

Requirements for Approval of Laboratories that Perform Erythrocyte Protoporphyrin Analyses

The Department of Health has the responsibility for approving laboratories that perform Erythrocyte Protoporphyrin (EP) analyses in accordance with regulations in Section 5.50 of Title 28, *Pennsylvania Code*, promulgated under the Commonwealth's Clinical Laboratory Act (25 P.S. §2151 et seq.). The following is a brief outline of the present approval requirements.

- All applicants must submit a description of the analytical work that they intend to perform in their facility and detailed methodologies for all pertinent EP analysis procedures.
- In addition, the applicant must submit Laboratory Personnel Qualification Appraisal Forms for personnel engaged in EP analysis.
- A current fee schedule for this service should also be submitted.
- If the laboratory is located in Pennsylvania, a copy of a currently valid permit to operate a clinical laboratory must be submitted. Laboratories which are not licensed may obtain information about the procedure for applying for a permit by contacting our Division of Laboratory Improvement at 610-450-2140. This requirement does not apply to out-of-state laboratories.
- If the laboratory is located outside of the Commonwealth of Pennsylvania, it is required that the person making application submit a certification from the health department of the state in which the facility is located, indicating that the applicant has satisfied all pertinent clinical laboratory laws of that state. In addition, such laboratories must submit evidence that they are licensed under the Federal Clinical Laboratory Improvement Amendments of 1988. Laboratories located in the Commonwealth must also be licensed in accordance with the federal statutes.

The Bureau of Laboratories current proficiency testing program for the determination of EP consists of three proficiency testing events per year. Each event utilizes 5-ml blood samples containing varying amounts of zinc protoporphyrin IX.

The stability of each lot of test samples is carefully monitored by the Toxicology laboratory of the Bureau during the course of all proficiency evaluations to insure that no changes occur in the specimens which would render analyses more difficult or impossible to perform. In addition to these intra laboratory studies, the Bureau also obtains the services of a number of referee laboratories to verify the EP content of the specimens. These facilities are selected on the basis of their expertise in the field of toxicology.

Pending the successful completion of the prerequisite requirements and the demonstration of proficiency, your laboratory will be issued an approval to perform this service and will be added to our list of facilities approved to conduct this determination. This list, which is revised approximately semiannually, is published in the *Pennsylvania Bulletin*. Continued approval will be contingent upon acceptable performance in proficiency surveys that will be sent to your laboratory periodically.

All approved facilities are required to use control procedures which assure that a degree of accuracy, specificity, and precision satisfactory to the Department are maintained at all times. If a laboratory fails two consecutive proficiency tests, the approval is removed. Re-approval may only be issued after a six-month period. During this period, the Bureau of Laboratories offers consultation and technical training in EP analyses to assist in developing proficiency.

If you have any questions regarding this proficiency testing program, please contact Peter Lambert at 484-870-6426.