Requirements for the Approval of Laboratories That Perform Erythrocyte Protoporphyrin and/or Zinc Protoporphyrin Analysis

A laboratory that wishes to perform erythrocyte protoporphyrin (EP) and/or zinc protoporphyrin (ZPP) 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 by the Department of Health Bureau of Laboratories' (Bureau) Division of Chemistry and Toxicology to conduct EP/ZPP analysis under Pennsylvania's clinical laboratory regulations [28 Pa. Code § 5.50].

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 EP/ZPP analysis to its test menu. **Laboratories that wish to change their method of EP/ZPP analysis must also notify the Division of Chemistry and Toxicology.**

Laboratories **that have <u>not</u> 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 EP/ZPP 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 EP/ZPP analysis and results reporting;
- a current fee schedule for EP/ZPP 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 EP/ZPP proficiency testing (PT) program.

Laboratories must successfully participate in the Bureau's PT program to perform EP/ZPP analysis on specimens collected in Pennsylvania. Laboratories may choose to enroll in additional EP/ZPP PT programs administered by other providers. However, approval to test Pennsylvania specimens is based on the laboratory's enrollment and successful performance in the Bureau's program.

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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 EP/ZPP analysis. Proficient laboratories will receive a letter informing them that they are approved and may begin performing EP/ZPP 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. 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.

Laboratories that continue to demonstrate an ability to obtain accurate EP/ZPP 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 consecutive events, or two out of three consecutive events, will have its approval to perform EP/ZPP 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

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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.

- 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

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