Clinical Laboratory Improvement Amendments (CLIA)

How to Obtain a CLIA Certificate

When is a CLIA Certificate Required?

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.

DO I NEED TO HAVE A CLIA CERTIFICATE?

CLIA requires all facilities that perform even one test, including waived tests, on "materials derived from the human body 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, human beings" to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

WHAT ARE THE DIFFERENT TYPES OF CLIA CERTIFICATES AND HOW LONG ARE THEY EFFECTIVE?

All types of certificates are effective for two years and the different types of certificates are:

- **Certificate of Waiver (COW):**
  Issued to a laboratory that performs only waived tests.
- **Certificate for Provider Performed Microscopy (PPM) procedures:**
  Issued to a laboratory in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient's visit. A limited list of microscopy procedures is included under this certificate type and these are categorized as moderate complexity.
- **Certificate of Registration:**
  Issued to a laboratory to allow the laboratory to conduct nonwaived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.
- **Certificate of Compliance (COC):**
  Issued to a laboratory once the State Department of Health conducts a survey (inspection) and determines that the laboratory is compliant with all applicable CLIA requirements. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

- **Certificate of Accreditation (COA):**
  Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

There are six CMS-approved accreditation organizations:

- AABB
- American Osteopathic Association (AOA)
- American Society of Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Contact information for the above CMS-approved accreditation organizations is available on the CMS CLIA web site at www.cms.hhs.gov/clia. If you apply for accreditation by one of the CMS-approved accreditation organizations, you must also apply to CMS for a COA concurrently.

WHAT IS A WAIVED TEST?

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result". The Food and Drug Administration (FDA) determines the criteria for tests being simple with a low risk of error and approves manufacturer's applications for test system waiver.

HOW CAN I FIND A LIST OF WAIVED TESTS?

For a list of waived tests sorted by analyte name, visit the FDA website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

For a list of waived tests sorted by the test categorization date and by the test system name, visit the FDA website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm.

WHERE CAN I FIND INFORMATION ABOUT TESTS CATEGORIZED AS NONWAIVED (I.E., MODERATE AND/OR HIGH COMPLEXITY)?

To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity), refer to the lists of tests online at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.

You may also contact the local survey agency at your State Health Department for categorization information concerning tests that you may be performing in your laboratory. A list of State Agency addresses, phone numbers and contact persons is available online under the heading State Survey Agencies (CLIA Contact List) at the CMS CLIA website. If you do not have online access or have questions concerning certification, you may contact the CMS CLIA Central Office at 410-786-3531 for the address and phone number of your local State Agency.

HOW DO I APPLY FOR A CLIA CERTIFICATE?

The CLIA application (Form CMS-116) is available online at the CMS CLIA website located at the end of this brochure. Forward your completed application to the address of the local State Agency for the State in which your laboratory is located. This information is available online or you may contact the CMS CLIA Central Office.

IS THERE ANY TYPE OF LABORATORY TESTING THAT IS NOT SUBJECT TO A CLIA CERTIFICATE?

Yes, there are some testing exceptions that do not require CLIA certification.

The following **exceptions to CLIA certification** apply regardless of a laboratory's location:

- Any laboratory that only performs testing for forensic purposes;
- Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, individual patients; or

- Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA guidelines and regulations. However, a CLIA certificate is needed for all other testing conducted by a SAMHSA-certified laboratory.

ARE THERE ANY STATES THAT EXEMPT ME FROM HAVING TO APPLY FOR A CLIA CERTIFICATE?

Any laboratory located in a state that has a CMS approved laboratory program is exempt from CLIA certification. Currently, there are two states with approved programs: Washington and New York. New York has a partial exemption; therefore, if your laboratory is located in that state, contact the New York State Agency concerning your need for a CLIA certificate.

IF I HAVE MORE THAN ONE LABORATORY LOCATION, DO I NEED A CLIA CERTIFICATE FOR EACH LOCATION?

You will need a CLIA certificate for **each** location where you perform testing **unless** you qualify for one of the exceptions listed below.

- Laboratories that are not at a fixed location; that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.
- Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing, may file a single application.
- Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical location or street address.

Contact your State Agency if you have questions or you are filing a single application for more than one testing site.

WHAT KIND OF FEES DO I HAVE TO PAY TO CMS FOR A CLIA CERTIFICATE?

If you apply for COW or a PPM certificate, you will pay a minimal certificate fee every two years. There are no registration or compliance fees.

If you apply for a COC, you will pay a one time minimal registration fee that covers the cost of the CLIA enrollment in addition to a compliance fee that covers the cost of the initial inspection by the State Agency. CMS will send you a Certificate of Registration. Once compliance has been determined by your inspection, you will pay a certificate fee to CMS and CMS will send you a COC. A two-year certificate cycle is then established, and you will pay a certificate fee and a compliance fee every two years. CMS will send you a COC as long as your laboratory is in compliance.

If you apply for a COA, you will pay a minimal registration fee that covers the cost of the CLIA enrollment. Once CMS receives verification from the accreditation organization that you have selected, you will pay a certificate fee and validation fee to CMS and CMS will send you a COA. A two year certificate cycle is then established and you will pay a certificate fee and a validation fee every two years. CMS will send you a COA as long as your laboratory remains compliant. You will pay survey and any other fees to the accreditation organization.

You can obtain more information concerning the amount of certificate fees from the CMS CLIA website under "CLIA Certificate Fee Schedule" or from your State Agency. For information concerning compliance (survey) fees, you may contact your State Agency or accreditation organization. These fees are based on the number and types of testing you perform and must cover the cost of the CLIA program because CLIA is entirely user fee funded.

WILL I RECEIVE AN IDENTIFYING CLIA NUMBER?

You will receive a ten-digit number on the CLIA certificate. This number will be utilized to identify and track your laboratory throughout its entire history. You should use this number when making inquiries to the State Agency and CMS about your laboratory.

WHEN CAN I BEGIN TESTING?

After you apply for your certificate, you will receive a coupon notifying you of the corresponding fee. Follow the instructions on the fee coupon for payment. After CMS receives your payment, your certificate will be mailed to you. You may begin testing once you have received your certificate containing your CLIA number. However, you need to check with your State Agency since some states have additional requirements.

WILL MY LABORATORY RECEIVE A CMS SURVEY?

Laboratories that have a COW or PPM certificate are not subject to routine surveys. However, CMS is currently conducting a project whereby a small percentage of laboratories that perform only waived testing may receive an educational visit. These visits provide helpful information to staff to help assure the quality of testing and have been extremely well received.

If your laboratory performs any nonwaived testing, the laboratory may have either a COC or COA. All laboratories with either of these certificate types must meet all nonwaived testing requirements and are subject to biennial surveys, by CMS or a CMS agent (such as a surveyor from the State Agency) or by a CMS-approved accreditation organization, if the laboratory is accredited. COA laboratories must also meet the requirements of their accreditation organization.

Additionally, a limited percentage of laboratories with a COA will receive a validation survey by CMS or a CMS agent. This is a survey performed by CMS or a CMS agent to evaluate the results of the most recent survey performed by an accreditation organization.

NOTE: If CMS or the State Agency receives a complaint against your laboratory, you may receive an unannounced on site survey, even though you only perform waived tests or PPM procedures.

IF I HAVE A CERTIFICATE FOR PPM PROCEDURES, A CERTIFICATE OF REGISTRATION, A COA OR A COC, CAN I ALSO PERFORM WAIVED TESTS?

Yes, these certificates permit laboratories to also perform waived tests.

IF I HAVE A COA OR A COC, CAN I ALSO PERFORM PPM PROCEDURES?

Yes, these certificates permit laboratories to perform PPM procedures as well as waived tests. The certificate you obtain should be for the highest (most complex) category of testing you perform.

DO I NEED TO NOTIFY ANYONE IF I MAKE ANY CHANGES IN MY LABORATORY?

For **all** types of CLIA certification, you must notify the State Agency or your accreditation organization within 30 days of any changes in:

- Ownership
- Name
- Location
- Director
- Technical supervisor (for high complexity testing only)

If you perform only waived tests and wish to add PPM procedures or other nonwaived (moderate or high complexity) testing to your menu, you must reapply for the appropriate certificate using the same form (Form CMS-116) you used for your initial CLIA certification. However, you cannot begin nonwaived testing until you have paid the appropriate fee, and have received the appropriate certificate.

If you perform PPM procedures and wish to add other nonwaived (moderate or high complexity) testing, you must first apply for the appropriate certificate.

If you have a COC or COA and wish to add tests categorized under a different laboratory specialty or subspecialty than those on your current certificate or that employ a different test method from those you are already performing, you must notify the State Agency or the accreditation organization of the new testing.

IF I HAVE ANY QUESTIONS ABOUT MY CERTIFICATE OR CHANGES IN MY TEST MENU, WHO SHOULD I CONTACT?

You should contact the State Agency where your laboratory is located. You can find this information as well as other information about CLIA at www.cms.hhs.gov/clia or you may contact the CMS CLIA Central Office at 410-786-3531.

WHERE CAN I FIND ADDITIONAL INFORMATION AND GUIDANCE?

Refer to the "The State Operations Manual", Appendix C – Interpretive Guidelines (CMS Publication 7) available on the CMS website at: www.cms.hhs.gov/clia.

Links to other laboratory-related resources can be found at these websites:

CDC: www.phppo.cdc.gov/clia/default.asp
FDA: www.fda.gov/cdrh/CLIA/index.html

NOTE: This brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings.

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Personnel Requirements by Testing Complexity

	Director*	Clinical Consultant/ Technical Consultant	Technical Supervisor**	General Supervisor	Testing Personnel
Waived Testing* **	MD, DO, or DPM licensed to practice in the jurisdiction where the laboratory is located; or qualified as director of a moderate or high complexity laboratory	Not Applicable	Not required	Not required	No specific requirements outlined in CLIA-88, however each laboratory must ensure waived testing personnel meet facility-defined minimum requirements and have documented training
Moderate Complexity* **	1. MD or DO with current medical license in State of laboratory's location[1] AND Board-certified in Anatomic and/or Clinical Pathology; OR 2. MD, DO or DPM with current medical license in State of laboratory's location[1] and laboratory training/experience consisting of: a. 1 year directing or supervising non-waived tests, OR b. 20 CME credit hours in laboratory practice commensurate with director responsibilities, OR c. Equivalent laboratory training (20 CME's) obtained during medical residency OR 3. Doctorate in chemical, physical, biological or clinical laboratory science with board certification OR 1 year experience directing or supervising non-waived testing	**A clinical consultant is only required if the director is not a physician or a board-certified doctoral scientist.** The clinical consultant must be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located[1]; or a doctoral scientist certified by an HHS-approved Board. **A technical consultant is only required if the laboratory director is not qualified as a high complexity director.** The technical consultant must be qualified as a high complexity laboratory director.	Not required	Not required	1. MD or DO with current medical license in State of laboratory's location[1]; OR 2. Doctorate in clinical laboratory science, chemical, physical or biological science; OR 3. Master's in medical technology, clinical laboratory, chemical, physical, or biological science; OR 4. Bachelor's in medical technology, clinical laboratory, chemical, physical or biological science; OR 5. Associate degree in chemical, physical or biological science or medical laboratory technology; OR 6. High school graduate or equivalent and successfully completed military training of 50 or more weeks and served as a medical laboratory specialist; OR 7. High school diploma or equivalent and appropriate training/experience as specified in 493.1423
High Complexity	1. MD or DO with current medical license in State of laboratory's location[1] AND Board-certified in Anatomic and/or Clinical Pathology; OR 2. MD, DO or DPM with current	Not Applicable	1. MD or DO with current medical license in State of laboratory's location and Board-certified in Anatomic and/or Clinical Pathology; OR 2. MD or DO with current medical	1. Qualify as Director for high-complexity testing; OR 2. Qualify as Technical Supervisor for high-complexity testing; OR 3. Doctorate in clinical	1. MD or DO with current medical license in State of laboratory's location[1]; OR 2. Doctorate in clinical laboratory science, chemical, physical or biological science;

	medical license in State of laboratory's location[1] and 1 year laboratory training during medical residency; OR 3. MD, DO or DPM with current medical license in State of laboratory's location[1] and 2 years experience directing/supervising high-complexity testing; OR 4. Doctorate degree in chemical, physical, biological or clinical laboratory sciences and board certification		license in State of laboratory's location[1] and 1 year training and experience in high-complexity testing in the respective specialty; OR 3. Doctorate in clinical laboratory science, chemical, physical or biological science and 1 year training and experience in the respective specialty; OR 4. Master's in medical technology, clinical laboratory science, or chemical, physical or biological science and 2 years training and experience in high-complexity testing in the respective specialty; OR 5. Bachelor's in medical technology, clinical laboratory science, or chemical, physical or biological science and 4 years training and experience in high-complexity testing in the respective specialty	laboratory science or chemical, physical or biological science and 1 year training and experience in high-complexity testing; OR 4. Master's in clinical laboratory science, medical technology or chemical, physical or biological science and 1 year training and experience in high-complexity testing; OR 5. Bachelor's in clinical laboratory science, medical technology or chemical, physical or biological science and 1 year training and experience in high-complexity testing; OR 6. Associate degree in medical laboratory technology (or pulmonary function) and 2 years laboratory (or blood gas analysis) training or experience, or both, in high-complexity testing	OR 3. Master's in medical technology, clinical laboratory, chemical, physical, or biological science; OR 4. Bachelor's in medical technology, clinical laboratory, chemical, physical or biological science; OR 5. Associate degree in chemical, physical or biological science or medical laboratory technology; OR 6. Education and training equivalent to an associate degree in a laboratory science or medical laboratory technology; OR 7. Anyone hired after April 24, 1995 must have an associate degree
***Laboratories with an annual test volume exceeding 500,000 must be directed by a high-complexity-qualified director, even if only waived and/or moderately complex tests are performed	*The Director may fulfill multiple roles listed here. While CLIA may allow for non-physician or non-doctoral degreed individuals to direct Waived and Moderate Complexity laboratories, CAP does not. CAP accredited laboratories must be directed by a physician or doctoral degreed individual. Refer to CLIA88 for grandfather provisions.		**CLIA requires at minimum a bachelor degreed individual for technical supervisor of most laboratory sections. CLIA requires special qualifications for technical supervisor in certain specialties (Transfusion Medicine, Cytopathology, Cytogenetics, Histopathology, Oral pathology, Histocompatibility) (493.1449). For these specialties, required qualifications include being a physician and/or doctoral scientist, and having specified training/ experience. Refer to CLIA for further details. For these specialties, the technical supervisor may be referred to as the section director.		

** CLIA requires at minimum a bachelor degreed individual for technical supervisor of most laboratory sections. CLIA requires special qualifications for technical supervisor in certain specialties (Transfusion Medicine, Cytopathology, Cytogenetics, Histopathology, Oral Pathology, Histocompatibility) (493.1449). For these specialties, required qualifications include being a physician and/or doctoral scientist, and having specified training/experience. Refer to CLIA for further details. For these specialties, the technical supervisor may be referred to as the section director.

*** Laboratories with an annual test volume exceeding 500,000 must be directed by a high-complexity-qualified director, even if only waived and/or moderately complex tests are performed

+ Military and VA personnel may be licensed in any US State

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☒ Initial Application ☐ Survey ☐ Change in Certificate Type ☐ Other Changes (Specify) _____ Effective Date _____	CLIA IDENTIFICATION NUMBER _____ D _____ *(If an initial application leave blank, a number will be assigned)*
FACILITY NAME	FEDERAL TAX IDENTIFICATION NUMBER
EMAIL ADDRESS	TELEPHONE NO. *(Include area code)* / FAX NO. *(Include area code)*
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* NUMBER, STREET *(No P.O. Boxes)*	MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate* NUMBER, STREET
CITY / STATE / ZIP CODE	CITY / STATE / ZIP CODE
SEND FEE COUPON TO THIS ADDRESS ☐ Physical ☐ Mailing ☐ Corporate SEND CERTIFICATE TO THIS ADDRESS ☐ Physical ☐ Mailing ☐ Corporate	CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate* NUMBER, STREET
NAME OF DIRECTOR *(Last, First, Middle Initial)*	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-VII and IX-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 ☐ A2LA

☐ 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.

PRA Disclosure Statement

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. Expiration Date: 3/31/2021. The time required to complete this information collection is estimated to average one hour 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 comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact LabExcellence@cms.hhs.gov.

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* ☐

	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 *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-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

If additional space is needed, check here ☐ and attach additional information using the same format.

VII. PPM TESTING *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived 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 _____

If also performing waived complexity tests, complete Section VI. 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) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.*

Identify the non-waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory e.g. (Potassium, Acme Chemistry Analyzer).

If additional space is needed, check here ☐ and attach additional information using the same format.

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, A2LA ,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	FOR PROFIT	GOVERNMENT
☐ 01 Religious Affiliation	☐ 04 Proprietary	☐ 05 City
☐ 02 Private Nonprofit		☐ 06 County
☐ 03 Other Nonprofit		☐ 07 State
_____ *(Specify)*		☐ 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.

PRINT NAME OF OWNER/DIRECTOR OF LABORATORY

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

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

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. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service are not considered laboratories. CLIA does not apply to a facility that only performs forensic testing. 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 **"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 '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: **https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.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.

Reminders - Before submitting the Form CMS-116:

1. Include the current or estimated annual test volume.
2. For Certificate for PPM, Certificate of Compliance, or Certificate of Accreditation, include the laboratory director qualifications.
3. Do not send any money with your application.
4. Send the completed Form CMS-116 to the appropriate State Agency **(http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf)**.

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. State agency contact information can be found at: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALITIES

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 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 **all specialties/subspecialities**, do not count calculations (e.g., A/G ratior, 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.