

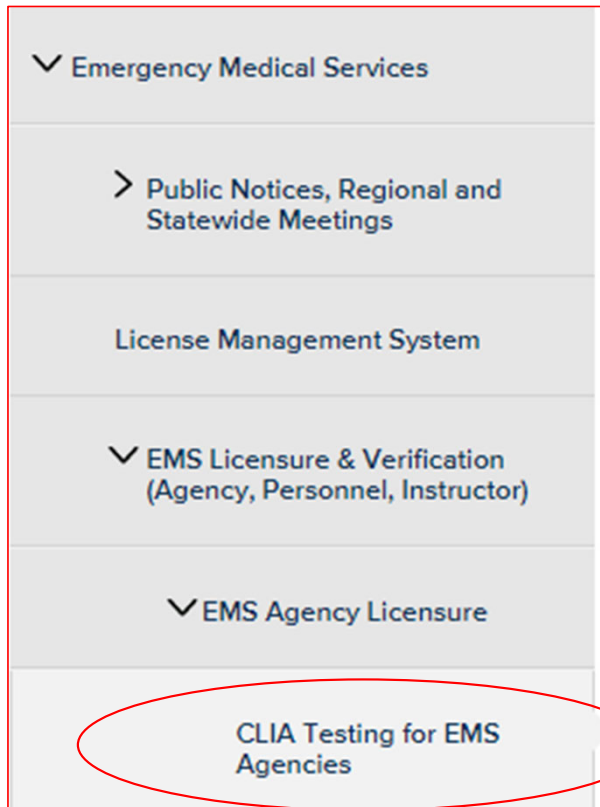
CLIA Certificate of Waiver

Updated: 07/01/2023

CLIA

- Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988, and under CLIA, a laboratory is defined as a facility that performs applicable testing 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 assessment of the health of, human beings.
- **Short info – if you do ANY testing of materials from human body (including glucose testing), you MUST have a CLIA Certificate of Waiver. (this is NOT a NEW requirement)**

OEMS Website – ems.ga.gov



Locate the CLIA link on our website

CLIA Testing for EMS Agencies

Since all EMS Agencies in Georgia are required to have devices that can check a patient's blood glucose, all EMS Agencies are required to have a CLIA Certificate of Waiver. Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988, and under CLIA, a laboratory is defined as a facility that performs applicable testing 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 assessment of the health of, human beings.

To learn more about CLIA and how to apply for a CLIA Certificate of Waiver, please review the following:

- [How to obtain a CLIA Certificate of Waiver - CMS](#)
- [Clinical Laboratory Improvement Amendments \(CLIA\) Website](#)
- [PDF Laboratory Quick Start Guide to CMS CLIA Certification](#)
- [Waived Tests \(CDC webpage with educational materials\)](#)

The State Agency for CLIA in Georgia is:

GEORGIA DEPARTMENT OF COMMUNITY HEALTH
Healthcare Facility Regulation
Division Diagnostic Services Unit
2 Peachtree Street, N.W., Suite 31-447
Atlanta, GA 30303-3142
(404) 657-5700
FAX: (404) 463-4398
Email: hfrd.diagnostic@dch.ga.gov

Finding Form CMS-116 (CLIA Application)

Click here

The screenshot shows the CMS website page for Clinical Laboratory Improvement Amendments (CLIA). The page title is "Clinical Laboratory Improvement Amendments (CLIA)". The left sidebar contains a list of links: "Clinical Laboratory Improvement Amendments (CLIA)", "How to Apply for a CLIA Certificate, Including International Laboratories", "Accreditation Organizations/Exempt States", "Categorization of Tests", "Certification Boards for Laboratory Directors of High Complexity Testing", "CLIA Brochures", "CLIA Regulations and Federal Register Documents", "CLIA Related Hearing Decisions and Compliance Topics", "Cytology Proficiency Testing", "Individualized Quality Control Plan (IQCP)", and "Interpretive Guidelines for". The main content area features a "Spotlight" section titled "Proposed Rule" with text about a proposed rule to update CLIA fees. Below this are two blue buttons: "PAY CLIA FEES ONLINE >" and "CERTIFICATION QUICK START GUIDE >". A red arrow points from the text "Click here" to the "CERTIFICATION QUICK START GUIDE >" button. The bottom of the page shows a Windows taskbar with the date 4/11/2022 and time 10:21 AM.

Click here to download application

LABORATORY QUICK START GUIDE TO CMS CLIA CERTIFICATION

NOVEMBER 2021

Laboratory Quick Start Guide to CMS CLIA Certification

The Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) regulates the quality and safety of U.S. clinical laboratories to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. CLIA has regulatory requirements for quality that all laboratories must meet. This guide helps laboratories seeking to apply for CLIA certification from CMS. More information can be found on the [CMS CLIA website](#).

STEP 1: Download and Complete Form CMS-116

- Include information based on the date of form completion.
- All applicable sections must be completed. Incomplete applications cannot be processed.
- Print legibly or type.
- To find out if the testing your laboratory is performing is categorized as waived, moderate, or high complexity refer to the [FDA website](#). If you are unable to locate the test complexity of your laboratory testing, contact your [State Agency](#).
- For a complete list of instructions, refer to page 6 of [Form CMS-116](#).

Complete General Information in section I.

First-time applicants check "Initial Application".

For an initial applicant, the **CLIA Identification Number** is left blank. When the application is processed, the number is assigned.

Facility Address 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.

International Lab Facilities

For CLIA purposes, an international laboratory is a facility outside the U.S. or its territories that performs clinical laboratory tests referred by and returned to a facility in the U.S. or its territories.

DISCLAIMER: This guide is a restatement of the law intended to assist people in understanding the basics about the CLIA program and that the reader should consult the relevant statutes and regulations for the full scope of the CLIA requirements.

Page 1

**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION**

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

Initial Application Anticipated Start Date _____

Survey

Change in Certificate Type

Other Changes (Specify) _____

Effective Date _____

FACILITY NAME _____

CLIA IDENTIFICATION NUMBER _____

_____ D _____
(If an initial application leave blank, a number will be assigned)

FEDERAL TAX IDENTIFICATION NUMBER _____

EMAIL ADDRESS _____

TELEPHONE NO. *(Include area code)* _____ FAX NO. *(Include area code)* _____

RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

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

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*

NUMBER, STREET *(No P.O. Boxes)* _____

NUMBER, STREET _____

CITY _____ STATE _____ ZIP CODE _____

CITY _____ STATE _____ ZIP CODE _____

SEND FEE COUPON TO THIS ADDRESS SEND CERTIFICATE TO THIS ADDRESS CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate* NUMBER, STREET

PICK ONE: PICK ONE: CITY _____ STATE _____ ZIP CODE _____

Physical Physical

Mailing Mailing

Corporate Corporate

NAME OF DIRECTOR *(Last, First, Middle Initial)* _____

Laboratory Director's Phone Number _____

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)*

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.

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 ACHC 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.

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: 03/31/2024. 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.

Form CMS-116 (12/21)

Select Initial Application

Enter an anticipate start date

Complete General Information
In Section I

Select Certificate of Waiver

Do not select any of
these options

DHHS/ CMS OMB No. 0938-0581
Form CMS-116 (12/21)

Leave Blank

Type of Laboratory = Ambulance or Other ("Medical First Responder vehicle")

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

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

Multiples Site = YES

#1 = Yes (mobile)

#2 = Yes, if governmental agency

#3 = No

(Must list ALL VINs for each vehicle on which a test will be performed. Attach as a document.)

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.

- 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.
- Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?
 Yes No
 If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.
- Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?
 Yes No
 If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

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

Leave Blank

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)

Be DESCRIPTIVE on which Glucose test(s) you use

Include any other testing of materials from the human body that you may perform at your agency.

I.E. any Point of Care testing, COVID Rapid test, etc.

Leave Blank

In the next three sections, indicate testing performed and estimated 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 by completing the table below. Include each analyte, test system, or device used in the laboratory.

ANALYTE / TEST	TEST NAME	MANUFACTURER
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation

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).*

- Listed below are the **only** PPM tests that can be performed by a facility having a Certificate for PPM. Mark the checkbox by each PPM procedure(s) to be performed.
- Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
 - Potassium hydroxide (KOH) preparations
 - Pinworm examinations
 - Fern tests
 - Post-coital direct, qualitative examinations of vaginal or cervical mucous
 - Urine sediment examinations
 - Nasal smears for granulocytes
 - Fecal leukocyte examinations
 - Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

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.

Leave Blank

VIII. NON-WAIVED TESTING (Including PPM testing if applying for a Certificate of Compliance or Certificate of 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 by completing the table below. Be as specific as possible. This includes each analyte test system or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity.

ANALYTE / TEST	TEST NAME	MANUFACTURER	M or H
Example: Potassium	Quick Potassium Test	Acme Lab Corporation	M

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.

If additional space is needed, check here and attach additional information using the same format." Include text box similar to Section VII.

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, ACHC, AABB, A2LA, CAP, COLA or ASHI)

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

Complete Section IX

Complete Section X if applicable

Print, Sign, and Date
(Do Not Forget)

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Healthcare Facility Regulation
Division Diagnostic Services Unit
2 Martin Luther King Jr. Drive SE
East Tower
Atlanta, GA 30334
(404) 657-5700

FAX: (404) 463-4398

Email: hfrd.diagnostic@dch.ga.gov

IX. TYPE OF CONTROL (CHECK THE ONE MOST DESCRIPTIVE OF OWNERSHIP TYPE)

VOLUNTARY NONPROFIT <input type="checkbox"/> 01 Religious Affiliation <input type="checkbox"/> 02 Private Nonprofit <input type="checkbox"/> 03 Other Nonprofit <i>(Specify)</i>	FOR PROFIT <input type="checkbox"/> 04 Proprietary	GOVERNMENT <input type="checkbox"/> 05 City <input type="checkbox"/> 06 County <input type="checkbox"/> 07 State <input type="checkbox"/> 08 Federal <input type="checkbox"/> 09 Other Government <i>(If 09 is selected, please specify the country or the province.)</i>
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Does this facility have partial or full ownership by a foreign entity or foreign government?
 Yes No
 If Yes, what is the country of origin for the foreign entity? _____

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 DIRECTOR OF LABORATORY _____

PRINT NAME OF OWNER OF LABORATORY _____

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (SIGN IN INK OR USE A SECURE ELECTRONIC SIGNATURE) _____ 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:
<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>

Once submitted, processing takes approximately 30 days. You will receive an invoice either by mail or email. Payment can be made electronically (immediate processing) or by check (approximately 10 days to process).

Certificates will be sent after payment is complete (could take up to 30 days)

Please keep in mind that the Department of Community Health processes CLIA applications