

**American Society of Crime Laboratory Directors/Laboratory Accreditation Board  
(ASCLD/LAB)**

**Proficiency Test Provider Program**

**Scope**

This document defines the requirements of proficiency test providers and their respective manufacturers to receive and retain ASCLD/LAB approval for participation in the ASCLD/LAB external proficiency testing program. For the purposes of this document the term “Quality System” encompasses the quality assurance program(s) of the Proficiency Test Provider and the manufacturer if they are two separate entities.

**Definitions**

**Approved Proficiency Test Provider:**

An individual, organization or company which has applied for and obtained approval from ASCLD/LAB to prepare and provide proficiency tests to participating forensic laboratories, in the forensic disciplines, for which the provider has been approved.

**Manufacturer:**

An agency, company, or individual other than the Proficiency Test Provider who/which prepares proficiency tests and conducts pre-distribution testing for the approved test provider. There may be instances when the Proficiency Test Provider is simply a marketing agency and in those instances the manufacturer may take on some of the functions normally handled by the approved test provider.

**Proficiency Review Committee (PRC):**

A committee of individuals appointed by the Board of ASCLD/LAB, because of their experience and expertise, to give guidance to ASCLD/LAB in the proficiency testing program for specific forensic disciplines and subdisciplines. The PRCs assist ASCLD/LAB in the approval process for test providers; in the review and approval of proficiency test provider quality programs; and in the review of proficiency tests taken by laboratories. Each PRC is made up of one Chair or two Co-Chairs and one or more additional members. The maximum number of members on each PRC will be subject to need, input from the PRC Chair, and final review and approval of the Board.

**Proficiency Test:**

Tests designed, prepared and distributed by approved test providers to evaluate the proficiency and capability of analysts, technical support personnel and the quality performance of the laboratory.

**Quality System:**

The organization structure, responsibilities, procedures, processes, and resources for implementing quality management. The quality system includes all activities which contribute to quality, directly or indirectly.

**Program Coordinator:**

An individual who coordinates the preparation, evaluation and distribution of proficiency tests with ASCLD/LAB and with participating laboratories. If the Program Coordinator does not possess a thorough understanding of the scientific principles and techniques involved in a particular type of analysis/examination etc., for which the proficiency test is intended to test, then the Program Coordinator must have the support of technical personnel who do possess the necessary knowledge, skills and experience to design, develop and manufacture the intended proficiency tests.

**Audit Cycle:**

An audit cycle is the period of time between on-site audits of a proficiency test provider and/or a manufacturer by ASCLD/LAB. An audit cycle will generally be a period of approximately five (5) years.

**Pre-Distribution Testing Laboratory:**

A laboratory that participates in the analysis of an external proficiency test prior to the general release of the test. The decision to act as a pre-distribution laboratory for a test provider is an independent decision of the director of the participating laboratory.

**I. Proficiency Test Design**

The proficiency test provider shall consult with the appropriate Proficiency Review Committee (PRC) prior to changing the nature, design or intent of a proficiency test format.

The manufacturer shall conduct a design review of the proficiency test format prior to manufacturing and release. Documentation of the review shall be maintained by the test provider.

The proficiency test provider shall comply with the test manufacturing guidelines established by the ASCLD/LAB PRC which oversees each respective test, when such guidelines are available.

The manufacturer will seek to design tests that recognize and compensate for the limitations of any form of reproduction.

The proficiency test design shall provide adequate protection against known conditions that might adversely affect the quality of the proficiency test.

The proficiency test design shall define the test objectives, test structure and desired result(s).

When appropriate, the test specimens should be representative of samples encountered in normal forensic casework.

The manufacturer shall use acceptable forensic protocols when producing test materials (i.e. proper test mark medium, jig for consistent marks, similar ammunition for test firing, etc.)

Prior to the beginning of each calendar year, the proficiency test provider shall make available to ASCLD/LAB a projected timeline of test shipment dates and projected release dates of summary reports for each test to be offered during the calendar year.

## **II. Personnel**

The manufacturer shall employ personnel who possess the appropriate knowledge of the particular specimens being manufactured for testing.

The proficiency test provider shall employ, contract or provide a consultant that possess an understanding of the scientific principles and techniques involved in the type of analysis/examination for which the proficiency test is intended to test.

Test Providers shall have sufficient employees/contractors/consultants responsible for the collection, processing, testing, storage and distribution of proficiency tests. The providers shall ensure that all personnel meet the education, training and experience requirements of their assigned duties as defined by the test provider.

## **III. Quality Assurance and Control**

Test providers shall be externally audited by a representative(s) of ASCLD/LAB at least every 5 years. Audits shall involve the provider and all associated test manufacturing sites.

Test providers/manufactures shall develop and maintain a documented quality assurance program which addresses the test design, preparation, labeling, packaging, and reporting of results for all tests. The program shall also define procedures for accepting and responding to questions and complaints from subscribers.

The Quality system shall include, but not be limited to procedures which:

- Assure review of proficiency test production records prior to test release
- Identify, recommend, or provide solutions for quality assurance problems
- Ensure implementation of corrective action procedures when quality assurance problems have been identified.
- Assure that all quality control checks are appropriate and adequate for their intended purpose
- Assure that all quality control checks are performed correctly
- Ensure that changes in proficiency test manufacturing processes do not adversely impact the effectiveness or characteristics of the proficiency tests

Quality Control shall include but not be limited to:

- Production and process control procedures adequate to maintain uniform and consistent proficiency tests
- Standards and procedures that assure that the samples are uncontaminated
- Adequate procedures for the identification and handling of all proficiency test samples to allow tracing to their original source

- Adequate provisions for monitoring the reliability, reproducibility and accuracy of proficiency test preparation
- Production and process control procedures adequate to minimize the incidence of non-conforming tests and specimens

ASCLD/LAB shall be notified when substantive quality manual changes are made.

The Quality Manual shall be made available upon request to ASCLD/LAB.

The proficiency test provider shall conduct and document annual internal audits and review of their quality system including all test manufacturing sites.

The proficiency test provider shall submit an *ASCLD/LAB Approved Test Provider Annual Report* to ASCLD/LAB, annually. The annual report will be for the prior calendar year and will be due to the ASCLD/LAB Proficiency Program Manager by April 1 of each year. The report will provide an overview of any relevant changes in operations, procedures, and/or facilities during the calendar year. The expected report content will be grouped by test number and include:

- Errors in test design or test data discovered after the release of the test
- Any corrective action plan(s) instituted, including what actions were taken
- Confirmation of retention of required test samples
- List of pre-distribution laboratories used, including how chosen and results obtained
- Identity of any sub-contractor test manufacturer(s)
- List of written complaints received from ASCLD/LAB accredited laboratories and actions taken to address the complaint (if any)

The *ASCLD/LAB Approved Test Provider Annual Report Cover Sheet* is to be utilized for the first page of this report.

Procedures shall be developed to facilitate traceability and inventory control of proficiency test components.

#### **IV. Test Manufacturing Facilities**

The facility shall provide an environment which precludes contamination, deleterious change or sample switching.

If applicable, the test provider shall have and maintain all required permits (federal, state, DEA, World Health, etc.).

#### **V. Test Manufacturing Equipment**

The proficiency test manufacturer shall have and follow a documented maintenance and/or calibration schedule for equipment. Records of maintenance and calibration shall be maintained throughout the audit cycle.

## **VI. Reagent and Supplies**

Reagents and supplies that affect the quality of the test shall be checked for suitability prior to their use in preparing samples.

There shall be a sufficient quantity of materials used in the manufacture of proficiency tests to allow for follow-up testing.

Materials used in the manufacture of proficiency tests shall be properly characterized, homogenous and/or uniformly prepared.

When necessary, materials used in the manufacture of proficiency tests shall be prepared in isolation (either by time or space) from each other.

Materials used in the manufacture of proficiency tests shall be stored and shipped under conditions which minimize degradation and cross contamination.

Materials used in the manufacture of proficiency tests shall be labeled correctly, accurately, and legibly.

## **VII. Standard Operating Procedures**

Standard operating procedures shall cover all steps in the proficiency test manufacturing and reporting process, including, but not limited to: identification, collection, processing, preparation, testing, storage and distribution of proficiency tests and test components, results analysis and summary reporting.

Standard operating procedures shall be reviewed and the review shall be documented by the test provider on an annual basis.

Standard operating procedures shall be available at all provider and test manufacturing sites.

## **VIII. Pre-distribution Testing**

Proficiency test providers shall have a documented pre-distribution testing program.

Pre-distribution testing shall be done to help prevent the release of defective tests and to ensure the quality of the test, the design, test questions, sample labeling, packaging, response form, quantity and quality.

Pre-distribution tests shall be taken by at least two laboratories (one of which shall not be associated with the manufacturer and shall be ASCLD/LAB accredited). Results shall be received from at least two of the pre-distribution labs in the allotted time frame before evaluating validity.

*Note:* A PRC may require more stringent supplemental requirements for pre-distribution testing.

A pre-distribution test shall be received in a manner as close to the final product as possible including labeling, packaging and reporting.

The manufacturer shall develop and maintain procedures to deal with and document the resolution of any test design problems revealed through quality control checks or pre-distribution testing. Tests shall not be released until the problem is rectified and the validity of the test can be verified.

**IX. Reserve Samples**

Ten sets or 20% (whichever is less) of each test shall be retained by the manufacturer for at least one year from the date the summary report is issued for that test.

These tests are held for referee testing and as replacement tests, according to the test provider's policy, should a test be damaged or lost in transit, etc.

**X. Records**

Quality Assurance records of the entire proficiency test process (manufacturer and provider) for each test distributed shall be maintained for five years from the release date of the summary report. These records should also include a complete history of the work performed.

**XI. Distribution**

Proficiency test sets shall be packaged to protect them from damage, contamination, or other deleterious change during shipment to subscriber laboratories.

Proficiency tests including all individual samples shall be clearly labeled and sealed.

Proficiency tests shall be shipped to a designated recipient(s) in subscriber laboratories.

The test provider shall maintain records of shipment dates and designated recipient(s) for a minimum of one year.

A brief description of the proficiency test design and clear instructions on how to complete the test's result form shall be included with each test.

The proficiency test shall be distributed such that there are at least 8 weeks for the subscriber laboratory to complete the test.

**XII. Proficiency Test Forms and Reports**

Test providers shall not provide any type of grading regarding pass/fail, satisfactory/unsatisfactory etc. for test results.

Test providers shall prepare preliminary, individual and summary reports as defined below.

**A. Subscriber's Response Form**

The proficiency test manufacturer shall provide the subscriber with a PRC approved response form with each proficiency test.

The response form shall include a unique identifier for each proficiency test set.

The response form should include a section for the subscribing laboratory to report procedural data when applicable.

The response form shall include a section for the subscriber to report their results.

The response form shall include the due dates, for the subscribing laboratory to complete the analysis and for the subscriber to return the proficiency test results.

#### **B. Preliminary Report for Test Subscriber**

The proficiency test provider shall issue a preliminary report to the test subscribers within thirty (30) calendar days of the reporting deadline.

The preliminary report shall include the purpose of the test, a description of how the test was manufactured and the target values.

#### **C. Individual Report for Test Subscribers**

The proficiency test provider shall provide an individual report for each participant that includes all of that participant's data and conclusions within ninety (90) days of the reporting deadline.

#### **D. Summary Report for Test Subscribers**

The proficiency test provider shall provide each test subscriber a comprehensive summary report within ninety (90) calendar days after the reporting deadline that includes the compiled results from all test subscribers, a description of the test design, objectives and details of manufacture.

Each test set shall be represented by a unique code in the summary report.

The summary report shall include the test results obtained from the pre-distribution testing or a statement that the results of the pre-distribution testing confirmed the specified target values.

#### **E. Summary Report for PRC**

The proficiency test provider shall send a summary report, or its electronic equivalent, to the ASCLD/LAB Quality Manager within ninety (90) calendar days after the reporting deadline. Summary reports that are submitted in printed form shall be submitted in triplicate.

The summary report shall contain a description of the test design, objectives and details of manufacture.

The summary report shall include the specified target results as well as the test results obtained from the pre-distribution testing laboratories.

The summary report shall clearly correlate the unique codes of each test with the ASCLD/LAB certificate number. The summary report submitted to the ASCLD/LAB Proficiency Test Program Manager shall consist only of the results from ASCLD/LAB accredited subscribers that have released their results.

The proficiency test provider shall retain documentation of all subscriber test results that have been released to ASCLD/LAB for review for a minimum of one year from the date of the summary report.

### **XIII. Confidentiality of Results**

Results of all individual proficiency tests shall be maintained confidentially by the proficiency test provider and manufacturer.

The proficiency test provider shall require a signed release from the laboratory's designated individual prior to releasing individual and/or laboratory proficiency test results to ASCLD/LAB and its Proficiency Review Committees.

The proficiency test provider shall immediately notify the Laboratory Director or designee whenever a legal request (e.g., a subpoena) for a laboratory's proficiency test results is received.

### **XIV. Post-distribution Procedures**

The proficiency test provider shall have methods in place to receive, acknowledge and act on written complaints from proficiency test subscribers.

Procedures shall be in place to facilitate the continuous improvement of proficiency tests.