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# Point-of-Care/CLIA Webinar Prep Series

*Getting Your Pharmacy Started!*



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# Webinar Prep Series

1. Overview
- 2. CLIA Application**
3. CLIA Waived Equipment
4. Laboratory Director & Staff
5. OSHA-Compliance
6. Policies and Procedures/Wrap Up

# CLIA

- Congress established the Clinical Laboratory Improvement Amendments (CLIA) in 1988
- Purpose was to ensure laboratory standards by qualified personnel and laboratories
- Every lab in the U.S. that handles human samples is required to obtain a CLIA certification

CLIA. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA>  
Accessed October 22, 2018.

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# Program Administration

- U.S. Department of Health and Human Services
  - Food and Drug Administration (FDA)
    - Test categorization
  - CMS
    - Oversees regulations of all clinical laboratories
  - College of American Pathologists (CAP)
    - Independent accreditation agency that performs inspections for CLIA

CLIA. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA>  
Accessed October 22, 2018.

# Test Categorization

- 3 CLIA categories
  - High
  - Moderate
  - **Waived**
    - Simple laboratory examinations and procedures that have an insignificant risk of an erroneous result



CLIA categorizations. <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm393229.htm>. Accessed October 25, 2018.

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# Types of Waived Tests

- FDA has a list of analytes that are used in laboratory test systems that have been “waived”
- Waiver may be granted to
  - Any test listed in the regulation
  - Any test system for which the manufacturer or producer applies for waiver if that test meets the statutory criteria and the manufacturer provides scientifically valid data verifying that the waiver criteria have been met
  - Test systems cleared by the FDA for home use

[https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analytes\\_waived.cfm](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analytes_waived.cfm)

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# Most Common Waived Tests

- Urine pregnancy-34%
- All other tests-20%
- Blood glucose-18%
- Urine dipstick-19%
- Ovulation tests-5%
- Fecal occult blood-4%

CLIA categorizations. <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm393229.htm>. Accessed October 25, 2018.

# How to enroll as a CLIA-waived Laboratory

1. Complete an application
  - Form CMS-116
  - Available online at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>
2. Forward completed application to the address of State Agency for Pennsylvania



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# CLIA APPLICATION FOR CERTIFICATION

1. General information
2. Type of certificate requested
3. Type of laboratory
4. Hours of Laboratory Testing
5. Multiple Sites
6. Waived Testing
7. Skip
8. Skip
9. Type of control
10. Director affiliation with other laboratories

# General Information

## 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*

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

☐ Physical

☐ Physical

☐ Mailing

☐ Mailing

☐ Corporate

☐ Corporate

NUMBER, STREET

NAME OF DIRECTOR (Last, First, Middle Initial)

CITY

STATE

ZIP CODE


CREDENTIALS

FOR OFFICE USE ONLY

Date Received

# Type of Certificate Requested

**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.
- |                                               |                               |                               |                               |
|-----------------------------------------------|-------------------------------|-------------------------------|-------------------------------|
| <input type="checkbox"/> The Joint Commission | <input type="checkbox"/> AOA  | <input type="checkbox"/> AABB | <input type="checkbox"/> A2LA |
| <input type="checkbox"/> CAP                  | <input type="checkbox"/> COLA | <input type="checkbox"/> ASHI |                               |

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.


**NOTE:** Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA 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](mailto:LabExcellence@cms.hhs.gov).

# Type of Laboratory and Testing Times

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

## 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: |        | 8:00am | 8:00am  | 8:00am    | 8:00am   | 8:00am |          |
| TO:   |        | 5:00pm | 5:00pm  | 5:00pm    | 5:00pm   | 5:00pm |          |

(For multiple sites, attach the additional information using the same format.)

# Multiple Sites

**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 <i>(Number, Street, Location if applicable)</i> |                                          |                                        |
| CITY, STATE, ZIP CODE                                            | TELEPHONE NO. <i>(Include area code)</i> |                                        |
| NAME OF LABORATORY OR HOSPITAL DEPARTMENT                        |                                          |                                        |

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# CLIA Sites

- A CLIA certificate is needed for each site where testing is performed unless the site qualifies for one of the exceptions below:
  - Laboratories that move from testing site to testing site
  - Mobile health, health screening fairs, or other temporary testing locations
  - Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing
  - Same campus locations (filing under same physical locations)

# Waived Testing

**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).*

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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)

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Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed \_\_\_\_\_

☐ Check if no waived tests are performed

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

[illegible]



# Sending the Application

**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.

|                                                                  |       |
|------------------------------------------------------------------|-------|
| <hr/>                                                            |       |
| PRINT NAME OF OWNER/DIRECTOR OF LABORATORY                       |       |
| <hr/>                                                            |       |
| <hr/>                                                            | <hr/> |
| SIGNATURE OF OWNER/DIRECTOR OF LABORATORY ( <i>Sign in ink</i> ) | 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>

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# PA State Agency Info

## Pennsylvania Department of Health Bureau of Laboratories

110 Pickering Way

Exton, PA 19341

(610) 280-3464

Contact: Oyenike Abiola Oladipo, MS, MPH

[www.health.state.pa.us/labs](http://www.health.state.pa.us/labs)

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# Initializing Testing

- After a site applies for a certificate, a fee coupon will be assessed
- Follow the instructions on the fee coupon for payment
- After CMS receives payment, the CLIA certificate will be mailed to the site
- Testing may begin once the certificate is received from both CMS and PA State Board of Health

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# CLIA Requirements

- Enrollment in the CLIA program by obtaining a certificate
- Certificate (and fee renewal) every two years
- Mandatory following of manufacturer instructions for the waived tests performed at site
- Notification to State Agency of any changes in ownership, name, address or director within 30 days
- Permit inspections by a CMS agent
  - Laboratory is not subject to a routine survey or inspection

Application for CLIA Certificate. [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How to Apply for a CLIA Certificate International Laboratories.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html). Accessed October 25, 2018.

# Fee Schedule

- \$150 application fee and biennial thereafter
- PPA will reimburse this fee after CLIA certificate is obtained through the Pennsylvania Department of Health and proof submitted to PPA
- Prior to this, pharmacy must also have someone attend and complete the POC testing and have completed the webinar series



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# Remember the Steps

- CLIA Waiver
- Lab License
- Physician Protocol



# Next Session

Tuesday, November 6, 8:30-9:30a

## **CLIA Waived Equipment**

Presenter: Luke Berenbrok

Register Now!

<https://bit.ly/2Mmrr7o>

