

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

| | | | | | |
|---|--|--------------------------------------|---|-------|----------|
| <input type="checkbox"/> Initial Application <input type="checkbox"/> Survey <input type="checkbox"/> Change in Certification Type <input type="checkbox"/> Other Changes (<i>Specify</i>) _____ | CLIA IDENTIFICATION NUMBER _____ D _____ <i>(If an initial application leave blank, a number will be assigned)</i> | | | | |
| FACILITY NAME | FEDERAL TAX IDENTIFICATION NUMBER | | | | |
| EMAIL ADDRESS | TELEPHONE NO. (<i>Include area code</i>) | FAX NO. (<i>Include area code</i>) | | | |
| FACILITY ADDRESS — <i>Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing address is specified</i> | MAILING/BILLING ADDRESS (<i>If different from street address</i>) | | | | |
| NUMBER, STREET (<i>No P.O. Boxes</i>) | NUMBER, STREET | | | | |
| CITY | STATE | ZIP CODE | CITY | STATE | ZIP CODE |
| NAME OF DIRECTOR (<i>Last, First, Middle Initial</i>) | | | FOR OFFICE USE ONLY Date Received _____ | | |

II. TYPE OF CERTIFICATE REQUESTED (*Check only one*)

- Certificate of Waiver (*Complete Sections I – VI and IX – X*)
- Certificate for Provider Performed Microscopy Procedures (PPM) (*Complete Sections I – 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
- | | | |
|---|-------------------------------|-------------------------------|
| <input type="checkbox"/> The Joint Commission | <input type="checkbox"/> AOA | <input type="checkbox"/> AABB |
| <input type="checkbox"/> CAP | <input type="checkbox"/> COLA | <input type="checkbox"/> 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 requirements. Proof of these requirements for the laboratory director must be submitted with the application.

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. The time required to complete this information collection is estimated to average 30 minutes to 2 hours 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 any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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

- | | | |
|--|--|---|
| <input type="checkbox"/> 01 Ambulance | <input type="checkbox"/> 11 Health Main. Organization | <input type="checkbox"/> 22 Practitioner Other (Specify) |
| <input type="checkbox"/> 02 Ambulatory Surgery Center | <input type="checkbox"/> 12 Home Health Agency | |
| <input type="checkbox"/> 03 Ancillary Testing Site in Health Care Facility | <input type="checkbox"/> 13 Hospice | <input type="checkbox"/> 23 Prison |
| <input type="checkbox"/> 04 Assisted Living Facility | <input type="checkbox"/> 14 Hospital | <input type="checkbox"/> 24 Public Health Laboratories |
| <input type="checkbox"/> 05 Blood Bank | <input type="checkbox"/> 15 Independent | <input type="checkbox"/> 25 Rural Health Clinic |
| <input type="checkbox"/> 06 Community Clinic | <input type="checkbox"/> 16 Industrial | <input type="checkbox"/> 26 School/Student Health Service |
| <input type="checkbox"/> 07 Comp. Outpatient Rehab Facility | <input type="checkbox"/> 17 Insurance | <input type="checkbox"/> 27 Skilled Nursing Facility/ Nursing Facility |
| <input type="checkbox"/> 08 End Stage Renal Disease Dialysis Facility | <input type="checkbox"/> 18 Intermediate Care Facility for Mentally Retarded | <input type="checkbox"/> 28 Tissue Bank/Repositories |
| <input type="checkbox"/> 09 Federally Qualified Health Center | <input type="checkbox"/> 19 Mobile Laboratory | <input type="checkbox"/> 29 Other (Specify) |
| <input type="checkbox"/> 10 Health Fair | <input type="checkbox"/> 20 Pharmacy | |
| | <input type="checkbox"/> 21 Physician Office | |
- Is this a shared lab? Yes No

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format)

| | 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)

Are you applying for the multiple site exception?

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

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

- Is this a laboratory that has temporary testing sites?
 Yes No
- 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.
- 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) | |

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING

Identify the waived testing performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.

e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the estimated **TOTAL ANNUAL TEST** volume for all waived tests performed _____

Check if no waived tests are performed

VII. PPM TESTING

Identify the PPM testing performed. Be as specific as possible.

e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Indicate the estimated **TOTAL ANNUAL TEST** volume for all PPM tests performed _____

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the "total estimated test volume" in section VIII.

Check if no PPM tests are performed

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

VIII. NON-WAIVED TESTING (Including PPM testing)

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.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the information included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

| SPECIALTY / SUBSPECIALTY | ACCREDITING ORGANIZATION | ANNUAL TEST VOLUME | SPECIALTY / SUBSPECIALTY | ACCREDITING ORGANIZATION | ANNUAL TEST VOLUME |
|---|--------------------------|--------------------|--|--------------------------|--------------------|
| HISTOCOMPATIBILITY | | | HEMATOLOGY | | |
| <input type="checkbox"/> Transplant | | | <input type="checkbox"/> Hematology | | |
| <input type="checkbox"/> Nontransplant | | | IMMUNOHEMATOLOGY | | |
| MICROBIOLOGY | | | <input type="checkbox"/> ABO Group & Rh Group | | |
| <input type="checkbox"/> Bacteriology | | | <input type="checkbox"/> Antibody Detection (transfusion) | | |
| <input type="checkbox"/> Mycobacteriology | | | <input type="checkbox"/> Antibody Detection (nontransfusion) | | |
| <input type="checkbox"/> Mycology | | | <input type="checkbox"/> Antibody Identification | | |
| <input type="checkbox"/> Parasitology | | | <input type="checkbox"/> Compatibility Testing | | |
| <input type="checkbox"/> Virology | | | PATHOLOGY | | |
| DIAGNOSTIC IMMUNOLOGY | | | <input type="checkbox"/> Histopathology | | |
| <input type="checkbox"/> Syphilis Serology | | | <input type="checkbox"/> Oral Pathology | | |
| <input type="checkbox"/> General Immunology | | | <input type="checkbox"/> Cytology | | |
| CHEMISTRY | | | RADIOBIOASSAY | | |
| <input type="checkbox"/> Routine | | | <input type="checkbox"/> Radiobioassay | | |
| <input type="checkbox"/> Urinalysis | | | CLINICAL CYTOGENETICS | | |
| <input type="checkbox"/> Endocrinology | | | <input type="checkbox"/> Clinical Cytogenetics | | |
| <input type="checkbox"/> Toxicology | | | TOTAL ESTIMATED ANNUAL TEST VOLUME: | | |

IX. TYPE OF CONTROL

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

(Specify)

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

| CLIA NUMBER | NAME OF LABORATORY |
|-------------|--------------------|
| | |
| | |
| | |
| | |
| | |
| | |
| | |

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary 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 further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, 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 or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in ink)*

DATE

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

INSTRUCTIONS FOR COMPLETION

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 of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition 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 which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.

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

- **Verification of State Licensure, as applicable**
- **Documentation of qualifications:**
 - **Education (copy of Diploma, transcript from accredited institution, CMEs),**
 - **Credentials, and**
 - **Laboratory experience.**

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.

I. GENERAL INFORMATION

For an initial applicant, check "initial application". For an initial survey or for a recertification, check "survey". For a request to change the type of certificate, check "Change in certificate type". For all other changes, including change in location, director, etc., check "other changes".

For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. Be specific when indicating the name of your facility, particularly when it is a component of a larger entity; e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. **NOTE: The information provided is what will appear on your certificate.**

Facility street address must be the actual physical location where testing is performed, including floor, suite and/or room, if applicable. **DO NOT USE A POST OFFICE BOX NUMBER OR A MAIL DROP ADDRESS FOR THE NUMBER AND STREET OF THE ADDRESS.** If the laboratory has a separate mailing address, please complete that section of the application.

NOTE: For Office Use Only—Date received is the date the form is received by the state agency or CMS regional office for processing.

II. TYPE OF CERTIFICATE REQUESTED

When completing this section, please remember that a facility holding a:

- **Certificate of Waiver** can only perform tests categorized as waived;*
- **Certificate for Provider Performed Microscopy Procedures (PPM)** can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;*
- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization.

*A current list of waived and PPMP tests may be obtained from your State agency. Specific test system categorizations can also be found on the Internet at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm>.

III. TYPE OF LABORATORY

Select your certificate type based on the highest level of test complexity performed by your laboratory. Laboratories performing non-waived tests can choose COA or COC based on the agency you wish to survey your laboratory.

A shared laboratory is when two or more sole practicing physicians collectively pool resources to fund a laboratory's operations. The definition of a shared laboratory may also include two or more physician group practices that share the expenses for the laboratory's operation.

IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format.

V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493. Hospice and HHA could qualify for an exception i.e. 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3).

VI. WAIVED TESTING

Indicate the estimated total annual test volume for all waived tests performed. List can be found at:

<http://www.cms.gov/CLIA/downloads/waivetbl.pdf>

VII. PPM TESTING

Indicate the estimated annual test volume for all PPM tests performed. List can be found at:

<http://www.cms.gov/clia/downloads/ppmp.list.pdf>

VIII. NON-WAIVED TESTING (INCLUDING PPM)

The total volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

IX. TYPE OF CONTROL

Select the type of control which most appropriately describes your facility.

X. DIRECTOR OF ADDITIONAL LABORATORIES

List all other facilities for which the director is responsible and that are under different certificate.

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

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate 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 verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency.

VIII. NON-WAIVED TESTING

**TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING
LABORATORY SPECIALTIES/SUBSPECIALTIES**

HISTOCOMPATIBILITY

HLA Typing (disease associated antigens)

MICROBIOLOGY**Bacteriology**

Gram Stain

Culture

Susceptibility

Strep screen

Antigen assays (H.pylori, Chlamydia, etc.)

Mycobacteriology

Acid Fast Smear

Mycobacterial culture

Mycobacterial susceptibility

Mycology

Fungal Culture

DTM

KOH Preps

Parasitology

Direct Preps

Ova and Parasite Preps

Wet Preps

Virology

RSV (Not including waived kits)

HPV assay

Cell culture

DIAGNOSTIC IMMUNOLOGY**Syphilis Serology**

RPR

FTA, MHATP

General Immunology

Allergen testing

ANA

Antistreptolysin O

Antigen/Antibody (hepatitis, herpes, rubella, etc.)

Complement (C3, C4)

Immunoglobulin

HIV

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

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

Rh(D) type

Antibody screening

Antibody identification

Compatibility testing

PATHOLOGY

Dermatopathology

Oral Pathology

PAP smear interpretations

Other Cytology tests

Histopathology

RADIOBIOASSAY

Red cell volume

Schilling test

CLINICAL CYTOGENETICS

Fragile X

Buccal smear

Prader-Willi syndrome

FISH studies for: neoplastic disorders, congenital disorders
or solid tumors.

CHEMISTRY

Routine Chemistry

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

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

Toxicology

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**

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 VI. WAIVED TESTING

NOTE: This is not a complete list of tests covered by CLIA. Other non-waived tests and their specialties/subspecialties can be found at <http://www.cms.gov/CLIA/downloads/subject.to.CLIA.pdf> and <http://www.cms.gov/CLIA/downloads/lcCodes.pdf>. You may also call your State agency for further information. State agency contact information can be found at: <http://www.cms.gov/CLIA/downloads/CLIA.SA.pdf>.

GUIDELINES FOR COUNTING TESTS FOR CLIA

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch 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 specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.
- For **general immunology**, testing for allergens should be counted as one test per individual allergen.
- 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 **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- 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 **cytology**, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.
- 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.
- For **chemistry**, each analyte in a profile counts as one test.
- For **urinalysis**, microscopic and macroscopia 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 ratiior, 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.