CLIA 101 - A Basic Introduction to CLIA

James A. Cometa
CLIA Compliance Team Leader
Centers for Medicare and Medicaid Services
Division of Laboratory Services

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What is CLIA?

In 1988, media reports focused public and Congressional attention on deficiencies in the quality of services provided by some of the nation's clinical laboratories.

Clinical Laboratory Improvement Amendments (CLIA) of 1988 [Public Law 100-578] --

- **Established quality standards to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed.**

CLIA –

Applies to laboratories that *examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings*.

Specifies performance requirements, based on test complexity and risk factors related to erroneous test results.

CLIA…

Sets standards to improve quality in all laboratory testing.

Includes specifications for quality control, quality assessment, patient test management, personnel and proficiency testing.

Minimum standards for laboratory practice and quality.

Note: States may establish requirements more stringent than in CLIA.

CLIA exceptions...

CLIA does <u>not</u> apply to:

-- Facilities only performing testing for forensic purposes

-- Research labs that test human specimens but do not report patient specific results for the assessment of the health of individual patients

CLIA exceptions (cont.)...

-- Labs certified by the Substance Abuse & Mental Health Services Administration, in which drug testing is performed meeting SAMHSA guidelines and regulations.

Labs under the jurisdiction of an agency of the Federal Government are subject to CLIA, except that the Secretary of HHS may modify the application of such requirements as appropriate.

CLIA & Department of Defense Labs

Memorandum of Agreement DoD and DHHS

CLIA comparable regulations "modified only as may be required to meet unique aspects of DoD missions, training, and preparations during peace, contingency, and war time operations which preclude compliance with [CLIA]."

CLIA & Veterans Health Administration Labs

- Congress decided that clinical laboratories within VA should not be regulated by DHHS, but should have equivalent standards.

- Equivalent standards were established.

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CLIA *jointly* administered by CMS, FDA and CDC

CMS:

Implementation of the program and monitoring regulatory compliance, including survey and certification of laboratories, enforcement, and financial management of the program.

CDC:

Assists in providing technical expertise.

FDA:

Test complexity categorization, including rules and guidance for CLIA complexity categorization.

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All labs performing testing must file a separate application for each laboratory location.

Exceptions:

Labs not a fixed location

Certain not-for-profit or Federal, State or local government labs

Labs within a hospital that are located at a contiguous building on the same campus and under common direction

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CLIA Certification Types (Basic Information)

Certification of Registration

- an initial certificate provided to all labs except those performing only waived and/or Provider Performed Microscopy Procedures (PPM) procedures

- valid for no more than two years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter

Certificate of Waiver

- labs that perform only waived tests

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CLIA Certification Types (Cont.)

Certificate for Provider-Performed Microscopy Procedures (PPM)

- tests largely performed in Physician Office Labs (POLs)

Certificate of Compliance

- issued after lab (other than waived and/or PPM procedures) demonstrates CLIA compliance

Certificate of Accreditation

- for labs seeking certification via accreditation agency requirements deemed by CMS to be equal to, or more stringent than CLIA

Also, state-exemption...

- When state licensure program equal to or more stringent than CLIA. (States must apply for state-exemption. Currently, Washington and most New York labs except POL's.)

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Non-waived labs must apply for CLIA certification and meet all 5 major CLIA quality requirements:

Personnel

Quality Control

Proficiency Testing

Patient Test Management

Quality Assessment

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Quality Requirements:

Personnel qualifications and responsibilities -
for each personnel position in a CLIA lab

Quality Control -
mechanisms to ensure test is working each test day

Patient Test Management -
record keeping system
patient identification
confidentiality
test referral

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Quality Requirements (cont.)

Proficiency Testing (PT) -

Periodic testing, by laboratories, of samples received from a PT program. The PT program grades the samples, based on the determined value of the sample, and reports the results to the laboratory. PT is important because it is a tool the laboratory can use to verify the accuracy of their testing.

Quality Assurance (QA) -

Ongoing, overall plan to monitor and ensure accurate, timely test results

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CLIA certification standards are based on test complexities:

- waived
- moderate (including, PPM)
- high

CLIA certifies laboratories/clinical laboratory practices, not tests or individuals performing tests.

Labs must demonstrate analytical validity. No statutory or regulatory requirement to establish the clinical validity or utility of tests.

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Test Complexity -

Waived Tests:

simple lab examinations and procedures

pose no reasonable risk of harm if performed incorrectly

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Test Complexity -

Moderate complexity, including the subcategory of Provider-Performed Microscopy Procedures (PPM):

mostly involve testing performed in physician office labs or which is essential for immediate patient care

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Test Complexity -

<u>High complexity</u>:

Risk of erroneous results is substantial because testing methodologies are often complex, usually involving multiple steps, and are characterized by…

High Complexity Testing…

complicated reagent preparation or the requirement for special reagents

equipment which requires multiple operational steps (maximum operator -equipment interaction)

complicated/extensive maintenance and troubleshooting

quality control requiring special materials and analyst interpretation

test performance involves exercise of independent judgment and decisions

may require a comprehensive understanding of the method, instrumentation, physiology, interpretation of data and clinical significance of the result

interpretation of test results requires extensive knowledge of factors that can influence test results

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Test Complexity –

Because high complexity tests are usually not automated and require more knowledge and training to perform/ interpret test results, they have the most stringent CLIA standards.

Biodosimetry-related tests that involve examination of human specimens would most likely be classified as high complexity.

A CLIA database for test categorization is available online. Contains the commercially marketed in vitro test systems categorized by the FDA since January 31, 2000 and tests categorized by the Centers for Disease Control and Prevention (CDC) prior to that date.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

The records can be searched by: test system name, specialty/subspecialty, analyte, document number, qualifier, effective date and complexity.

The data is updated monthly.

FDA Website

- http://www.fda.gov/cdrh/clia/
- Lists all waived analytes and tests
- Links to CMS, CDC websites
- CLIA database

Personnel Requirements - High Complexity Testing

Personnel standards for high complexity testing more rigorous than those for other testing since the testing itself is more complicated.

In general, personnel conducting high complexity testing will need more education and experience than for other testing.

CLIA's detailed personnel requirements for laboratories performing high complexity testing are found in 42 CFR 493.1441ff.

Laboratories Performing High Complexity Testing

Sec. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of Sec. 493.1443 of this subpart and provides overall management and direction in accordance with Sec. 493.1445 of this subpart.

Sec. 493.1443 Standard: Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R.
(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and
(b) The laboratory director must--
(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

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Survey Process

Only moderate & high complexity labs subject to routine, announced biennial surveys

Performed by lab's choice of:

- State Agency med. techs. trained by CMS, or
- CMS-approved accrediting organizations with equivalent standards

Outcome-oriented survey process with QA focus

CLIA Survey Process

- Entrance Interview.
- Tour lab.
- Observe testing.
- Interview personnel.
- Review records, data/information.
- Assess outcomes & determine compliance.
- Conduct exit conf. & generate survey report.

If any problems, lab develops plan to correct.

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By law, CLIA fees assessed CLIA laboratories must be sufficient to cover the general costs of administering the program.

Type of Laboratory	Number of Specialties	Annual Test Volume	Biennial Certificate Fee
Waived	N/A	N/A	$150
PPM	N/A	N/A	$200
Low Vol. A	N/A	2,000 or fewer	$150
Schedule A	3 or Fewer	2,001-10,000	$150
Schedule B	4 or More	2,001-10,000	$150
Schedule C	3 or Fewer	10,001-25,000	$430
Schedule D	4 or More	10,001-25,000	$440
Schedule E	N/A	25,001-50,000	$650
Schedule F	N/A	50,001-75,000	$1,100
Schedule G	N/A	75,001-100,000	$1,550
Schedule H	N/A	100,001-500,000	$2,040
Schedule I	N/A	500,001-1,000,000	$6,220
Schedule J	N/A	Greater than 1,000,000	$7,940

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CLIA UPDATE – December 2005
Division Of Laboratory Services
Centers For Medicare & Medicaid Services

ENROLLMENT	Number of Labs	Number of POLs
Laboratories Registered (Exempt/Non-Exempt)	194,734	105,914
Laboratories Registered (Non-Exempt Only)	188,741	104,409
By Certificate Type (Non-Exempt only)		
Compliance (CMS Surveys)	20,480	13,545
Waiver	113,445	52,632
Provider Performed Microscopy	39,209	32,388
Accreditation	15,607	5,844

CLIA EXEMPT STATES	Number of Labs
New York	2,931
Washington	3,062

CERTIFICATE OF ACCREDITATION BY ORGANIZATION (Non-Exempt only)	Number of Labs*
Commission on Office Laboratory Accreditation	6,256
College of American Pathologists	5,229
Joint Commission on Accreditation of Health Care Organizations	3,127
American Osteopathic Association	49
American Association of Blood Banks	219
American Society for Histocompatibility and Immunogenetics	128

*The above data represents labs whose membership with the accreditation organization has been confirmed. Some labs are accredited by more than one organization.

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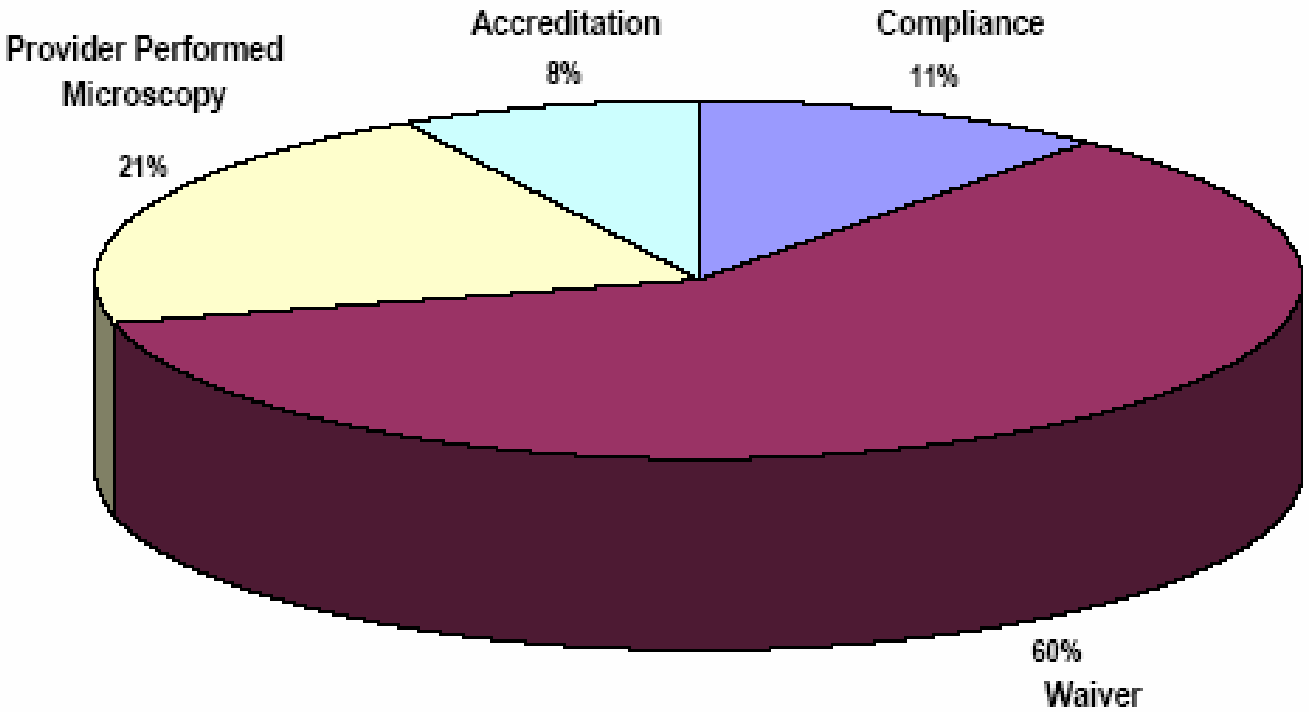
CLIA Labs by Certificate Type
(Non-Exempt Only)



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Relevant websites:

www.cms.gov/clia For CMS-based CLIA information

http://www.phppo.cdc.gov/clia/regs/toc.aspx For CLIA regulations

http://www.phppo.cdc.gov/clia/default.aspx For CDC CLIA

http://www.fda.gov/cdrh/clia/ For FDA CLIA information