

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.)

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