



CLINICAL LABORATORY APPLICATION TO OPERATE A MOBILE LABORATORY

ALL SECTIONS MUST BE COMPLETED
NO PATIENT TESTING MAY BE PERFORMED UNTIL A PERMIT HAS BEEN ISSUED

FOR DEPARTMENT USE ONLY
STATE ID#: _____
CHECK RECEIVED: Y N
CHECK #: _____

LABORATORY INFORMATION

LABORATORY NAME:			DIRECTOR:	
LABORATORY PHYSICAL ADDRESS:			M.D. OR D.O. GIVE MEDICAL LICENSE NUMBER:	
CITY:	STATE:	ZIP CODE:	TELEPHONE NUMBER:	FAX NUMBER:
LABORATORY MAILING ADDRESS:			FEDERAL TAX ID #	E-MAIL ADDRESS:
CITY:	STATE:	ZIP CODE:	OWNER NAME:	
LABORATORY BILLING ADDRESS:			CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) #:	
CITY:	STATE:	ZIP CODE:	NAME OF CONTACT PERSON:	CONTACT PERSON TELEPHONE NUMBER:

VEHICLE INFORMATION

Vehicle Identification Number	License Plate Number and State

LICENSED MEMBER OF THE HEALING ARTS INFORMATION – Attach copies of Pennsylvania licenses

Name	License Number

A check or money order for \$100, payable to the PA Department of Health, must accompany this application.

TEST INFORMATION**TESTING CONDUCTED WITHIN THE MOBILE LABORATORY:****CLINICAL CHEMISTRY:**

	Test Name	Instrument/Test Kit
<input type="checkbox"/>	Blood Glucose (including whole blood)	
<input type="checkbox"/>	Cholesterol	
<input type="checkbox"/>	Glycohemoglobin	
<input type="checkbox"/>	Lipid Panel	
<input type="checkbox"/>	Pregnancy	
<input type="checkbox"/>	Urinalysis	
<input type="checkbox"/>	Other	

MICROBIOLOGY:**Bacteriology**

	Test Name	Instrument/Test Kit
<input type="checkbox"/>	Throat Screen	
<input type="checkbox"/>	Other	

Virology

	Test Name	Instrument/Test Kit
<input type="checkbox"/>	COVID-19	
<input type="checkbox"/>	Influenza	
<input type="checkbox"/>	Other	

Non-syphilis Serology

	Test Name	Instrument/Test Kit
<input type="checkbox"/>	Hepatitis C	
<input type="checkbox"/>	HIV	
<input type="checkbox"/>	Rapid Syphilis	
<input type="checkbox"/>	Other	

OTHER:

	Test Name	Instrument/Test Kit
<input type="checkbox"/>		
<input type="checkbox"/>		
<input type="checkbox"/>		
<input type="checkbox"/>		
<input type="checkbox"/>		

If necessary, attach additional sheets indicating the testing to be performed and the instruments/test kits.

EXPECTED TESTING LOCATIONS

Provide as much information as possible on the expected locations where screening site testing will be provided. It is not necessary to predict all the locations where screenings may be conducted. However, records must reflect each location where patient testing has been performed.

Location (Name and/or Address):	Date(s):

LABORATORY DIRECTOR SIGNATURE

I hereby certify that the information provided in and attached to this application is true and correct to the best of my knowledge, information, and belief and understand that it is subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsification to authorities and denial or revocation of a permit to operate a clinical laboratory within the Commonwealth.

Printed Name

Signature

Date

DEFINITION OF A MOBILE LABORATORY

Any person or organization desiring to operate a clinical laboratory within the Commonwealth of Pennsylvania must obtain a permit in accordance with the Pennsylvania Clinical Lab Act. **This is an application for a permit to operate a mobile laboratory.** A mobile laboratory is a moveable, self-contained, operational laboratory with its own personnel, equipment, and records. A vehicle that only transports instruments, specimens, and supplies from one testing site to another is **NOT** considered a mobile laboratory (See the Application for a Pennsylvania Clinical Laboratory Permit to Operate Screening Sites).

This application must be submitted to the Department of Health Bureau of Laboratories along with supporting documentation and the appropriate fees. **Please read the instructions before completing the application.**

APPLICATION INSTRUCTIONS

Laboratory Information

Complete the information for the mobile laboratory including name, physical, mailing and billing addresses. The physical address for the mobile laboratory may be a primary testing site where the mobile laboratory is typically located or an office that serves as a home base for the mobile laboratory. The physical address must be in Pennsylvania. Include the director and owner information.

Pennsylvania's Clinical Laboratory Act and the federal Clinical Laboratory Improvement Amendments (CLIA) require that a qualified laboratory director be responsible for the proper operation of a mobile laboratory. As per the state regulations, the laboratory director must hold a doctor of science degree or its equivalent in the basic sciences of chemistry, biology or microbiology or a doctoral degree in public health, medicine, osteopathy, pharmacy, dentistry or veterinary medicine from a college or university recognized by the National Committee of Regional Accrediting Agencies or the Department of Education of the Commonwealth of Pennsylvania; **and** have at least two years of laboratory experience **OR** be certified by the American Board of Pathology, American Osteopathic Board of Pathology, American Board of Microbiology, American Board of Bioanalysis, American Board of Clinical Chemistry, or another national board which provides accreditation in laboratory specialties.

Organizations must also hold a federal CLIA certificate. If an existing Pennsylvania CLIA number will be used for a mobile laboratory, provide the CLIA number on the application. Provide a copy of the CLIA application (CMS-116) indicating that the certificate will cover multiple testing sites (Section V. Multiple Sites, 1). Indicate the VIN number of the mobile laboratory in this section of the CLIA application. If the organization does not have a Pennsylvania CLIA certificate, a CLIA application must also be submitted.

Provide the name, phone number and email address of the person that should be contacted with questions regarding the application.

Vehicle Information

Provide the Vehicle Identification Number (VIN), the vehicle's license plate number and the state in which it is licensed.

Licensed Member of the Healing Arts Information

28 Pa. Code § 5.41 requires that requests for clinical laboratory testing be made by a member of the healing arts licensed to practice in this Commonwealth, or other persons authorized by statute, or authorized agents of the foregoing. One or more persons authorized to request laboratory tests must be assigned to each mobile laboratory. This person is not required to be present within the vehicle but must provide a standing order for testing to be performed and be available to provide consultation to the patients who have received results. All documents related to standing orders for each mobile laboratory must be kept on file and made available to the Bureau upon request. Please submit a copy of the current license of each individual that may issue standing orders with the application.

Test Information

Provide information on the testing to be performed within the mobile laboratory. The tests typically approved for use within mobile laboratories are listed. Check the box next to each test to be performed and indicate which instrument or test kit will be used. Approval may be granted to perform tests other than those listed provided the tests requested are suitable for use in a mobile setting.

The mobile laboratory must be equipped to provide suitable conditions for testing and the storage of instruments, test kits, supplies, and specimens. Testing may only be conducted while the mobile laboratory is stationary. The mobile laboratory must have a means of storing any biological and/or chemical waste generated from testing until it can be properly disposed of.

Testing Locations

Provide as much information as possible on the expected locations where the mobile laboratory will be used. It is not necessary to predict all locations where the mobile laboratory may be used. However, records must reflect each location where patient testing has been performed. A listing of past testing sites and expected future locations must be provided to the Bureau upon request.

Laboratory Directors Signature

The laboratory director must sign and date the application. The laboratory director being issued the permit to operate screening sites will also be responsible for all testing conducted at the sites.

CLINICAL LABORATORY PERMIT FEES

The laboratory will be issued a permit to operate a mobile laboratory. The mobile laboratory permit and all correspondence will be sent to the mailing address. A \$100 initial permit fee must accompany the mobile laboratory application.

Mobile laboratory permits are valid from the issue date until the following August 15th. An annual fee is required to renew a mobile laboratory permit. The renewal fee is based on the number of categories in which testing is performed and ranges from \$100 to \$500 per year.

Information on these permit fees and other Bureau programs and licensure can be found on the Bureau's website at www.health.pa.gov/topics/Labs/Pages/Laboratories.aspx.

SUBMITTING THE APPLICATION

The original application, signed by the laboratory director, must be mailed to the Bureau at the address below. A copy should be retained for reference during the application process. Ensure the following items are included with the application.

- Documentation of laboratory director qualifications (copy of current medical license, CV, etc.)
- CLIA application (CMS-116)
- Copies of current medical licenses of members of the healing arts ordering laboratory testing
- A check or money order for \$100 made payable to the Pennsylvania Department of Health

**Bureau of Laboratories
Division of Laboratory Improvement
P. O. Box 500
Exton, PA 19341**

**For overnight delivery services, our physical location is:
110 Pickering Way
Exton, PA 19341**

Division of Laboratory Improvement staff are available to answer questions and provide guidance in completing the application and can be reached at (610) 280-3464 from 7:30 AM to 4:00 PM Monday through Friday.

Additional information on clinical laboratory regulations, including applications for other types of laboratory permits, is available on the Bureau of Laboratories' website at www.health.pa.gov/topics/Labs/Pages/Laboratory-Improvement.aspx.

Please allow four to six weeks for review of application and receipt of the mobile laboratory permit.