What You Need to Know About Waived Testing & Competency Assessment for Non-waived Testing

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Objectives

• General overview of CLIA
• Guidance on regulations regarding waived testing
• Guidance on regulations regarding competency assessment for non-waived testing
What is “CLIA”? 

• Clinical Laboratory Improvement Amendments 

• Federal program that establishes quality laboratory standards to protect patient safety and improve healthcare
The CLIA regulations.....

• Established uniform quality standards for all laboratory testing to ensure accuracy, reliability and timeliness of patient test results regardless of where the test was performed
CLIA Definition of Laboratory

• Any facility that examines human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings
All clinical laboratories…..

- that perform testing on patient specimens must:
  - apply for a CLIA certificate
  - pay appropriate fees and
  - follow applicable CLIA requirements
Test Complexity

• Waived

• Moderate complexity including the subcategory of Provider Performed Microscopy (PPM)

• High complexity

Laboratories are certified at the highest level of testing performed
CLIA Certificate Types

- Certificate of Compliance (COC)
- Certificate of Accreditation (COA)
- Certificate for PPM procedures (PPMP)
- Certificate of Waiver (CoW)
Current Enrollment Statistics

- Total Number of Laboratories: 244,564
  - Compliance Labs: 18,959
  - Accredited Labs: 16,081
  - Waived Labs: 165,058
  - PPM Labs: 36,784
Waived Tests….

- Simple laboratory examinations and procedures
- Cleared by FDA for home use;
- Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- Pose no reasonable risk of harm to the patient if the test is performed incorrectly.
Certificate of Waiver (CoW)

- Enroll in the CLIA program
- Pay biennial certificate fees
- Only perform tests categorized as waived
- Not subject to routine inspections
- Must follow manufacturer’s instructions
CoW Personnel Requirements

- Must have a Laboratory Director
  - There are no educational and experiential requirements for LD
- There are no other personnel requirements
CoW Site Visits

• Announced, designed to help educate on sound laboratory practices

• Surveyors determine:
  o Testing being conducted in manner that protects patient safety
  o Regulatory compliance
  o Performing tests appropriate for a CoW lab
CDC Educational Materials

- CDC has published “Ready, Set, Test” booklet - describes recommended practices for physicians, nurses, medical assistants and others performing patient testing under a CLIA Waiver Certificate.

- CDC also offers an on-line training course corresponding to “Ready, Set, Test”.
Good Laboratory Practices for Waived Testing Sites

Poster and postcards

Educational booklet with job aids
Non-waived Testing

- Includes moderate and high complexity tests
- Must follow:
  - All manufacturer’s instructions and
  - Applicable CLIA requirements
  - AO requirements
  - State requirements (ex. Maryland, New York)

When in doubt, always follow the most stringent requirements
New FDA BGM Limitation

• FDA required limitation in manufacturer’s BGM instructions/pkg inserts that prohibit use of meter for critically ill patients.

• CMS only recently made aware of this limitation being placed in instructions/inserts.
What does this limitation mean?

- Devices used outside of the manufacturer’s requirements are considered to be test modification/off label use.

- This is not a new CLIA regulation!
Test modification/off label use

• Any change to a test system/device or manufacturer’s instructions or intended use that affects the test’s performance specifications for accuracy, precision, sensitivity or specificity.

• Modified tests become high complexity tests under CLIA
If using meters with the “critically ill” limitation:

- Define “critically ill” for their specific patient populations
- Establish performance specifications (42 CFR §493.1253)
If using meters with the “critically ill” limitation

- Obtain a CLIA Certificate of Compliance (COC) or Certificate of Accreditation (COA), pay applicable fees
- Meet all other high-complexity requirements (ex. Proficiency Testing, Personnel requirements)
Definition of “Critically Ill”

• Due to myriad of factors, circumstances and patient populations, it is up to each laboratory/facility to define “critically ill” for its specific patient populations.

• FDA and CMS will not define “Critically Ill”
Other Laboratory Options

- Use POC test systems without the “critically ill” limitation
- Send glucose tests to main laboratory
  - Presents patient care issues due to volume of blood required, need for frequent testing
Performance Specification
Resources

• 42 CFR § 493.1253 of the CLIA Interpretive Guidelines (IG)

• CLIA Brochure #2, “Verification of Performance Specifications” on the CLIA/CMS website
  o www.cms.hhs.gov/CLIA
CLIA Personnel & Competency Policies

Topics for Discussion

- CLIA Personnel Policies
- Rationale for Policies
  - Outcomes
- Goal of Discussion
- Competency Assessment
High Complexity Personnel

- Laboratory director (LD)
- Technical Supervisor (TS)
- Clinical Consultant (CC)
- General Supervisor (GS)
- Testing Personnel (TP)
Moderate Complexity Personnel

- Laboratory director (LD)
- Clinical consultant (CC)
- Technical consultant (TC)
- Testing personnel (TP)
CLIA Personnel Policies

• Use CMS Interpretive Guidelines (IG) & S & C Letter 10-07-07-CLIA as a guide

• Qualification evaluations are done @ highest level of academic achievement for the position
CLIA Personnel Policies

• All required positions & a sample of TP are reviewed once.
  • Review add’l. TP on subsequent surveys along w/ any changes or new personnel
  • If a LD changes, quals. are reviewed by the appropriate AO/SA upon notification prior to approval.
  • LD responsibilities correspond to all quality standards
CLIA Personnel Policies

• Phlebotomists, microplating personnel, clerks, reagent & specimen prep, etc. who do not test are NOT reviewed.

• MT(ASCP) & nursing licenses alone aren’t acceptable.

• Even if certification is required by CLIA; e.g., CT, degrees & transcripts, etc. are still required.

• If a State license is required by CLIA, it alone is acceptable. Most States do an extensive review.

• Surveyor may still request documentation.
CLIA Personnel Policies

• Consider test complexity when evaluating credentials.

• Agency evaluations aren’t acceptable, except for foreign credentialing equivalency purposes.

• Foreign educated individuals must be evaluated by a nationally recognized agency for equivalency.
CLIA Personnel Policies

• If an individual doesn’t meet education, training or experience requirements, position not filled or responsibilities not met, a condition level deficiency is cited.

• Competency is assessed per the regulations for TC/TS.

• Solo practitioners are not assessed.
CLIA Personnel Policies: Rationale

• Individuals download qualifications from the Web, use fraudulently to obtain CLIA certificates, and bill Medicare for millions of $$. 

• More than 100 false applications recorded so far. Many shell labs caught by pre-approval review of application credentials. 

• ASCP has changed its credentialing process after discovering individuals who submitted false credentials for their certification.
CLIA Personnel Policies: Rationale

• There is great risk to CLIA & patients if an individual in a regulated position is ID’d as unqualified & quality issues are also found.

• Lab w/ multiple, consecutive PT failures had TP w/ falsified HEW card. All lab results had to be reviewed.
CLIA Personnel Policies: Rationale

- Offshore operation upgrades degrees for a fee; diploma mills; quickie degrees.
- TP (with only 10\textsuperscript{th} grade education) not following mfg'rs. instructions for intended use (endocervical) - testing males for GC/Chlamydia
- Lab w/ all personnel unqualified for high complexity micro testing it performed.
CLIA Personnel Policies: Rationale

- **Immediate Jeopardy** found in lab where GS had no foreign equivalency done.
- TP w/ no HS degree or GED – test results impacted.
- POL w/ repeated deficiencies – MD’s high school age son performing testing.
CLIA Personnel Policies - Goals

1. All oversight agencies have and enforce consistent personnel policies.

2. Patients are protected by qualified personnel at all levels.
CLIA Competency Assessment

• Competency is required for all technical, supervisory & testing personnel (TP).

• Requires 6 elements for all tests for TP.

• Various related requirements are interspersed throughout the regulations.
CLIA Competency Assessment

- Competency is NOT the same as a performance evaluation/ training.
- Quality management includes personnel, processes, & procedures, as does competency.
CLIA Competency Assessment

• Studies indicate that more education & training produce higher quality results.
• The means to confirm training effectiveness is competency evaluation.
• In CLIA, laboratory director’s qualifications are stringent due to overall quality responsibility.
• But qualifications for testing personnel are minimal, based on test complexity.
CLIA Competency Assessment

• CLIA survey experience indicates many problems caused by personnel errors which may have a patient impact.

• Routine competency evaluations help prevent errors; highlight importance of competency, regardless of education.
CLIA Competency Assessment: Key Requirement

Technical Consultant/Supervisor Responsibilities

(§493.1413(b)(8)(9) and §493.1451(b)(8)(9))

• Evaluating the competency of all testing personnel & assuring that the staff maintain their competency to perform test procedures & report test results promptly, accurately, & proficiently
CLIA Competency Assessment

**Must Include:**

1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing & testing.

2. Monitoring the recording & reporting of test results
CLIA Competency Assessment

Must Include:

3. Review of intermediate test results or worksheets, QC records, PT results, & preventive maintenance records

4. Direct observation of performance of instrument maintenance & function checks
CLIA Competency Assessment

**Must Include:**

5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples; and

6. Assessment of problem solving skills
Competency Assessment Tips

• Operator training prior to testing is critical & required

• Competency assessments must be documented

• Individual conducting competency assessments must be qualified (TS/GS or TC)
Competency Assessment Tips

• **Competency assessment is not PT!**

• PT can be used to meet some elements of competency, but not all!

• Pathologists should be evaluated by the laboratory director as technical supervisors.
Competency Assessment Tips

• Competency records should match the laboratory’s actual procedures performed by its personnel.

• When observing test performance, use the procedure manual (PM) / package insert (PI) to ensure PM is current.

• Competency for clinical & technical consultants & supervisors is based on their regulatory responsibilities.
Competency Assessment Tips

- Laboratory director is not subject to competency requirements, but is accountable. Responsibilities checked on surveys.
- Do not have to do all at one time; can combine elements.
- Can often combine analytes on multichannel analyzers.
Competency Assessment Tips

- Can use competency assessment for QA when confirming tests ordered match reported/charted results.
- Follow up on QC corrective actions will demonstrate problem solving ability.
- Checklists are only minimally ok.
Competency Assessment Tips

• Competency evaluations must be done for Provider Performed Microscopy (PPM) individuals.

• Personnel performing pre & post analytic activities, but not in regulatory positions are not subject to competency, but it’s good QA.
Resources:

- CLIA Website
  - http://www.cms.gov/CLIA

- CDC: Ready, Set, Test booklet
  - http://www.cdc.gov/dls/waivedtests
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