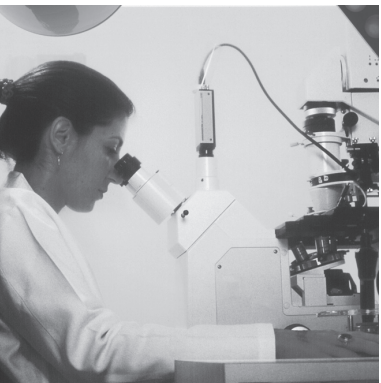
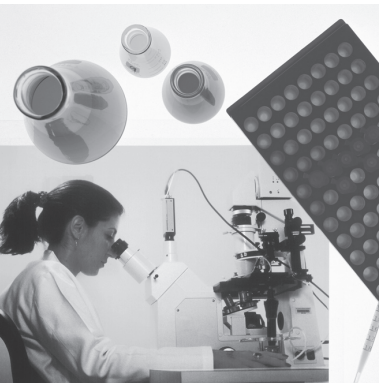
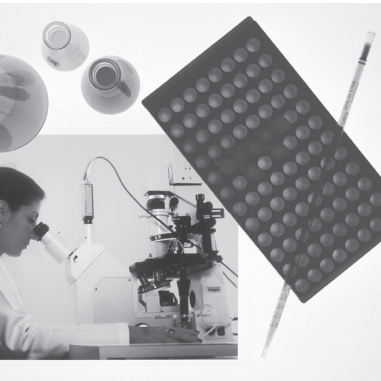


CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.



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HOW DO I APPLY FOR CLIA CERTIFICATION?

Who Needs a Certificate?

CLIA requires every facility that “tests human specimens 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, a human being” to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

Who Runs the Certification Process?

CMS regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total CLIA covers approximately 175,000 laboratory entities.

The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations has the responsibility for implementing the CLIA Program.

What Form Do I Use to Apply?

To receive a CLIA certification, a laboratory must apply using the CLIA application (Form CMS-116). This form collects information about your laboratory operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA.

This form should also be used if your laboratory is looking to change its status under CLIA. For example a laboratory that has been operating under a Certificate of Waiver can ask to receive a Certificate of Compliance on this form.

The form can be found at:

<http://www.cms.hhs.gov/forms/cms116.pdf>

SAMPLE FROM FORM CMS-116:

VI. WAIVED TESTING					
Indicate the estimated TOTAL ANNUAL TEST volume for all waived tests performed. _____					
VII. NONWAIVED TESTING (Including PPMP testing)					
If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.					
Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the information included with the application package.)					
If applying for certificate of accreditation, indicate the name of the accreditation organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (JCAHO, AOA, AABB, CAP, COLA or ASHI)					
SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME

Waived tests are not exempt from CLIA. Facilities performing only those tests categorized as waived must apply for a clia certificate of waiver. The form will require some basic information including the following:

1. **Type of Laboratory**
2. **Hours of Routine Operation**

3. **Volume of Waived Testing** (if your lab is conducting waived testing.)
4. **Volume of Non-Waived Testing** (Including PPMP.) There Are Specific Instructions on the form CMS-116 when completing this section.
5. **Individuals Involved in Laboratory Testing.**

What Type of Certificate Should You Apply For?

The answer depends on what type of tests your lab is providing. A facility holding a:

- *Certificate of Waiver* can only perform tests categorized as waived;
- *Certificate for Provider Performed Microscopy Procedures (PPMP)* can only perform tests categorized as PPMP, or tests categorized as PPMP and waived tests;
- *Certificate of Compliance* can perform tests categorized as waived, PPMP and moderate and/or high complexity tests provided the applicable CLIA quality standards are met; and
- *Certificate of Accreditation* can perform tests categorized as waived, PPMP and moderate and/or high complexity tests provided the laboratory is currently accredited by an approved accreditation organization.

If you are applying for a Certificate of Accreditation, you must include evidence of accreditation for your laboratory by an approved accreditation organization for CLIA purposes or evidence of application for such accreditation with the completed Form CMS-116.

Waived and PPMP laboratories may apply directly for their certificate as they aren't subject to routine inspections, but are still subject to inspections if one is warranted. Those laboratories which must be surveyed routinely; i.e., those performing moderate and/or high complexity testing, can choose whether they wish to be surveyed by CMS (Certificate of Compliance) or by a private accrediting organization (Certificate of Accreditation).

If you are applying for a Certificate of Accreditation, you must include evidence of accreditation for your laboratory by an approved accreditation organization for CLIA purposes or evidence of application for such accreditation with the completed Form CMS-116.

List of approved accrediting organizations under CLIA:

- American Association of Blood Banks
- American Osteopathic Association
- American Society of Histocompatibility and Immunogenetics
- College of American Pathologists
- COLA
- Joint Commission on Accreditation of Healthcare Organizations

What Happens After I Submit the Form?

Once the completed Form CMS-116 has been returned to the applicable state agency and it is processed, a fee remittance coupon will be issued. Process time takes approximately 2 months once the form is received, but varies depending on the state. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. Certificate fees range from \$150 to approximately \$8,000 depending on the type and volume of tests conducted at your lab.

If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

You should also contact your State agency for additional forms that may be necessary to complete the registration process or for any additional questions. For example, the State of California has additional licensure requirements and you would need to contact them directly to determine what additional information is needed.

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