



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DAVID L. LAKEY, M.D.
COMMISSIONER

P.O. Box 149347 • Austin, Texas 78714-9347
1-888-963-7111 • www.dshs.state.tx.us
TTY: 1-800-735-2989

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)
Please visit <http://wwwn.cdc.gov/clia/regulatory/default.aspx> for a complete listing of the CLIA Laboratory Requirements - 42 CFR Part §493.

If you have any questions about the application process, please call your CLIA zone office. Zone office information is provided in this packet.

42 CFR Part §493 – Laboratory Requirements

§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

Facility Name:	Date:
Direct Phone Number to Laboratory Director's Office:	
Name of Person Completing Form:	

*** 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.

[illegible]

Qualification Appraisal

☐ Laboratory Director

Check all that apply for applicant listed below:

☐ Technical Consultant

☐ Technical 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:

Lab CLIA

_____	_____
_____	_____
_____	_____
_____	_____

Schools Attended and Degrees Received (or attach your CV)

Name and location	From	To	Program Title	Degree or Credential
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

Board Certifications, Licenses, Registrations, or board eligibility

Licensure/Certification	Year	Name of Granting Agency	Registration Number
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

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

(Please attach additional pages as needed)

Name and Address of Laboratory	Title/Position	From-To (month & year)	Microbiology	Hematology	Chemistry	Pathology	Specify
_____	_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____	_____

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 .

Disclosure of Ownership

I. Identifying Information			
Name of Owner Laboratory Name		CLIA Number	Federal Tax ID No.
Street Address		City, County	State Zip Code
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,		
Name	Address	EIN
(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		
Name	Address	EIN

Name of Authorized Representative	Title	
Signature		Date

**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION****I. GENERAL INFORMATION**

☐ Initial Application			☐ Survey			CLIA IDENTIFICATION NUMBER _____ D _____ <i>(If an initial application leave blank, a number will be assigned)</i>		
Effective Date _____								
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 or corporate address is specified</i>			MAILING/BILLING ADDRESS <i>(If different from facility address) send Fee Coupon or certificate</i>					
NUMBER, STREET <i>(No P.O. Boxes)</i>			NUMBER, STREET					
CITY		STATE	ZIP CODE		CITY		STATE	ZIP CODE
SEND CERTIFICATE TO THIS ADDRESS Physical ☐ Mailing ☐ Corporate ☐			SEND FEE COUPON TO THIS ADDRESS Physical ☐ Mailing ☐ Corporate ☐			CORPORATE ADDRESS <i>(If different from facility) send Fee Coupon or certificate</i> NUMBER, STREET		
NAME OF DIRECTOR <i>(Last, First, Middle Initial)</i>			CITY		STATE		ZIP CODE	
CREDENTIALS			FOR OFFICE USE ONLY Date Received _____					

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

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

	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 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 (✓) 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)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY 010			HEMATOLOGY 400		
☐ Transplant			☐ Hematology		
☐ Nontransplant			IMMUNOHEMATOLOGY		
MICROBIOLOGY			☐ ABO Group & Rh Group 510		
☐ Bacteriology 110			☐ Antibody Detection (transfusion) 520		
☐ Mycobacteriology 115			☐ Antibody Detection (nontransfusion) 530		
☐ Mycology 120			☐ Antibody Identification 540		
☐ Parasitology 130			☐ Compatibility Testing 550		
☐ Virology 140			PATHOLOGY		
DIAGNOSTIC IMMUNOLOGY			☐ Histopathology 610		
☐ Syphilis Serology 210			☐ Oral Pathology 620		
☐ General Immunology 220			☐ Cytology 630		
CHEMISTRY			RADIOBIOASSAY 800		
☐ Routine 310			☐ Radiobioassay		
☐ Urinalysis 320			CLINICAL CYTOGENETICS 900		
☐ Endocrinology 330			☐ Clinical Cytogenetics		
☐ Toxicology 340			TOTAL ESTIMATED ANNUAL TEST VOLUME:		

IX. TYPE OF CONTROL (check the one most descriptive of ownership type)**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

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 for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

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

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M (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 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 applicable CLIA quality standards are met following a CLIA survey; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization. (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 group 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 493.493.35(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/clia/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 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

DIAGNOSTIC IMMUNOLOGY

Syphilis Serology (210)

RPR

FTA, MHATP

General Immunology (220)

Allergen testing

ANA

Antistreptolysin O

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

Complement (C3, C4)

Immunoglobulin

HIV

Mononucleosis assay

Rheumatoid factor

Tumor marker (AFP, CA 19-9, CA 15-3, CA 125)*

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

HEMATOLOGY (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.

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

Endocrinology (330)

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

Toxicology (340)

Acetaminophen
Blood alcohol
Blood lead (Not waived)
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide
NAPA
Quinidine
Salicylates
Theophylline
Tobramycin
Therapeutic Drug Monitoring

Urinalysis (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

NOTE: This is not a complete list of tests covered by CLIA. Other non-waived tests and their specialties/ subspecialties can be found at <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf> and <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/lccodes.pdf>. You may also call your State agency for further information. State agency contact information can be found at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>.

GUIDELINES FOR COUNTING TESTS FOR CLIA

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.
- For **general immunology**, testing for allergens should be counted as one test per individual allergen.
- For **hematology**, each **measured** individual analyte of a **complete blood count** or **flow cytometry** test that is ordered **and reported** is counted separately. The **WBC differential** is counted as one test.
- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For **cytology**, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.
- For **clinical cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.
- For **chemistry**, each analyte in a profile counts as one test.
- For **urinalysis**, microscopic and macroscopia examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **all specialties/subspecialties**, do not count calculations (e.g., A/G 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.

HFC Compliance Zones
Texas Department of State Health Services

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

Map of Texas showing HFC Compliance Zones. The map is divided into six color-coded regions: Zone 1 (green, Austin area), Zone 2 (pink, Arlington area), Zone 3 (orange, San Antonio area), Zone 4 (blue, Houston area), Zone 5 (yellow, Tyler area), and Zone 6 (white, Statewide/Certified Only Facilities). A legend at the bottom left explains the color coding. The map includes county names and is titled 'HFC Compliance Zones' and 'Texas Department of State Health Services'.



HEALTH FACILITY COMPLIANCE GROUP

ZONE II
1301 S BOWEN STE 200
ARLINGTON TX 76013
Marsha Wall, Manager
Maria Carson, Admin Asst
Office - 817.264.4752
Fax - 817.264.4760

ZONE III
2303 SE Military Dr, Bldg. 514
San Antonio TX 78223-3597
Larrie Collier, Manager
Helen Obaya, Admin Asst
Office - 210.531.4944
Fax - 210.531.4533

ZONE IV
5425 Polk Ave, STE J
Houston TX 77023-1497
Atkin Wilridge Jr., Manager
Jacquelyn Marquez, Admin Asst
Office - 713.767.3340
Fax - 713.767.3367

ZONE V
1517 W Front ST
Tyler TX 75702
Jeanette Ray, Manager
Lauri Craddock, Admin Asst
Office - 903.533.5214
Fax - 903.533.5257

ZONE VI
PO BOX 149347 AUSTIN TX
78714-9347 MC: 1979
Kaimy Chappell, Manager
Tamika Collier, Admin Asst
Office - 512.834.6792
Fax - 512.834.6653