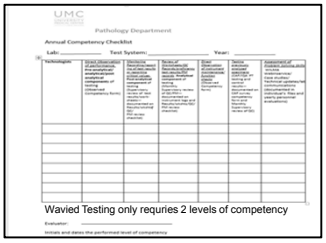
- Make sure all testing in included in the Activity Menu
- If stopped testing – Remove
- If Started testing – Insert
- Make sure CAP is aware of all changes

Source: www.CAP.org

51

Competency

Common Deficiency



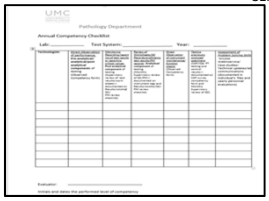
Wavied Testing only requries 2 levels of competency

- Non-waived
  - High Complexity
  - Moderately Complex
- Assessment Program
  - Defined set of skills/knowledge of job
  - Criterial for levels of acceptance
  - Process of reevaluation
  - Six components of competency
- 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

52

Six Levels of Competency

CLIA '88

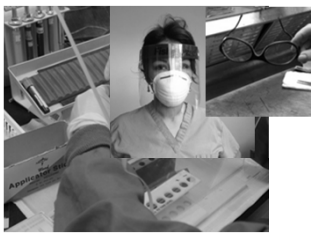


All 6 levels must be assessed for each Test System a Tech is deemed Competent to perform. Must be re-evaluated if the method or instruments change.

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

53

Staff Role in Maintaining Accreditations



- Familiarize yourself with all lab policies
  - Hospital Wide
  - Lab Administration
  - Safety
  - Lab Specific policies
    - QC, critical values, corrective actions
    - QNS and Clotted Samples
- Wear required PPE for task performed
- Fire Exits, Eye wash, Showers
- Make sure your personnel file is up to date
  - Current Continuing Education
  - ASCP Certification is current
- Be able to locate
  - Specimen Collection Manual
  - Current policies using MediaLaB
  - MSDS

54

Laboratories in the news

Cleveland Clinic

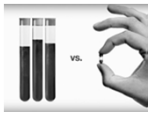
- CMS validation inspection
- CMS found disparities in CAP inspection
- Using expired reagents
- Did not calibrate instruments
- No QC
- Poor procedures in Blood Bank
  - Not checking temperature of blood being returned from operating room
- Weren't following PT rules
- Lab could not document that the techs met educational requirements for their job
- 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.

55

Laboratories in the news

Theranos

- Using the "nanotainer" collecting device (on analyte not approved)
- Only approved for herpes simplex 1 procedure for all of its testing
  - Costs less than other labs
- Running PT samples incorrectly
  - Not the same as patient
  - Not using laboratory routine methods
  - Splitting samples and running on 2 different analyzers



56

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

57

Theranos

The Movie

https://www.youtube.com/watch?v=VINIbbmI0BU

58

References

1. CLSI, Training and Competency Assessment, 4 th Edition, CLSI Guideline QMS03 , Wayne, PA: Clinical and Laboratory Standards Institute, 2016.
2. Malone, Bill. Competency Assessment:Does the New CLIA Guidance Mean a Big Change? Clinical Laboratory News JUN 2013. Assessed AUG 2015.
3. Malone, Bill. Laboratory Accreditation Guidelines Are Updated. Assessed AUG 2015.
4. Barr,Joanne. Laboratory Inspection: The View from JCAHO. LaboratoryMedicine. March2003.Number3. Volume.34 pp199-201.
5. Yost,Judith. Laboratory Inspection: The View from CMS. LaboratoryMedicine. February2003. Number2 Volume34. pp136-140
6. Carlson,Desiree. Laboratory Inspection: The View from CAP. LaboratoryMedicine. May2003 Number5 Volume34. pp373-380.
7. Clinical Laboratory Improvement Amendments (CLIA) CMS.gov. https://www.cms.gov/Regulations-and-Guidance/Legislation/" CLIA Index.html Accessed JULY 2016
8. CAP – Laboratory Accreditation Guide to CAP Accreditation www.cap.org accessed 10/29/18
9. Chilliprod,S.,Bornhorst,J.,Klachka,F., Top Deficiencies Across Accreditation Agencies. https://www.aacc.org/publications/cln/articles/2018/July/top-deficiencies-across-accreditation-agencies. Accessed 10/29/18
10. Chesson,Mike. Fined $769,000 after lab closed its reopen : health system fined $769,000 accessed 10/10/18
11. Chesson,MD, CHQualME History of Quality Improvement Movement. Chapter 1 pp1-7 marchofdimes.com accessed 10/2016
12. Chesson,MD, CHQualME Assessment:How can your lab always be ready? http://www.nap.org/the-quality-and-regulatory-readiness-hub/ can-your-lab-always-be -ready. Accessed 11/2017
13. CAP Standards for Laboratory Accreditation 2013 edition www.cap.org accessed 11/2016
14. Paxton,Anne. Checklists 2015:signposts are clarity, consistency http://www.capjournal.org/2015/checklists-2015-signposts -clarity-consistency/ Accessed 7/25/2016
15. Peter?T,Rotz,DR Duncan?HB et al. Impact of Laboratory Accreditation on Patient Care and the Health System. *Am J Clin Pathol* 2010;134:550-555.
16. CMS Clinical Laboratory Improvement Amendments (CLIA) Laboratory Director Responsibilities What are my responsibilities as a Laboratory Director https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloadable/brochure2.pdf Accessed 11/2018
17. CAP Checklist Laboratory General Checklist www.cap.org accessed 10/16
18. CAP Checklist All Checklists www.cap.org accessed 10/16
19. Lab Soft News: Problems with Theranos' Lab Proficiency Testing: Another Layer of Difficulty http://labsoftnews.typepad.com/lab_soft_news/2015/11/theranos-and-proficiency-testing-.html Accessed 7/25/16
20. Gaster Ellen. Problems at hospital lab show lax regulation, hidden mistakes http://archive.sentinel.com/watchdog/watchdogreports/problems-at-hospital-lab-show-lax-regulation-hidden-mistakes-b5f5f6186d1-302924061.html

59