CLIA APPLICATION

The Texas Department of State Health Services on behalf of the Centers for Medicare and Medicaid Services (CMS) CLIA Program requests the following information to apply for a CLIA Certificate. Please forward the information to your appropriate CLIA Zone Office in order for your CLIA application to be accepted and processed. Your application will not be processed until all requested information is received and approved by this office.

1. The Office of Management and Budget (OMB) approved the CMS-116 form for a period of three years (through 8/31/2017). This means that the new form CMS-116 can now be used by the laboratory community. Accordingly, the form and its accompanying instructions are now available on the CMS Website by using this link: http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf (form enclosed).

2. Listing of Tests Performed in the Facility with a direct phone number to the named Laboratory Director’s office in order that we may contact them and confirm that they are affiliated with the laboratory - (form enclosed)

3. Qualification Appraisal (form enclosed) along with copies of educational documentation, training and experience for the Laboratory Director and Technical Consultant or Technical Supervisor which meets the CLIA qualifications for the position, for the type of CLIA Certificate for which you are applying. CLIA personnel qualifications can be found at: http://www.cms.hhs.gov/CLIA/downloads/apcsubm.pdf

4. Disclosure of Ownership – (form enclosed)

   If you have any questions about the application process, please call your CLIA zone office. Zone office information is provided in this packet.
§493.35 Application for a certificate of waiver.
(c) Application format and contents. The application must--(1) Be made to HHS or its designee on a form or forms prescribed by HHS;(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and (3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including-- (i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency testing purposes);(ii) The methodologies for each laboratory test procedure or examination performed, or both; and (iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

§493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedure and certificate of compliance.
(c) Application format and contents. The application must--(1) Be made to HHS or its designee on a form or forms prescribed by HHS;(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and (3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including-- (i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency testing purposes);(ii) The methodologies for each laboratory test procedure or examination performed, or both; and (iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

For an electronic version of the complete CLIA Laboratory Requirements please visit: http://wwwn.cdc.gov/clia/regulatory/default.aspx
### Listing of Tests Performed in the Facility

<table>
<thead>
<tr>
<th>Facility Name:</th>
<th>Date:</th>
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<tbody>
<tr>
<td>Direct Phone Number to Laboratory Director’s Office:</td>
<td></td>
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<tr>
<td>Name of Person Completing Form:</td>
<td></td>
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</tbody>
</table>

*** Please list the manufacturer’s name and model of the instrument or manufacturer’s name of the test kit used for patient testing. For example, do not list “hematology machine or strep kit”. This will ensure that you will receive the correct certificate based on the tests performed in your laboratory.

List only the tests that you are performing in house (at or by your facility). Do not list the tests that you collect and send out to a reference laboratory.

<table>
<thead>
<tr>
<th>Name of Laboratory Test</th>
<th>*** Name of Instrument or Kit Used for Testing</th>
<th>CPT Code</th>
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Qualification Appraisal

Check all that apply for applicant listed below:

Laboratory Director  Technical Consultant  Supervisor

For directing Moderate High complexity laboratories, and Provider Performed Microscopy Procedure (PPMP) laboratories, in compliance with 42 CFR 493.1357, 1405, 1443

General Information

Applicant’s Name: (Print) ____________________________________________
Laboratory Name: __________________________________________________
Phone and Fax: _____________________________________________________
Directorship Type: High Complexity Moderate Complexity PPMP
CLIA lab info New CLIA lab? yes no If no, laboratory CLIA #

Other CLIA labs currently directed:

<table>
<thead>
<tr>
<th>Lab CLIA #</th>
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Schools Attended and Degrees Received (or attach your CV)

<table>
<thead>
<tr>
<th>Name and location</th>
<th>From</th>
<th>To</th>
<th>Program Title</th>
<th>Degree or Credential</th>
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Board Certifications, Licenses, Registrations, or board eligibility

<table>
<thead>
<tr>
<th>Licensure/Certification</th>
<th>Year</th>
<th>Name of Granting Agency</th>
<th>Registration Number</th>
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</table>

Clinical laboratory experience (list current or most recent first):

(Please attach additional pages as needed)

<table>
<thead>
<tr>
<th>Name and Address of Laboratory</th>
<th>Title/Position</th>
<th>From-To (month &amp; year)</th>
<th>Microbiology</th>
<th>Hematology</th>
<th>Chemistry</th>
<th>Pathology</th>
<th>Specify</th>
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Signature Required – Applicant certifies that all statements in this form are true, accurate and correct

Applicant Signature: ____________________________________________ Date: _________________________

To qualify the applicant must attach copies of diplomas and licenses to completed application.

An Equal Employment Opportunity Employer
Disclosure of Ownership

I. Identifying Information

<table>
<thead>
<tr>
<th>Name of Owner</th>
<th>Laboratory Name</th>
<th>CLIA Number</th>
<th>Federal Tax ID No.</th>
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<th>Street Address</th>
<th>City, County</th>
<th>State</th>
<th>Zip Code</th>
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Telephone No.:  
Fax No.:  

II. (a) List names, addresses for individuals, or the EIN for organizations having direct or indirect ownership of a controlling interest in the entity,

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>EIN</th>
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(b) Type of Entity:  □ Sole Proprietorship  □ Partnership  □ Corporation  □ Unincorporated Associations  □ Other (specify)

(c) If the disclosing entity is a corporation, list names, addresses of the Directors, and EIN for corporations

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>EIN</th>
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Name of Authorized Representative  
Title  
Signature  
Date
# CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

## I. GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Initial Application</th>
<th>Survey</th>
<th>CLIA IDENTIFICATION NUMBER</th>
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(If an initial application leave blank, a number will be assigned)

<table>
<thead>
<tr>
<th>FACILITY NAME</th>
<th>FEDERAL TAX IDENTIFICATION NUMBER</th>
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<tr>
<th>EMAIL ADDRESS</th>
<th>TELEPHONE NO. (Include area code)</th>
<th>FAX NO. (Include area code)</th>
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**FACILITY ADDRESS** — **Physical Location of Laboratory (Building, Floor, Suite if applicable.)** Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified

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<th>NUMBER, STREET</th>
<th>NUMBER, STREET</th>
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**SEND CERTIFICATE TO THIS ADDRESS**

- Physical ☐
- Mailing ☐
- Corporate ☐

**SEND FEE COUPON TO THIS ADDRESS**

- Physical ☐
- Mailing ☐
- Corporate ☐

**CORPORATE ADDRESS (if different from facility) send Fee Coupon or certificate**

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<th>NUMBER, STREET</th>
<th>NUMBER, STREET</th>
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**NAME OF DIRECTOR (Last, First, Middle Initial)**

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<tr>
<th>CITY</th>
<th>STATE</th>
<th>ZIP CODE</th>
<th>CITY</th>
<th>STATE</th>
<th>ZIP CODE</th>
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**CREDENTIALS**

<table>
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<th>FOR OFFICE USE ONLY</th>
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<td>Date Received</td>
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## II. TYPE OF CERTIFICATE REQUESTED

((Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)

- ☐ 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.

- ☐ The Joint Commission
- ☐ 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 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 regulations. Proof of these qualifications for the laboratory director must be submitted with this application.
III. TYPE OF LABORATORY (Check the one most descriptive of 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)

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format) If testing 24/7 Check Here

<table>
<thead>
<tr>
<th>SUNDAY</th>
<th>MONDAY</th>
<th>TUESDAY</th>
<th>WEDNESDAY</th>
<th>THURSDAY</th>
<th>FRIDAY</th>
<th>SATURDAY</th>
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(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 in 1-3 below)

Are you applying for a single site CLIA certificate to cover multiple testing locations?
- 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 is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as 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?
   - Yes  
   - No  
   If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.

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 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 (to be) 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 (to be) 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 specialty/subspecialty category and the “total estimated annual 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 applying for a Certificate of Compliance or Accreditation)*

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 (3) 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 instructions 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)*

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<tr>
<th>SPECIALTY / SUBSPECIALTY</th>
<th>ACCREDITING ORGANIZATION</th>
<th>ANNUAL TEST VOLUME</th>
<th>SPECIALTY / SUBSPECIALTY</th>
<th>ACCREDITING ORGANIZATION</th>
<th>ANNUAL TEST VOLUME</th>
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<tbody>
<tr>
<td>HISTOCOMPATIBILITY 010</td>
<td>HEMATOLOGY 400</td>
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<td>IMMUNOHEMATOLOGY</td>
<td>ABO Group &amp; Rh Group 510</td>
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<tr>
<td>☐ Transplant</td>
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<td>☐ Antibody Detection (transfusion) 520</td>
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<td>☐ Nontransplant</td>
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<td>☐ Antibody Detection (nontransfusion) 530</td>
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<td>☐ Antibody Identification 540</td>
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<td>☐ Bacteriology 110</td>
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<td>☐ Compatibility Testing 550</td>
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<td>☐ Mycobacteriology 115</td>
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<td>☐ Mycology 120</td>
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<td>☐ Parasitology 130</td>
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<td>☐ Virology 140</td>
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<td>DIAGNOSTIC IMMUNOLOGY</td>
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<td>Histopathology 610</td>
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<td>☐ Syphilis Serology 210</td>
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<td>Oral Pathology 620</td>
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<tr>
<td>☐ General Immunology 220</td>
<td></td>
<td></td>
<td>Cytology 630</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHEMISTRY</td>
<td></td>
<td></td>
<td>Radiobioassay</td>
<td></td>
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<tr>
<td>☐ Routine 310</td>
<td></td>
<td></td>
<td>CLINICAL CYTOGENETICS 900</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Urinalysis 320</td>
<td></td>
<td></td>
<td>Clinical Cytogenetics</td>
<td></td>
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<tr>
<td>☐ Endocrinology 330</td>
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<td>☐ Toxicology 340</td>
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<td>☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
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<td>TOTAL ESTIMATED ANNUAL TEST VOLUME:</td>
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</tr>
</tbody>
</table>
### IX. TYPE OF CONTROL (check the one most descriptive of ownership type)

<table>
<thead>
<tr>
<th>VOLUNTARY NONPROFIT</th>
<th>FOR PROFIT</th>
<th>GOVERNMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ 01 Religious Affiliation</td>
<td>□ 04 Proprietary</td>
<td>□ 05 City</td>
</tr>
<tr>
<td>□ 02 Private Nonprofit</td>
<td></td>
<td>□ 06 County</td>
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<tr>
<td>□ 03 Other Nonprofit</td>
<td></td>
<td>□ 07 State</td>
</tr>
<tr>
<td>(Specify)</td>
<td></td>
<td>□ 8 Federal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ 9 Other Government</td>
</tr>
<tr>
<td></td>
<td>(Specify)</td>
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</tr>
</tbody>
</table>

### 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:

<table>
<thead>
<tr>
<th>CLIA NUMBER</th>
<th>NAME OF LABORATORY</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

### 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

NOTE: Completed 116 applications must be sent to your local State Agency.

SEE ATTACHED LIST OF STATE AGENCY CONTACT INFORMATION.

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

INSTRUCTIONS FOR COMPLETION

CLIA requires every facility that tests human specimens 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 (42 CFR PART 493) 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” and provide the effective date of the change. For all other changes, including for change in location, director, lab closure, etc., check “closure/other changes” and provide the effective date of the change.

CLIA Identification Number: For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. For all other applicants, enter the 10 digit CLIA identification number already assigned and listed on your CLIA certificate.

Facility Name: 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.

Physical Facility Address: This address is mandatory and must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

If the laboratory has a separate mailing and/or corporate address (from the Facility Address), please complete the appropriate sections on the form.

Mailing Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to an alternate location, such as an accounts payable office. A Post Office box number or Mail Stop number may be used as part of the Mailing Address for this section.

Corporate Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to another location, such as, the main headquarters or home office for the laboratory. A Post Office box number or Mail Stop number may be used as part of the Corporate Address for this section.

Form Mailing: Select the address (Physical, Mailing, Corporate) where the CLIA fee coupon and CLIA certificate are to be mailed.

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

II. TYPE OF CERTIFICATE REQUESTED

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

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 laboratory is currently accredited by an approved accreditation organization. (If your CMS-approved accreditation organization is not listed, contact your local State Agency for further instructions.)

* A current list of waived and PPM 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 the type that is most descriptive of the location where the laboratory testing is performed.

If selecting ‘mobile laboratory’ (code 19), a mobile laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment, and records. For record keeping purposes, include, on a separate sheet of paper, the vehicle identification numbers (VINs) of all vehicles used for mobile laboratory testing.

If selecting ‘physician office’ (code 21), also answer a related question regarding ‘shared labs’.

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

If selecting ‘Practitioner Other’ (code 22), this type includes practitioners such as, dentists, chiropractors, etc.

IV. HOURS OF ROUTINE OPERATION
Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format and check box marked ‘24/7’ if laboratory testing is performed continuously, e.g., 24 hours a day, 7 days a week. Do not use military time.

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 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3) Hospice and HHA could qualify for an exception.

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 total annual test volume for all PPM tests performed. List can be found at: http://www.cms.gov/cla/downloads/ppmp.list.pdf

VIII. NON-WAIVED TESTING (INCLUDING PPM)
The total Estimated Annual Test 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 for test counting information. (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 ownership or control which most appropriately describes your facility.

X. DIRECTOR OF ADDITIONAL LABORATORIES
List all other facilities for which the director is group responsible and that are under different certificates. 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 (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

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.

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

Toxicology (340)
- Acetaminophen
- Blood alcohol
- Blood lead (Not waived)
- Carbamazepine
- Digoxin
- Ethosuximide
- Gentamicin
- Lithium
- Phenobarbital
- Phenytoin
- Primidone
- Procaainamide
- 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 VI. WAIVED TESTING

Endocrinology (330)
- Cortisol
- HCG (serum pregnancy test)
- T3
- T3 Uptake
- T4
- T4, free
- TSH

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 macroscopy 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/subspecialities, 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.
Facility Types

Abortion Facilities
Ambulatory Surgical Centers
Birthing Centers
Community Mental Health Centers
Comprehensive Outpatient Rehabilitation Facilities
End Stage Renal Disease
Federally Qualified Health Centers
• Freestanding Emergency Medical Care Facilities
• Hospitals
• Outpatient Physical Therapy
• Portable X-Ray
• Psychiatric Hospitals
• Rural Health Centers
• Special Care Facilities

HFC Compliance Zones

D Zone 1: HFC Group - Austin
D Zone 2: HFC Group - Arlington
D Zone 3: HFC Group - San Antonio
D Zone 4: HFC Group - Houston
D Zone 5: HFC Group - Tyler
D Zone 6: HFC Group Austin (Statewide/Certified Only Facilities)
0 Zone 6: HFC Group - Austin (CLIA)
Health Facility Compliance Group

ZONE II
1301 S Bowen Ste. 200
Arlington, TX 76013
Shannon Sisco, Manager
Vacant, Admin. Asst.
Office- 817.264.4752
Fax- 817.264.4760

ZONE III
6711 S. New Braunfels Ave.
Houston Hall Bldg. 518
San Antonio, TX 78221-3597
Larrie Collier, Manager
Helen Obaya, Admin. Asst.
Office- 210.531.7397
Fax- 210.531.7793

ZONE IV
5425 Polk Ave. Ste. J
Houston, TX 77023-1497
Frank Arch, Manager
Jacquelyn Jacquez-Velez, Admin. Asst.
Office- 713.767.3340
Fax- 713.767.3367

ZONE V
2521 W. Front St.
Tyler, TX 75702
Jeannette (Ray) Potter, Manager
Lauri Craddock, Admin. Asst.
Office- 903.533.5214
Fax- 903.595.5092

ZONE VI
MC: 1979
P.O. Box 149347
Austin, TX 78714-9347
Rachel Turner, Manager
Vacant, Admin. Asst.
Office- 512.834.6792
Fax- 512.834.6653