This publication was archived on 18 July 2024

This publication is no longer current and is not being updated.

Forensic Science Regulator

Overseeing Quality

Codes of Practice and Conduct

DNA Analysis

FSR-C-108

Issue 2

1. Introduction

1.1.1 This appendix provides further explanation of some of the requirements of:

a. The 'Codes of Practice and Conduct for Forensic Science Providers and Practitioners in the Criminal Justice System' (the Codes);
b. ISO/IEC 17025:2017 'General Requirements for the Competence of Testing and Calibration Laboratories';
c. ISO/IEC 17020:2012 'Conformity assessment – Requirements for the operation of various types of bodies performing inspection'; and
d. ILAC G19:2014 'Modules in a Forensic Science Process, specifically pertaining to the provision of DNA evidence'.

1.1.2 It is primarily intended for managers and staff involved in DNA examination process.

1.1.3 In addition, the following guides are relevant to this topic:

a. FSR-G-201 'Validation';
b. FSR-G-202 'The interpretation of DNA evidence (including low-template DNA)';
c. FSR-G-206 'The Control and Avoidance of Contamination In Crime Scene Examination involving DNA Evidence Recovery';
d. FSR-G-208 'The Control and Avoidance of Contamination in Laboratory Activities involving DNA Evidence Recovery and Analysis';
e. FSR-G-213 'Allele Frequency Databases and Reporting Guidance for the DNA (Short Tandem Repeat) profiling';
f. FSR-G-222 'DNA Mixture Interpretation';
g. FSR-G-223 'Software Validation for DNA Mixture Interpretation';
h. FSR-P-302 'DNA Contamination Detection: The Management and use of Staff Elimination Databases'; and
i. UKAS (2019) LAB 13: 'Guidance on the Application of ISO/IEC 17025:2017 Dealing with Expressions of Opinions and Interpretations'.

1.1.4 To facilitate international data exchange for law enforcement purposes, the European Council Framework Decision 2009/905/JHA on 'Accreditation of forensic service providers carrying out laboratory activities' applies to the

areas of DNA analysis and fingerprint examination. Transposition of the requirements of the Decision into domestic legislation has been achieved through 'The Accreditation of Forensic Science Provider Regulations 2018', which came into effect on 25 March 2019 and were further amended in 2019 (UK Statutory Instruments, 2018).

1.1.5 The Regulations require those commissioning DNA analysis work for criminal justice use to instruct organisations that hold the required accreditation.

1.1.6 This appendix should be read alongside the Codes, ISO/IEC 17025:2017, ISO/IEC 17020:2012 and ILAC G19:08/2014.

2. Scope

2.1.1 This appendix provides further explanation of some of the requirements of the application of the Codes, ISO/IEC 17020:2012 and ISO/IEC 17025:2017 specifically pertaining to the detection, recovery, analysis, interpretation and the use of DNA evidence.

2.1.2 The requirements are for all short tandem repeat (STR)-based analyses and other chromosomal or mitochondrial DNA analyses conducted for the criminal justice system, whether performed in a conventional DNA profiling laboratory or by an alternative analysis method elsewhere.

3. Terms and Definitions

3.1.1 The terms and definitions set out in the Forensic Science Regulator's Codes, interpretation of DNA FSR-G-202 and DNA mixture interpretation FSR-G-222 apply to this appendix. Terms and definitions specific to this appendix are listed in the Glossary (Section 16).

3.1.2 The word 'shall' has been used in this document where there is a corresponding requirement in ISO/IEC 17025:2017, ISO/IEC 17020:2012 or the Codes; the word 'should' has been used to indicate generally accepted practice where the reason for not complying or any deviation shall be recorded.

4. Modification

4.1.1 This is the second issue of this document. It is a major rewrite of the previous version.

4.1.2 The Regulator uses an identification system for all documents. In the normal sequence of documents this identifier is of the form 'FSR-#-###' where (a) (the first '#') indicates a letter to describe the type of document and (b) '###' indicates a numerical, or alphanumerical code to identify the document. For example, this document is FSR-C-108, and the 'C' indicates that it is a codes document. Combined with the issue number this ensures that each document is uniquely identified.

4.1.3 If it is necessary to publish a modified version of a document (for example, a version in a different language), then the modified version will have an additional letter at the end of the unique identifier. The identifier thus becoming FSR-#-####.

4.1.4 In all cases the normal document bearing the identifier FSR-#-### is to be taken as the definitive version. In the event of any discrepancy between the normal version and a modified version then the text of the normal version shall prevail.

5. Implementation

5.1.1 This appendix is available for incorporation into a forensic unit's quality management system from the date of publication. It is effective from 01 January 2021.

6. Packaging and General Chemicals and Materials

ISO/IEC 17025:2017, 6.6; ISO/IEC 17020:2012, 6.2 and the Codes, 13

6.1.1 Any sample packaging and/or collection kits used shall be fit for purpose.

6.1.2 The packaging of collected material shall preserve the integrity of the potential material for forensic examination and minimise the risk of loss, degradation or contamination.

6.1.3 It is critical that consumables and reagents used for recovery and analysis are demonstrated to be free from detectable human DNA; quality assurance testing in the form of batch testing to demonstrate successful clean production standards, a validated technique of post-production treatment, or both should be used (Section 10.1).

6.1.4 The limit of detection chosen for any testing should be equal to, or more sensitive than, the procedures that the consumables and critical reagents are to be used in.

6.1.5 All testing must be traceable and the exact nature of the test and the results available for disclosure.

6.1.6 Policies and procedures for handling consumables shall include that:

a. Areas used for the storage and handling of consumables are secure;
b. Access is restricted to authorised personnel only;
c. Measures are taken to protect or minimise contamination from the environment; and
d. Precautions shall be taken to minimise the contamination of consumables prior to and during use.

6.1.7 Any detected or reported problems with packaging or materials already in the evidential chain will require an appropriate risk or case assessment to be undertaken and where appropriate, the material to be removed from the DNA supply chain.

7. Contamination Avoidance, Monitoring and Detection

ISO/IEC 17025:2017, 6.3.4, 7.4; ISO/IEC 17020:2012, 6.2 and the Codes, 20.2

7.1.1 The forensic unit shall have policies and procedures for DNA anti-contamination. Steps shall be taken to prevent or minimise contamination between:

a. Personnel and the exhibit/DNA sample;

b. Contaminated consumables (for example, swabs, tubes, personal protective equipment [PPE]/barrier clothing) and the exhibit/DNA sample;
c. Exhibits or DNA samples; and
d. Contaminated equipment and exhibit/DNA sample.

7.1.2 The forensic unit shall have policies and procedures to ensure that the cleaning methods used are validated and shown to be effective at removing DNA.

7.1.3 The forensic unit shall have policies and procedures to monitor the ongoing effectiveness of cleaning through environmental monitoring (EM).

7.1.4 The forensic unit shall have policies and procedures to ensure that access to laboratory areas is restricted to individuals covered by an adequate elimination database. See Section 11.

7.1.5 Elimination databases (see FSR-P-302) should include all those who are associated with the DNA process chain:

a. Those involved in the collection/recovery of evidence, its analysis, and the processing environment; and
b. Any high-risk personnel, for example, staff, visitors and sub-contractors who have access to exhibits and areas where these activities occur.

7.1.6 Policies and procedures for elimination databases should include, but are not limited to:

a. Reporting policies;
b. Data formats and data;
c. Searching procedures and algorithms;
d. Retention periods;
e. Legacy profiles and archive;
f. Sharing agreements (i.e. between laboratories/providers and with international manufacturers' elimination databases);
g. Agreements/consents;
h. Release forms;
i. Investigation process; and
j. Additional retained information.

7.1.7 Casework DNA analysis laboratories shall maintain a log of negative (blank/no template) control and quality control (QC) consumable batch test results to record drop-in and gross contamination events. The purpose will be:

a. To act as a monitoring tool;
b. To provide data that may be used in probabilistic models for reporting purposes; and
c. To identify possible manufacturer contamination by checking unsourced profiles against relevant local, national and international elimination databases.

8. Selection of Methods

ISO/IEC 17025:2017, 7.2.1; ISO/IEC 17020:2012, 7.1 and the Codes, 21.1

8.1.1 It is expected that forensic units shall use a validated human specific quantification technique for casework samples, which is verified to demonstrate its limit of detection, limit of quantitation, accuracy, reproducibility and measurement of uncertainty appropriate to the sensitivity of the DNA profiling service offered.

8.1.2 The quantification method may also be capable of demonstrating whether polymerase chain reaction (PCR) inhibition is likely to occur due to the nature of the tested sample. Where a quantification method is used that does not demonstrate whether PCR inhibition is likely, the possibility of inhibition should be explored when a partial or no profile has been obtained. Policies may require this routinely or only when the quantification value indicates an unexpected profiling result.

8.1.3 If no profile or an unsatisfactory or unexpected result is obtained, the possibility of inhibition, contamination (by reference to elimination databases), degradation, or over amplification should be explored, and rework considered and recorded.

8.1.4 In exceptional instances, where in the professional opinion of the scientist a separate quantification step normally required in a protocol is not advisable (that is, the amount of available evidential material risks the ability to obtain

an interpretable profile) or not required, this should be clearly communicated to the customer and shall be documented and available for disclosure purposes.

8.1.5 For rapid DNA devices, if quantification is not an integral part of the analytical method, then alternative means to assess and address the effects of both degradation and inhibition for each casework sample type are required as the samples are of variable composition, quality and quantity. Some samples are irreplaceable.

8.1.6 The interpretation method should include consideration of:

a. Allele drop-in;
b. Allele drop-out;
c. Gross-contamination;
d. Stochastic characteristics, and if used, any associated thresholds or triggers such as heterozygote balance relative to peak height, area or DNA quantity;
e. Stutter and artefactual peak characteristics;
f. Mixtures of two or more individuals covering a range of ratios per contributor, including male and female contributors;
g. Determining the number of contributors;
h. Methodology for reporting a single test result or replicate analyses as a single figure, for example, likelihood ratio; and
i. Forming propositions (related or unrelated individuals).

9. Validation of Methods

ISO/IEC 17025:2017, 7.2.2 and the Codes, 21

9.1.1 The validation procedure contained in the Codes and validation guidance FSR-G-201 shall be followed whether this is an adopted method that has been developed and validated elsewhere or developed by the forensic unit. The Codes allow for tailoring the validation procedure through verification of the extent and scope of supporting external validation studies.

9.1.2 The validation procedure shall include, but is not limited to:

a. A determination of the end-user's requirements;

b. A risk assessment of the method;
c. A review of the end-user's requirements and specification;
d. The acceptance criteria;
e. The validation plan;
f. The outcomes of the validation exercise;
g. An assessment of acceptance criteria compliance;
h. The validation report;
i. The statement of validation completion; and
j. The implementation plan.

9.2 Validation of measurement-based methods

ISO/IEC 17025:2017, 7.2.2 and the Codes, 21.2

9.2.1 For DNA methods the parameters/characteristics in the validation plan shall include, as appropriate:

a. Equipment calibration/performance, reagents, reference materials, consumables;
b. Characterisation of the genetic markers (mode of inheritance, chromosomal location, detection mechanism, polymorphism);
c. Species specificity (human/non-human, targeted species);
d. Sensitivity (for example, limits of detection, quantitation and/or the range of DNA quantity that will produce reliable results with reference to stochastic effects);
e. Contamination;
f. Matrix and substrate effects;
g. Interferences and cross-sensitivities;
h. Stability (for example, to environmental and chemical factors);
i. Repeatability and reproducibility (concordance);
j. Ruggedness/robustness;
k. Performance variation between representative case-type materials;
l. Population studies (databases, independence);
m. Effect of mixtures on obtaining reliable results;
n. Precision;
o. Accuracy (measurement standards);

p. Measurement uncertainty;
q. Match criteria;
r. Polymerase chain reaction (PCR) conditions (thermocycling parameters, concentration of primers, magnesium chloride, DNA polymerase, etc.) and preferential amplification/co-amplification; and
s. Post-PCR treatments, electrophoresis and detection parameters.

9.2.2 Also see the Scientific Working Group on DNA Analysis Method's (SWGDAM's) revised validation guidelines, (SWGDAM, 2016).

9.3 Profile Requirement

9.3.1 The forensic unit shall demonstrate that the method can routinely achieve the 'correct profile' (reference and casework). As a minimum this includes:

a. No errors using the same profiling chemistry kit;[1]
b. One base pair resolution;
c. Profile is not as a result of contamination;
d. Profile is not as a result of a sample or demographic switch; and
e. Discordance and mutations are identified and accounted for.

9.3.2 The forensic unit shall demonstrate that the method can obtain profiles of the appropriate quality **(**predominantly casework). As a minimum this includes optimal representation of the DNA content for:

a. Single source DNA;
b. Low template DNA;
c. DNA major/minor and equal mixtures from:
    i. Good quality DNA;
    ii. Degraded DNA; and
    iii. Mixed quality (good quality and degraded DNA).

[1] Known primer binding differences between profiling chemistry kits are not deemed to be errors.

10. Assuring the Quality of Test Results

ISO/IEC 17025:2017, 7.7; the Codes, 27

10.1 Consumables

(ISO/IEC 17025:2017, 6.6; ISO/IEC 17020:2012, 6.2)

10.1.1 Organisations shall use consumables that are quality assured to be DNA free or are ‘forensic DNA grade’ (compliant to ISO18385:2016) in the recovery and processing of DNA samples. This requirement also applies to reagents used in processes upstream from DNA processing in joint, split or sequential cases involving other disciplines.

10.1.2 Assurance can be provided by the consumables being independently assessed as compliant with ISO 18385:2016 or through quality control (QC) testing of batches of reagents and consumables.

10.1.3 Materials used shall not leach any chemicals (for example, plasticizers) that may affect the processes used or the results obtained from the analysis of the sample.

10.1.4 Validation shall be undertaken to demonstrate consistency in recovery and release of DNA for sampling materials (for example, swabs). Ongoing verification of the performance across batches shall be evidenced by QC testing. Any changes in composition of the sampling material shall be risk assessed and either validated or verified to ensure that the performance is as good as, or better than, previously validated sampling materials.

10.1.5 Post-production treatment of consumables, such as ethylene oxide treatment, shall include QC for each treatment, such as DNA spiked samples placed across the batch to be treated, which demonstrate the required reduction level of amplifiable DNA (at least 1,000-fold). If there is inadequate QC of the efficiency of the post-production treatment, then appropriate post-treatment QC testing is required.

10.1.6 If QC testing is relied upon, then for short tandem repeat (STR) profiling the recommended manufacturer’s protocol, combined with the most sensitive

DNA detection method (for example, post-PCR clean up) for which the consumables are intended shall be used in the QC procedure.

10.1.7 Manufacturers that do not have their own testing capability may request a single increased PCR amplification cycle number as part of their requirement for batch testing their consumables.

10.1.8 QC acceptance of a consumables batch tested using STR profiling is as follows.

a. No more than two designated alleles above the analytical threshold (AT) passes.
b. For two or more peaks above AT, replication (re-PCR) is required. For replication the same alleles do not need to be replicated to count towards contamination versus drop-in as demonstrated by Moore et al. (2020).
c. Four or more alleles above the AT is a fail.

10.1.9 For consumables that cannot undergo pre-treatment such as ethylene oxide treatment, then as a minimum five batch test samples should be processed and four out of the five samples should pass the criteria set out in ‘a’ above for the batch to be considered acceptable. For batch sizes greater than 100,000 more test samples should be considered

10.1.10 For consumables that have undergone pre-treatment such as ethylene oxide treatment and where confirmation of the previously passed batches is sought then fewer samples can be tested as determined by previous batch test results.

10.1.11 Consumables that fail should be embargoed and investigated further, following repeat batch testing consumables that continue to fail should be rejected for use. For consumables that have undergone pre-treatment such as ethylene oxide treatment another treatment might resolve the issue.

10.1.12 The test results shall be made available to the test requester (for example, manufacturers, kit assemblers, police forces) who if they wish can submit batch testing samples to another accredited laboratory.

10.2 Quality Assurance and Quality Control

10.2.1 The quality assurance (QA) and QC measures that can be used for the DNA analysis process are set out in Tables 1 and 2.

10.2.2 QCs used should enable the assurance of the test and monitor the methods used from sampling to profile designation

Table 1. Quality Assurance Measures

	Batch Testing	**Duplication (Repeats)**[1,2,3]	**Elimination Databases**[4]
Reagent/consumable contamination	Yes	No	Yes
Environmental contamination	No	No	Yes
Process contamination	No	Yes	Yes
Optimal operation	Yes	Yes	Yes
Process drift	Yes[5]	Yes	No
Degradation	No	Yes	No
Inhibition	Yes	Yes	No
Quality profile/expected result	Yes	Yes	Yes
Sized correctly	No	Yes	No

Notes:

1. Duplicate or subsample from an item that has been previously processed and produced a valid test result.
2. The number of duplicates/repeat sampling can be used to calculate the duplication rate and the error rate for that duplicate rate.
3. Duplication rates might start at 10% for units new to processing reference database samples or using a new PCR chemistry kit and then be reduced to 5% after demonstrating few systemic and profile errors. The duplication rate for recovered biological casework material that is not affected by quantity of material is typically around 2%.
4. These include staff (police, scientific), manufacturers and unsourced profiles believed to be from the consumable supply chain.
5. Performance testing includes threshold tests and contamination checks.

Table 2. Quality Control Measures

	Positive[1]	**Negative**	**Allelic Ladder**	**Quantification**	**Internal PCR Control**
Reagent/consumable contamination	Yes	Yes	No	Yes	No
Environmental contamination	Yes	Yes	No	Yes[2]	No
Process contamination	Yes	Yes	No	Yes[2]	No
Optimal operation	Yes[3]	No	Yes	Yes	Yes
Process drift	Yes	Yes	Yes	Yes	Yes
Degradation	No	No	No	Yes[4]	Yes[4]
Inhibition	Yes	No	No	Yes[4]	Yes[4]
Quality profile / expected result	Yes	No	No	No	No
Sized correctly	Yes	No	Yes	No	No

Notes:

1. Applicable body fluid sample type or extracted DNA containing optimal amount of material identified through validation to gauge successful test and monitor performance drift if sub-optimal/stochastic characteristics are observed.
2. Positive quantification results from negative (blank) control.
3. Optimal performance threshold level testing in addition to contamination checks.
4. Includes degradation and inhibition internal controls in quantification and STR profiling kit.

10.2.3 For DNA profiling the QCs shall be used to monitor extraction, PCR, fragment sizing, allele designation and contamination. These include the following.

a. A positive control or previously processed sample (duplicate) should be used to monitor extraction. For some sample types such as body tissue and bone there is no suitable sample type positive control, therefore the duplication of previously processed samples is used for QC and QA monitoring purposes.

b. A negative (blank) control shall be used from extraction to monitor contamination through the analytical process. For results greater than the determined and monitored drop-in rate (Taylor et al*.,* 2016) the batch (run) shall be assessed and appropriate re-analysis performed.

c. A control shall be used to verify that optimal PCR performance is achieved.

d. Either quantification or a means to assess and address the effects of both degradation and inhibition for casework sample types shall be employed. This requirement is not necessary for reference samples as these are good quality DNA rich samples and failure to obtain a full profile is expected to be extremely low.

11. Databases

ISO/IEC 17025:2017, 7.11 and the Codes, 23.4

11.1.1 Laboratories shall maintain local databases of profiles detected from batch testing reagents and negative (blank/no template) controls, and from environmental monitoring as a way of detecting contamination events as part of an integrated elimination database. Profiles derived from these databases that are not identified to staff in the DNA examination process should be shared with the Contamination Elimination Database (CED) held by the Forensic Information Databases Service (FINDS) and checked against relevant manufacturer staff elimination databases.

11.1.2 Elimination databases may be locally or remotely maintained. Laboratories should maintain local DNA elimination databases of staff, visitors, suppliers and sub-contractors. See FSR-P-302 ‘DNA Contamination Detection: The Management and use of Staff Elimination DNA databases’.

11.1.3 Laboratories shall utilise, as required, DNA allele frequency and haplotype (for example, mitochondria, Y chromosome) databases constructed without identifiable individuals. They should be relevant to the issues on which an interpretation of the significance of the evidence is based. Databases used for calculations shall be peer reviewed and robust. Any limitations on their

use shall be documented and revealed alongside any interpretation or opinion provided.

11.1.4 Other databases (subject to acting within the law) may be held as directed by the customer as the data owner (such as for intelligence-led screens) or the Forensic Science Regulator (for quality assurance checks, such as batch to batch for casework contamination checks).

12. Expression of Opinions and Interpretation

12.1.1 For interpreting and reporting DNA mixtures and complex profiles the forensic unit shall have opinions and interpretations, as set out in the United Kingdom Accreditation Service publication LAB 13 (UKAS, 2019), included in the ISO/IEC 17025:2017 scope of accreditation.

13. Review

13.1.1 This document is subject to review in accordance with the Forensic Science Regulator's Codes and other appendices.

13.1.2 If you have any comments please send them to the address as set out on the Internet site at www.gov.uk/government/organisations/forensic-science-regulator or email: FSREnquiries@homeoffice.gov.uk.

14. References

Council Framework Decision 2009/905/JHA of 30 November 2009 on accreditation of forensic service providers carrying out laboratory activities. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009F0905 [Accessed 25/08/2020].

Forensic Science Regulator, Codes of Practice and Conduct for Forensic Science Providers and Practitioners in the Criminal Justice System. Available at: www.gov.uk/government/collections/forensic-science-providers-codes-of-practice-and-conduct [Accessed 25/08/2020].

Forensic Science Regulator, Allele frequency databases and reporting guidance for the DNA (Short Tandem Repeat) profiling, FSR-G-213. Available

at:https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/915100/FSR-G-213_DNA_profile_interpretation_Issue_2_Final.pdf [Accessed 07/09/2020].

Forensic Science Regulator, DNA contamination detection: The management and use of staff elimination DNA databases, FSR-P-302. Available at: www.gov.uk/government/publications/dna-contamination-detection [Accessed 25/08/2020].

Forensic Science Regulator, DNA mixture interpretation, FSR-G-222. Available at: www.gov.uk/government/publications/dna-mixture-interpretation-fsr-g-222 [Accessed 25/08/2020].

Forensic Science Regulator, Software validation for DNA mixture interpretation, FSR-G-223. Available at: www.gov.uk/government/publications/software-validation-for-dna-mixture-interpretation-fsr-g-223 [Accessed 25/08/2020].

Forensic Science Regulator, The interpretation of DNA evidence (including low-template DNA), FSR-G-202. Available at: www.gov.uk/government/publications/the-interpretation-of-dna-evidence [Accessed 25/08/2020].

Forensic Science Regulator, The control and avoidance of contamination in crime scene examination involving DNA evidence recovery, FSR-G-206. Available at: www.gov.uk/government/publications/crime-scene-dna-anti-contamination-guidance [Accessed 25/08/2020].

Forensic Science Regulator, The control and avoidance of contamination in laboratory activities, involving DNA evidence recovery and analysis, FSR-G-208. Available at: www.gov.uk/government/publications/laboratory-dna-anti-contamination-guidance [Accessed 25/08/2020].

Forensic Science Regulator, Validation, FSR-G-201. Birmingham: Forensic Science Regulator. Available at: www.gov.uk/government/publications/forensic-science-providers-validation [Accessed 25/08/2020].

ILAC G19:08/2014 Modules in a Forensic Science Process. International Laboratory Accreditation Cooperation. Available at: http://ilac.org/news/ilac-g19082014-published/ [Accessed 25/08/2020].

ISO/IEC 17020:2012 Conformity assessment – Requirements for the operation of various types of bodies performing inspection.

ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories.

ISO 18385:2016 Minimizing the risk of human DNA contamination in products used to collect, store and analyse biological material for forensic purposes. Geneva, Switzerland: International Organization for Standardization. Available at: www.iso.org/standard/62341.html [Accessed 25/08/2020].

Moore, D., Clayton, T. and Thomson, J. (2020) 'A comprehensive study of allele drop-in over an extended period of time'. Forensic Science International: Genetics, vol. 48, 102332. doi.org/10.1016/j.fsigen.2020.102332.

PAS 377:2012 Specification for consumables used in the collection, preservation and processing of material for forensic analysis – Requirements for product, manufacturing and forensic kit assembly.

SWGDAM (2016) Validation Guidelines for DNA Analysis Methods. Scientific Working Group on DNA Analysis Method. Available at: www.swgdam.org/publications [Accessed 25/08/2020].

Taylor, D., Bright, J. A., McGoven, C., Hefford, C., Kalafut, T. and Buckleton, J. (2016) 'Validating multiplexes for use in conjunction with modern interpretation strategies', Forensic Science international: Genetics, vol. 20, pp 6–19 (reports the allele counts observed in analytical batch negative controls are considered to be drop-in events).

UKAS (2019) LAB 13: Guidance on the Application of ISO/IEC 17025:2017 Dealing with Expressions of Opinions and Interpretations, Edition 3, April 2019 Available at: www.ukas.com/download/publications/publications-

relating-to-laboratory-accreditation/LAB-13-Edition-3-April-2019.pdf [Accessed 25/08/2020].

UK Statutory Instruments (2018) No. 1276 The Accreditation of Forensic Service Providers Regulations 2019. Available at: www.legislation.gov.uk/uksi/2018/1276 [Accessed 25/08/2020].

15. Abbreviations and Acronyms

Abbreviation	Meaning
AT	Analytical threshold
DNA	Deoxyribonucleic acid
ENFSI	European Network of Forensic Science Institutes
FBI	Federal Bureau of Investigation
FSR	Forensic Science Regulator
IEC	International Electrotechnical Commission.
ISO	International Organization for Standardization
NIST	National Institute of Standards and Technology
PCR	Polymerase chain reaction
QC	Quality control
STR	Short tandem repeat
SWGDAM	Scientific Working Group on DNA Analysis Method

16. Glossary

Allele:

A genetic variant at a particular location within an individual's DNA. DNA profiling tests examine a range of alleles that are known to vary widely between individuals. Alleles are represented by peaks in a DNA profile.

Allelic Drop-in:

Additional random alleles present in a profile originating from random fragmented sources and regarded as independent events.

Allelic Drop-out:

Alleles missing from a DNA profile, so that it is partially represented.

Artefact:

Artefacts are ‘nuisance’ peaks in a profile; often associated with the amplification and detection processes, such as spikes, dye blobs, spectral pull-up. They do not represent genuine alleles; they are screened out by the scientist or the software.

Blank (See Negative Control):

A sample containing no DNA for detecting the background level of DNA in the matrix or contamination.

Casework Sample:

Biological material of unknown origin believed to have originated from a person of interest (perpetrator or victim) that may connect them to a specific crime event. Samples from individuals (i.e. reference samples) are not considered to be casework samples.

Consumables:

Single-use commodities used in the collection, preservation and processing of material for forensic analysis.

Contamination:

The undesirable introduction of substances or trace materials.

DNA Analysis:

The processes of DNA recovery (includes sampling and extraction), quantitation, amplification, separation, sequencing, designation, data analysis and profile interpretation.

DNA Contamination:

The introduction of DNA, or biological material containing DNA, to an exhibit or subsample derived from an exhibit during or after its recovery from the scene of crime or a person.

DNA Contamination (Profile):

A spurious DNA profile(s) in a crime-related stain comprising three or more alleles from one or more individual(s). The contributors are considered to be of no relevance to the case (for example, may be introduced into plastic ware during the manufacturing process, or may have originated from a scientist processing the samples in the laboratory).

DNA Evidence:

Evidence provided to an investigating agency, prosecuting authority or court that sets out the results of DNA analysis or the relevance of such results in the context of a criminal prosecution. It covers any material seized as evidence with the intention that it be subjected to DNA analysis.

DNA Free:

Human DNA is not detectable by the most sensitive DNA profiling techniques available.

DNA Profile:

This is a format for the representation of an individual's genetic information that can be compared to other profiles, for example stored on a database.

Duplicate:

Either a second sample or subsample from an item.

Duplication:

The analysis of either a second sample or subsample from an item through the complete process at a specific time later. The result is used to confirm the original result, monitor performance over time, identify any quality issues with the previous and current process, and calculate duplication and error rates.

Duplication Rate:

The number of unique samples duplicated and expressed as a percentage of the total number of unique samples processed within a specified timeframe.

Elimination Database:

Collection of DNA profiles held in a searchable format from staff whose access/role/activities are deemed to be a potential DNA contamination risk. This may include not just the staff working within a specific facility, but also profiles from visitors to the facility, staff of manufacturers supplying consumables for DNA processing, and unsourced contamination profiles. The profiles are used to identify instances of inadvertent contamination.

Environmental Monitoring (EM):

A sampling and analytical (DNA) process for equipment, furniture and work areas that both monitors and audits the cleaning procedures and decontamination methods applied within the facility.

Error Rate:

The number of errors for duplicated samples expressed as a percentage of the total number of duplicate samples processed within a specified timeframe.

Examination:

Activity or process of observing, searching, detecting, recording, prioritising, collecting, analysing, measuring, comparing and/or interpreting.

Forensic DNA Grade:

Consumables that are compliant with the requirements set out in ISO 18385:2016 Minimizing the risk of human DNA contamination in products used to collect, store and analyse biological material for forensic purposes.

Forensic Unit:

A forensic unit is a legal entity or a defined part of a legal entity that performs any part of the forensic science process. [SOURCE: ILAC-G19:08/2014 Modules in a Forensic Science Process.]

Gross Contamination:

The transfer of DNA from a single person where a partial or complete DNA profile (these alleles are 'dependent') is obtained as a result of a contamination event. This is unlike the *drop-in* phenomenon, which is associated with random allelic events (the alleles are 'independent' of each other). Consequently, drop-in is routinely used to refer to the observation of just one or two extra alleles per profile (also see systemic contamination).

The term is also used in environmental monitoring (EM) sampling where a profile from multiple persons from an unidentified number of events is obtained and the donors cannot be identified.

Haplotype:

A group of alleles that are inherited together from one parent. The Y-chromosome represents a single haplotype inherited from father to son.

Negative Control (Blank):

Contains the analyte at a concentration below a specified limit. The intention is that no DNA is present and no profile or alleles above the drop-in rate are expected.

Over-amplification:

Over production of polymerase chain reaction (PCR) products due to the presence of too much DNA for the amplification process, which can inhibit PCR or affect the resolution of the PCR fragment separation.

Peak:

A DNA profile consists of a series of peaks. Most of these will represent alleles. However, there will also be a number that are artefacts.

Peak Height:

The height of a peak typically measured in relative fluorescent units and generated during electrophoresis and fluorescence detection of DNA amplification (PCR) products generated during the analysis of a DNA profile.

Polymerase Chain Reaction (PCR):

PCR or amplification of specific short DNA sequences.

Polymerase Chain Reaction (PCR) Inhibition:

No or suboptimal production of PCR products due to the presence of substances that affect or inhibit the amplification process.

Polymorphism:

The occurrence of two or more variants on a gene.

Positive Control:

Contains DNA at a concentration above a specified limit.

Quantification:

The concentration and volume information of male and/or total DNA.

Reference Sample:

A biological sample obtained from a known person with the purpose of creating a DNA profile for comparison.

Short Tandem Repeat (STR):

A microsatellite consisting of one to six or more nucleotides that is repeated adjacent to each other along the DNA strand.

Sporadic Contamination:

Unpredictable, erratic contamination event that is not detected by quality control batch testing.

Stutter:

A stutter is an artefact of the amplification process that leads to smaller peaks close to the main allelic peak. The most common stutter peak is one that represents one repeat unit smaller than the allelic peak (-4). Stutters with other numbers of repeats are also possible, but less common. Over-stutters are one repeat unit larger than the allelic peak (+4).

Systemic Contamination:

General, universal contamination event seen across a batch or between batches of test results (also see gross contamination).

Unsourced Contaminant:

A DNA profile identified as a contaminant, i.e. following all relevant elimination database checks of which the source has not been identified. No template (negative) controls and quality control batch tests are considered as having originated from the manufacturing supply chain; historically most have been found to come from manufacturing staff.

17. Further Reading

Bodner, M., Bastisch, I., Butler, J. M., Fimmers, R., Gill, P., Gusmão, L., Morling, N., Phillips, C., Prinz, M., Schneider, P.M. and Parson, W. (2016), 'Recommendations of the DNA Commission of the International Society for Forensic Genetics (ISFG) on quality control of autosomal Short Tandem Repeat allele frequency databasing (STRidER)', Forensic Science International: Genetics, vol. 24, pp 97–102.

Caddy, B. (2008) A Review of the Science of Low Template DNA Analysis. Available at: www.gov.uk/government/uploads/system/uploads/attachment_data/file/117556/Review_of_Low_Template_DNA_1.pdf [Accessed 25/08/2020].

Coble, M. D., Buckleton, J., Butler, J. M., Egeland, T., Fimmers, R., Gill, P., Gusmão, L., Guttman, B., Krawczak, M., Morling, N., Parson, W., Pinto, N., Schneider, P. M., Sherry, S. T., Willuweit, S. and Prinz, M. (2016) 'DNA Commission of the International Society for Forensic Genetics: Recommendations on the validation of software programs performing biostatistical calculations for forensic genetics applications', Forensic Science International: Genetics, vol. 25, pp 191–197.

Council Decision 2008/616/JHA of 23 June 2008 on the implementation of Decision 2008/615/JHA on the stepping up of cross-border cooperation. Available at: http://eur-lex.europa.eu/legal-

content/EN/TXT/?qid=1481187358403&uri=CELEX:32008D0616 [Accessed 25/08/2020].

ENFSI 'DNA Contamination prevention guidelines'. European Network of Forensic Science Institutes. Available at: http://enfsi.eu/documents/forensic-guidelines/ [Accessed 25/08/2020].

ENFSI 'Recommendations for the training of DNA staff: Concept Training Document'. European Network of Forensic Science Institutes. Available at: http://enfsi.eu/documents/other-publications/ [Accessed 25/08/2020].

ENFSI 'Recommended Minimum Criteria for the Validation of Various Aspects of the DNA Profiling Process'. European Network of Forensic Science Institutes. Available at: http://enfsi.eu/documents/forensic-guidelines/ [Accessed 25/08/2020].

FBI Laboratory 'National DNA Index System (NDIS) Operational Procedures Manual'. USA: Federal Bureau of Investigation. Available at: www.fbi.gov/file-repository/ndis-operational-procedures-manual.pdf/view [Accessed 25/08/2020].

Forensic Science Regulator (2008) 'Response to Professor Brian Caddy's Review of the Science of Low Template DNA Analysis'. Available at: www.gov.uk/government/uploads/system/uploads/attachment_data/file/117557/response-caddy-dna-review.pdf. [Accessed 25/08/2020].

Gill, P., Brenner, C. H., Buckleton, J. S., Carracedo, A., Krawczak, M., Mayr, W. R., Morling, N., Prinz, M., Schneider, P. M. and Weir, B. S. (2006) 'DNA commission of the International Society of Forensic Genetics: Recommendations on the interpretation of mixtures', Forensic Science International, vol. 160, pp 90–101.

Gill, P., Gusmão, L., Haned, H., Mayr, W. R., Morling, N., Parson, W., Prieto, L., Prinz, M., Schneider, H., Schneider P. M. and Weir, B. S. (2012) 'DNA commission of the International Society of Forensic Genetics: Recommendations on the evaluation of STR typing results that may include drop-out and/or drop-in using probabilistic methods', Forensic Science International: Genetics, vol. 6 (6), pp 679–688.

NIST 'Standard Reference Material PCR-Based DNA Profiling Standard (ATCC® NIST-2391d™)', National Institute of Standards and Technology. Available at: www-s.nist.gov/srmors/view_datafiles.cfm?srm=2391d [Accessed 25/08/2020].

Published by:
The Forensic Science Regulator
5 St Philip's Place
Colmore Row
Birmingham
B3 2PW
www.gov.uk/government/organisations/forensic-science-regulator