CLIA Regulations

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All information obtained from:

https://www.cdc.gov/clia/law-regulations.html

Outline

- Introduction to CLIA and regulatory hierarchy
- Types of CLIA certificates
- Test complexity
- General accreditation requirements
- Proficiency testing
- Facility administration
- Quality management systems
- Personnel requirements

Role of CLIA

- Program administered by CMS
- Congress passed CLIA in 1988 to establish quality standards for all non-research testing
  - » Regulates laboratories that test patient specimens
- Mandates that all laboratories meet applicable federal requirements and have a certificate to operate
- Purpose is to ensure that laboratories produce accurate and reliable test results

Each laboratory must be either:

CLIA-exempt

OR

Possess one of the 5 types of CLIA certificates

Types of CLIA Certificates

- Certificate of registration
- Certificate of compliance
- Certificate of accreditation
- Certificate of waiver
- Certificate for provider-performed microscopy (PPM) procedures

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS

CLIA ID NUMBER

EFFECTIVE DATE

LABORATORY DIRECTOR

EXPIRATION DATE

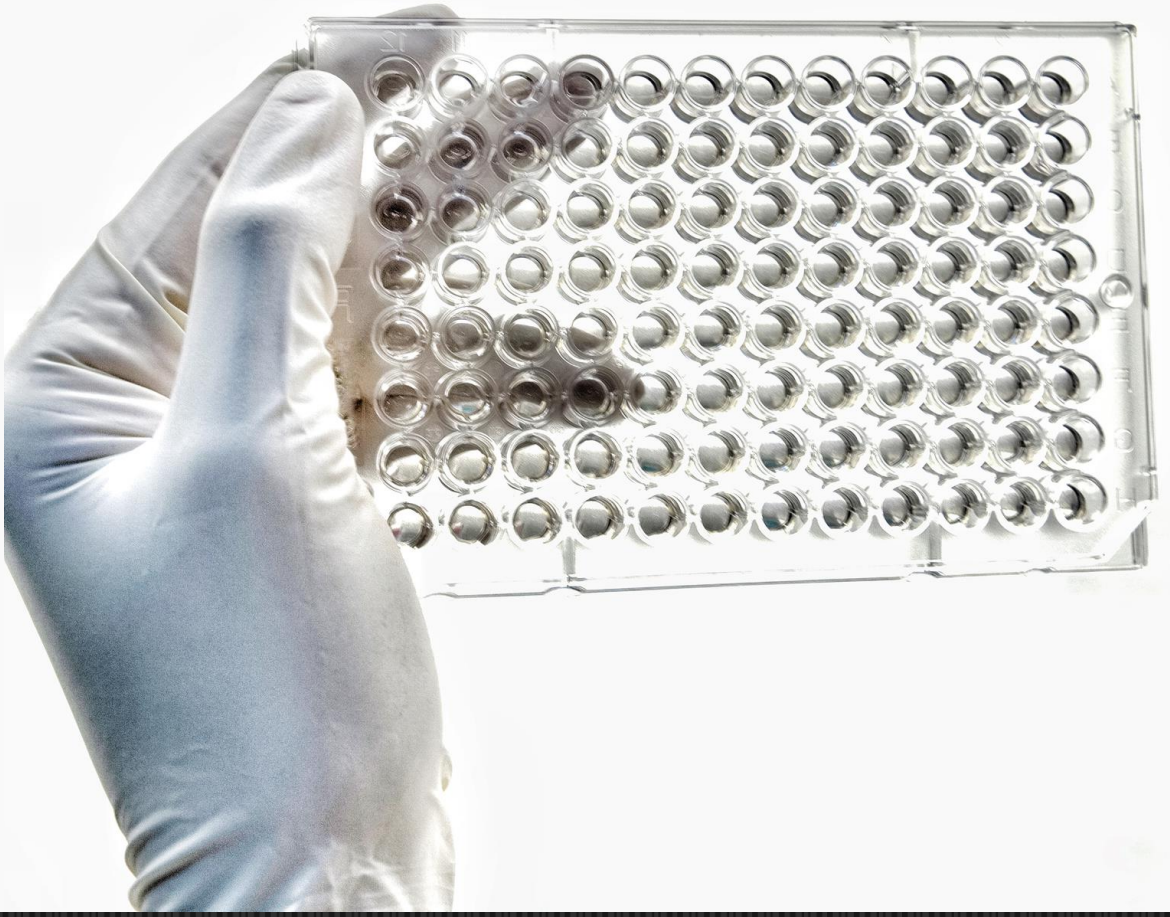
Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

Categorization of Assays



- Waived
- Nonwaived
  - » Moderate complexity, including the subcategory of PPM procedures
  - » High complexity
- A laboratory may perform only waived tests, nonwaived tests, or any combination

Criteria for Test Categorization (Complexity)

- Score 1, 2, or 3 for each
  - » Knowledge
  - » Training and experience
  - » Reagents and materials preparation
  - » Characteristics of operational steps
  - » Calibration, quality control, and proficiency testing materials
  - » Test system troubleshooting and equipment maintenance
  - » Interpretation and judgment
- Determined by FDA during pre-market approval

Provider Performed Microscopy

Criteria

Exam performed by a practitioner using a microscope
The procedure must be categorized as moderately complex
Labile specimen with limited handling or processing
Control materials are not available to monitor the entire testing process

There is a defined list of procedures that qualify

To perform PPM, labs must meet applicable requirements and be subject to inspection

Withdrawal of Accreditation

- CMS may take an adverse action against a laboratory that fails to participate successfully in an approved PT program
- After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory retains its certificate of accreditation for 45 days

Proficiency Testing (Non-waived Testing)

- Each laboratory must enroll in a proficiency testing (PT) program that meets CLIA criteria and is approved
- The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification
- List of approved programs
- Authorize release of PT data to CMS

Rules for testing PT samples

- Must be integrated into the laboratory's regular patient workload by personnel who routinely perform testing
  - » Attestation
- Must use the laboratory's primary routine methods
- The laboratory must test samples the same number of times that it routinely tests patient samples
- The laboratory must document the handling, preparation, processing, examination, and each step in the testing
- No interlaboratory communication
- No PT referral

Facility Administration

- Adequate space, ventilation, and utilities necessary for conducting all phases of the testing process
- Sufficient equipment, instruments, reagents, materials, and supplies
- Must be in compliance with applicable Federal, State, and local requirements
- Safety procedures must be established, accessible, and observed to ensure protection from hazards
- Records and specimens maintained and stored under conditions that ensure proper preservation

Retention requirements

- The laboratory must retain its records for a minimum of **2 years**
  - » Test requisitions and authorizations
  - » Test procedures- at least 2 years after a procedure has been discontinued
  - » Analytic systems records
  - » Proficiency testing
  - » Quality assessment records

Exceptions

- Immunohematology reports
- Pathology test reports for at least 10 years after the date of reporting
- Cytology slide preparations for at least 5 years from the date of examination
- Histopathology slides for at least 10 years from the date of examination
  - » Pathology specimen blocks for at least 2 years from the date of examination
  - » Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen

Quality System

- Must establish and maintain written policies and procedures that implement and monitor a quality system for all phases of the total testing process
  - » Pre-analytic
  - » Analytic
  - » Post-analytic
- Must include a quality assessment component
  - » Ongoing monitoring that identifies, evaluates and resolves problems

Quality System Standards

- Confidentiality of patient information
- Specimen identification and integrity
- Complaint investigations
- Communications
- Personnel competency assessment policies
- Evaluation of proficiency testing performance
- General laboratory systems quality assessment

Pre-analytic quality

- Lab must meet the applicable pre-analytic system(s) requirements
- Must monitor and evaluate the overall quality of the pre-analytic systems and correct identified problems

Standards

- Test request- patient identifiers, requisition components, etc.
- Specimen submission, handling, and referral

Analytic Systems quality

Standards

- Performance verification/validation of instruments and assays
- Procedure manual
- Test systems, equipment, instruments, reagents, materials, and supplies
- Establishment and verification of performance specifications
- Maintenance and function checks
- Calibration and calibration verification procedures
- Control procedures
- Comparison of test results
- Corrective action
- Test records

Post-analytic quality

Standards

» Test report

- Must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry
- Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request
- What the reports should include

Personnel for Non-waived Testing

- Qualifications for PPM-not discussed further
- Focus on qualifications for high and moderate complexity testing

Moderate Complexity Testing

- Laboratory director qualifications
  - » Licensed by the State in which the laboratory is located
- Be a MD or DO
  - » Certified in anatomic or clinical pathology, or both
  - » Laboratory training or experience consisting of:
    - ▪ >1 year directing or supervising non-waived laboratory testing; or
    - ▪ > 20 continuing medical education credit hours in laboratory practice
    - ▪ Laboratory training equivalent to medical residency
- PhD in a chemical, physical, biological, or clinical laboratory science
  - » With certification by professional organization
  - » Have had at least one year experience directing or supervising non-waived laboratory testing
- Separate requirements for folks holding a masters degree or bachelors degree

High Complexity Testing

Same requirements as moderate, except a longer experiential component

- 2 years of experience directing high complexity testing

Laboratory Director Responsibilities

- Responsible for the overall operation and administration of the laboratory
  - » Employment of personnel who are competent to perform test procedures
  - » Record and report test results promptly, accurately and proficiently
  - » Assuring compliance with the applicable regulations
- May perform the duties of all other CLIA-define roles or delegate these responsibilities to personnel meeting the qualifications
- Must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed
- Each individual may direct no more than five laboratories

Other CLIA Personnel Requirements

Technical consultant

- Possess a current license issued by the state where lab is located
- MD, DO with board certification or podiatrist + one year of training
- PhD or masters degree + one year of training
- Bachelors degree in chemical, physical, or biological science or medical technology + 2 years experience
- Responsible for technical and scientific oversight of the laboratory

Clinical consultant

- Qualified laboratory director
- Consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care

Personnel requirements cont'd

Testing personnel

- Possess a current license
- Qualify for any of the previously defined positions
- Bachelors degree in clinical laboratory science or medical technology
- High school graduate or equivalent + documented training
- Responsible for specimen processing, test performance, and for reporting test results