

Institute of Medicine
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Workshop on Policy Issues in the Development of
Personalized Medicine in Oncology

HOW DOES CLIA OVERSEE LABORATORY DEVELOPED TESTS?

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What is CLIA?

Clinical Laboratory Improvement Amendments of 1988

- Regulates all testing on humans for health purposes using minimum quality standards
- Accurate, reliable testing regardless of location

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CLIA Regulations

- Comprehensive set of requirements for laboratories
- Apply to laboratories regardless of location
- Requirements based on test complexity: high complexity, moderate complexity, or waived

CLIA Requirements

- Registration, certification, accreditation
- Proficiency testing
- Facilities
- Quality Systems
- Personnel
- Inspections
- Enforcement

Quality Systems: Analytic

- Procedure manual
- Requirements for reagents, equipment, instruments, etc.
- Establishment and verification of performance specifications
- Maintenance and function checks
- Calibration procedures
- Control procedures
- Test records

Establishment and Verification of Performance Specifications

- Laboratories must **VERIFY** performance specifications for FDA-approved test systems.
- Laboratories must **ESTABLISH** performance specifications for laboratory-developed tests.

Establishment and Verification of Performance Specifications

Unmodified, FDA-cleared or approved test system: lab must verify

- Accuracy
- Precision
- Reportable range of test results
- Normal values

Establishment and Verification of Performance Specifications

Test system not subject to FDA clearance or approval: lab must establish

- Accuracy
- Precision
- Reportable range of test results
- Normal values

Establishment and Verification of Performance Specifications

Test system not subject to FDA clearance or approval: lab must establish

- Analytical sensitivity
- Analytical specificity to include interfering substances
- Any other performance characteristic required for test performance

Establishment and Verification of Performance Specifications

Laboratory must determine calibration and control procedures based on performance specifications established or verified.

Laboratory Developed Tests: Performance Specifications

- CLIA requires laboratories to establish analytic validity.
- CLIA is not authorized to regulate clinical validity or clinical utility.

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Laboratory Developed Tests: Performance Specifications

- Reviewed by surveyor at time of inspection
- No “pre-market” review
- Surveyor resources
 - CMS genetics subject matter expert
 - Consult CDC or FDA

Quality Systems: Preanalytic and Postanalytic

- Test Request
- Specimen submission, handling, referral
- Test Report

Quality Systems: General

- Confidentiality
- Specimen identification and integrity
- Communications and complaints

Proficiency Testing

- CMS-approved PT for 84 listed analytes
- All other analytes, including laboratory-developed tests, are required to undergo an evaluation of accuracy twice annually.
- Evaluate results and take corrective action
- Project to update proficiency testing

Personnel

- Personnel requirements are based on level of test complexity.
- Laboratory-developed tests are categorized as high complexity tests.
- Laboratories performing high complexity tests are subject to the most stringent personnel requirements

Inspections

- Laboratories are inspected every two years.
- Many laboratories choose to be inspected by accreditation organizations, whose standards are often more stringent than CLIA regulations.
- Some states have additional laboratory requirements.

Summary

- CLIA contains comprehensive requirements for clinical laboratory testing.
- Laboratory-developed tests are subject to the highest level of CLIA oversight.
- Establishment of analytic validity is required.
- Establishment of clinical validity and clinical utility is not required.
- CLIA does not require pre-market review of laboratory-developed tests.
- CLIA standards = quality laboratory testing

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