

Instructions for Completion of Out of State Registration/Licensure Application

Registration is required for out-of-state laboratories, which perform tests on specimens received from Pennsylvania (§5.83 of the regulations).

Licensure is required for laboratories which:

- a. Operate a collecting, receiving or relay station in Pennsylvania (§5.11 (g) of the regulations);
- b. Want to be directly reimbursed by Pennsylvania Blue Shield;
- c. Want to perform testing in the subspecialties of Blood Alcohol, Drugs of Abuse, Blood Lead and Erythrocyte Protoporphyrin. In addition to licensure, Departmental approval is required to perform these tests (§5.50 of the regulations). The Bureau's Division of Clinical Chemistry and Toxicology will contact you with instructions on this approval process.
- d. Operate screening testing sites in Pennsylvania.

In order to obtain **registration/licensure** the following information must be submitted:

- a. A completed application
- b. Qualifications of director (CV, résumé, transcripts, copy of medical license)
- c. A copy of your CLIA (Clinical Laboratory Improvement Amendments) certificate
- d. A copy of your state clinical laboratory license, if applicable
- e. A copy of your laboratory's most recent inspecting agency's findings and a copy of your Plan of Correction (§2161 of the Act)
- f. A statement indicating your intent to comply with all Pennsylvania clinical laboratory regulations, particularly the following:
 - i. That an individual direct no more than two laboratories without Departmental approval (§5.22 of the regulations)
 - ii. That a general supervisor be on-site during all hours of testing (§5.23 (b)(1) of the regulations)
 - iii. 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)
 - iv. That the appropriate agency be notified when laboratory findings indicate the presumptive presence of reportable diseases (§5.49 of the regulations)
 - v. 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, P.O. Box 500, Exton, PA 19341. (§5.62 of the regulations) See attached for additional information.

If you do not indicate otherwise, you will be issued a state license for all of the categories/subcategories for which you hold a CLIA certificate. If you wish to limit your service in Pennsylvania, please submit the categories/subcategories for which you require licensure.

3/9/2009