

LABORATORY QUICK START GUIDE TO CMS CLIA CERTIFICATION

SEPTEMBER 2020



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 the test complexity of your laboratory testing, contact your [State Agency](#).
- For a complete list of instructions, refer to page 6 of [Form CMS-116](#).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

Initial Application Survey Change in Certificate Type Other Changes (Specify) _____

Effective Date _____

FACILITY NAME _____

EMAIL ADDRESS _____

FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified
NUMBER, STREET (No P.O. Boxes) _____

CITY _____ STATE _____ ZIP CODE _____

SEND FEE COUPON TO THIS ADDRESS: Physical Mailing Corporate

SEND CERTIFICATE TO THIS ADDRESS: Physical Mailing Corporate

NAME OF DIRECTOR (Last, First, Middle Initial) _____

CREDENTIALS _____

FOR OFFICE USE ONLY
Date Received _____

II. TYPE OF CERTIFICATE REQUESTED (Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements.)

Certificate of Waiver (Complete Sections I – VI and IX – X)

Certificate for Provider Performed Microscopy Procedures (PPM) ((Complete Sections I-VII and IX-X)

Certificate of Compliance (Complete Sections I – X)

Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

The Joint Commission AAHHS/HFAP AABB A2LA

CAP COLA ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

PRA Disclosure Statement
According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 3/31/2021. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS Disclaimer***** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact LabExcellence@cms.hhs.gov.

Form CMS-116 (09/17) 1



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 by 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.



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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.

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Other Changes (Specify) _____

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mailing or corporate address is specified

NUMBER, STREET (No P.O. Boxes) _____

CITY _____ STATE _____ ZIP CODE _____

SEND FEE COUPON TO THIS ADDRESS SEND CERTIFICATE TO THIS ADDRESS

Physical Physical

Mailing Mailing

Corporate Corporate

NAME OF DIRECTOR (Last, First, Middle Initial) _____

CITY _____ STATE _____ ZIP CODE _____

CREDENTIALS _____

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NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

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- **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.

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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

SURVEY SCHEDULE

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

REQUIREMENTS/ CHANGE OF:	Certificate of Waiver	Certificate for Provider Performed Microscopy Procedures	Certificate of Registration	Certificate of Compliance	Certificate of Accreditation
Ownership	30 days	30 days	30 days	30 days	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

