



Commonwealth of Pennsylvania
 Bureau of Laboratories
 P.O. Box 500
 Exton, PA 19341-0500
 Phone: (610) 280-3464

FOR DEPARTMENT USE ONLY
STATE ID # _____
CHECK REC'D Y OR N

Application for Out-of-State Laboratory

ALL SECTIONS MUST BE COMPLETED, please allow a minimum of 4-6 weeks for initial review*

LABORATORY NAME:			DIRECTOR:	
LABORATORY PHYSICAL ADDRESS:			IF 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:

Is the laboratory accredited? YES NO IF YES, which agency _____
 Does your state have a licensure law? YES NO UNKNOWN
 Does your state have a forensic licensure law? YES NO
 Do you operate a collection station in Pennsylvania? YES NO

Do you intend to perform Toxicology testing? YES NO

Enrollment into the Pennsylvania Toxicology Proficiency Testing Program is a requirement for state licensure.

If YES, choose all that apply below:

- Alcohol: ___Blood ___Serum/Plasma
- Drugs Urine: ___Screening ___Conformation
- Drugs of Abuse ___Blood ___Serum
- Blood Lead
- Erythrocyte Protoporphyrin

A check or money order for \$100.00, payable to the "Commonwealth of Pennsylvania, Department of Health", must accompany this application.

I hereby certify that the information stated herein is true and complete to the best of my knowledge and belief.

Print Laboratory Director Name

Signature of Director

Date

Print Owner/Corporation Name

Authorized Signature

Date

PLEASE SEE THE OTHER SIDE FOR INSTRUCTIONS AND ADDITIONAL DOCUMENTATION REQUIRED.

Please complete the check list and include all documentation required with the application.

- Completed application
- Information for the director (CV, résumé, board certifications, transcripts and current medical license)
- Copy of your CLIA (Clinical Laboratory Improvement Amendments) certificate
- Copy of your state's clinical laboratory license, if applicable
- A list of all laboratory tests that may be performed on specimens collected in Pennsylvania
- Copy of your laboratory's most recent inspecting agency's findings and a copy of your Plan of Correction (§2161 of the Act) if applicable
- A copy of your most recent proficiency testing summary for each analyte for which licensure is requested
For licensure in Toxicology, enrollment into the Pennsylvania Toxicology Proficiency Testing Program is a requirement for state licensure.
- A statement, signed by the director, indicating your intent to comply with all Pennsylvania clinical laboratory regulations, include the following:
 - That an individual direct no more than two Pennsylvania laboratories without Departmental approval (§5.22 of the regulations).
 - That a general supervisor be on-site during all hours of testing (§5.23 (b)(1) of the regulations).
 - That the Bureau be notified within 30 days when there is a change in director, owner, location or testing menu (§5.22 (a) of the regulations).
 - That the appropriate agency be notified when laboratory findings indicate the presumptive or confirmed presence of reportable diseases (§5.49 of the regulations) for specimens collected in Pennsylvania or from Pennsylvania residents.
 - That the laboratory has notified its proficiency testing agency to authorize the release of its proficiency testing results to the Pennsylvania Department of Health, Bureau of Laboratories, PO Box 500, Exton, PA 19341. (§5.62 of the regulations).

* Initial review is defined as the time the application is first reviewed for completion of required documents.

Please return the application with all documentation required from the above check list and a check or money order for \$100.00, payable to “Commonwealth of Pennsylvania, Department of Health” to:

Pennsylvania Department of Health
Bureau of Laboratories
Division of Laboratory Improvement
P.O. Box 500
Exton, PA 19341-0500

For overnight delivery services, our physical location is:

110 Pickering Way
Exton, PA 19341