Laboratory Quick Start Guide to CMS CLIA Certification

The Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) regulates the quality and safety of U.S. clinical laboratories to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. CLIA has regulatory requirements for quality that all laboratories must meet. This guide helps laboratories seeking to apply for CLIA certification from CMS. More information can be found on the CMS CLIA website.

STEP 1: Download and Complete Form CMS-116

- Include information based on the date of form completion.
- All applicable sections must be completed. Incomplete applications cannot be processed.
- Print legibly or type.
- To find out if the testing your laboratory is performing is categorized as waived, moderate, or high complexity-refer to the FDA website. If you are unable to locate test complexity of your laboratory testing, contact your State Agency.
- For a complete list of instructions, refer to page 6 of Form CMS-116.

Complete General Information in section I.

First-time applicants check “Initial Application.”

For an initial applicant, the CLIA Identification Number is left blank. When the application is processed, the number is assigned.

Facility Address must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

International Lab Facilities

For CLIA purposes, an international laboratory is a facility outside the U.S. or its territories that performs clinical laboratory tests referred to and returned to a facility in the U.S. or its territories.

Disclaimer: This guide is a restatement of the law intended to assist people in understanding the basics about the CLIA program, and that the reader should consult the relevant statutes and regulations for the full scope of the CLIA requirements.
Complete Type of Certificate Requested in section II.

In section II, Type of Certificate Requested, select your certificate based on the highest level of test complexity performed by the laboratory (Note: all CLIA certificates are valid for 2 years):

- **Waived tests** are simple examinations and procedures that have an insignificant risk of an erroneous result. See CLIA Currently Waived Analytes.

- **Moderate complexity tests** require minimal scientific and technical knowledge.

- **High complexity tests** are more difficult to perform or interpret than moderate and waived tests. Specialized scientific knowledge and training are required.

More information about each certificate can be found below:

- **Certificate of Waiver (COW):** Issued to a laboratory that only performs waived tests.

- **Certificate for Provider Performed Microscopy Procedures (PPMP):** Issued to a laboratory in which a physician, midlevel practitioner, or dentist performs only specific microscopy procedures during a patient's visit. See list of PPMP procedures, which are a subset of moderate complexity tests.

- **Certificate of Registration (COR):** A COR is temporary and permits the laboratory to conduct nonwaived (moderate and/or high complexity) tests until the laboratory is inspected and found to be in compliance with CLIA regulations. The COR is valid for no more than 2 years. Only laboratories applying for a Certificate of Compliance or a Certificate of Accreditation will receive a COR. Under a COR, a laboratory is also permitted to conduct waived tests.

A laboratory performing non-waived tests can choose **Certificate of Compliance** or **Certificate of Accreditation** based on the agency you wish to survey your laboratory.

- **Certificate of Compliance (COC):** Issued to a laboratory after an inspection by a CLIA state survey agency that finds the laboratory to be in compliance with all applicable CLIA requirements.

- **Certificate of Accreditation (COA):** Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. A non-profit accreditation organization's requirements must equal or exceed CLIA program requirements to receive CMS approval.
To help laboratories begin COVID-19 testing, CLIA has expedited its review of applications for a CLIA certificate. Once the laboratory has identified a qualified laboratory director and provided all required information on the CMS-116 application, a CLIA number will be assigned. This CLIA number will allow laboratories to begin testing before a paper certificate is mailed as long as applicable CLIA requirements have been met (e.g., establishing performance specifications).

**STEP 2: Send Completed CMS-Form 116 to the appropriate State Agency**

- Send via mail or email
- Include state-specific paperwork.

As your local CLIA contact, the SA can answer your questions on CLIA certificates and laboratory testing. They can also advise about any state requirements that apply to your laboratory.

**STEP 3: Receive Fee Coupon (i.e., invoice); See coupon image below**

- Refer to CLIA Fee Schedule
- Receive 10-digit alphanumeric CLIA identification number, with the “D” in the third position identifying the provider/supplier as a laboratory certified under CLIA.
- Amount due will be included on Fee Coupon as the Total Payment Due (outlined below in yellow)

**STEP 4: Pay Applicable Fees**

- Using the U.S. Treasury online platform—include the CLIA Identification Number and charge to a debit or credit card; this secure federal government platform applies payments nightly to outstanding fees
- Writing a check—include the provider number and allow 10 business days for outstanding fees to be applied
STEP 5: Receive Certificate and Begin Testing

- View laboratory certificate data on CLIA website
- Laboratories with a Certificate of Registration will usually have an initial survey performed during the first year of testing to confirm compliance with CLIA regulations

STEP 6: Maintain Certificate

- Maintain your valid and current CLIA Certificate per the following schedule:
- Update laboratory’s demographics, as needed (e.g. address, specialties)
- Laboratories must notify the appropriate State Agency (and the accreditation organization as applicable) of any of the following changes. Laboratories with a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures must notify their State Agency immediately to perform testing outside of their current certificate.
- Laboratories with a Certificate of Waiver, Accreditation or PPMP will receive a renewal invoice 6 months prior to the certificate expiration. Laboratories with a Certificate of Compliance will receive a certificate fee invoice following their compliance survey, and a compliance fee invoice 1 year prior to the certificate expiration.

### CERTIFICATE TYPE

| Certificate of Waiver (COW) | Not routinely surveyed |
| Certificate for Provider Performed Microscopy Procedures (PPMP) | Every 2 years |
| Certificate of Compliance |
| Certificate of Accreditation |

### REQUIREMENTS/CHANGE OF:

| Ownership | Certificate of Waiver 30 days | Certificate for Provider Performed Microscopy Procedures 30 days | Certificate of Registration 30 days | Certificate of Compliance 30 days | Certificate of Accreditation 30 days |
| Name | 30 days | 30 days | 30 days | 30 days | 30 days |
| Location | 30 days | 30 days | 30 days | 30 days | 30 days |
| Director | 30 days | 30 days | 30 days | 30 days | 30 days |
| Technical Sup | N/A | N/A | 30 days | 6 mos | 6 mos |
| Testing | Immediately | Immediately | 6 mos | 6 mos | 6 mos |