

## 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> )	<b>FOR OFFICE USE ONLY</b>  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/<br>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)	



## NON-WAIVED TESTING (Moderate & High Complexity Testing)

For any other test(s) currently performed at your facility and not previously listed on this form, enter the annual test volume. **DO NOT** include blood draws or specimens sent to another site for testing. Tests are grouped by Specialty. Only common tests are listed. Write-in any test(s) performed that are not listed. Transfer any specialty total(s) to section **VIII. NON-WAIVED TESTING** on page 3 of the CMS-116.

### HISTOCOMPATIBILITY

\_\_\_\_\_ Transplant  
 \_\_\_\_\_ Nontransplant

**TOTAL**

### MICROBIOLOGY

#### Bacteriology

\_\_\_\_\_ Affirm  
 \_\_\_\_\_ Antibiotic Sensitivity  
 \_\_\_\_\_ Cultures  
 \_\_\_\_\_ Gram Stains  
 \_\_\_\_\_ Rapid Strep Tests  
 \_\_\_\_\_ Wet Preps

#### Mycobacteriology

\_\_\_\_\_ Mycobacteriology: \_\_\_\_\_

#### Mycology

\_\_\_\_\_ Dermatophyte Cultures (DTM)  
 \_\_\_\_\_ KOH Skin Scrapings

#### Parasitology

\_\_\_\_\_ Ova & Parasites  
 \_\_\_\_\_ Preps, direct  
 \_\_\_\_\_ (pinworm, fecal leukocytes, scabies)

#### Virology

\_\_\_\_\_ Influenza A/B  
 \_\_\_\_\_ RSV  
 \_\_\_\_\_ HIV

**TOTAL**

### DIAGNOSTIC IMMUNOLOGY

#### Syphilis

\_\_\_\_\_ FTA, MHA-TP  
 \_\_\_\_\_ RPR

#### General Immunology

\_\_\_\_\_ Immunoglobulins (A, G, M, etc.)  
 \_\_\_\_\_ Mononucleosis  
 \_\_\_\_\_ Rheumatoid Factor

**TOTAL**

### CHEMISTRY

#### Routine

\_\_\_\_\_ Albumin  
 \_\_\_\_\_ Alkaline Phosphatase  
 \_\_\_\_\_ ALT (SGPT)  
 \_\_\_\_\_ AST (SGOT)  
 \_\_\_\_\_ B-Type Natriuretic Peptide (BNP)  
 \_\_\_\_\_ Bilirubin, Direct  
 \_\_\_\_\_ Bilirubin, Total  
 \_\_\_\_\_ BUN  
 \_\_\_\_\_ Calcium

\_\_\_\_\_ Chloride  
 \_\_\_\_\_ Cholesterol, HDL  
 \_\_\_\_\_ Cholesterol, Total  
 \_\_\_\_\_ CO2, Total  
 \_\_\_\_\_ CPK  
 \_\_\_\_\_ CPK isoenzymes (CKMB)  
 \_\_\_\_\_ Creatinine  
 \_\_\_\_\_ Glucose  
 \_\_\_\_\_ Glycosylated Hemoglobin (A1C)  
 \_\_\_\_\_ LDH  
 \_\_\_\_\_ LDH isoenzymes  
 \_\_\_\_\_ Magnesium  
 \_\_\_\_\_ Myoglobin  
 \_\_\_\_\_ pH (blood gas)  
 \_\_\_\_\_ pCO2  
 \_\_\_\_\_ pO2

\_\_\_\_\_ Potassium  
 \_\_\_\_\_ Protein, Total  
 \_\_\_\_\_ Sodium

\_\_\_\_\_ Triglycerides  
 \_\_\_\_\_ Troponin

#### Urinalysis

\_\_\_\_\_ Urine dip, nonwaived  
 \_\_\_\_\_ Urine sediment exam

#### Endocrinology

\_\_\_\_\_ Pregnancy, serum  
 \_\_\_\_\_ PSA  
 \_\_\_\_\_ TSH

#### Toxicology

\_\_\_\_\_ Acetaminophen  
 \_\_\_\_\_ Carbamazepine/Tegretol  
 \_\_\_\_\_ Digoxin  
 \_\_\_\_\_ Drug screen, blood  
 \_\_\_\_\_ Drug screen, urine  
 \_\_\_\_\_ Gentamycin  
 \_\_\_\_\_ Phenobarbital  
 \_\_\_\_\_ Phenytoin/Dilantin  
 \_\_\_\_\_ Salicylate  
 \_\_\_\_\_ Theophylline  
 \_\_\_\_\_ Valproic Acid/Depakote  
 \_\_\_\_\_ Vancomycin

**TOTAL**

### HEMATOLOGY

\_\_\_\_\_ D-Dimer  
 \_\_\_\_\_ Differential, automated  
 \_\_\_\_\_ Differential, manual  
 \_\_\_\_\_ Fern Test  
 \_\_\_\_\_ Hemoglobin

\_\_\_\_\_ Hematocrit  
 \_\_\_\_\_ Nasal smears (eosinophils)  
 \_\_\_\_\_ PTT  
 \_\_\_\_\_ Platelet, automated  
 \_\_\_\_\_ Platelet, estimate manual  
 \_\_\_\_\_ Post-coital (vaginal/cervical)  
 \_\_\_\_\_ Prothrombin Time (PT/INR)  
 \_\_\_\_\_ RBC, automated  
 \_\_\_\_\_ RBC, manual  
 \_\_\_\_\_ Reticulocyte Count  
 \_\_\_\_\_ Sperm, count & morphology  
 \_\_\_\_\_ Sperm, post-vas (presence/motility)  
 \_\_\_\_\_ WBC, automated  
 \_\_\_\_\_ WBC, manual

**TOTAL**

### IMMUNOHEMATOLOGY

\_\_\_\_\_ ABO Group & Rh Group  
 \_\_\_\_\_ Antibody Detection (transfusion)  
 \_\_\_\_\_ Ab Detection (nontransfusion)  
 \_\_\_\_\_ Antibody Identification  
 \_\_\_\_\_ Compatibility Testing

**TOTAL**

### PATHOLOGY

\_\_\_\_\_ Histopathology  
 \_\_\_\_\_ MOH's\*  
 \_\_\_\_\_ Oral Pathology  
 \_\_\_\_\_ Cytology

**TOTAL**

### RADIOBIOASSAY

\_\_\_\_\_ Radiobioassay

**TOTAL**

### CLINICAL CYTOGENETICS

\_\_\_\_\_ Clinical Cytogenetics

**TOTAL**

### ADDITIONAL TEST(S)

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

\*To count MOH's testing, count each stage/block as 1 test when H & E stain is used; Count 1 test for each slide made when special stains are used.

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
<b>HISTOCOMPATIBILITY</b>			<b>HEMATOLOGY</b>		
<input type="checkbox"/> Transplant			<input type="checkbox"/> Hematology		
<input type="checkbox"/> Nontransplant			<b>IMMUNOHEMATOLOGY</b>		
<b>MICROBIOLOGY</b>			<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			<b>PATHOLOGY</b>		
<b>DIAGNOSTIC IMMUNOLOGY</b>			<input type="checkbox"/> Histopathology		
<input type="checkbox"/> Syphilis Serology			<input type="checkbox"/> Oral Pathology		
<input type="checkbox"/> General Immunology			<input type="checkbox"/> Cytology		
<b>CHEMISTRY</b>			<b>RADIOBIOASSAY</b>		
<input type="checkbox"/> Routine			<input type="checkbox"/> Radiobioassay		
<input type="checkbox"/> Urinalysis			<b>CLINICAL CYTOGENETICS</b>		
<input type="checkbox"/> Endocrinology			<input type="checkbox"/> Clinical Cytogenetics		
<input type="checkbox"/> Toxicology			<b>TOTAL ESTIMATED ANNUAL TEST VOLUME:</b>		

**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