pennsylvania
DEPARTMENT OF HEALTH

Bureau of Laboratories

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

The Department of Health has the responsibility for approving laboratories that perform analyses of human blood or serum for drugs subject to abuse in accordance with regulations (28 PA Code §5.50) 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 analysis procedures for detecting and quantifying drugs or their biotransformation products in blood or serum.

- In addition, the applicant must submit Laboratory Personnel Qualification Appraisal Forms for personnel engaged in analysis of drugs in blood or serum.

- A current fee schedule for this service should also be submitted.

- If the laboratory is located outside 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, all laboratories must submit evidence that they are licensed in accordance with the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) which are administered by the Centers for Medicare and Medicaid Services (CMS).

- The facility must be registered with the Drug Enforcement Administration (DEA) of the United States Department of Justice as an analytical laboratory and must hold a currently valid registration number. Laboratories employing procedures which utilize DEA exempt chemical preparations for standardization and quality assurance purposes may request an exception to this requirement.

When these prerequisite requirements have been met, the laboratory will be evaluated using proficiency testing specimens to ascertain that the facility can reliably perform determinations of drugs in blood and/or serum.

The proficiency testing process utilizes blood and serum specimens containing drugs subject to abuse and other substances as explained in the following paragraph. Contingent upon the correct analysis of the test specimens, the facility will be issued an approval to conduct analyses of drugs in blood or serum. This approval then remains in effect provided the laboratory’s analysts are able to demonstrate an acceptable level of proficiency when examining test samples that will be forwarded to them periodically.

The Bureau of Laboratories' proficiency testing program for the determination of substances subject to abuse in blood or serum consists of three surveys a year. Each survey utilizes 20 ml blood or serum samples containing varying amounts and combinations of the following drugs: amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, codeine, fentanyl, glutethimide, LSD, methadone, methaqualone, morphine, phencyclidine, phenothiazines, propoxyphene, and their respective metabolites where applicable. Blood or serum containing medications or other substances which may be incorrectly identified as drugs of abuse are also frequently incorporated into the samples.

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

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All approved facilities are required to use quality control materials or standards to assure that a degree of accuracy, specificity, and precision satisfactory to the Department are maintained at all times. For grading purposes, in the qualitative (screening) portion of the proficiency testing event, participant laboratories are permitted one false positive drug determination without penalty. Any false negative responses reported, however, will result in an unsatisfactory performance rating for the survey. Participant laboratories will be graded only on those analytes for which they offer testing. In the quantitative (confirmatory) portion of the proficiency testing event, a mean concentration and standard deviation are determined for each analyte using either the reference laboratories' results or the findings of the entire participant population. After discarding outliers beyond three standard deviations, the mean and standard deviation are recalculated.
The acceptable range of analyte concentrations is then computed using the recalculated mean and standard deviation. The acceptable range is defined as the mean concentration of the analyte plus or minus two standard deviations. Reported values lying within this range are considered acceptable, and those that exceed this range are unacceptable. Participants will be graded only for those substances that were presumptively detected during the initial screening process. Grades for confirmatory testing will not be lowered for not performing additional analyses for substances present that were not detected by initial screening analyses. Laboratories are notified of their performance following each survey and receive reports summarizing the performance of participants and reference laboratories.

If a laboratory reports concentration values for more than one analyte outside of acceptable limits, it is considered to have performed unsatisfactorily in the survey. Facilities that perform unsatisfactorily in a survey are required to investigate the cause of the problem and file a corrective action report documenting that they have remedied any deficiencies in their procedures for processing specimens. It is recommended that laboratories that report one unacceptable value in a survey also file corrective action reports, since there should be no doubt about the reliability of a laboratory's procedures when the results are used for medico legal purposes.

Laboratories that perform unsatisfactorily in a proficiency survey are placed in probationary status and 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. Perfect performance in the next regularly scheduled survey is required to regain regular approval status when a laboratory is on probation. If a laboratory fails two consecutive proficiency tests, the approval is removed. Reinstatement in the program will then require unequivocal demonstration that proficiency has again been achieved.

Lists of approved laboratories are published semiannually as notices in the *Pennsylvania Bulletin* at approximately six-month intervals. Commonwealth courts utilize these lists to determine that laboratories meet the Department of Health's standards before admitting their drug 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.