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Accreditation Requirements for Waived Vs. Nonwaived Tests

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Learning Objectives

• Define the two basic test categories of waived and non-waived testing

• Explain essential accreditation (testing) standards that distinguish waived from non-waived

• Apply principles of quality assurance and continuous compliance in waived testing
  - CAP checklist requirements
  - Inspection field scenarios
Clinical Laboratory Improvement Amendment 1988 (CLIA 88)

- Regulations apply to labs processing human material for medical purposes
- All labs must be CLIA-registered and certified
- All labs must comply with basic administrative and operational (technical) requirements
CLIA 88: Sec. 493.5
Categories of tests by complexity

a) Laboratory tests are categorized as one of the following:
   1) Waived tests.
   2) Tests of moderate complexity, including the subcategory of PPM procedures.
   3) Tests of high complexity.

b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.
CLIA88: Sec. 493.5

...CLIA Certificates

c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates:

1) Certificate of registration or registration certificate (commitment to uphold standards)
2) Certificate of waiver
3) Certificate for PPM procedures
4) Certificate of compliance (directly assessed by CMS)
5) Certificate of accreditation (compliance assessed by authorized agencies, e.g. CAP)
Clinical Laboratory Improvement Amendment 1988 (CLIA 88) Administrative & Operational Requirements

Requirements enforced “Non-waived”
- Tests: High complexity
- Moderate complexity

Requirements “Waived” (exceptions)
- Simple/home kits
Sec. 493.15
Laboratories performing waived tests

a) Requirement. Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

b) Criteria. Test systems are simple laboratory examinations and procedures which—
   1) Are cleared by FDA for home use;
   2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
   3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.
CMS inspection of waived testing

Under certain circumstances such as:

- If a complaint is alleged
- To determine if a laboratory is testing beyond the scope of its certificate
- If there is risk of harm due to inaccurate testing
- To collect information about waived tests
Clinical Laboratory Improvement Amendment 1988 (CLIA88) Administrative & Operational Requirements

- Requirements enforced “Non-waived”
  - Tests: High complexity
- Requirements “Waived”
  - Simple/home kits
    - waived
  - Moderate complexity
    - PPM
    - PPT
  - Full/Limited Service Laboratory
    - Point Of Care (POC)
Accreditation by College of American Pathologists (CAP)

CAP accreditation standards or requirements at least equal but often exceed those of CLIA 88.
Administrative Lab Requirements
(apply to all labs)

• Limit testing to scope of certificate
• Designate competent director and testing personnel
• Notify CMS of organizational or menu changes
• Conduct testing as required by approved method or manufacturer’s instructions
• Permit inspections, announced or not, and make all records available to inspectors
• Be subject to penalties specified for noncompliance
Lab Operational Requirements (non-waived labs)

• General record keeping and document control system

• Personnel assignment & competence assessment as required per type CLIA certificate

• Compliant (successful) proficiency testing: Participate in & treat required proficiency testing in the same manner as patient’s
Lab Operational Requirements...

- Patient test management policies (pre-analytical, analytical and post-analytical):
  - procedure manuals
  - specimen handling (procurement, transport, analysis, results reporting)
  - patient safety (ID, critical/significant values, errors, clinical integration)
Lab Operational Requirements...

- Quality Control policies to ensure high technical testing quality
  - testing and storage environment
  - reagents
  - instrument maintenance; calibration; correlation, QC logs
  - method performance specifications: (accuracy, precision, analytic sensitivity, specificity, interference and reportable range)
  - technical quality reviews/corrective action
Lab Operational Requirements...

- Quality Assurance/QM/QI program for comprehensive ongoing analysis of all lab operations, their relevance to patient care and effectiveness of undertaken corrective actions
- Inspection readiness (achieving compliance/accreditation)
Standards of Waived Lab Operations

• Under CLIA 88
• Accrediting Agency rules (CAP etc)
• Health Care Facility/System rules (e.g., DVA)
CLIA 88: Waived Certificate requirements

- Enroll in the CLIA program
- Pay applicable certificate fees biennially, and
- Follow manufacturers' test instructions (voluntary compliance with waived requirements is encouraged as “good lab practice”)

The current list of tests waived under CLIA may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.
Waived Lab Requirements under CAP accreditation program equal or exceed those of CLIA 88

Same as non-waived for most

Proficiency testing; Instrument maintenance; Procedure manuals; Personnel; Specimen handling; Results reporting; General QC/QA; Safety etc

with a few exceptions....
Reagents

- Lot-to-lot reagent validation not required
- Follow manufacturer’s instructions for handling and validating
Instrument correlation

• Not required:
  • Initial correlation between waived instruments, e.g., glucose meters
  • Correlation between waived instruments and main lab instrument
  • Multi-instrument comparison
Quality Control

• Follow manufacturer’s instructions
• QC results must be judged acceptable and recorded before releasing patient results.
• Document corrective action if control results exceed tolerance limits
Quality Control...

- Internal control results need not be documented only if an unacceptable instrument control automatically locks the instrument and prevents the release of patient results.
- Frequency of QC is defined by the manufacturer.
- External controls run as required by the manufacturer.
Calibration and calibration verification

- Follow manufacturer’s instructions
- Calibration verification every six months is not necessary unless required by the manufacturer
Analytical Measurement Range

- Follow manufacturer’s instructions
- Initial analytical measurement range validation and six-month interval validation are not necessary unless required by the manufacturer.
Method performance specifications

• Verification not required, except for reference range
Common Waived Lab Deficiencies

- Laboratories not following manufacturers instructions
- Failure to identify incorrect results
- Testing beyond a laboratory’s CLIA certificate
- Untrained staff
- Lack of quality controls
Common Waived Lab Deficiencies...

- Poor equipment
- Poor storage of reagents
- Poor record keeping
- Misunderstanding of CLIA requirements.
CAP Accreditation Checklists

• Apply to waived testing anywhere in the lab
• Most under Point of care (POC)
• Can be under any section
POC.03850 Phase II
Do testing personnel follow test manufacturer's instructions? NOTE: This requirement applies to both waived and non-waived testing.

POC.04750 Phase II
For all waived tests, does the POC Program follow manufacturer instructions for handling and storing reagents?

POC.08050 Phase II
For waived tests, does the POCT program follow manufacturer instructions for calibration, calibration verification, and related functions?
POC.07037    Phase II

Are control results documented for quantitative and qualitative tests, as applicable?

NOTE: Quality control must be performed according to manufacturer instructions. To detect problems and evaluate trends, testing personnel or supervisory staff must review quality control data on days when controls are run. The laboratory director or designee must review QC data at least monthly. All unacceptable control results and corrective actions must be documented.
**POC.07124 Phase II**
Is there evidence of corrective action when control results exceed defined acceptability limits?

**POC.07211 Phase II**
Are the results of controls verified for acceptability before reporting results?
Scenario 1

Which of the following personnel must be included in the new CAP Laboratory Personnel Evaluation Roster?

A. Laboratory Director  
B. Phlebotomist who performs bleeding times  
C. Point of care personnel performing waived testing.  
D. All of the above  
E. Both “A” and “B”
Scenario 2

You are leading a team to inspect a laboratory with a POCT program in which several i-STATs and other small instruments are utilized. The team member who inspects this section informs you that she could not find evidence of i-STAT correlation with other i-STATs or with instruments in the main Lab and asks if she should cite a deficiency.

What should be your response?

A. Maybe, but need to request more information
B. No; as long as routine instrument maintenance is done
C. Yes; it is required for all instruments
D. No; it is up to the lab director to decide which instruments need to be correlated
Scenario 3

Upon inspecting a small clinic lab, you discover that the supervisor has not reviewed several months of temperature charts. Also, earlier in the year, a QC result was out of range, and there was no corrective actions documented.

Which of the following actions is the best approach in this situation?

A. Contact the CAP central office for instructions
B. Describe the deficiencies in the Part A of the ISR regarding lack of supervisory review.
C. Cite a deficiency in part B of the ISR and inform the supervisor
D. Discuss your concerns with the lab director at the Summation conference
Scenario 4

While inspecting a small rural hospital laboratory, you notice several reagents used beyond their expiration dates. When you review the policy regarding reagents, you note a detailed section on additional quality control procedures to be used for expired reagents. The lab manager explains that due to the price of shipping and lack of storage space, the lab director developed the additional QC procedures, which were consistently followed and include discarding the reagents if results were out of range.
Scenario 4

Which of the following actions is the best approach in this situation?

A. Cite a deficiency for using expired reagents regardless of the QC results.
B. Recommend discontinuing the use of expired reagents with next shipment.
C. Move on as the lab director is responsible for the QC and testing policies.
D. Mark the deficiency corrected-onsite if the policy is revised to no longer allow use of expired reagents.
Scenario 5

After completing your inspection of the POCT sites, the team leader asks if you could inspect the clinic laboratory located across the street. After a short tour, you request a copy of the QC records for the previous six months and for the first three months of last year. The supervisor quickly presents the current month’s records, but states that all records are stored at the hospital. Within an hour you have all the records you requested except for the instrument maintenance and function checks. The supervisor states that the lab manager is still looking for those. You cite the clinic lab for no documentation of review of instrument maintenance.
Scenario 5....

As you leave the Summation Conference, the clinic lab supervisor rushes over and presents you with the missing records. Although there are maintenance records, there is no indication of monthly supervisor review.

Which of the following is the best approach in this situation?

A. Mark the deficiency corrected-on-site as the records were found.
B. Retain the deficiency because of the lack of supervisory review.
C. Remove the deficiency since the records were found.
D. Change the deficiency into a recommendation to perform regularly reviews of QC records.
Scenario 6

You are the team leader for an inspection of a rural hospital lab, one of several directed by the same pathologist. She is not present on the day of the inspection, but you speak with her by phone at length regarding the laboratory. Although she only physically visits the lab quarterly, as defined in the policies of the laboratory, she is well versed in the PT performance problem as well as the QM indicator data. She explains that the lab manager emails her at least twice a week and they speak on the phone often. There is clear documentation of the activities she performs during the on-site visits and interviews with the lab manager and hospital leadership indicate they are satisfied with the direction provided by the pathologist.
Scenario 6...

You also direct a small lab, but you visit weekly.

Which of the following is the best approach in this situation?

A. Cite a deficiency for inadequate on-site visits.
B. Recommend that the lab director visit at least monthly.
C. Mark the deficiency corrected-onsite if the policy is changed to monthly visits.
D. Move on as the laboratory and lab director are in compliance.
Assistance

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Questions?

Thank you!