CLIA CERTIFICATION QUICK START GUIDE

March 2026

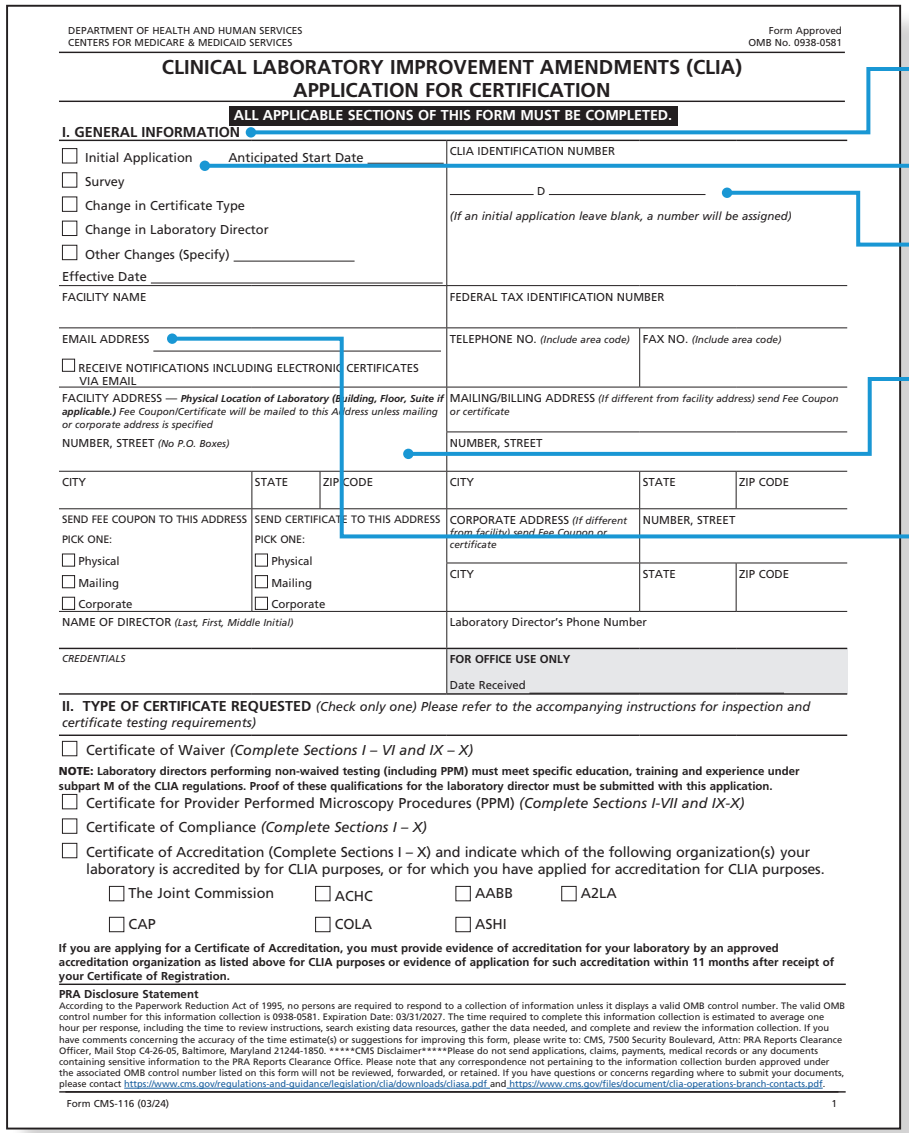
The Centers for Medicare & Medicaid Services (CMS) supports the Clinical Laboratory Improvement Amendments (CLIA) and its regulations to ensure U.S. clinical laboratories provide accurate, reliable, and timely patient test results. Under CLIA, laboratories are generally required to have the appropriate certificate before they can begin testing.

This guide explains how laboratories can apply for CLIA certification from CMS. For more information, visit the CMS CLIA website.

STEP 1

Complete Form CMS-116

- Download this fillable form and type your responses in each section. Make sure you save it as a PDF on your computer.
- Include information as of the date you complete this form.
- Complete all applicable sections. CMS cannot process incomplete applications.
- Check the FDA website to find out if your laboratory's tests are categorized as waived, moderate, or high complexity. If you can't find test complexity information, contact your State Agency.



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

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

☐ Initial Application Anticipated Start Date _____
☐ Survey
☐ Change in Certificate Type
☐ Change in Laboratory Director
☐ Other Changes (Specify) _____
Effective Date _____

CLIA IDENTIFICATION NUMBER
_____ D _____
(If an initial application leave blank, a number will be assigned)

FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS

☐ RECEIVE NOTIFICATIONS INCLUDING ELECTRONIC CERTIFICATES VIA EMAIL

TELEPHONE NO. *(Include area code)* | FAX NO. *(Include area code)*

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

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*

NUMBER, STREET

CITY | STATE | ZIP CODE

SEND FEE COUPON TO THIS ADDRESS
PICK ONE:
☐ Physical
☐ Mailing
☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS
PICK ONE:
☐ Physical
☐ Mailing
☐ Corporate

CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*

NUMBER, STREET

CITY | STATE | ZIP CODE

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

Laboratory Director's Phone Number

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)*

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.

☐ 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 ☐ ACHC ☐ 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.

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: 03/31/2027. 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 https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliasa.pdf and https://www.cms.gov/files/document/clia-operations-branch-contacts.pdf.

Form CMS-116 (03/24) 1

Complete GENERAL INFORMATION in Section I

- First-time applicants check **"Initial Application."**
- For first-time applicants, leave the **CLIA IDENTIFICATION NUMBER** blank. When the application is processed, the number is assigned.
- **FACILITY ADDRESS** must reflect the physical location where you perform laboratory testing. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.
- Include your laboratory's most up-to-date **EMAIL ADDRESS** so you get important updates from CMS, including fee coupons and electronic CLIA certificates.

Tip: Include a business email address that many laboratory staff access and use.

After March 1, 2026, CMS will send all fee coupons and CLIA certificates by email. Mailing and corporate address fields, along with checkboxes for selecting a mailing address, are no longer required and may be left blank on this form.

International Lab Facilities

Under CLIA, 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. 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 the certificate that corresponds to the highest level of test complexity your laboratory performs (**Note:** all CLIA certificates are valid for 2 years):

- **Waived tests** are simple tests that have a low risk of an incorrect result. Refer to CLIA Currently Waived Analytes.
- **Moderate complexity tests** require minimal scientific and technical knowledge.
- **High complexity tests** are more difficult to perform or interpret than waived and moderate tests. Specialized scientific knowledge and training are required.

More information about each certificate type:

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

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☐ Change in Laboratory Director
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CITY | STATE | ZIP CODE

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PICK ONE:
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☐ Mailing
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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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Form CMS-116 (03/24) 1

- **Certificate of Registration (CoR):** Issued to temporarily allow 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 the State Agency or CMS surveyor finds the laboratory in compliance with all applicable CLIA requirements.
- **Certificate of Accreditation (CoA):** Issued to a laboratory by a CMS-approved Accreditation Organization (AO). AOs are private nonprofits which meet all applicable federal participation requirements but may have more stringent health and safety requirements.

Complete TYPE OF LABORATORY in Section III

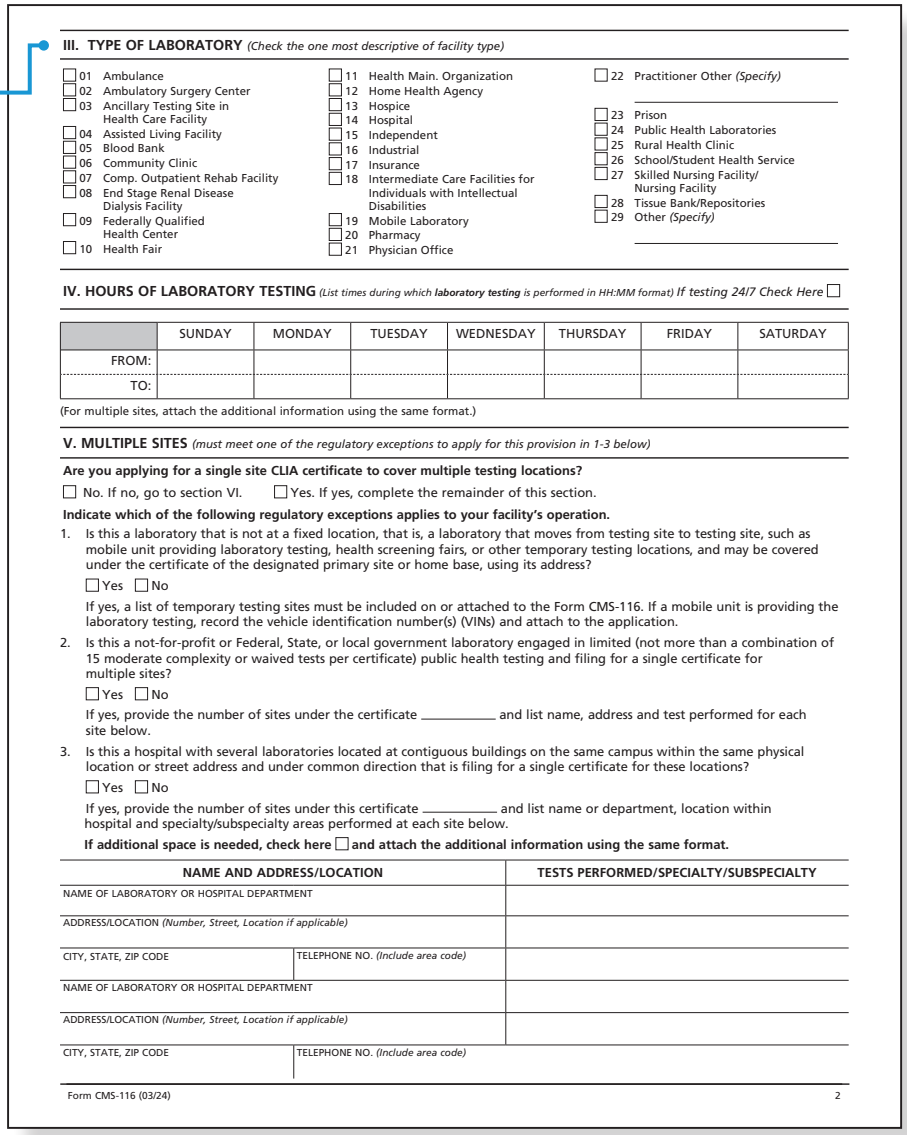
In Section III, select the **TYPE OF LABORATORY** that best describes the facility where your laboratory performs testing. Contact your State Agency with questions.

STEP 2

Submit Completed Form CMS-116 to the Appropriate State Agency

- Submit your completed CLIA application to your State Agency.
- For PPM, CoR, CoC, and CoA, include documentation that the laboratory director's qualifications are met:
  - State licensure, as applicable
  - Education (e.g. diploma, transcript, foreign education equivalency, etc.).
  - Credentials (e.g. board certification, continuing education hours, etc.).
  - Laboratory experience

Important: Some states may have additional requirements. Contact your State Agency to find out if you need to submit additional forms or documentation with your application.



III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

- ☐ 01 Ambulance
- ☐ 02 Ambulatory Surgery Center
- ☐ 03 Ancillary Testing Site in Health Care Facility
- ☐ 04 Assisted Living Facility
- ☐ 05 Blood Bank
- ☐ 06 Community Clinic
- ☐ 07 Comp. Outpatient Rehab Facility
- ☐ 08 End Stage Renal Disease Dialysis Facility
- ☐ 09 Federally Qualified Health Center
- ☐ 10 Health Fair
- ☐ 11 Health Main. Organization
- ☐ 12 Home Health Agency
- ☐ 13 Hospice
- ☐ 14 Hospital
- ☐ 15 Independent
- ☐ 16 Industrial
- ☐ 17 Insurance
- ☐ 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities
- ☐ 19 Mobile Laboratory
- ☐ 20 Pharmacy
- ☐ 21 Physician Office
- ☐ 22 Practitioner Other *(Specify)* _____
- ☐ 23 Prison
- ☐ 24 Public Health Laboratories
- ☐ 25 Rural Health Clinic
- ☐ 26 School/Student Health Service
- ☐ 27 Skilled Nursing Facility/ Nursing Facility
- ☐ 28 Tissue Bank/Repositories
- ☐ 29 Other *(Specify)* _____

IV. HOURS OF LABORATORY TESTING *(List times during which **laboratory testing** is performed in HH:MM format)* *If testing 24/7 Check Here* ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision in 1-3 below)*

Are you applying for a single site CLIA certificate to cover multiple testing locations?

☐ No. If no, go to section VI. ☐ Yes. If yes, complete the remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?
   ☐ Yes ☐ No
   If yes, a list of temporary testing sites must be included on or attached to the Form CMS-116. If a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.
2. Is this a not-for-profit or Federal, State, or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?
   ☐ Yes ☐ No
   If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.
3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?
   ☐ Yes ☐ No
   If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	

Form CMS-116 (03/24) 2

STEP 3

Receive Fee Coupon (Invoice) and Pay Your CLIA Certification Fee

You'll receive a Fee Coupon via email that includes:

- Your laboratory's unique 10-character alphanumeric CLIA Identification Number.
- Total Payment Due

Your fee varies based on certificate type and test volume. Refer to CLIA Fee Schedule.

Pay your CLIA certification fee(s) on pay.gov. We accept bank account (ACH), debit, or credit cards. Your secure payment gets processed overnight.

STEP 4

Receive Certificate and Begin Testing

- You'll receive your CLIA certificate via email. Or you can view, print (and reprint) online.
- Laboratories with a CoR typically have an initial survey in the first year to determine whether the laboratory is in compliance with all applicable CLIA requirements.

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF WAIVER

LABORATORY NAME AND ADDRESS
WESTFIELD STATE UNIVERSITY -HEALTH SERVICES
SCANLON HALL,DPT HLTH SVCS,1ST FL,WEST WING
577 WESTERN AVE
SCANLON HALL, 1ST FLOOR, WEST WING
WESTFIELD, MA 01086-1630

CLIA ID NUMBER
22D0981035

EFFECTIVE DATE
12/18/2024

LABORATORY DIRECTOR
PATRICIA C. BERUBE

EXPIRATION DATE
12/17/2026

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.
This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Gregg Brandish, Director
Division of Clinical Laboratory Improvement & Quality
Quality & Safety Oversight Group
Center for Clinical Standards and Quality

STEP 5

Maintain Certificate

Keep your CLIA certificate current according to this survey schedule:

- Contact your State Agency when you have a change in the laboratory's demographics, such as specialties, address, email address, or if the laboratory stops testing or closes.
- Laboratories must notify their State Agency (and the accreditation organization, if applicable) of the following changes. **Laboratories with a CoW or a PPM must immediately notify their State Agency before testing outside of their current certificate.**
- Laboratories with a CoW, CoA, or PPM will receive a renewal invoice 6 months before their certificate expires.
- Laboratories with a CoC will receive a certificate fee invoice after their compliance survey, and a survey fee invoice 1 year before their certificate expires.

CERTIFICATE TYPE	SURVEY SCHEDULE
Certificate of Waiver (CoW)	Not routinely surveyed
Certificate for Provider Performed Microscopy Procedures (PPM)	Not routinely surveyed
Certificate of Compliance (CoC)	Every 2 years
Certificate of Accreditation (CoA)	Every 2 years

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 Supervisor	N/A	N/A	30 days	30 days	N/A
Testing	Immediately	Immediately	6 months	6 months	6 months