

Requirements for Approval of Laboratories that Perform Blood and/or Serum Alcohol Analyses

The Department of Health has the responsibility for approving laboratories that perform analyses of human blood and/or serum and plasma for ethanol in accordance with regulations (28 PA Code §§ 5.50 and 5.103) promulgated under the Commonwealth's Clinical Laboratory Act (35 P.S. §2151-2165). The following is a brief outline of the present approval requirements:

- An applicant, after obtaining a permit to operate a clinical laboratory under Pennsylvania Law, must submit a description of the analytical work that will be performed and a detailed description of methodologies for all pertinent alcohol analysis procedures.
- In addition, the applicant must submit Laboratory Personnel Qualification Appraisal Forms for personnel engaged in alcohol analysis.
- A current fee schedule for this service should also be submitted.
- 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 if such laws exist.
- 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.

When these prerequisite requirements have been met, the laboratory will be evaluated using proficiency testing specimens to ascertain that the facility can reliably perform alcohol determinations.

The proficiency testing process utilizes blood and/or serum and plasma specimens containing varying concentrations of ethanol. Contingent upon the correct analysis of the test specimens, the facility is issued an approval to conduct blood and/or serum and plasma alcohol analyses for Pennsylvania clients.

This approval will remain in effect provided the laboratory personnel are able to demonstrate an acceptable level of proficiency when examining test samples that will be forwarded to them periodically. The Bureau of Laboratories' current proficiency testing program for the determination of blood and/or serum and plasma alcohol content consists of three surveys per year.

The Bureau's Division of Chemistry and Toxicology carefully monitors the stability of the constituents in each lot of test samples during the course of the proficiency evaluations to insure that no significant changes occur in the specimens. In addition to these intra-laboratory studies, the Bureau also obtains the services of a number of reference laboratories to verify the concentrations and detectability of the substances of interest. These facilities are selected on the basis of their expertise in the field of clinical toxicology.

Laboratories that perform unsatisfactorily in a proficiency survey are required to submit a report of corrective action. These facilities may receive additional test specimens following the receipt of their corrective action report if a serious deficiency is discovered or the corrective action report is inadequate. If a laboratory fails two consecutive proficiency tests, the approval is removed. Reinstatement in the program will then require a demonstration that proficiency has again been achieved.

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. The list of approved laboratories is published approximately semi-annually as notices in the *Pennsylvania Bulletin*. Commonwealth Courts use these lists to determine that laboratories meet the Department of Health's standards before admitting their alcohol analysis findings into evidence.

Please contact Jennifer Okraska for any questions you may have regarding this program at 484-870-6405 or jokraska@pa.gov.