



CLIA CERTIFICATE TYPES

Facilities that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of disease must apply for for a CLIA certificate from the Centers for Medicare and Medicaid Services (CMS) and pay the certificate fee before testing begins.

The application for a CLIA certificate is the CMS-116 form. The type of CLIA certificate a laboratory needs depends on the category of tests performed and choice of inspection agency. Keep in mind that:

- Even if you only perform one test, your facility is considered a laboratory and must have a CLIA certificate.
- There are a few exceptions, but generally each testing location requires its own CLIA certificate.

Certificate of Waiver

This certificate allows a laboratory to perform only waived tests. Anyone may perform waived tests, but waived laboratories must follow the manufacturer's instructions for the tests performed. Laboratories with a Certificate of Waiver are not routinely inspected, but the CLIA regulations do allow inspections of waived laboratories under certain circumstances.

Certificate for Provider-Performed Microscopy Procedures (PPMP)

This specialized certificate is issued to a laboratory in which the provider (must be a physician, nurse midwife, nurse practitioner, physician assistant, or dentist) performs only a limited list of tests that use a microscope and are performed during the exam of a patient. Because these tests are a sub-category of moderate complexity, the laboratory must comply with CLIA requirements for Proficiency Testing, Facility Administration, Quality System, and Personnel.

This certificate also permits the laboratory to perform waived tests. Labs with a certificate of PPMP are not routinely inspected, but the CLIA regulations do allow inspections of PPMP laboratories under certain circumstances.

Certificate of Compliance

The certificate of compliance is one of the two choices for moderate and/or high complexity testing. This certificate is for laboratories that want a government inspection. A certificate of compliance is issued to a laboratory after a CMS inspection by the local state agency that finds the lab to be in compliance with all applicable CLIA requirements.

Certificate of Accreditation

The other choice for moderate and/or high complexity testing is the Certificate of Accreditation. This certificate is for laboratories that want private accreditation instead of the government inspection. Accrediting organizations are non-government agencies approved by CMS that have standards equivalent to or more stringent than the federal program. This certificate is issued to a laboratory that is in compliance with all applicable requirements after inspection by the accrediting organization.

Certificate of Registration

This certificate allows a laboratory to perform non-waived testing until the lab is inspected and determined

to be in compliance with the CLIA regulations. A laboratory that requests a Certificate of Compliance or Certificate of Accreditation on the CMS-116 form is issued the Certificate of Registration initially.

Changing Your CLIA Certificate Type

The CLIA certificate must match the level of testing performed. You may change your CLIA certificate type if you add or delete a category of tests or wish to change inspection agency. Contact your local state agency or submit a new CMS-116 form.

Resources

- How to Apply for a CLIA Certificate: www.cms.hhs.gov/clia/06_how_to_apply_for_a_clia_certificate,_including_foreign_laboratories.asp (Includes a link to a printable CMS-116 application form and the address list for mailing.)
- List of currently waived tests: www.cms.hhs.gov/clia/downloads/CR4136.waivetbl.pdf
- List of Provider Performed Microscopy Procedures: www.cms.hhs.gov/clia/downloads/ppmp.list.pdf
- List of Accrediting Organizations: www.cms.hhs.gov/clia/downloads/ao.list.pdf
- CLIA Certificate Fee Schedule: www.cms.hhs.gov/clia/11_clia_certificate_fee_schedule.asp

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