MINIMUM REQUIREMENTS FOR DNA COLLECTION, ANALYSIS, AND INTERPRETATION

A document for emerging laboratories

International Forensic Strategic Alliance

October 2014

IFSA

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INTERNATIONAL FORENSIC STRATEGIC ALLIANCE

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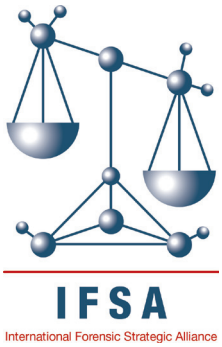
IFSA MRD 2



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INTRODUCTION

The International Forensic Strategic Alliance (IFSA) has developed this document to be minimum requirements which will enable emerging forensic providers in developing countries to produce scientific services to the Criminal Justice System.

The purpose of this document is to establish a baseline or starting point that must be followed in order to achieve reliable results. Forensic providers should build on this foundation and strive to continually improve the quality of services provided.

This document describes the minimum requirements for DNA collection, analysis, and interpretation. It addresses the following framework:

1. Competence of Personnel.
2. Equipment and Consumables.
3. Collection, Analysis, Interpretation, Reporting.
4. Procedures, Protocols, Validation.
5. Quality Management.

Note: This document does not apply to laboratories performing Rapid DNA Analysis or modified Rapid DNA Analysis. The next version of the DNA Minimum Requirements Document (forthcoming in 2015-2016) will address emerging DNA technologies such as the aforementioned.

FOREWORD

The International Forensic Strategic Alliance (IFSA) is a multilateral partnership between the six regional networks of operational forensic laboratories:

- the American Society of Crime Laboratory Directors (ASCLD)
- the European Network of Forensic Science Institutes (ENFSI)
- the Senior Managers of Australian and New Zealand Forensic Laboratories (SMANZFL)
- the Academia Iberoamericana de Criminalística y Estudios Forenses (AICEF)
- the Asian Forensic Sciences Network (AFSN)
- the Southern Africa Regional Forensic Science Network (SARFS)

and works closely with its two strategic partners, United Nations Office on Drugs and Crime (UNODC) and INTERPOL.

IFSA recognises the importance of a quality management framework in forensic laboratories to provide quality and standardised results, be it procedures undertaken in the field or in the laboratory.

In February 2012, at the special IFSA meeting hosted by UNODC and convened in Vienna to discuss the needs of the emerging forensic laboratories in developing countries, a decision was taken to create a set of minimum requirement documents (MRD) filling the gap in recommendations available for the current management of these laboratories.

The first series of three documents in the specific areas of identification of seized drugs, DNA analysis, and crime scene investigation have been created. These documents have focused on the critical quality areas, using simple terms and illustrations as well as a glossary to guide the users through the important concepts of the documents.

These documents are meant to act as a start-up guide for emerging forensic laboratories to quickly establish their quality management system and scientific/technical capabilities. Once achieved, the laboratories should continue to build on this foundation and strive to continually improve the quality of services through undergoing accreditations to established standards.

In the drafting of these documents, scientific working groups and experts from the six regional forensic science networks, as well as IFSA strategic partners, made valuable contributions during the various rounds of consultation. The final MRD documents presented in this series would not be possible without the involvement of all.

It is IFSA's hope that these documents will play an important role for emerging forensic laboratories in their journey towards building quality forensic services.

IFSA Board

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1 COMPETENCE OF PERSONNEL

All laboratory staff must have a clear understanding of their duties and responsibilities and should fulfil these at all times according to a code of ethics (see the examples in the footnote below) adopted by the laboratory.

This section recommends minimum education and training required for laboratory staff to conduct DNA analysis[1].

1.1 EDUCATION

Technician: Higher education requirements should be based on the nature and complexity of tasks to be performed.

Analyst: University degree with a strong emphasis in biological science including coursework in statistics. Laboratory personnel shall have the education, training and experience commensurate with the examination conducted in the laboratory.

1.2 TRAINING

The laboratory should have a documented training plan for new staff or new tasks, documenting the required standards of performance, competency and assessment plan. The assessment can be done, for example, by fulfilled training plans or the analysis of unknown samples. The training should be delivered by experienced staff.

The laboratory's training program shall include a training manual covering all DNA analytical procedures that the analyst/technician will employ in the course of casework, as well as on the code of ethics.

The training program shall teach and assess the technical skills and knowledge required to perform DNA analysis. Where possible, the training should be augmented by participation to external courses or workshops.

A program for continued education (conference attendance, webinars, review of scientific literature) should be established as an extension of credentialing and to ensure analysts stay abreast of technical developments.

Staff should be assessed as competent prior to assuming independent casework. A competency test will ensure proper skills and knowledge was acquired during training.

Examples of Code of Ethics adopted by regional forensic science networks:
- The American Society of Crime Laboratory Directors (ASCLD) – www.ascld.org
- The European Network of Forensic Science Institutes (ENFSI) – www.enfsi.eu
- The Senior Managers of Australian and New Zealand Forensic Laboratories (SMANZFL) – www.anzfss.org
- The Academia Iberoamericana de Criminalística y Estudios Forenses (AICEF) – www.aicef.net
- The Asian Forensic Sciences Network (AFSN) – www.asianforensic.net

Training and competency tests should be documented and records retained according to guidelines established by the laboratory.

All analyst/technician(s), regardless of previous experience shall complete a competency test(s) covering the routine DNA methodologies to be used prior to participating in independent DNA analysis. All analyst/technician(s) shall participate in ongoing proficiency testing, and the results recorded.

2 EQUIPMENT AND CONSUMABLES

2.1 FACILITIES

Evidence receipt and storage shall be separated from the analytical areas.

The laboratory shall have appropriate utilities such as uninterrupted electricity power supply, air conditioning, air-tight windows, purified water, and adequate separated space and plumbing. Negative pressure ventilation shall be maintained in the analytical area.

Biological specimens shall be stored in an area protected from bacterial contamination, cross-contamination, heat, and sunlight. Some biological samples may require refrigeration or freezing. Refrigerators and freezers' temperatures shall be monitored to prevent sample degradation and the laboratory shall specify an acceptable range of temperature for this equipment.

The facility shall be equipped with refrigerators and freezers dedicated to the storage of consumables. Biological samples shall not be stored with consumables.

Analytical and sample storage areas shall be secured and access controlled.

2.2 EQUIPMENT

The laboratory shall use equipment that is suitable for the methods employed by the laboratory.

At a minimum, the laboratory must have a procedure for conducting performance checks and calibration of all equipment deemed critical.

Examples of critical equipment include but are not limited to:

- Thermal cyclers including quantitative Polymerase Chain Reaction (PCR);
- Thermal cycler temperature verification systems;
- Electrophoresis detection systems;
- Robotic systems;
- Genetic Analyzers; and
- Mechanical pipettes

The laboratory shall have a schedule and follow a documented program to ensure that instruments and equipment are properly maintained, serviced, calibrated and verified. Performance of equipment shall be monitored and records kept of performance checks.

Only trained staff shall operate the instruments. The manufacturer's operation manual and other relevant documentation, for example, Standard Operating Procedures (SOP) for each equipment shall be readily available in the laboratory. Methods used on the equipment shall be validated prior to application on casework.

The laboratory shall have and follow a written procedure for monitoring, cleaning, and decontaminating facilities and equipment. It is the responsibility of laboratory management to design and implement appropriate cleaning techniques and protocols.

2.3 CONSUMABLES

The laboratory shall use reagents and consumables that are suitable for the methods employed. This includes but is not limited to: 'PCR grade', 'DNAse free', 'DNA free'.

Commercial reagents shall be labeled with the identity of the reagent and the expiration date as provided by the manufacturer or as determined by the laboratory.

In-house reagents shall be labeled with the identity of the reagent, the date of expiration and the identity of the individual preparing the reagent.

The laboratory shall identify critical reagents and evaluate them prior to use in the DNA analysis. These critical reagents shall include, but are not limited to, the following:

- Test kits for performing DNA extraction, quantitative PCR and genetic typing; and
- Proteinase, thermo-stable DNA polymerase, primer sets and allelic ladders, used for genetic analyses that are not tested as test kit components.

All consumables must be stored at appropriate temperatures as recommended by manufacturer. Different reagents within the same kit may need to be stored at different temperatures. All reagents prepared in-house must be stored at the appropriate temperature and shall have an expiration date to ensure they perform as expected.

Reagents shall be protected from direct sunlight.

3 COLLECTION, ANALYSIS, INTERPRETATION AND REPORTING

3.1 COLLECTION

This section addresses collection of DNA evidence from items submitted to the laboratory. Collection of DNA evidence at crime scenes is covered under the Crime Scene Investigation Minimum Requirements publication and is applicable to a laboratory that also collects and processes crime scene evidence.

The laboratory shall have records of requests for analysis and the items of evidence submitted. A unique identifier shall be assigned to each exhibit. Should there be significant discrepancy between the submission documentation and physical evidence, the client must be informed as soon as possible and the discrepancy shall be recorded with the case notes.

A system to document a chain of custody for the evidence shall be established in the laboratory. Only authorised staff shall have access to exhibits.

Each exhibit shall be properly stored to maintain the integrity of the evidence.

The following should be ensured:

- Individuals processing biological evidence must wear proper Personal Protective Equipment (PPE) such as lab coats, disposable gloves, and masks to limit the potential for contamination;
- Examination of evidence for the presence of biological fluids such as blood or semen should be conducted utilizing biochemical, microscopic or immunological techniques;
- Evidence items are examined in a clean room;
- Activity in this room is limited to examination of biological material;
- Surfaces are decontaminated with a 10% household bleach solution or equivalent prior and after examination of each item of evidence;
- If possible, disposable bench paper is used to cover surfaces;
- Items are inventoried and marked with a unique identifier; and
- Examination is documented and notes are retained.

Items of evidence are examined separately in time, space or examiner to avoid cross-contamination.

If crime and reference samples are processed in the same area, the following shall apply to minimize the risk of contamination:

- Have designated separate benches and equipment for crime and reference sample testing;
- Crime and reference samples must never be processed at the same time;
- Crime samples shall be processed first, before the reference samples; and
- All laboratory benches and equipment are to be thoroughly cleaned when switching from crime to reference sample testing, or vice versa.

3.2 ANALYSIS

DNA analysis is a complex process of sample extraction, quantitation (optional), amplification, electrophoresis, and interpretation.

DNA analysis utilizes the properties of electrophoresis which can be obtained by flat gel-based methods or capillary based methodologies.

Types of DNA analysis include:

- Autosomal STR markers;
- Y-STR markers;
- X-STR markers;
- Mitochondrial markers; and
- Other markers used for ancestry and/or phenotypic characteristics.

Sample extraction

The laboratory shall have separated space for DNA extraction and utilize procedures for the isolation of DNA for forensic analysis. Extraction procedures shall include:

- Extraction methods for single source stains; and
- Differential extraction methods for semen containing stains (sexual assault related samples).

All extraction methods should contain a reagent blank control which is carried through the process of quantitation, amplification and interpretation.

Quantitation

DNA quantitation of human DNA should be performed on samples prior to amplification. This step could be skipped for reference samples (for example a set volume of liquid blood or use of a punch or cut-out sample of a dried stain).

All quantitation procedures will contain standards to determine the quantitative or qualitative value of the isolated DNA.

Amplification

All samples should be amplified utilizing developmentally validated commercial or in-house DNA Typing kits. It is noted however that in-house kits shall be subjected to developmental validation procedures.

In order to utilize available forensic DNA databases, it is recommended that commercially available kits selected should contain at a minimum the recommended INTERPOL Standard Set of Loci (ISSOL)[2], CODIS Core Loci; or loci that are compatible to the database used in the region.

Positive and negative controls as well as a reagent blank must be amplified with the evidence items.

All controls (amplification positive, negative and any reagent blanks) must be carried out through analysis and interpretation.

The reagent blank shall be amplified in the most sensitive volume of the extraction set of samples.

The negative control shall be amplified in the highest volume allowable with the amplification kit.

Further analysis of a sample can be terminated based on a quantitation threshold with the notion that this sample will not yield an interpretable DNA profile. However this assessment has to be supported by a validation study.

Pre and post amplification processes should be conducted in physically separate areas to avoid sample contamination.

Equipment such as pipettes should be dedicated to a specific area.

Electrophoresis

At least one allelic ladder shall be run with each set of samples.

The reagent blank and negative control shall be run under the most sensitive conditions, (i.e. injection time and/or voltage). The amplicon volume of both controls shall also satisfy the most sensitive conditions.

Quality Control

The sensitivity of methods for DNA analysis requires the following safeguards against contamination:

- Pre and post amplification processes must be conducted in physically separate areas to avoid sample contamination.
- Equipment such as pipettes shall be dedicated to a specific area.
- Work surfaces and instruments used in the examination of items shall be cleaned before contact with evidence, between evidence items, and after evidence processing is complete.
- It is common practice for Glassine paper, Kimwipes®, butcher paper, or Benchkote® paper to be placed on the benchtop while processing evidence to act as a barrier. The paper shall be changed and the benchtop cleaned between items.
- Centrifuges, thermal cycler, tube racks, pipettes and any other equipment deemed appropriate shall be cleaned before and after each use.
- Instruments such as forceps, scissors, scalpels, and tube openers shall be cleaned just prior to use. Some laboratories purchase sterile disposable instruments. These shall be opened just prior to sample processing and discarded after one use.
- Cleaning shall be done with a 10% bleach solution or a commercially available reagent such as Cidex® Plus which will minimize potential risks of DNA contamination.
- If an item is cleaned with bleach, it must be rinsed with purified water or alcohol to prevent the build-up of sodium hypochlorite crystals. Instruments or equipment cleaned with bleach shall be rinsed to avoid corrosion.

- The bench and equipment must be cleaned between the analysis of EVERY exhibit, even when analyzing related items (e.g. multiple items of clothing from the same person).
- The creation of a staff elimination database is highly recommended as an added quality assurance procedure.

3.3 INTERPRETATION

The laboratory shall have and follow written guidelines for the interpretation of data to include all amplification positive and negative controls as well as reagent blanks.

Laboratories should have and follow written guidelines for DNA mixture interpretation that address major and minor contributors, inclusions, exclusions and policies for reporting results and statistics[3].

The statistical interpretation shall be based on:

- Ethnic Population Database. The laboratory should follow recommendations by expert groups such as the International Society for Forensic Genetics (ISFG)[4] or the Scientific Working Group for DNA Analysis Methods (SWGDAM)[5] for the minimum number of profiles to be included in the database. This number will vary depending on the type of marker analyzed.
- Statistical calculations derived from a relevant documented population database appropriate for the calculation.

A laboratory performing genetic analysis such as Y-chromosomal[6] or mtDNA typing[7] shall have and follow documented statistical interpretation guidelines specific for such testing.

3.4 REPORTING

The laboratory shall have written procedures for recording observations and test results.

The laboratory shall maintain all analytical results used to support report conclusions. All analytical results used to support the conclusions in the report shall be retained.

Comprehensive documentation shall be maintained for peer review.

Reports shall include:

- Name of the analyst;
- Name of the organization;
- Date issued;
- Unique case identifier;
- Description of evidence examined;
- Disposition of evidence;
- Methodology used;
- Loci or amplification system;
- Results of analysis; and
- Conclusions encompassing a quantitative or qualitative interpretation statement. The significance of a match should be associated to a statistical statement.

Signature of the individual responsible for the content of the report (secure electronic signatures are acceptable).

Reports may only be issued by personnel who have been experienced, appropriately trained and have been authorized to do so.

Peer review

The laboratory shall conduct and document administrative and technical review of case records according to a written policy. This review will ensure that all conclusions reached and supporting data are consistent with laboratory policy and guidelines.

Casework documentation shall contain sufficient information such that the reviewer is able to evaluate case notes and interpret data. Before a report is released it should go through a technical and administrative review.

In the event where the staff-in-charge of the case does not agree with the opinion of the reviewer, the matter will be referred to higher authority who is competent to determine the disputed issue.

Technical review shall include the following at a minimum:

- Case notes, worksheets and electronic data;
- DNA types (allele calls) to verify interpretation based on documented interpretation guidelines;
- All DNA profiles to ensure proper inclusions and exclusions;
- All inconclusive results;
- All controls, including internal lane standards and allelic ladders;
- Any statistical analysis if applicable;
- Chain of custody and disposition of all evidence; and
- Review of final report's content to ensure that all results and conclusions are supported by documented data.

Technical review shall be documented in the case record. Technical review shall be conducted by an individual qualified in the methodology used.

Administrative review shall include:

- Any clerical errors in the final report;
- Compliance with section 3.4; and
- Chain of custody and disposition of all evidence.

Case records

The laboratory shall have procedures for retention, control, confidentiality, and release of case records.

3.5 DATABASES

Numerous forensic databases have been established globally to solve cold cases and ensure 'safe' convictions. Since legislation/regulations pertaining to what data can be entered in a database differ between different countries, this document cannot address standards pertaining to DNA databases.

Recommendations and best practices have been published by the INTERPOL DNA Monitoring Expert Group for the establishment of a national DNA database[8]. The ENFSI DNA Working Group has published a document on the review and recommendations of DNA Database management[9].

4 PROCEDURES, PROTOCOLS AND VALIDATION

4.1 PROCEDURES AND PROTOCOLS

The laboratory shall have and follow analytical protocols and procedures. These procedures should include biological evidence identification, sample preparation, extraction methods, quantitation, amplification, analysis and interpretation.

Protocols and procedures shall be documented, tracked, and controlled. In-house developed procedures shall be tested prior to application to demonstrate they are fit-for-purpose.

All protocols and procedures must specify reagents and controls. Procedures should be a step-by-step process sufficiently detailed to ensure uniformity and consistency of testing and analysis of data/results.

If methods are changed at any time, the date that the change took place must be recorded, so that for every sample, it is clear which method has been used in the processing of that sample.

4.2 VALIDATION

All exhibit analysis protocols and procedures shall be validated to demonstrate their reliability and efficacy. In-house equipment shall be used for validation studies. Staff performing validations shall be competent in the technologies used.

General guidelines:

- Select staff responsible for the validation study from beginning to end;
- Read peer-reviewed publications and manufacturer's recommendations;
- Draft a validation plan based on the aforementioned. The plan shall include reagents, samples, and equipment needed, and the testing to be conducted;
- Select appropriate controls;
- Document the validation studies;
- Summarize results;
- Draft SOP and interpretation guidelines based on validation results; and
- Draft a training manual and competency test for staff.

Staff shall be trained and pass a competency test prior to using the method on casework. The training and competency test shall be documented.

The following studies shall be performed for DNA analysis:

- Reproducibility (study using human DNA controls);
- Precision and accuracy (study using human DNA controls);
- Sensitivity; and
- Mixtures using case-type samples.

In addition, analytical thresholds shall be determined for the instrumentation used:

- Limit of detection;
- Dynamic range;
- Stochastic threshold; and
- Stutter range.

Contamination checks shall be performed with negative controls (blanks).

The laboratory must have a documented relevant population distribution data which should include the distributions for the locus or loci obtained from relevant populations.

In-house developed databases should be tested for independence.

5 QUALITY MANAGEMENT

The laboratory shall establish, follow and maintain a documented quality management system that is appropriate to the testing activities and is equivalent to what is required by these minimum requirements.

The laboratory shall document, maintain and follow a procedure regarding document retention that specifically addresses:

- Proficiency tests;
- Analytical results;
- Sample/Exhibit continuity records;
- Sample receipt;
- Processing records;
- Sample retention;
- Corrective action;
- Audits;
- Training records;
- Continuing education;
- Court testimony monitoring; and
- Educational background (school, major etc).

The quality system as applicable to DNA shall be reviewed annually and documented.

In order to fully support a quality management program, the managerial staff must have the authority and resources needed to discharge their duties and in order to meet the minimum requirements as stated in this document.

This quality management program must specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the validity of the DNA analysis.

6 GLOSSARY

The following glossary is not to be considered an exhaustive list of terminology encountered in DNA testing however these terms are widely utilized in the forensic DNA community.

Accuracy	The degree of conformity of a measured quantity to its actual (true) value.
Administrative Review	A procedure used to check for consistency with laboratory policy and for editorial correctness. This review may be performed by non-technical lab staff.
Allele	One of two or more alternative forms of a gene. A single allele for each locus is inherited separately from each parent.
Allelic Dropout	Failure to detect an allele within a sample or failure to amplify an allele during PCR.
Amplification	Increasing the number of copies of a desired DNA sequence.
Analyst	An employee that has successfully completed the laboratory's training requirements for sample analysis, passed a competency test, and has entered into the proficiency testing program. This individual conducts and/or directs the analysis of samples, interprets data and (if applicable) reaches conclusions.
Analytical Procedure	An orderly step-by-step procedure designed to ensure operational uniformity and to minimize analytical drift.
Analytical Procedures Manual	A document containing the analytical procedures used in the laboratory.
Annually	Occurs once per calendar year.
Assessment	Systematic, independent examinations to determine whether actual activities comply with planned activities are implemented effectively, and achieve effectiveness. Assessments usually include a comparison of actual results to expected results.
Calibrate	To set measurement equipment against a known standard.
Calibration	The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system or values represented by a material and the corresponding known values of a measurement.
Capillary Electrophoresis	DNA samples are placed in a small, thin (capillary) tube filled with gel, which is then subject to a high voltage current that separates the strands by length.
Case Notes	The documentation of procedures, standards, controls and instruments used, observations made, results of tests performed, charts, graphs, photographs, and other documents generated which are used to support the examiner's conclusions.

Casework Reference Sample	Biological material obtained from a known individual and collected for purposes of comparison to forensic samples.
Competence	Ability to perform a specific task according to procedures.
Competency	The demonstration of technical skills and knowledge necessary to perform DNA analysis successfully.
Competency Test	The evaluation of a person's ability to perform work in any functional area prior to the performance of independent work.
Competent	Ability to achieve the correct result. Accurate and precise. Properly or sufficiently qualified or capable. Capable of performing an allotted or required function. Legally qualified or fit to perform an act.
Compliance	To comform.
Contamination	The unintentional introduction of exogenous DNA into a DNA sample or PCR reaction.
Continuing Education	An educational activity (such as a class, lecture series, conference, seminar or short course) that is offered by a recognized organization or individual that brings participants up-to-date in their relevant area of knowledge.
Control Sample	A standard of comparison for verifying or checking the findings of an experiment.
Controls	Tests performed in parallel with experimental samples and designed to demonstrate that a procedure worked correctly.
Critical Equipment or Critical Instruments	Those that require calibration prior to use and periodically thereafter.
Critical Reagent	Determined by empirical studies or routine practice to require testing on established samples before use in order to prevent unnecessary loss of sample.
Cycle	The PCR cycle consists of three steps: 1) denaturation of the template, 2) annealing of primers to complementary sequences at an empirically determined temperature, and 3) extension of the bound primers by a DNA polymerase.
Database	A collection of related information about a subject matter organized in a useful manner that provides a base or foundation for procedures such as retrieving information, drawing conclusions, and making decisions.
Developmental Validation	The acquisition of test data and determination of conditions and limitations of new or novel DNA methodology for use on forensic and/or casework reference samples.
Deviation	An unexpected or unplanned or undesirable event.
Discrepancy	Any reported result that differs from the consensus results. Discrepancies may be classified as administrative, systematic, analytical or interpretive.

DNA (discipline)	The identification and comparison of deoxyribonucleic acid (DNA) from biological samples.
DNA Profile (type)	The genetic constitution of an individual at defined locations (also known as loci) in the DNA. A DNA profile (type) derived from nuclear DNA typically consists of one or two alleles at several STR loci.
Document (noun)	Written or electronically generated information and work instructions. For example: manual, procedures, forms, worksheets.
Equipment	A durable item, instrument, or device used in a process or procedure.
Establish	To define, document, and implement.
External Proficiency Testing	A test program managed and/or controlled independent of the laboratory system.
Evidence	Original item received by the submitting agency.
Evidence Sample	Also known as Questioned sample.
Exclusion	A conclusion that eliminates an individual as a potential contributor of DNA obtained from an evidentiary item based on the comparison of known and questioned DNA profiles (or multiple questioned DNA profiles to each other).
Facility	A location or operational area within an organization.
Forensic DNA Analysis	The process of identification and evaluation of biological evidence in criminal matters using DNA technologies.
Forensic Sample	A biological sample originating from and associated with a crime scene.
Genetic System	Each locus analyzed and reported by a laboratory.
Genotype	Allele calls generated from analysis.
Goal	A statement of purpose defining the mission of an organization.
Guidelines	A set of general principles used to provide direction and parameters for decision making.
Heterozygote	An individual having different alleles at a particular locus; usually manifested as two distinct peaks for a locus in an electropherogram.
Homozygote	An individual having the same (or indistinguishable) alleles at a particular locus; manifested as a single peak for a locus in an electropherogram.
Hypothesis	The relationship that is to be evaluated.
Inclusion	A conclusion for which an individual cannot be excluded as a potential contributor of DNA obtained from an evidentiary item based on the comparison of known and questioned DNA profiles (or multiple questioned DNA profiles to each other).
Inconclusive/ Uninterpretable	An interpretation of conclusion in which the DNA typing results are insufficient for comparison purposes.

Inspect	To measure, examine, or test one or more characteristics of a product or service and compare results with specific requirements.
Internal Proficiency Testing Program	Proficiency testing program whose management and control is within the laboratory.
Internal Validation	The accumulation of test data within a laboratory to demonstrate that established method and procedures perform as expected in the laboratory.
Known Sample	Biological material whose identity or type is established; biological material for which the identity of the donor is established and used for comparison purposes.
Label	An inscription affixed for identification.
Laboratory	A facility (1) employing at least two full-time employees who are qualified DNA analysts and (2) having and maintaining the capability to perform the DNA analysis of forensic samples and/or casework reference samples at that facility.
Limited Access	Access limited to personnel authorized by the laboratory director.
Locus (loci)	The physical location of a gene on a chromosome. Any one of the possible alleles for a gene may be present at the gene's locus.
Material	A supply item used in the manufacturing process.
Method	The course of action or technique followed in conducting a specific analysis or comparison leading to an analytical result.
Methodology	Used to describe the analytical processes and procedures used to support a DNA-typing technology: for example, extraction methods (manual v. automated), quantification methods (slot blot, fluorometry, real-time), typing test kit, and platform (capillary electrophoresis, real-time gel and end-point gel systems).
Mixture	A DNA typing result originating from two or more individuals.
Negative Amplification Control (NEG)	Used to detect DNA contamination of the amplification reagents. This control consists of only amplification reagents without the addition of template DNA.
Objective	A measurable, definable accomplishment that furthers the goals of the organization.
Organization	An institution, or part thereof, that has its own functions and executive management.
Platform	The type of analytical system utilized to generate DNA profiles, such as capillary electrophoresis, real-time gel, and end-point gel instruments or systems.
Policy	A guiding principle, operating practices, or plans of action governing decisions made on behalf of an organization.
Polymerase Chain Reaction (PCR)	An enzymatic process by which a specific region of DNA is replicated during repetitive cycles. See also cycle.

Positive Amplification Control (POS)	An analytical control sample that is used to determine if the PCR performed properly. This control consists of amplification reagents and a known DNA sample.
Precision	Characterizes the degree of mutual agreement among a series of individual measurements, values and/or results.
Procedure	The manner in which an operation is performed; a set of directions for performing an examination or analysis - the actual parameters of the methods employed.
Process	A set of related tasks and activities that accomplish a work goal, i.e., that transforms input into output products and services.
Product	Tangible result of a process or procedure.
Proficiency Tests	Tests to evaluate the competence of analysts and the quality performance of a laboratory; in open tests, the analysts are aware that they are being tested; in blind tests, they are not aware. Internal proficiency tests are conducted by the laboratory itself; external proficiency tests are conducted by an agency, independent of the laboratory being tested.
Profile	See Genotype.
Qualification (Qualified)	With respect to individuals, the aspects of an individual's education, training, and experience that are necessary to successfully meet the requirements of a position. Specifically for equipment, verification that specified attributes required to accomplish the desired task has been met.
Quality	Characteristics of a product or service that bear on its ability to meet requirements, including those defined during agreement review.
Quality Assurance	Those planned and systematic actions necessary to provide sufficient confidence that a laboratory's product or service will satisfy given requirements for quality.
Quality System	The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. Includes all activities that contribute to quality, directly or indirectly.
Quantitative PCR	A method of determining the concentration of DNA in a sample by use of the polymerase chain reaction.
Reagent	A substance used because of its chemical or biological activity.
Reagent Blank Control (RB, also Extraction Negative Control)	An analytical control sample that contains no template DNA and is used to monitor contamination from extraction to final fragment or sequence analysis. This control is treated the same as, and parallel to, the forensic and/or casework reference samples being analyzed.
Reliability	Possessing the quality of being dependable. May refer to personnel, materials, or equipment.
Review	An evaluation of documentation to check for consistency, accuracy and completeness.

Service	The performance of those adjustments or procedures specified which are to be performed by the user, manufacturer, or other service personnel in order to ensure the intended performance of instruments and equipment.
Shall	A term used to indicate a requirement.
Standard	A statement which describes an acceptable level of performance, excellence, or attainment in that particular activity.
Stochastic Threshold	The peak height value above which it is reasonable to assume that, at a given locus, allelic dropout of a sister allele has not occurred.
Stutter	A minor peak typically observed on repeat unit smaller than a primary STR allele resulting from strand slippage during amplification.
Technical Review	An evaluation of DNA data, results and conclusions, checking consistency, accuracy, and completeness. This review must be conducted by qualified technical laboratory staff.
Test Kit	A preassembled set of reagents that allow the user to conduct a specific DNA extraction, quantification or amplification.
Training Manual	A document stating the training policy and describing the various elements of the training program of an organization.
Validation	The process of performing a set of experiments which establish the efficacy and reliability of a technique or procedure or modification thereof. Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.
Verification	To affirm the accuracy of something. New or changed processes are verified against the design goals before being implemented. Confirmation by examination and provision of objective evidence that specified requirements have been met.

7 REFERENCES

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