ASB Standard 153, First Edition
2022

Standard Practices for Proficiency Testing for Forensic Toxicology Laboratories and Breath Alcohol Programs

Standard Practices for Proficiency Testing for Forensic Toxicology Laboratories and Breath Alcohol Programs

ASB Approved Xxxxx 2022

ANSI Approved Xxxxx 2022

410 North 21st Street
Colorado Springs, CO 80904

This document may be downloaded from: www.aafs.org/academy-standards-board

Foreword

Proficiency testing in forensic toxicology evaluates the overall performance, accuracy and reliability of a laboratory through the testing of specimens whose composition is unknown to the participant(s). Although strong quality control is an important part of a valid and robust forensic toxicology program, it does not replace proficiency testing. Proficiency testing enables a laboratory to assess their capabilities and uncover areas for improvement in the event that its results do not compare favorably to expected results. Examples of improvement may include increasing an assay's precision, lowering detection limits, or adding analytes to the scope of testing, consistent with the mission of the laboratory. Proficiency testing also gives a laboratory confidence that it is producing accurate results when performance is successful.

The American Academy of Forensic Sciences established the Academy Standards Board (ASB) in 2015 with a vision of safeguarding Justice, Integrity and Fairness through Consensus Based American National Standards. To that end, the ASB develops consensus based forensic standards within a framework accredited by the American National Standards Institute (ANSI), and provides training to support those standards. ASB values integrity, scientific rigor, openness, due process, collaboration, excellence, diversity and inclusion. ASB is dedicated to developing and making freely accessible the highest quality documentary forensic science consensus Standards, Guidelines, Best Practices, and Technical Reports in a wide range of forensic science disciplines as a service to forensic practitioners and the legal system.

This document was revised, prepared, and finalized as a standard by the Toxicology Consensus Body of the AAFS Standards Board. The draft of this standard was developed by the Toxicology Subcommittee of the Organization of Scientific Area Committees (OSAC) for Forensic Science.

Questions, comments, and suggestions for the improvement of this document can be sent to AAFS-ASB Secretariat, asb@aafs.org or 401 N 21st Street, Colorado Springs, CO 80904.

All hyperlinks and web addresses shown in this document are current as of the publication date of this standard.

ASB procedures are publicly available, free of cost, at www.aafs.org/academy-standards-board.

Keywords: *forensic toxicology, proficiency testing, quality assurance*

Table of Contents *(to be updated when the document is finalized)*

Standard Practices for Proficiency Testing for Forensic Toxicology Laboratories and Breath Alcohol Programs

1 Scope

This document defines the minimum scope, requirements, and frequency for proficiency testing for laboratories engaged in the following sub-disciplines: postmortem forensic toxicology, human performance toxicology (e.g., drug-facilitated crimes, driving-under-the-influence of alcohol or drugs, breath alcohol program), and general forensic toxicology (non-lethal poisonings or intoxications). This document is not intended to cover employment drug testing or court ordered toxicology (e.g., probation and parole, drug courts, child services).

2 Normative References

There are no normative reference documents. Annex A, Bibliography, contains informative references.

3 Terms and Definitions

For purposes of this document, the following definitions and acronyms apply.

3.1
analytical scope
A selection of drugs, drug metabolites and other chemicals covered in an analytical testing scheme.

3.2
breath alcohol program
An organizational structure including policies, procedures, responsibilities and resources necessary for implementing core breath alcohol activities. The Breath Alcohol Program includes, but may not be limited to, requirements or specifications for reference materials, training of operators, maintenance and calibration of instrumentation, the evidential breath alcohol test sequence, and record retention.

3.3
consensus result
A value that serves as an agreed-upon reference for comparison that is based on results of laboratories participating in the proficiency test.

3.4
interlaboratory comparison
Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.
(Source: ISO/IEC 17043:2010)

3.5
intralaboratory comparison
Organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predefined conditions. (Source: ISO 17025:2017)

3.6
nominal quantity value
Rounded or approximate value of a characterizing quantity of a measuring instrument or measuring system that provides guidance for its appropriate use. (Source: JCGM 200)

3.7
proficiency testing
Evaluation of participant performance against pre-established criteria by means of interlaboratory comparison.
(Source: ISO/IEC 17043:2010)

3.8
proficiency testing round
Single complete sequence of distribution of proficiency test items, and the evaluation and reporting of the results to the participants.
(Source: ISO/IEC 17043:2010)

3.9
proficiency testing scheme
Proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection.
(Source: ISO/IEC 17043:2010)

4 Proficiency Test Requirements

4.1 A forensic toxicology laboratory shall participate in proficiency testing.

4.2 Forensic toxicology laboratories shall use externally prepared proficiency tests from proficiency test providers accredited to ISO/IEC 17043 when available and appropriate. Results shall be submitted as specified by the proficiency test provider.

4.3 When externally prepared proficiency tests from accredited providers are not available, a laboratory shall participate in intralaboratory or interlaboratory comparisons. While intra-/interlaboratory comparisons may not meet the definition of proficiency tests, they are valuable for laboratories to assess the reliability of test results.When blood alcohol (ethanol) testing is included in a laboratory's analytical scope of testing, the laboratory shall have a proficiency testing program to evaluate their capabilities in this analysis. Requirements of the proficiency tests include the following.

a) Specimens shall be prepared in whole blood, plasma, serum, or other matrix that represents the casework of the laboratory. Synthetic or animal-based matrices may be used. At a minimum, the most common matrix tested in the laboratory shall be included in the proficiency testing scheme.

b) Ethanol testing shall be quantitative.

c) The volatiles acetone, isopropanol and methanol shall be included in the proficiency testing scheme when included in the laboratory's analytical scope of testing.

d) At a minimum, testing shall be performed by the laboratory on two different rounds of four specimens per calendar year (see Table 1). The two rounds should be separated by several months throughout the calendar year.

Alternative testing paradigms are appropriate if the total number of proficiency specimens per calendar year is at least eight and no fewer than two rounds of tests are provided. For example, three rounds of three specimens spread throughout the calendar year would be acceptable, as would four rounds of two. Multiple proficiency test schemes may be combined to achieve this requirement.

4.4 When a breath alcohol program includes breath alcohol calibration or the management of calibrated breath alcohol instrumentation, the laboratory shall participate in a proficiency testing program to evaluate their capabilities. Requirements of the proficiency tests include the following.

a) Specimens shall be prepared in gas phase or as simulator solutions.

b) Ethanol testing shall be quantitative.

c) At a minimum, testing shall be performed by the breath alcohol program on two different rounds of four specimens per calendar year (see Table 1). The two rounds should be separated by several months throughout the calendar year.

Alternative testing paradigms are appropriate if the total number of proficiency specimens per calendar year is at least eight and no fewer than two rounds of tests are provided. For example, three rounds of three specimens spread throughout the calendar year would be acceptable, as would four rounds of two. Multiple proficiency test schemes may be combined to achieve this requirement.

4.5 When drugs, drug metabolites and other chemicals are included in a laboratory's analytical scope of testing, the laboratory shall have a proficiency testing program to evaluate their capabilities in these analyses. Requirements of the proficiency tests include the following.

a) Specimens shall be prepared in whole blood, serum, urine, or another matrix that represents the casework of the laboratory. Synthetic or animal-based matrices may be used. At a minimum, the most common matrix tested in the laboratory in casework shall be subject to proficiency testing.

b) The proficiency testing program should include alternative matrices (e.g., oral fluid or hair), when included in the laboratory's scope of routine testing.

c) Testing shall be qualitative and/or quantitative, depending on the scope of testing performed by the laboratory on routine casework.

d) Laboratories shall perform proficiency testing that challenges the scope and sensitivity of testing (see ASB Standards 119, 120, 121). Representative analytes from general drug classes shall be included in the proficiency test scheme.

e) At a minimum, testing shall be performed by the laboratory on two different rounds of four specimens per calendar year. The two rounds should be separated by several months throughout the calendar year (see Table 1).

Alternative testing paradigms are appropriate if the total number of proficiency specimens per calendar year is at least eight and no fewer than two rounds of tests are provided. For example, three rounds of three specimens spread throughout the calendar year would be acceptable, as would four rounds of two. Multiple proficiency test schemes may be combined to achieve this requirement.

Table 1—Overview of Proficiency Test Requirements

Type of Proficiency Testing	Minimum # Rounds/Year	Minimum # Specimens/Year
Blood Alcohol	2	8
Breath Alcohol Program	2	8
Drugs, Metabolites, and Other Chemicals	2	8

4.6 For a testing laboratory, the proficiency test specimens shall be subjected to the same tests/scheme as routine casework that is analyzed in the laboratory.

4.7 For a calibration laboratory, the proficiency test shall be performed on an instrument that has been appropriately calibrated.

4.8 Proficiency test results shall be evaluated by the laboratory.

4.8.1 The laboratory shall investigate and document the cause(s) of any instance in which a positive result is reported for an analyte not present in the test specimen (a false positive result).

4.8.2 The laboratory shall investigate and document the cause(s) of any instance in which a negative result is reported for an analyte present in the test specimen and within the scope and sensitivity of the laboratory's routine testing (a false negative result).

4.8.3 A laboratory shall have predefined criteria for acceptability of quantitative results in proficiency tests.

4.8.3.1 The laboratory's predefined acceptability criteria for blood alcohol and breath alcohol shall in no instance be less stringent than as follows:

a) Blood alcohol

- ±10% of the consensus result or ±2 standard deviations of the consensus result (whichever is greater)

b) Breath alcohol

- For breath alcohol consensus-based proficiency tests:
  - ±10% of the consensus result or ±2 standard deviations of the consensus result (whichever is greater)
- For breath alcohol proficiency tests consisting of known, traceable reference material:
  - ±10% of a reported nominal quantity value or ±0.005 g/210L (whichever is greater)

4.8.3.2 Acceptability criteria for drugs, drug metabolites and other chemicals may be defined either by the proficiency test provider and adopted by the laboratory or defined directly by the laboratory. Recommended quantitative acceptability criteria for this type of testing follows.

a) Drugs, drug metabolites and other chemicals

— ±20% of the consensus result or ±2 standard deviations of the consensus result (whichever is greater)

4.8.4 The laboratory shall investigate and document the cause(s) of any unacceptable quantitative performance. The investigation shall include evaluating and documenting the risk of having reported inaccurate results to the customer.

4.9 The laboratory shall annually evaluate their proficiency testing program. The evaluation shall be documented.

4.9.1 The laboratory should include the following questions in their annual review of their proficiency testing program.

a) Did the past year's proficiency test(s) challenge the laboratory's scope and sensitivity?

b) Was the number of drugs[a] provided in the proficiency specimens over the past year sufficient?

1) A minimum of 10 different drugs per year may be considered appropriate for impaired driving testing. See ANSI/ASB Standard 120 for further information on scope of testing for impaired driving investigations.

2) A minimum of 10 different drugs per year may be considered appropriate for drug-facilitated crime testing. See ANSI/ASB Standard 121 for further information on scope of testing for drug-facilitated crime investigations.

3) A minimum of 20 different drugs per year may be considered appropriate for medicolegal death investigation testing. See ANSI/ASB Standard 119 for further information on scope of testing for medicolegal death investigations.

c) Is there a popular drug or drug class encountered in routine casework that has not been included in proficiency specimens?

4.9.2 If review of the proficiency testing program determines that it has not met the needs of the laboratory, changes shall be made to the program. Such changes may include selecting a new proficiency test provider and/or supplementing the program with intra-/interlaboratory comparisons.

4.10 Documentation of proficiency testing and other intra-/interlaboratory comparisons shall include the laboratory's supporting data, test results, provider reports, and any documentation of follow-up. Documentation shall be maintained for a minimum of seven years.

[a] In this section, drug refers to primary analyte and/or metabolite. For example, if cocaine and metabolites were identified in one specimen, that would count as one drug.

Annex A
(informative)

Bibliography

The following bibliography is not intended to be an all-inclusive list, review, or endorsement of literature on this topic. The goal of the bibliography is to provide examples of publications addressed in the standard.

1] ISO/IEC 17043:2010 *Conformity Assessment - General Requirements for Proficiency Testing*.[b]

2] ISO/IEC 17025:2017 *General Requirements for the Competence of Testing and Calibration Laboratories*.[c]

3] Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)* (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200)

4] ANSI/ASB Standard 119, *Standard for the Analytical Scope and Sensitivity of Forensic Toxicology Testing for Medicolegal Death Investigations,* First Edition 2021.[d]

5] ANSI/ASB Standard 120, *Standard for the Analytical Scope and Sensitivity of Forensic Toxicology Testing in Impaired Driving Investigations,* First Edition 2021.[d]

6] ANSI/ASB Standard 121, *Standard for the Analytical Scope and Sensitivity of Forensic Toxicology Urine Testing in Drug-Facilitated Crime Investigation,* First Edition 2021. [d]

[b] Available from: https://webstore.ansi.org/Standards/ISO/ISOIEC170432010
[c] Available from: https://webstore.ansi.org/Standards/ISO/ISOIEC170252017
[d] Available from: https://www.aafs.org/academy-standards-board

Academy Standards Board
410 North 21st Street
Colorado Springs, CO 80904

https://www.aafs.org/academy-standards-board