Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

❑ Initial Application ❑ Change in Certification Type	CLIA Identification Number _____D_____ *(If an initial application leave blank, a number will be assigned)*
Facility Name	Federal Tax Identification Number Telephone No. *(Include area code)* Fax No. *(Include area code)*
Facility Address — *Physical Location of Laboratory (Building, Floor, Suite if applicable.)*	Mailing/Billing Address *(If different from street address, include attention line and/or Building, Floor, Suite)*
Number, Street *(No P.O. Boxes)*	Number, Street
City State ZIP Code	City State ZIP Code
Name of Director *(Last, First, Middle Initial)*	

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

❑ Certificate of Waiver *(Complete Sections I – VI and VIII – X)*

❑ Certificate for Provider Performed Microscopy Procedures *(PPMP) (Complete Sections I – X)*

❑ Certificate of Compliance *(Complete Sections I – X)*

❑ Certificate of Accreditation (Complete Sections I through 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

❑ JCAHO ❑ AOA ❑ AABB

❑ 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 for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

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

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

Is this a Medicare/Medicaid certified facility? ❑ Yes ❑ No

If yes, indicate Medicare provider number_____ Medicaid number _____

IV. HOURS OF LABORATORY TESTING *(List times during which **laboratory testing** is performed)*

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM: AM							
PM							
TO: AM							
PM							

(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, provide total number of sites under this certificate_____ and complete remainder of this section.

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

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, list name, address and tests 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, 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 Number ( )	
Name of Laboratory or Hospital Department		
Address/Location *(Number, Street, Location if applicable)*		
City, State, ZIP Code	Telephone Number ( )	
Name of Laboratory or Hospital Department		
Address/Location *(Number, Street, Location if applicable)*		
City, State, ZIP Code	Telephone Number ( )	

VI. WAIVED TESTING

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

VII. NONWAIVED TESTING *(Including PPMP 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 certificate of accreditation, indicate the name of the accreditation organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (JCAHO, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY		_____	**HEMATOLOGY**		_____
❑ Transplant	_____		❑ Hematology	_____	
❑ Nontransplant	_____				
			IMMUNOHEMATOLOGY		_____
MICROBIOLOGY		_____	❑ ABO Group & Rh Group	_____	
❑ Bacteriology	_____		❑ Antibody Detection (transfusion)	_____	
❑ Mycobacteriology	_____		❑ Antibody Detection (nontransfusion)	_____	
❑ Mycology	_____		❑ Antibody Identification	_____	
❑ Parasitology	_____		❑ Compatibility Testing	_____	
❑ Virology	_____				
DIAGNOSTIC IMMUNOLOGY		_____	**PATHOLOGY**		_____
❑ Syphilis Serology	_____		❑ Histopathology	_____	
❑ General Immunology	_____		❑ Oral Pathology	_____	
			❑ Cytology	_____	
CHEMISTRY		_____			
❑ Routine	_____		**RADIOBIOASSAY**		_____
❑ Urinalysis	_____		❑ Radiobioassay	_____	
❑ Endocrinology	_____				
❑ Toxicology	_____		**CLINICAL CYTOGENETICS**		_____
			❑ Clinical Cytogenetics	_____	

TOTAL ESTIMATED ANNUAL TEST VOLUME _____

VIII. TYPE OF CONTROL

Enter the appropriate two digit code from the list below ____ ____ *(Enter only one code)*

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT	
01 Religious Affiliation	04 Proprietary	05 City	08 Federal
02 Private		06 County	09 Other Government
03 Other _____ *(Specify)*		07 State	_____ *(Specify)*

IX. 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:

NAME OF LABORATORY	ADDRESS	CLIA IDENTIFICATION NUMBER

X. INDIVIDUALS INVOLVED IN LABORATORY TESTING

Indicate the total number of individuals involved in laboratory testing (directing, supervising, consulting or testing). Do not include individuals who only collect specimens or perform clerical duties. For nonwaived testing, only count an individual one time, at the **highest** laboratory position in which they function. (Example: Pathologist serves as director, technical supervisor and general supervisor. This individual would only be counted once (under director).)

A. WAIVED TESTING

Total No. of Individuals _____

B. NONWAIVED TESTING *(Including PPMP testing)*

Total No. of Individuals _____
Director _____
Clinical consultant _____
Technical consultant _____
Cytotechnologist _____
Technical supervisor _____
General supervisor _____
Testing personnel _____

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.**

THE GENERAL INFORMATION SECTION AND 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, the CLIA identification 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 or billing address, please complete that section of the application.

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** (PPMP) can only perform tests categorized as PPMP, or tests categorized as PPMP and waived tests;*
- **Certificate of Compliance** can perform tests categorized as waived, PPMP 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, PPMP and moderate and/or high complexity 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 reviewed via the Internet on *www.cdc.gov/phppo/dls/*.

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

III. TYPE OF LABORATORY

Select the type of laboratory designation that is most appropriate for your facility from the list provided. If you cannot find your designation within the list, contact your State agency for assistance.

IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility.

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 regulatory exceptions outlined on the form.

VI. WAIVED TESTING

Include only the estimated annual volume for those tests that are waived.

VII. NON-WAIVED TESTING *(Including PPMP)*

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., JCAHO, etc.).

VIII. TYPE OF CONTROL

Select the code which most appropriately describes your facility. Proprietary/for profit entities must choose "04".

IX. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

List all other facilities for which the director is responsible. Note that for a Certificate of PPMP, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

X. INDIVIDUALS INVOLVED IN LABORATORY TESTING

Self explanatory

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.

TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALTIES

HISTOCOMPATABILITY
HLA Typing (disease associated antigens)

SYPHILIS SEROLOGY
RPR
FTA, MHA-TP

GENERAL IMMUNOLOGY
Mononucleosis Assays
Rheumatoid Arthritis
Febrile Agglutins
Cold Agglutinins
HIV
Antibody Assays (hepatitis, herpes, etc.)
ANA Assays
Mycoplasma pneumoniae Assays

PARASITOLOGY
Direct Preps
Ova and Parasite Preps
Wet Preps

CHEMISTRY
Routine Chemistry
Albumin
Ammonia
Bilirubin, Total
Bilirubin, direct

Calcium
Chloride
Cholesterol, total
CO2, total
Creatinine
Glucose
pH
pO2
pCO2
Phosphorous
Potassium
Protein, total
Sodium
Triglycerides

BUN
Uric acid
ALT/SGPT
AST/SGOT

SGGT
Alk Phos
Amylase
CPK/CPK isoenzymes
CKMB
HDL Cholesterol
Iron
LDH
LDH isoenzymes
Magnesium
Ferritin
Folic Acid
Vitamin B12
PSA

Urinalysis
Automated urinalysis
Urinalysis with microscopic analysis
Urine specific gravity by refractometer
Urine specific gravity by urinometer
Urine protein by sulfasalicylic acid

BACTERIOLOGY
Gram Stains
Cultures
Sensitivities
Strep Screens
Antigen assays (chlamydia, etc.)
H. pylori

MYCOBACTERIOLOGY
Acid Fast Smears
Mycobacterial Cultures
Sensitivities

MYCOLOGY
Fungal Cultures
DTM
KOH Preps

VIROLOGY
RSV
HPV assays
Cell cultures

Endocrinology
TSH
Free T4
Total T4
Trilodothyronine (T3)

T3 Uptake
Ferritin
Folate
PSA
B12
Serum-beta-HCG

Toxicology
Acetaminophen
Blood alcohol
Carbamazephine
Digoxin
Ethosuximide
Gentamycin
Lithium
Phenobarbitol
Phenytoin

Primidine
Procainamide
NAPA
Quinidine
Salicylates
Theophylline
Tobramycin
Valproic acid

HEMATOLOGY

WBC count
RBC count
Hemoglobin
Hematocrit (Other than spun micro)
Platelet
Differential
MCV
Activated Clotting Time
Prothrombin time
Partial thromboplastin time
Fibrinogen
Reticulocyte count
Manual WBC by hemocytometer
Manual platelet by hemocytometer
Manual RBC by hemocytometer
Sperm count

RADIOBIOASSAY

Red cell volume
Schilling's test

IMMUNOHEMATOLOGY

ABO group
Rh(D) type
Antibody Screening
Antibody Identification
Compatability testing

PATHOLOGY

Dermatopathology
Oral pathology
PAP smear interpretations
Other cytology tests
Histopathology

CYTOGENETICS

Fragile X
Buccal smear

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.

- Testing for allergens should be counted as one test per individual allergen.

- For **chemistry** profiles, each individual analyte is counted separately.

- 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 **complete blood counts**, each **measured** individual analyte that is ordered **and reported** is counted separately. Differentials are counted as one test.

- Do not count calculations (e. g., A/G ratio, MCH, and T7), quality control, quality assurance and proficiency testing assays).

- 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 **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.