Clinical Laboratory Improvement Amendments (CLIA)

How to Obtain a CLIA Certificate

When is a CLIA Certificate Required?

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.

DO I NEED TO HAVE A CLIA CERTIFICATE?

CLIA requires all facilities that perform even one test, including waived tests, on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

WHAT ARE THE DIFFERENT TYPES OF CLIA CERTIFICATES AND HOW LONG ARE THEY EFFECTIVE?

All types of certificates are effective for two years and the different types of certificates are:

- **Certificate of Waiver (COW):**
  Issued to a laboratory that performs only waived tests.
- **Certificate for Provider Performed Microscopy (PPM) procedures:**
  Issued to a laboratory in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient's visit. A limited list of microscopy procedures is included under this certificate type and these are categorized as moderate complexity.
- **Certificate of Registration:**
  Issued to a laboratory to allow the laboratory to conduct nonwaived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.
- **Certificate of Compliance (COC):**
  Issued to a laboratory once the State Department of Health conducts a survey (inspection) and determines that the laboratory is compliant with all applicable CLIA requirements. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

- **Certificate of Accreditation (COA):**
  Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

There are six CMS-approved accreditation organizations:

- AABB
- American Osteopathic Association (AOA)
- American Society of Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Contact information for the above CMS-approved accreditation organizations is available on the CMS CLIA web site at www.cms.hhs.gov/clia. If you apply for accreditation by one of the CMS-approved accreditation organizations, you must also apply to CMS for a COA concurrently.

WHAT IS A WAIVED TEST?

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result". The Food and Drug Administration (FDA) determines the criteria for tests being simple with a low risk of error and approves manufacturer's applications for test system waiver.

HOW CAN I FIND A LIST OF WAIVED TESTS?

For a list of waived tests sorted by analyte name, visit the FDA website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

For a list of waived tests sorted by the test categorization date and by the test system name, visit the FDA website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm.

WHERE CAN I FIND INFORMATION ABOUT TESTS CATEGORIZED AS NONWAIVED (I.E., MODERATE AND/OR HIGH COMPLEXITY)?

To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity), refer to the lists of tests online at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.

You may also contact the local survey agency at your State Health Department for categorization information concerning tests that you may be performing in your laboratory. A list of State Agency addresses, phone numbers and contact persons is available online under the heading State Survey Agencies (CLIA Contact List) at the CMS CLIA website. If you do not have online access or have questions concerning certification, you may contact the CMS CLIA Central Office at 410-786-3531 for the address and phone number of your local State Agency.

HOW DO I APPLY FOR A CLIA CERTIFICATE?

The CLIA application (Form CMS-116) is available online at the CMS CLIA website located at the end of this brochure. Forward your completed application to the address of the local State Agency for the State in which your laboratory is located. This information is available online or you may contact the CMS CLIA Central Office.

IS THERE ANY TYPE OF LABORATORY TESTING THAT IS NOT SUBJECT TO A CLIA CERTIFICATE?

Yes, there are some testing exceptions that do not require CLIA certification.

The following **exceptions to CLIA certification** apply regardless of a laboratory's location:

- Any laboratory that only performs testing for forensic purposes;
- Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, individual patients; or

- Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA guidelines and regulations. However, a CLIA certificate is needed for all other testing conducted by a SAMHSA-certified laboratory.

ARE THERE ANY STATES THAT EXEMPT ME FROM HAVING TO APPLY FOR A CLIA CERTIFICATE?

Any laboratory located in a state that has a CMS approved laboratory program is exempt from CLIA certification. Currently, there are two states with approved programs: Washington and New York. New York has a partial exemption; therefore, if your laboratory is located in that state, contact the New York State Agency concerning your need for a CLIA certificate.

IF I HAVE MORE THAN ONE LABORATORY LOCATION, DO I NEED A CLIA CERTIFICATE FOR EACH LOCATION?

You will need a CLIA certificate for **each** location where you perform testing **unless** you qualify for one of the exceptions listed below.

- Laboratories that are not at a fixed location; that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.
- Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing, may file a single application.
- Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical location or street address.

Contact your State Agency if you have questions or you are filing a single application for more than one testing site.

WHAT KIND OF FEES DO I HAVE TO PAY TO CMS FOR A CLIA CERTIFICATE?

If you apply for COW or a PPM certificate, you will pay a minimal certificate fee every two years. There are no registration or compliance fees.

If you apply for a COC, you will pay a one time minimal registration fee that covers the cost of the CLIA enrollment in addition to a compliance fee that covers the cost of the initial inspection by the State Agency. CMS will send you a Certificate of Registration. Once compliance has been determined by your inspection, you will pay a certificate fee to CMS and CMS will send you a COC. A two-year certificate cycle is then established, and you will pay a certificate fee and a compliance fee every two years. CMS will send you a COC as long as your laboratory is in compliance.

If you apply for a COA, you will pay a minimal registration fee that covers the cost of the CLIA enrollment. Once CMS receives verification from the accreditation organization that you have selected, you will pay a certificate fee and validation fee to CMS and CMS will send you a COA. A two year certificate cycle is then established and you will pay a certificate fee and a validation fee every two years. CMS will send you a COA as long as your laboratory remains compliant. You will pay survey and any other fees to the accreditation organization.

You can obtain more information concerning the amount of certificate fees from the CMS CLIA website under "CLIA Certificate Fee Schedule" or from your State Agency. For information concerning compliance (survey) fees, you may contact your State Agency or accreditation organization. These fees are based on the number and types of testing you perform and must cover the cost of the CLIA program because CLIA is entirely user fee funded.

WILL I RECEIVE AN IDENTIFYING CLIA NUMBER?

You will receive a ten-digit number on the CLIA certificate. This number will be utilized to identify and track your laboratory throughout its entire history. You should use this number when making inquiries to the State Agency and CMS about your laboratory.

WHEN CAN I BEGIN TESTING?

After you apply for your certificate, you will receive a coupon notifying you of the corresponding fee. Follow the instructions on the fee coupon for payment. After CMS receives your payment, your certificate will be mailed to you. You may begin testing once you have received your certificate containing your CLIA number. However, you need to check with your State Agency since some states have additional requirements.

WILL MY LABORATORY RECEIVE A CMS SURVEY?

Laboratories that have a COW or PPM certificate are not subject to routine surveys. However, CMS is currently conducting a project whereby a small percentage of laboratories that perform only waived testing may receive an educational visit. These visits provide helpful information to staff to help assure the quality of testing and have been extremely well received.

If your laboratory performs any nonwaived testing, the laboratory may have either a COC or COA. All laboratories with either of these certificate types must meet all nonwaived testing requirements and are subject to biennial surveys, by CMS or a CMS agent (such as a surveyor from the State Agency) or by a CMS-approved accreditation organization, if the laboratory is accredited. COA laboratories must also meet the requirements of their accreditation organization.

Additionally, a limited percentage of laboratories with a COA will receive a validation survey by CMS or a CMS agent. This is a survey performed by CMS or a CMS agent to evaluate the results of the most recent survey performed by an accreditation organization.

NOTE: If CMS or the State Agency receives a complaint against your laboratory, you may receive an unannounced on site survey, even though you only perform waived tests or PPM procedures.

IF I HAVE A CERTIFICATE FOR PPM PROCEDURES, A CERTIFICATE OF REGISTRATION, A COA OR A COC, CAN I ALSO PERFORM WAIVED TESTS?

Yes, these certificates permit laboratories to also perform waived tests.

IF I HAVE A COA OR A COC, CAN I ALSO PERFORM PPM PROCEDURES?

Yes, these certificates permit laboratories to perform PPM procedures as well as waived tests. The certificate you obtain should be for the highest (most complex) category of testing you perform.

DO I NEED TO NOTIFY ANYONE IF I MAKE ANY CHANGES IN MY LABORATORY?

For **all** types of CLIA certification, you must notify the State Agency or your accreditation organization within 30 days of any changes in:

- Ownership
- Name
- Location
- Director
- Technical supervisor (for high complexity testing only)

If you perform only waived tests and wish to add PPM procedures or other nonwaived (moderate or high complexity) testing to your menu, you must reapply for the appropriate certificate using the same form (Form CMS-116) you used for your initial CLIA certification. However, you cannot begin nonwaived testing until you have paid the appropriate fee, and have received the appropriate certificate.

If you perform PPM procedures and wish to add other nonwaived (moderate or high complexity) testing, you must first apply for the appropriate certificate.

If you have a COC or COA and wish to add tests categorized under a different laboratory specialty or subspecialty than those on your current certificate or that employ a different test method from those you are already performing, you must notify the State Agency or the accreditation organization of the new testing.

IF I HAVE ANY QUESTIONS ABOUT MY CERTIFICATE OR CHANGES IN MY TEST MENU, WHO SHOULD I CONTACT?

You should contact the State Agency where your laboratory is located. You can find this information as well as other information about CLIA at www.cms.hhs.gov/clia or you may contact the CMS CLIA Central Office at 410-786-3531.

WHERE CAN I FIND ADDITIONAL INFORMATION AND GUIDANCE?

Refer to the "The State Operations Manual", Appendix C – Interpretive Guidelines (CMS Publication 7) available on the CMS website at: www.cms.hhs.gov/clia.

Links to other laboratory-related resources can be found at these websites:

CDC: www.phppo.cdc.gov/clia/default.asp
FDA: www.fda.gov/cdrh/CLIA/index.html

SECTION	Approval date:	
Clinical Services	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Laboratory Services	Revision date:	

POLICY:

The site will operate in compliance with Clinical Laboratory Improvement Amendment (CLIA) regulations. Therefore, the site shall meet all quality standards to ensure accuracy, reliability, and timeliness of patient test results. All lab results are to be communicated to the provider and member in a timely manner.

PROCEDURE:

I. Laboratory test procedures are performed according to current site-specific CLIA certificate:
   A. All sites that perform laboratory testing for human health assessment, diagnosis, prevention, or treatment of disease, have a current, unrevoked, unsuspended site-specific CLIA certificate, or evidence of renewal.
      The CLIA certificate on site includes one of the following:
      a. Certificate of Waiver: Site is able to perform only exempt waived tests so, therefore, has a current CLIA Certificate of Waiver. The current listing of waived tests may be obtained at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm
         - There are no specific CLIA regulations regarding the performance of waived tests. Therefore, site personnel are expected to follow the manufacturer's instructions.
         - Laboratories with Certificates of Waiver may not be routinely inspected by DHS Laboratory Field Services Division, but may be inspected as part of complaint investigations and/or on a random basis to determine whether only waived tests are being performed.
      b. Certificate for Provider-Performed Microscopy (PPM): Physicians, dentists or mid-level practitioners are able to perform PPM procedures and waived tests.
      c. Certificate of Registration: Allows moderate and/or high complexity lab testing to be conducted until compliance with CLIA regulations is determined by survey.
         - For moderate and/or high complexity lab testing, the CLIA regulations list specific requirements for laboratory proficiency testing, patient test management, quality control, quality assurance, personnel and inspections.
      d. Certificate of Compliance: Lab has been surveyed and found to be in compliance with all applicable CLIA requirements.
      e. Certificate of Accreditation: Lab is accredited by an accreditation organization approved by the Centers of Medicare & Medicaid Services (CMS).

   B. CLIA certification/re-certification includes an evaluation every two years (or sooner, if complaint driven) by DHS of personnel licenses/training, laboratory site inspection and demonstration of testing proficiency of moderate and high-complexity test sites.

II. Testing personnel performing clinical lab procedures have been trained.
   A. Prior to testing biological specimens, personnel are appropriately trained for the type and complexity of the laboratory services performed. Personnel have demonstrated the ability to perform all testing operations reliably and to report results accurately.
   B. Site personnel that perform CLIA waived tests have access to and are able to follow test manufacturer's instructions.
   C. When requested, site personnel are able to provide a step-by-step verbal explanation or demonstration of test procedure and how to determine test results.
   D. The required training and certification are established by legislation (CA B&P Codes, §1200-1213) for personnel performing moderate and high complexity tests. Reviewers are not expected to complete an in-depth evaluation of personnel performing moderate and high complexity tests.

III. Lab Supplies are inaccessible to unauthorized persons.

IV. Lab test supplies (e.g., vacutainers, culture swabs, test solutions) shall not be expired. Site follows the procedures below to monitoring for expiration date and a method of dispose of expired lab test supplies. A tracking log is the preferred method of tracking expiration dates (see Attachment).

Frequency of monitoring:	Method of disposal:
☐ Monthly, ☐ Weekly, or ☐ Other:	Describe:

V. The provider will review, initial, and date the original copy of each laboratory report, which is then filed in the member's medical record.

NOTE: For questions regarding CLIA certification, laboratory licensing, and personnel, call CA Department of Public Health Laboratory Field Services at (510) 620-3800.