

Instructions for the Application Process and Demographic Changes

APPLICATION PROCESS FOR ALL NEW PENNSYLVANIA LABORATORIES

1. A laboratory must have both a federal Clinical Laboratory Improvement Amendments (CLIA) certificate and a Pennsylvania clinical laboratory permit (see exceptions below).
2. Complete and return a Clinical Laboratory Application together with a \$100 initial filing fee. The federal CLIA application (CMS-116 form) must be included with the state application. The Centers for Medicare & Medicaid Services (CMS) will bill the laboratory separately.
3. A copy of the director's medical license, any board certifications (if applicable), and any Continuing Educational Units (CEUs) (if applicable) must be included with the application. For the Department to qualify a director as a moderate or high complexity director under CLIA, additional documents may be required.
4. Annual licensure fees will be billed each year and must be paid by the invoice due date for a permit to be renewed (see fees below).

ADDITIONAL REQUIREMENTS FOR LABORATORIES APPLYING FOR A CLIA CERTIFICATE OF WAIVER (COW)

1. Once the above listed information is received by the Department and the CMS/CLIA fee has been paid, a laboratory permit will be issued.
2. Any CLIA-waived laboratory may be subject to an on-site inspection as part of a CLIA COW laboratory project.

ADDITIONAL REQUIREMENTS FOR LABORATORIES APPLYING FOR A CLIA CERTIFICATE OF PROVIDER PERFORMED MICROSCOPIC PROCEDURES (PPMP)

1. Once the above listed information is received by the Department and the CMS/CLIA fee has been paid, a laboratory permit will be issued.
2. The laboratory must enroll in a proficiency testing program or implement a policy for performing peer review at least twice per year for PPMP procedures.
3. Any CLIA-PPMP laboratory may be subject to an on-site inspection as part of a CLIA Certificate of PPMP laboratory project.

ADDITIONAL REQUIREMENTS FOR LABORATORIES APPLYING FOR A CLIA CERTIFICATE OF COMPLIANCE

1. Once the above listed information is received by the Department, a letter of acknowledgement will be sent to the laboratory indicating the need for an on-site survey. The laboratory may be given provisional approval to begin testing.
2. The laboratory must enroll in a proficiency testing program for CLIA regulated analytes. The laboratory must have a method to verify non-regulated analytes at least twice a year.
3. After approximately 90 days, a Lab Examiner will contact the laboratory to schedule an on-site inspection.
4. Once the laboratory is found to be in complete compliance with state and federal CLIA requirements, a clinical laboratory permit will be issued.

ADDITIONAL REQUIREMENTS FOR LABORATORIES APPLYING FOR A CLIA CERTIFICATE OF ACCREDITATION

1. Once the above listed information is received by the Department, a letter of acknowledgement will be sent to the laboratory indicating the need for an on-site survey. No testing may be performed until the laboratory has been notified by the Department that licensure is in effect.
2. The laboratory must enroll in a proficiency testing program for CLIA regulated analytes. The laboratory must have a method to verify non-regulated analytes at least twice a year.
3. The laboratory must provide a letter of acknowledgement from the accrediting organization to which it has applied.
4. A Lab Examiner will contact the laboratory to schedule an on-site inspection.
5. Once the laboratory is found to be in complete compliance with state and federal CLIA requirements, a clinical laboratory permit will be issued.

ADDITIONAL REQUIREMENTS FOR LABORATORIES PERFORMING TOXICOLOGY, BLOOD LEAD, OR ERYTHROCYTE PROTOPORPHYRIN TESTING

1. Laboratories requesting licensure to perform quantitative testing for drugs in blood and/or serum or urine, alcohol, blood lead or erythrocyte protoporphyrin must be approved by the Department's Division of Chemistry and Toxicology.
2. Laboratories performing this testing must be enrolled in the Pennsylvania Toxicology Proficiency Testing Program.
3. Once the above listed information is received by the Department, an invoice will be sent to the laboratory for all applicable proficiency testing fees.
4. Once the fees have been paid, pre-licensure proficiency testing specimens will be sent to the laboratory.
5. Once proficiency testing samples have been tested and results are found to be acceptable, a letter of acknowledgement will be sent to the laboratory indicating the need for an on-site survey.
6. The above requirements will be followed based on CLIA certificate type.

EXCEPTIONS FOR OBTAINING A PENNSYLVANIA CLINICAL LABORATORY PERMIT

A permit is **NOT** required under the following instances:

1. Ambulance Services performing glucose testing **ONLY**
2. Plasma centers
3. Home Health and Home Hospice Services performing testing for Home Use **ONLY**

OUT OF STATE PERFORMING TESTING ON PENNSYLVANIA RESIDENTS

Laboratories outside of the Commonwealth performing testing on specimens originating from the Commonwealth must have a valid Pennsylvania Clinical Laboratory Permit. Follow the instructions above for submitting the appropriate application.

OVERSIGHT OF MORE THAN TWO (2) CLINICAL LABORATORIES IN PA

The Department continues to exercise enforcement discretion of 28 Pa. Code § 5.22 (f) to allow laboratory directors to oversee more than two clinical laboratories with proper documentation.

1. The laboratory director must complete and submit an attestation form indicating the laboratory director understands and will complete their duties for each laboratory they plan to oversee.
2. A copy of the director's medical license, any board certifications (if applicable), and any CEUs (if applicable) must be included with the application. For the Department to qualify a director as a moderate or high complexity director under CLIA, additional documents may be required.

ANNUAL FEES

LICENSURE FEES:

Clinical Chemistry including Urinalysis	\$100
Microbiology including Syphilis & Non-Syphilis Serology	\$100
Hematology including Immunohematology	\$100
Tissue Pathology including Exfoliative Cytology	\$100
Radioisotope Technics	\$100

PROFICIENCY TESTING FEES:

(See Division of Chemistry and Toxicology – Toxicology Proficiency Testing Program Fees)

Payment Options:

Payment for renewals may be made on-line with a credit card at www.PALabsBillPayment.health.pa.gov or

Payment may be submitted by check or money order, made payable to the Pennsylvania Department of Health.

Failure to pay on or before August 15 will result in the revocation of your Pennsylvania laboratory permit pursuant to Section 2156 (b) of the Clinical Laboratory Act, 35 P.S. § 2151 - § 2165. Once a laboratory receives a revocation notice, the laboratory must reapply for their license. In addition, the outstanding balance and application fees must be paid.

MULTISITE CERTIFICATION/LICENSURE

CLIA allows for multiple laboratory locations to be covered by a single CLIA certificate. In order to apply for the CLIA multiple site certificate, the laboratories must meet one or more of the following regulatory exceptions:

- A laboratory that has temporary testing sites
- A not-for-profit or federal, state, or local government laboratory engaged in limited public health testing (no more than a combination of 15 waived or moderate complexity tests) being performed at multiple testing sites
- A hospital with multiple testing sites located at contiguous buildings on the same campus within the same physical location or street address and under common direction

There is no provision in the Clinical Laboratory Act for multisite licensure. Each testing site must apply for and maintain a separate clinical laboratory permit.

LABORATORY PERMIT TO OPERATE SCREENING SITES

Screening sites are locations where certain tests are performed on a temporary basis. The following situations require a Pennsylvania clinical laboratory permit to operate screening sites:

- The collection and testing of specimens at temporary sites. An organization may visit the same site multiple times. However, testing supplies may not be stored at the site between visits.

An application to operate screening sites must be submitted to the Bureau along with supporting documentation. A screening site permit must be issued before patient testing may be performed.

Note: On-site testing is limited to CLIA-waived instruments/test kits only.

LABORATORY PERMIT TO OPERATE A MOBILE LAB

A mobile laboratory is a movable, self-contained, operational laboratory with its own personnel, equipment, and records. Testing performed inside a vehicle which travels between temporary testing sites requires a laboratory permit to operate a mobile laboratory, not a permit to operate screening sites. A CLIA certificate is also required for the mobile laboratory. A vehicle which is only used to transport testing supplies/staff between temporary testing sites is not considered a mobile laboratory if no testing takes place inside the vehicle.

An application to operate a mobile laboratory must be submitted to the Bureau along with supporting documentation. A mobile lab permit must be issued before patient testing may be performed.

Note: If an organization performs testing at some temporary sites using a mobile laboratory and testing at other temporary sites without the mobile laboratory, it must obtain both a Pennsylvania clinical laboratory permit to operate a mobile laboratory and a permit to operate screening sites.

CLINICAL LABORATORY PERMIT CHANGES

The laboratory must notify the Bureau immediately of a change in director or location and within 30 days of a change in owner, laboratory name or test menu. To facilitate this process, the laboratory must complete and submit a Change of Status form to the Bureau of Laboratories. Once received, changes will be made to both the State permit and CLIA certificate, if applicable.

REQUIREMENTS FOR SUBMISSION OF A CMS 116 FORM

ALL LABORATORIES

- Change of ownership
- Certificate type change to PPMP, Compliance or Accreditation
- Adding a multiple site exception
- Personnel – Director (PPM, Certificate of Compliance)

REQUIREMENTS FOR SUBMISSION OF A CHANGE OF STATUS FORM

ALL LABORATORIES

- Change of director – Must also submit a copy of the director’s medical license, and board certifications, if applicable
- Change of address (physical/mailing/billing)
- Change of laboratory name
- Change of ownership – You must also submit an updated CMS 116 Form
- Change of federal tax ID number
- Change of State permit type (ex. Physician’s Office Lab to Independent Lab)
- Lab is closing or discontinuing all clinical testing
- Change of CLIA certificate type (ex. Waiver to Compliance) – If changing to PPMP, Compliance or Accreditation, you must also submit an updated CMS-116 Form

PHYSICIAN’S OFFICE LABORATORIES

- Change in test menu, such as adding and/or deleting tests – When adding a test, include the FDA 510(K) number
- Changing from a waived method to a non-waived kit/method for the same analyte (**NOT** changing from one waived kit/method to another)
- Changing from a non-waived method to a waived kit/method for the same analyte

ALL OTHER LABORATORIES

- Change in test menu, such as adding a **category** of testing (ex. Hematology, Clinical Chemistry) when the laboratory is not currently licensed to perform testing in that category or deleting a **category** of testing when the laboratory is authorized to perform unlimited testing in that category
- Change in any Toxicology testing, including adding and/or deleting tests **and** changing from one test method to another for the same analyte

Do **not** submit copies of procedures, validation studies, training documentation, etc. unless requested. Please keep these documents to be reviewed at the time of your next on-site inspection.

The Change of Status Form must be signed by the director for a director change to be valid. For all other changes, the form may be signed by the director and/or owner of the laboratory.

PLEASE NOTE:

If your changes result in a change to your permit, you will receive a confirmation letter from the Department indicating the changes that were made. Please keep this letter with your records.

If your changes do not result in a change to your permit, your form will be filed. You will not receive a confirmation letter from the Department.

The Pennsylvania’s Clinical Laboratory Act requires that a clinical laboratory be overseen by a qualified laboratory director who provides direct and personal supervision of the laboratory’s operation. The Department requires each laboratory director to complete and sign a director’s attestation form. This is for the Director to attest to their willingness to assume all directorship responsibilities for the Commonwealth of Pennsylvania purposes, and to understand that they are responsible for the accuracy and reliability of all testing performed to ensure that the laboratory meets and will continue to meet the requirements of the Clinical Laboratory Act (CLA), 35 P.S § 2151 - § 2165, and its regulations, 28 Pa Code § 5.1 - § 5. 104.

28 Pa. Code § 5.22(g) requires that a director be present for a reasonable period of each working day in each laboratory for which they are a director. The Department interprets the term “present” to include a remote/virtual (i.e., telephonic, email, video conferencing) presence, as well as a physical on-site presence.

Directors of laboratories performing only waived testing are required to be continuously available virtually to the laboratory during all times when testing is performed to provide telephone or electronic consultation as needed. For laboratories performing moderate/high complexity testing, the Department requires the director to be on-site once every 6 months, with at least 4 months between the minimum two on-site visits. The director’s on-site visits may not be delegated. The on-site visits combined with the daily remote presence enables the director to participate and actively oversee the planning, organization, direction and review of all laboratory operations to the extent necessary to ensure compliance with the regulations, including ensuring the proper storage and quality of reagents, supplies. The director is required to provide documentation of the on-site visits, including evidence of performing activities that are part of the laboratory director’s responsibilities, upon request by the Department of Health.

The Clinical Laboratory Act regulations define a supervisor as “[a] properly qualified individual, who, under the direction of an authorized director, may supervise the general activities of a clinical laboratory, or a properly qualified individual who under the direction of an authorized director, may supervise the technical work in a laboratory category.”

If the Director will not be on-site during all hours of testing, then the Director must employ a qualified general supervisor who will be on the premises during all normal scheduled working hours in which tests are being performed.

SUPERVISOR QUALIFICATIONS AND INTERPRETATION OF ACCEPTABLE EXPERIENCE FOR LABORATORIES THAT PERFORM NON-WAIVED TESTING.

28 Pa Code § 5.23. requires 2 years’ experience acceptable to the Department for a doctoral degree, 4 years’ experience for a M.A or M.S. degree or 6 years’ experience for a B.S. or B.A. with major in biological, physical, or chemical sciences. The Department interprets the term “acceptable experience” for laboratories performing non-waived tests to include:

- Performing non-waived testing OR
- Other experience as determined and documented by the laboratory director to be appropriate.

PLEASE NOTE: THE EDUCATIONAL QUALIFICATION REQUIREMENTS MUST BE MET.