



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

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

**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.**

**1. Is this a laboratory that has temporary testing sites?**

- Yes  No

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



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**IX. TYPE OF CONTROL**

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**VOLUNTARY NONPROFIT**01 Religious Affiliation  
02 Private  
03 Other \_\_\_\_\_  
*(Specify)***FOR PROFIT**

04 Proprietary

**GOVERNMENT**05 City  
06 County  
07 State08 Federal  
09 Other Government  
\_\_\_\_\_  
*(Specify)*

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**X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES**

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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.

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

DATE

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

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**INSTRUCTIONS FOR COMPLETION**

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

\*\*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. 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.

## **VI. WAIVED TESTING**

Indicate the estimated total annual tests volume for all waived tests performed.

## **VII. PPM TESTING**

Indicate the estimated annual test volume for all PPM tests performed.

## **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 which most appropriately describes your facility.

## **X. DIRECTOR OF ADDITIONAL LABORATORIES**

List all other facilities for which the director is responsible.

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.

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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.

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

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### HISTOCOMPATABILITY

HLA Typing (disease associated antigens)

### SYPHILIS SEROLOGY

RPR  
FTA, MHATP

### GENERAL IMMUNOLOGY

Mononucleosis Assays  
Rheumatoid Arthritis  
Febrile Agglutinins  
Cold Agglutinins  
HIV  
Antibody Assays (hepatitis, herpes, etc.)  
ANA Assays

### PARASITOLOGY

Direct Preps  
Ova and Parasite Preps  
Wet Preps

### CHEMISTRY

#### **Routine Chemistry**

Albumin	ALT/SGPT
Ammonia	AST/SGOT
Alk Phos	Amylase
Bilirubin, Total	BUN
Bilirubin, direct	CK/CK isoenzymes
Calcium	Cholesterol, total
Chloride	Creatinine
CO <sub>2</sub> , total	Folate
Ferritin	HDL Cholesterol
Glucose	LDH
Iron	LDH isoenzymes
Magnesium	Phosphorous
pH	Potassium
pO <sub>2</sub>	Protein, total
pCO <sub>2</sub>	GGT
PSA	Troponin
Sodium	Triglycerides
Vitamin B12	Uric acid

#### **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  
(H. pylori, Chlamydia, etc.)

### MYCOBACTERIOLOGY

Acid Fast Smears  
Mycobacterial Cultures  
Mycobacterial Sensitivities

### MYCOLOGY

Fungal Cultures  
DTM  
KOH Preps

### VIROLOGY

RSV  
HPV assays  
Cell cultures

### **Endocrinology**

TSH  
Free T4  
Total T4  
Trilodothyronine (T3)  
Serum-beta-HCG

### **Toxicology**

Acetaminophen	Primidine
Blood alcohol	Procainamide
Carbamazepine	NAPA
Digoxin	Quinidine
Ethosuximide	Salicylates
Gentamycin	Theophylline
Lithium	Tobramycin
Phenobarbitol	Valproic acid
Phenytoin	

**HEMATOLOGY**

WBC count  
RBC count  
Hemoglobin  
Hematocrit (Other than spun micro)  
Platelet count  
Differential  
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

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## GUIDELINES FOR COUNTING TESTS FOR CLIA

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- 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.
- For flow **cytometry** each measured individual analyte that is ordered and reported is counted separately.