



# CLINICAL LABORATORY APPLICATION TO OPERATE SCREENING SITES

**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:

## 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 AT SCREENING SITES** (Note: On-site testing is limited to CLIA-waived instruments/test kits only)**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"/>	COVID-19 Antibodies	
<input type="checkbox"/>	Hepatitis C	
<input type="checkbox"/>	HIV	
<input type="checkbox"/>	Other	

**OTHER:**

	Test Name	Instrument/Test Kit
<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.

<b>Location (Name and/or Address):</b>	<b>Date(s):</b>

**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 SCREENING SITES

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 screening sites.** Screening sites are locations where limited testing is provided on a temporary basis. Screening site testing is conducted using instruments and supplies that are transported to the site each day of use. Locations where instrumentation and supplies are stored, and laboratory testing is performed on a part-time basis are fixed sites, **not** screening sites. **Temporary sites operated by organizations which collect and send specimens to their own laboratory for testing do not require a screening site permit.**

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 laboratory including physical, mailing and billing addresses. Include the director and owner information. Provide the name, phone number and email address of the person that should be contacted with questions regarding the application.

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 screening sites. 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 CLIA number will be used for screening sites, provide the CLIA number on the application. Provide a copy of the CLIA application (CMS-116) indicating that the certificate will cover multiple temporary testing sites (Section V. Multiple Sites, 1). If the organization does not have a CLIA certificate, a CLIA application must also be submitted.

### 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 screening site. This person is not required to be present at the screening site 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 screening site 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 on-location at screening sites. Only CLIA-waived instruments/test kits may be used to conduct testing at screening sites. The tests typically approved for use at screening sites 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 CLIA-waived and are suitable for use in a setting designed for screening.

The screening site environment must be suitable for testing and the temporary storage of instruments, test kits, supplies, and specimens. These items must be transported to and from the site under conditions which do not compromise the accuracy of testing. Biological and/or chemical waste generated from screening site testing must be disposed of at the site or properly stored and returned to the laboratory for proper disposal.

### 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 locations where screenings may be conducted. 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 screening sites. The screening site permit and all correspondence will be sent to the mailing address. A \$100 initial permit fee must accompany the screening site application.

Screening permits are valid from the issue date until the following August 15<sup>th</sup>. An annual fee is required to renew a screening 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](http://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](http://www.health.pa.gov/topics/Labs/Pages/Laboratory-Improvement.aspx).

**Please allow four to six weeks for review of application and receipt of the screening site permit.**