

REV

# CLINICAL LABORATORY APPLICATION FOR OUT OF STATE LABORATORIES

FOR DEPARTMEN	NT USE ONLY
STATE ID#	
CHECK REC'D	Y OR N

## ALL SECTIONS MUST BE COMPLETED (Please allow a minimum of 4-6 weeks for initial review\*)

LABORATORY NAME:			DIRECTOR:	DIRECTOR:		
LABORATORY PHYSICAL ADDRESS:		IF M.D. OR D.O. GIVE MEDICAL LICENSE NUMBER:				
DITY:	STATE:	ZIP CODE:	TELEPHONE NUMBER:	FAX NUMBER:		
ABORATORY MAILING ADDRESS:			FEDERAL TAX ID #:	E-MAIL ADDRESS:		
ITY:	STATE:	ZIP CODE:	OWNER NAME:			
ABORATORY BILLING ADDRESS:			NAME OF CONTACT PERSON:	CONTACT PERSON TELEF	PHONE NUMBER:	
CITY:	STATE:	ZIP CODE:	CLIA#:			
If YES, choose all that apply Alcohol:Bloc Drugs Urine:Scre Drugs of AbuseBloc Blood Lead Erythrocyte Protoporphyri	station in Pennsylvicology testing?  nsylvania Toxico below: odSerun eeningConfir n  y order for \$10	vania? Y vlogy Proficier n/Plasma rmation n	ole to the "Pennsylva	a requirement for state licer		
w cortify that the information stated ben		•	ny this application.			
y certify that the information stated her	ein is true and complet	te to the best of my	r knowledge and beliet.			
Laboratory Director Name	me Signature of D		rector Date			
Owner/Corporation Name		Authorized Si	gnature	ture Date		
)23					Page 1 of 1	
Bureau of Laboratories	110 Pickering Way, E	Exton, PA 19341	Phone: (610) 280-3464	4   Fax: (610) 450-1932	www.health.pa.gov/labs	

## INSTRUCTIONS FOR COMPLETING THE CLINICAL LABORATORY APPLICATION FOR OUT OF STATE LABORATORIES

#### **Laboratory Name**

This is the name that will be used for all aspects of the facility (billing, etc.). This name must be exactly the same as it appears on your CLIA certificate. Name may only be 32 characters including spaces.

#### **Laboratory Address**

This is the physical location of the laboratory where testing and treatment is performed. Use the mailing/billing address only if the facility wants bills and other correspondence sent to a separate address. Both physical and mailing/billing addresses must be exactly as it appears on your CLIA certificate.

#### Director

This must be a person who holds a doctorate level degree and who qualifies under Section 5.21 of the Clinical Laboratory Regulations. The director must be the same for both State and CLIA purposes. Neither the state nor the federal government recognizes co-directors.

#### **Medical License Number**

Indicate the medical license number for an M.D. or D.O.

#### **Telephone/Fax Number**

Provide telephone and fax numbers for the physical location.

#### Laboratory Owner/Federal Tax ID Number

Provide the name of the person(s) or corporation that owns the laboratory and the federal tax ID number.

#### **Contact Person**

Provide the name of the person to contact in the event that there are questions about the application.

#### **CLIA Number/Type of CLIA Certificate Requested**

Provide the CLIA number assigned by the Centers for Medicare and Medicaid Services (CMS).

### THE APPLICATION MUST BE SIGNED BY THE DIRECTOR AND OWNER. THE FOLLOWING MUST ALSO BE SUBMITTED WITH THE COMPLETED APPLICATION:

Copy of your current CLIA (Clinical Laboratory Improvement Amendments) certificate
Copy of your state's clinical laboratory license, if applicable
List of all laboratory tests that may be performed on specimens collected in Pennsylvania
Copy of director qualifications (CV, resume, board certifications, transcripts, medical license, etc.)
Copy of your laboratory's most recent inspecting agency's findings, including a plan of correction, if applicable
Copy of your laboratory's most recent proficiency testing summary for each analyte for which licensure is requested
Statement, signed by the director, indicating your intent to comply with all Pennsylvania clinical laboratory regulations, including 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).

ALLOW 4-6 WEEKS FOR INITIAL REVIEW\*

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

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#### Return the application with all required documentation to:

Bureau of Laboratories P.O. Box 500 Exton, PA 19341

For overnight delivery services, our physical location is:

110 Pickering Way Exton, PA 19341

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