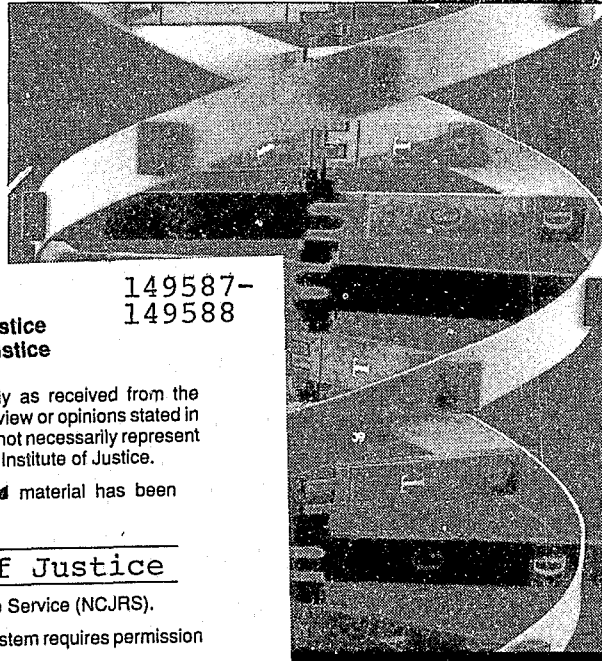


# CRIME LABORATORY DIGEST

APRIL 1994

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# Guidelines for DNA Proficiency Test Manufacturing and Reporting

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and  
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## Introduction

The Quality Assurance Subcommittee of the Technical Working Group on DNA Analysis Methods (TWGDAM) and the DNA Proficiency Review Committee (PRC) of the American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB) have combined their efforts to issue this set of manufacturing guidelines for quality proficiency tests.

It is the intent of the authors of these guidelines to provide clear instructions to the **commercial vendors** of DNA proficiency tests. These guidelines address the needs of the forensic community in its effort to assess the quality of the work it produces as well as the competence of its examiners. It should be noted that these guidelines apply specifically to commercial proficiency test providers. Commercial proficiency test providers are those agencies which market and sell proficiency test sets to forensic laboratories. Several of the current proficiency test providers do not manufacture the tests they sell. Thus, these guidelines have been written to be inclusive of the manufacturing, marketing, and evaluation steps used by commercial vendors.

These guidelines will also be used by the ASCLD-LAB DNA PRC as a basis for the approval of proficiency test providers for laboratories accredited by ASCLD-LAB. ASCLD-LAB accredited laboratories **MUST** utilize approved proficiency test providers in order to maintain their accreditation status.

### I. Proficiency Test Design Review

- A. The purpose of the proficiency test design review is to provide maximum protection against oversights that might adversely affect the quality of the proficiency test.
- B. The proficiency test manufacturer shall conduct a design review of the proficiency test format prior to manufacturing. It is highly desirable that this review be conducted by a person(s) other than the individual(s) who originally developed the proficiency test.
- C. An adequate test design should define the simulated case, the specific results desired (*e.g.*, match/nonmatch), and a thorough characterization of the samples to be used in the test. The target quantity of analyte per sample (*e.g.*, nanograms genomic DNA) shall be specified by the manufacturer.

### II. Personnel

- A. The proficiency test manufacturer shall utilize employees who possess an understanding of the scientific principles and techniques involved in the applicable field of forensic science.
- B. The proficiency test manufacturer shall assure that employees responsible for the collection, processing, testing, storage, and distribution of proficiency tests are adequate in number and have the educational background, training, and experience to assure competent performance of their assigned functions.

### III. Quality Assurance

- A. Each proficiency test manufacturer shall prepare and implement a documented quality assurance program adequate to assure that established and documented quality control procedures are performed.
- B. The quality assurance program shall:
  1. Assure that proficiency test production records have been reviewed.
  2. Recommend or provide solutions for quality assurance problems and verify the implementation of such solutions.

3. Assure that all quality control checks are appropriate and adequate for their intended purpose and performed correctly.
  4. Assure that changes in packaging, formulation, equipment, and manufacturing processes do not adversely impact the effectiveness or characteristics of the proficiency tests.
- C. The proficiency test manufacturer shall assure that the proficiency test samples have the purity, potency, identity, and effectiveness that it purports.

#### IV. Facilities

A. The facilities shall:

1. Provide adequate space for proficiency test preparation to preclude sample or test mix-ups of any kind.
  2. Provide adequate lighting and ventilation.
  3. Provide adequate, clean, and convenient hand-washing facilities for personnel.
  4. Provide for safe and sanitary disposal of trash and items used during the collection and processing of proficiency tests.
  5. Provide work surfaces that are clean and regularly decontaminated.
- B. There shall be written cleaning and decontamination procedures and schedules to assure that proficiency tests and related specimens are not contaminated.

#### V. Equipment

- A. Equipment used in the manufacturing of proficiency tests shall be maintained in a clean and orderly manner and kept in a location which facilitates cleaning and maintenance.
- B. All measuring equipment shall be suitable for its intended purpose and capable of producing valid results.
- C. Where maintenance and/or calibration of equipment is necessary, a written schedule for the maintenance, adjustment, and calibration of equipment shall be developed and followed.
1. Such a schedule shall be posted on or near each piece of equipment or be readily available to personnel performing maintenance.
  2. A written record shall be maintained documenting when scheduled maintenance and/or calibration activities are performed.

#### VI. Supplies

- A. All supplies and reagents used in the manufacturing of proficiency tests shall be properly stored in a safe, sanitary, and orderly manner.
- B. Representative samples of new lots of reagents and solutions shall be tested by methods described in the standard operating procedures.
- C. Supplies and reagents that do not bear an expiration date shall be stored in a manner such that the oldest is used first.

#### VII. Standard Operating Procedures

- A. Written standard operating procedures shall be maintained and shall include all steps to be followed in the identification, collection, processing, preparation, testing, storage, and distribution of proficiency tests.
- B. Standard operating procedures shall be readily available to personnel for use in the areas where the procedures are performed.

C. Specimens used in the manufacturing of proficiency tests shall meet the following guidelines:

1. Those requirements as specified in Sections 9.1.3 and 9.1.4 of the TWGDAM "Guidelines for a Quality Assurance Program for DNA Analysis," (*Crime Laboratory Digest* (1991) 18:65-69).
2. Samples shall be sufficient in quantity to allow for duplicate testing, if necessary.
3. Samples should be homogeneous and uniformly prepared.
4. Samples shall be prepared in isolation (either by time or space) from each other in order to avoid mix-ups, mislabeling, or cross-contamination.
5. Samples shall be stored and shipped under conditions which minimize degradation and damage.

D. Labels shall be correct, accurate, and legible.

**VIII. Laboratory Quality Control**

A. Production and process control procedures shall be implemented to minimize the incidence of nonconforming tests and specimens.

B. Laboratory quality control procedures shall include:

1. The establishment of scientifically sound and appropriate specifications, standards, and test procedures to assure that proficiency tests are reliable, effective, and safe. It is highly desirable that the samples used to prepare the proficiency sets be tested for the hepatitis B and human immunodeficiency (HIV) viruses. Sample sets must be clearly marked with an approved biohazard warning label in accordance with the Occupational Safety and Health Administration's Bloodborne Pathogen statute (29 CFR 1910.1030 (g) (1) (i) (A), (B), (C), and (D)).
2. Adequate provisions for monitoring the reliability and accuracy of proficiency test preparation.
3. Adequate identification and handling of all proficiency test samples to allow tracing to their original source.

**IX. Predistribution Testing**

A. The purpose of predistribution testing is to demonstrate that measurable characteristics of the proficiency test sets conform to all requirements, including design, labeling, and packaging and that the material being tested is of sufficient quantity and quality.

B. Predistribution testing shall be conducted by at least two laboratories, one of which may be the proficiency test manufacturer.

**X. Reserve Samples**

A. Ten sets, or 10 percent (whichever is less) of each manufacturing lot shall be retained by the manufacturer for possible reanalysis and comparison if circumstances dictate. These specimens shall be stored for a minimum of 1 year after the return of all results.

B. It is highly desirable that proficiency test sets be retained by the proficiency test manufacturer for archival purposes.

**XI. Records**

A. Records of the entire proficiency test manufacturing process shall be maintained so that all steps can be clearly traced.

B. Records shall be maintained in a legible and indelible manner and provide a complete history of the work performed.

- C. Records shall be maintained of all supplies and reagent lot numbers.

## XII. Distribution

- A. Proficiency test sets shall be packaged to protect them from damage, contamination, or other environmental insults during shipment to the subscribing laboratories.
- B. Proficiency test sets and the individual samples shall be clearly labeled and sealed.
- C. Proficiency test sets should be shipped according to US Department of Transportation standards in a manner that assures sample integrity.
- D. Proficiency test sets should be shipped to a designated individual(s) in the subscribing laboratory. The test provider should maintain records of shipment dates and designated recipient(s).
- E. The proficiency test manufacturer shall provide with each proficiency test set a brief description of the proficiency test design and clear instructions for how to complete the test.

## XIII. Proficiency Test Forms and Reports

### A. Subscriber's Form

1. The proficiency test manufacturer shall provide a form with each proficiency test set for the subscriber to complete.
2. This form shall include the following:
  - a. A unique identifier for each proficiency test set prepared.
  - b. A section for providing information about the procedure used by the subscribing laboratory.
  - c. A section for reporting results in a tabular form.
  - d. A section for reporting the conclusions of the analysis in accordance with the subscribing laboratory's reporting guidelines.
  - e. A section where the subscriber can comment on the design of the test or the quality of the samples contained within the proficiency test set.
  - f. The deadline for results to be returned. This should allow sufficient time for the subscribing laboratory to complete the analysis.

### B. Preliminary Report

1. The proficiency test provider shall issue a preliminary report to the test subscribers within 3 weeks of the reporting deadline.
2. This report shall describe the origin of the samples used in the test (e.g., expected matches and nonmatches).

### C. Final Report – Individual Subscriber Profile

1. The proficiency test provider is responsible for providing a report showing the individual results from each participant.
2. Each participant shall be represented by a unique code.
3. This report shall include:
  - a. A statement of expected results (e.g., matches and nonmatches).
  - b. Qualitative and quantitative results.
  - c. Appropriate statistical analysis.
  - d. Any additional comments provided by the participants.

#### D. Final Report – Comprehensive Summary

1. The proficiency test provider shall send each test subscriber a comprehensive summary report consisting of the compiled results from all subscribers. Each participant shall be represented by a unique code.
2. This summary shall be provided in a timely fashion and contain:
  - a. A description of the test design and its objective.
  - b. A description of the process used to manufacture the test samples.
  - c. The results obtained from the predistribution testing.
  - d. All results, including "inconclusive," "uninterpretable," and "no result."
  - e. Final target values based on consensus results reported by participating laboratories and predistribution testing.
  - f. An appropriate statistical analysis of all quantitative data where 10 or more sample results have been received. This information shall be displayed in both tabular and graphic formats.

#### XIV. Confidentiality of Results

- A. The results of all individual proficiency tests, including the laboratory identifying code, are to be considered confidential by the proficiency test provider and manufacturer.
- B. Results of individuals and/or laboratories **MUST** only be released to accrediting and/or certifying bodies if a signed release from the laboratory director is on file prior to the release of this information.
- C. The laboratory director or designated contact person shall be immediately notified whenever a request for their confidential results is received by the proficiency test provider/manufacturer.
- D. Records shall be maintained of all requests for confidential disclosures.

#### XV. Post-Distribution Control and Complaint Control

- A. The proficiency test provider shall develop methods to receive, acknowledge, and act on complaints or other information as provided by the proficiency test subscriber.
- B. Procedures shall be developed to acquire as much information as possible as a basis for proficiency test improvement and technical responsiveness to subscriber needs.

#### XVI. Internal Administrative Audits

- A. The proficiency test provider shall conduct annual audits of the proficiency test manufacturer to verify compliance with the quality assurance program.
- B. The audits shall be performed in accordance with written procedures by trained individuals.
- C. Audit results shall be documented in a written report.
- D. Follow-up corrective action, including reaudit of deficient matters, shall be taken when necessary.