Form Approved
OMB No. 0938-0581
Expires: XX/XXXX

Clinical Laboratory Improvement Amendments (CLIA) Application (Form CMS-116)

Clinical Laboratory Improvement Amendments (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, or the assessment of the health, of a human being to meet certain federal requirements.

If your facility performs tests for these purposes, it's considered under the law to be a laboratory. CLIA applies even if your laboratory performs only one or a few basic tests, and even if you're not charging for testing. The CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation to determine the fees to be assessed, establish baseline data, and fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. **Any information you submit should be based on your facility's laboratory operation as of the date you complete the form.**

Note: Waived tests aren't exempt from CLIA. Facilities that only perform tests categorized as waived must apply for a CLIA certificate of waiver. Specific test system categorizations can also be found at: **Accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm**

Facilities that only collect or prepare specimens (or both) or only serve as a mailing service aren't considered laboratories. CLIA doesn't apply to a facility that only performs forensic testing.

Proof of laboratory director qualifications must be submitted with this form. Documentation must include:

- Verification of State Licensure, as applicable
- Documentation of qualifications:
  - Documentation to show CLIA personnel qualifications are met (e.g., diploma, transcript)
  - Credentials
  - Laboratory experience

People who attended foreign schools must have their credentials evaluated to determine U.S. education equivalency. Failure to submit this information will delay the processing of your application.

How to submit Form CMS-116

- Include the current or estimated annual test volume
- For Certificate for Provider-performed Microscopy (PPM) Procedures, Certificate of Compliance, or Certificate of Accreditation, include laboratory director qualifications
- Don't send any money with your form
- Send your completed Form CMS-116 to the appropriate state agency (**CMS.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf**).

What happens next

Once you submit Form CMS-116 and your state agency processes the form, you'll receive a fee remittance coupon. The fee remittance coupon will show your CLIA identification number and the amount due for the certificate, and any compliance (survey) or validation fee that applies.

If you're applying for a Certificate of Compliance or Certificate of Accreditation, you'll initially pay for and receive a Certificate of Registration. A Certificate of Registration 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 CMS receives verification of accreditation by an approved accreditation organization.

Get help & more information

For more information about CLIA, or if you have questions about this form, contact your state agency. State agency contact information can be found at:
CMS.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

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Clinical Laboratory Improvement Amendments (CLIA) Application (Form CMS-116)

Complete all sections that apply. Please type or print legibly.

For Office Use Only. Date received (mm/dd/yyyy)
__/__/____

1. General Information

◯ Initial application
Anticipated start date (mm/dd/yyyy):
__/__/____

◯ Survey
◯ Change in certificate type
◯ Change in laboratory director
◯ Other changes (specify): _____
Effective date (mm/dd/yyyy):
__/__/____

CLIA Identification Number (leave blank if this is an initial application—a number will be assigned)
__ D ____

Facility name	Federal Tax Identification Number (TIN)
	___-___-____

Email address 1	Email address 2 (optional)

Email address 3 (optional)	Email address for CLIA fee coupons (if applicable)

Phone number	Fax number
(___)___-____	(___)___-____

Facility address (physical location—no P.O. Boxes)

Facility address line 2 (building, floor, suite, if applicable)

City	State	ZIP code
	__	_____-____

Name of Laboratory Director (Last, First, Middle initial)	Laboratory Director phone number
	(___)___-____

Name of Owner	Owner phone number
	(___)___-____

2. Type of Certificate Requested

Check only one. Select your certificate type based on the highest level of test your laboratory performs. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the entity you want to survey your laboratory.

◯ **Certificate of Waiver** can only perform tests categorized as waived* (complete sections 1–6 and 9–10)

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 qualifications for the laboratory director must be submitted with this form.

◯ **Certificate for Provider Performed Microscopy Procedures (PPM)** can only perform tests categorized as PPM, or tests categorized as PPM and waived tests* (complete sections 1–6 and 9–10)

◯ **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests if the applicable CLIA quality standards are met after a CLIA survey (complete sections 1–10)

◯ **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/ or high complexity non-waived tests if the laboratory is currently accredited by an approved accreditation organization. (complete sections 1–10)

If you're applying for a Certificate of Accreditation, you must provide evidence of accreditation by an approved accreditation organization for CLIA purposes, or evidence that you applied for accreditation, within 11 months after you receive your Certificate of Registration.

Which organization(s) is your laboratory accredited by (or you applied for accreditation from) for CLIA purposes?

◯ The Joint Commission ◯ ACHC ◯ AABB ◯ A2LA ◯ CAP ◯ COLA ◯ ASHI

If your accreditation organization isn't listed, contact your local state agency for instructions.

*Specific test system categorizations can also be found at: **Accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm**

3. Type of Laboratory

Check the one that most closely describes your 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): _____

Is the laboratory located within a CMS-certified health care facility (facilities with asterisk*)? ..... ◯ Yes ◯ No

If yes, list CMS Certification Numbers (CCNs):

_____ _____ _____

4. Hours of Laboratory Testing

List times during which laboratory testing is performed in HH:MM format. ◯ Check here if testing 24/7.

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
From:							
To:							

5. Multiple Sites

You must have a CLIA certificate for each location unless you meet one of the CLIA exceptions described in 42 CFR 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3).

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

◯ **No. If no,** go to section 6. ◯ **Yes. If yes,** complete the rest of this section.

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

◯ This is a laboratory that's not at a fixed location that moves from testing site to testing site (such as a 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.

If selected, you must include a list of temporary testing sites with this CMS-116 Form. If a mobile unit provides the testing, record the vehicle identification number(s) (VINs) and attach it to the form.

◯ This is 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.

If selected, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.

◯ This is a hospital with multiple laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction filing for a single certificate for these locations.

If selected, 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.

1. Name of laboratory or hospital department

Address/Location (number and street, P.O. Box, or route) (if applicable)

City	State	ZIP code
		-

Phone number

( ) -

Tests performed/specialty/subspecialty

2. Name of laboratory or hospital department

Address/Location (number and street, P.O. Box, or route) (if applicable)

City	State	ZIP code
		-

Phone number

( ) -

Tests performed/specialty/subspecialty

Need more space? ◯ **Check here and attach the additional information using the same format.**

6. Waived Testing to Be Performed

If **only** applying for a Certificate of Waiver, complete this section and skip sections 7 (PPM Testing to Be Performed) and 8 (Non-Waived Testing to Be Performed).

Include each analyte, test system, or device used in the laboratory.

Analyte/Test	Test Name	Manufacturer
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation

Indicate the **Estimated Total Annual Test** volume for all waived tests performed: _____

◯ Check if no waived tests are performed

Need more space? ◯ Check here and attach the additional information using the same format.

7. PPM Testing to Be Performed

If **only** applying for a Certificate for PPM, complete this section and skip section 8 (Non-Waived Testing).

Listed below are the **only** PPM tests that can be performed by a facility with a Certificate for PPM. Mark each PPM procedure that will be performed.

◯ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
◯ Potassium hydroxide (KOH) preparations
◯ Pinworm examinations
◯ Fern tests
◯ Post-coital direct, qualitative examinations of vaginal or cervical mucous
◯ Urine sediment examinations
◯ Nasal smears for granulocytes
◯ Fecal leukocyte examinations
◯ Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

Indicate the **Estimated Total Annual Test** volume for all PPM tests performed: _____

If also performing waived complexity tests, complete section 6. For laboratories applying for a Certificate of Compliance or Certificate of Accreditation, include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section 8.

◯ Check if no PPM tests are performed

8. Non-Waived Testing to Be Performed

Complete this section **only** if you're applying for a Certificate of Compliance or a Certificate of Accreditation.

Be as specific as possible, including each analyte, test system, or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity. Specific test system categorizations can be found at: **Accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm**

Analyte/Test	Test Name	Manufacturer	M or H
Example: Potassium	Quick Potassium Test	Acme Corporation	M

Need more space? ◯ Check here and attach the additional information using the same format.

Non-waived test volumes

The Total Estimated Annual Test Volume in this section includes all non-waived testing, including PPM tests previously counted in section 7.

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.

- Check the box for each specialty/subspecialty in which the laboratory performs testing.
- Enter the estimated annual test volume for each specialty.
- Don't include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. Go to Guidelines for Counting Tests on page 9 for more details.
- If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the specialty/subspecialty for which you're accredited for CLIA compliance. (The Joint Commission, ACHC, AABB, A2LA, CAP, COLA, or ASHI)
- The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.

Specialty/ Subspecialty	Accrediting Organization	Annual Test Volume	Specialty/ Subspecialty	Accrediting Organization	Annual Test Volume
Histocompatibility 010			**Hematology 400**		
◯ Transplant			◯ Hematology		
◯ Nontransplant			**Immunohematology**		
Microbiology			◯ ABO Group & Rh Group 510		
◯ Bacteriology 110			◯ Antibody Detection (transfusion) 520		
◯ Mycobacteriology 115			◯ Antibody Detection (nontransfusion) 530		
◯ Mycology 120			◯ Antibody Identification 540		
◯ Parasitology 130			◯ Compatibility Testing 550		
◯ Virology 140			**Pathology**		
Diagnostic Immunology			◯ Histopathology 610		
◯ Syphilis Serology 210			◯ Oral Pathology 620		
◯ General Immunology 220			◯ Cytology 630		
Chemistry			**Radiobioassay 800**		
◯ Routine 310			◯ Radiobioassay		
◯ Urinalysis 320			**Clinical Cytogenetics 900**		
◯ Endocrinology 330			◯ Clinical Cytogenetics		
◯ Toxicology 340			**Total Estimated Annual Test Volume:**		

9. Type of Control

Check the one most descriptive of ownership type:

Voluntary Nonprofit:
- ◯ 01 Religious Affiliation
- ◯ 02 Private Nonprofit
- ◯ 03 Other Nonprofit (specify): _____

For Profit:
- ◯ 04 Proprietary

Government:
- ◯ 05 City
- ◯ 06 County
- ◯ 07 State
- ◯ 08 Federal
- ◯ 09 Other Government: _____

(If 09 is selected, please specify the country/province.)

Does this facility have partial or full ownership or control by a non-United States-based government or entity? . . ◯ Yes ◯ No

If yes, what is the country of origin for the foreign entity? _____

10. Director Affiliation with Other Laboratories

If the director of this laboratory serves as director for additional laboratories that are separately certified, complete this section.

Note: For a Certificate for PPM, Certificate of Compliance or Certificate of Accreditation an individual can serve as the director for no more than five certificates.

CLIA Number	Name of Laboratory

ATTENTION: Read carefully before signing

Any person who is convicted of intentionally violating any CLIA requirements under section 353(1) of the Public Health Service Act may be imprisoned or fined or both.

Consent: The applicant agrees that the laboratory identified in this application will be operated according to the standards set by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant agrees to permit the Secretary, or any designated Federal officer or employee, to inspect the laboratory and its operations and its pertinent records at any reasonable time, and to furnish any requested information or materials necessary to determine the laboratory's eligibility for its certificate or compliance with CLIA requirements.

Note: "Owner" means any person who owns any interest in a laboratory, except for an interest in a laboratory whose stock and/or securities are publicly traded. (The purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

Print name of Laboratory Director/Owner

Signature of Laboratory Director/Owner (sign in ink or use a secure electronic signature)	**Date signed** (mm/dd/yyyy)
	☐☐/☐☐/☐☐☐☐

How to submit your form

Send your completed Form CMS-116 to your local state agency. Don't send any payment with your form.

Find your state agency contact information at: **CMS.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf**

Tests Commonly Performed and their Corresponding Laboratory Specialties/Subspecialties

Histocompatibility (010)

- HLA Typing (disease associated antigens)

Microbiology

Bacteriology (110)

- Gram Stain
- Culture
- Susceptibility
- Strep screen
- Antigen assays (H.pylori, Chlamydia, etc.)

Mycobacteriology (115)

- Acid Fast Smear
- Mycobacterial culture
- Mycobacterial susceptibility

Mycology (120)

- Fungal Culture
- DTM
- KOH Preps

Parasitology (130)

- Direct Preps
- Ova and Parasite Preps
- Wet Preps

Virology (140)

- RSV (Not including waived kits)
- HPV assay
- Cell culture

Diagnostic immunology

Syphilis Serology (210)

- RPR
- FTA, MHATP

General Immunology (220)

- Allergen testing
- ANA
- Antistreptolysin O
- Antibody (herpes, rubella, etc.)
- Complement (C3, C4)
- Hepatitis (Antigen/Antibody)
- HIV (Antigen/Antibody)
- Immunoglobulin
- Mononucleosis assay
- Rheumatoid factor
- Tumor marker (AFP, CA 19-9, CA 15-3, CA 125)*

  * Tumor markers can alternatively be listed under Routine Chemistry instead of General Immunology.

Hematology (400)

- Complete Blood Count (CBC)
- WBC count
- RBC count
- Hemoglobin
- Hematocrit (Not including spun micro)
- Platelet count
- Differential
- Activated Clotting Time
- Prothrombin time (Not including waived instruments)
- Partial thromboplastin time
- Fibrinogen
- Reticulocyte count
- Manual WBC by hemocytometer
- Manual platelet by hemocytometer
- Manual RBC by hemocytometer
- Sperm count

Immunohematology

- ABO group (510)
- Rh(D) type (510)
- Antibody screening
- Antibody identification (540)
- Compatibility testing (550)

Pathology

- Dermatopathology
- Oral Pathology (620)
- PAP smear interpretations (630)
- Other Cytology tests (630)
- Histopathology (610)

Radiobioassay (800)

- Red cell volume
- Schilling test

Clinical Cytogenetics (900)

- Fragile X
- Buccal smear
- Prader-Willi syndrome
- FISH studies for: neoplastic disorders, congenital disorders or solid tumors.

Chemistry

Routine Chemistry (310)

- Albumin
- Ammonia
- Alk Phos
- ALT/SGPT
- AST/SGOT
- Amylase
- Bilirubin
- Blood gas (pH, pO2, pCO2)
- BUN
- Calcium
- Chloride
- Cholesterol
- Cholesterol, HDL
- CK/CK isoenzymes
- CO2
- Creatinine
- Ferritin
- Folate
- GGT
- Glucose (Not fingerstick)
- Iron
- LDH/LDH isoenzymes
- Magnesium
- Potassium
- Protein, electrophoresis
- Protein, total
- PSA
- Sodium
- Triglycerides
- Troponin
- Uric acid
- Vitamin B12

Endocrinology (330)

- Cortisol
- HCG (serum pregnancy test)
- T3
- T3 Uptake
- T4
- T4, free
- TSH

Toxicology (340)

- Acetaminophen
- Blood alcohol
- Blood lead (Not waived)
- Carbamazepine
- Digoxin
- Ethosuximide
- Gentamicin
- Lithium
- Phenobarbital
- Phenytoin
- Primidone
- Procainamide
- NAPA
- Quinidine
- Salicylates
- Theophylline
- Tobramycin
- Therapeutic Drug Monitoring

Urinalysis (320)**

- Automated Urinalysis (Not including waived instruments)
- Microscopic Urinalysis
- Urine specific gravity by refractometer
- Urine specific gravity by urinometer
- Urine protein by sulfosalicylic acid

** Dipstick urinalysis is counted in section 6 (Waived Testing to Be Performed)

Note: This is not a complete list of tests covered by CLIA. Contact your State agency for more information. State agency contact information can be found at:
CMS.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

Guidelines for Counting Tests for CLIA

- For **chemistry**, each non-calculated analyte is counted separately (e.g., Lipid Panel consisting of a total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides equals 4 tests).
- For **clinical cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests. NOTE: For all other genetic tests, the number of tests is determined by the number of results reported in the final report.
- For manual gynecologic and nongynecologic **cytology**, each slide (not case) is counted as one test.
- For **flow cytometry**, each measured individual analyte (e.g. T cells, B cells, CD4, etc.) that is ordered and reported should be counted separately.
- For **general immunology**, testing for allergens should be counted as one test per individual allergen.
- **Genetics testing** platforms are used in many of the testing specialties/subspecialties. The laboratory should select the specialty or subspecialty according to the analyte the test is identifying.
- For **hematology**, each **measured** individual analyte of a **complete blood count** or **flow cytometry** test that is ordered **and reported** is counted separately. The **WBC differential** is counted as one test.
- For **histocompatibility**, each HLA typing (including disease associated antigens) is counted as one test, each HLA antibody screen is counted as one test and each HLA crossmatch is counted as one test. For example, a B-cell, a T-cell, and an auto-crossmatch between the same donor and recipient pair would be counted as 3 tests.
- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per test request from each specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each gram stain or acid-fast bacteria (AFB) smear requested from the primary source is counted as one. For example, if a sputum specimen has a routine bacteriology culture and gram stain, a mycology test, and an AFB smear and culture ordered, this would be counted as five tests. For parasitology, the direct smear and the concentration and prepared slide are counted as one test.
- For **urinalysis**, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **all specialties/subspecialties**, do not count calculations (e.g., A/G ratio, MCH, T7, etc.), quality control, quality assurance, or proficiency testing assays.

If you need additional information concerning counting tests for CLIA, please contact your state agency.