

A laboratory that wishes to perform blood lead analysis on specimens collected in the Commonwealth of Pennsylvania must be licensed as a clinical laboratory under the Pennsylvania Clinical Laboratory Act [25 P.S. § 2151 et seq.]. The laboratory must also be specifically approved [28 Pa. Code § 27.34(5)] by the Department of Health Bureau of Laboratories' (Bureau) Division of Chemistry and Toxicology to conduct blood lead analysis under Pennsylvania's clinical laboratory regulations [28 Pa. Code § 5.50]. Laboratories that wish to perform blood lead analysis for occupational health purposes must also be approved by the United States Department of Labor Occupational Safety and Health Administration under 29 CFR § 1910.1025(j)(2)(iii) [28 Pa. Code § 27.34(6)].

Laboratories **that have already been issued a Pennsylvania clinical laboratory permit** must submit a Change of Status Form to the Bureau's Division of Laboratory Improvement. The form should indicate that the laboratory wishes to add blood lead analysis to its test menu. **Laboratories that wish to change their method of blood lead analysis must also notify the Division of Chemistry and Toxicology.**

Laboratories **that have not already been issued a Pennsylvania clinical laboratory permit** must submit a Pennsylvania clinical laboratory permit application to the Bureau's Division of Laboratory Improvement. There are separate applications for laboratories located inside and outside Pennsylvania. The laboratory should submit the appropriate application based on its location.

Both the Change of Status Form and the applications are available on the Division of Laboratory Improvement's page on the Bureau's website, www.health.pa.gov/labs.

In addition to the Change of Status Form or application, a laboratory applying for approval to perform blood lead analysis must also submit:

- a description of the procedure used to validate/verify the test method and validation/verification data;
- all standard operating procedures for blood lead analysis and results reporting;
- a current fee schedule for blood lead analysis;

All documents must be mailed to the Bureau's Division of Laboratory Improvement at the address listed at the end of this document.

Once the required documents have been received and determined to be complete and acceptable, the Bureau will contact the laboratory about enrollment in its blood lead proficiency testing (PT) program.

Laboratories must successfully participate in the Bureau's PT program to perform blood lead analysis on specimens collected in Pennsylvania. Laboratories may choose to enroll in additional blood lead PT programs administered by other providers. However, approval to test



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Pennsylvania specimens is based on the laboratory's enrollment and successful performance in the Bureau's program.

The Bureau's blood lead PT program has been approved by the Centers for Medicare and Medicaid Services in accordance with the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988). Participation in the Bureau's program satisfies both Pennsylvania and federal PT requirements.

The Bureau will mail the laboratory an invoice for the PT program enrollment fee. The invoice must be paid by check.

The check should be made payable to: **Pennsylvania Department of Health
Bureau of Laboratories**

- Include the laboratory's Pennsylvania clinical laboratory permit number on the check
- Include the invoice number on the check
- Return the check and invoice to the Bureau's Division of Laboratory Improvement at the address listed at the end of this document.

Once the check is received, the Bureau's Division of Chemistry and Toxicology will ship an initial PT event consisting of five samples. **If the laboratory has other outstanding fees, it must pay them before the Bureau will ship PT samples.**

The laboratory must test the initial set of PT samples and submit the results to the Division of Chemistry and Toxicology. The laboratory must receive a grade of 80% or better to be deemed proficient in blood lead analysis. Proficient laboratories will receive a letter informing them that they are approved and may begin performing blood lead analysis.

Approved laboratories must continue to successfully participate in the Bureau's PT events by obtaining scores of 80% or greater. Each PT event consists of five samples of 5 mL of blood. The blood samples contain varying amounts of lead. Three events are held each year. The Division of Chemistry and Toxicology carefully monitors the stability of the constituents in each sample to ensure that no significant changes affect the evaluation of participants' results. Reference laboratories are also used to verify the concentration of the lead in the samples.

Laboratories that continue to demonstrate an ability to obtain accurate blood lead results will be included in a **list of approved laboratories published twice each year in the Pennsylvania Bulletin.**

A laboratory that receives a score of less than 80% must submit a report of corrective action that identifies the reason(s) for its failure and the steps taken to improve performance. **Laboratories that do not submit results by the event due date will receive a score of 0%. A laboratory that receives a grade of less than 80% on two**



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consecutive events, or two out of three consecutive events, will have its approval to perform blood lead analysis revoked. The Bureau will notify the laboratory of the loss of approval in writing.

To regain approval, the laboratory must submit a report of corrective action and obtain scores of 80% or greater on two consecutive PT events. The Bureau will notify the laboratory in writing once its approval is restored.

A laboratory may purchase off-cycle PT events. Off-cycle PT events are subject to sample availability. The Bureau will not ship off-cycle events until payment has been received. If a laboratory wishes to use an off-cycle event to regain approval, the Bureau must receive an acceptable report of corrective action before off-cycle samples are shipped.

Laboratories must report patient blood lead results to the Department of Health as required by Pennsylvania's reportable disease regulations [28 Pa. Code § 27.22 and § 27.34(a)]. Failure to comply with the reporting requirements may result in the loss of approval to perform blood lead analysis or revocation of the laboratory's Pennsylvania clinical laboratory permit [28 Pa. Code § 5.49].

- Mail Pennsylvania clinical laboratory permit applications, Change of Status Forms, and checks to:

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

- Mail proficiency testing results to the address below, fax them to 610-280-3461, or email them to ra-dhtoxptprograms@pa.gov.

Pennsylvania Department of Health
Bureau of Laboratories
Division of Chemistry and Toxicology
P.O. Box 500
Exton, PA 19341-0500