Forensic Science Regulator

Guidance

Methods Employing Rapid DNA Devices

FSR-G-229

Issue 1

© Crown Copyright 2021

The text in this document (excluding the Forensic Science Regulator’s logo, any other logo, and material quoted from other sources) may be reproduced free of charge in any format or medium providing it is reproduced accurately and not used in a misleading context. The material must be acknowledged as Crown copyright and its title specified.

This document is not subject to the Open Government Licence.

1. Introduction 5
1.1 Background 5
2. Scope 6
3. Modification 6
4. Implementation 7
5. Terms and Definitions 7
6. Forensic Science Regulator Guidance 7
7. Standards and Regulation for DNA Analysis 8
8. Validation 8
8.2 DNA Technology 8
8.3 Sample Preparation 10
8.4 Sample Retrieval and Reprocessing 10
8.5 Reference Samples (Buccal) 10
8.6 Recovered Biological Samples (Casework Stains) 10
8.7 Analysis Interpretation Software 11
8.8 The Loading of DNA Profiles from Rapid DNA Devices to The NDNAD 11
9. Security 12
10. Verification 14
11. Profile Requirement (FSR-C-108) 14
12. Buccal Swab Requirement (FSR-C-108) 14
13. Quality Assurance 15
13.2 Consumables 15
13.3 Size Standards and Allelic Ladders 15
13.4 Contamination Checks 15
13.5 Pass Criteria for Reference (Buccal) Samples 15

13.6 Pass Criteria for Recovered Biological Samples (Casework Stains) 16

14. Ongoing Monitoring 16

14.2 Consumables..16

14.3 Rapid DNA Devices 16

14.4 Environment and Environmental Controls..17

15. Staff Competency 17

16. Proficiency Tests 18

17. Acknowledgements...18

18. Review 18

19. References 19

20. Abbreviations and Acronyms 21

21. Further Reading...22

1. Introduction

1.1 Background

1.1.1 Technological advances have resulted in laboratory-based systems being able to process samples using direct amplification for short tandem repeat (STR) DNA profiling to produce a result within a couple of hours, that is rapid DNA profiling or Rapid DNA. Many of these systems are automated for high volume throughput.

1.1.2 The more recent innovation is the development of mobile portable devices that can also produce STR DNA profile results in under two hours for a small number of samples per run. These devices extract, amplify and separate the amplified products and designate the profile in the single device and are therefore described as 'Rapid DNA devices'.

1.1.3 Methods using Rapid DNA devices could be deployed as follows.

a. In sampling suites (for example, custody suites or offices) for processing buccal samples in order to obtain investigative leads during the custody retention period of the individual, or for immigration border control use.

b. At incidents (crime scene, mass disaster) for processing samples in order to obtain investigative or victim identification leads.

c. As part of the laboratory work flow. For use in the criminal justice system (CJS) this requires accreditation to British Standard BS EN ISO/IEC 17025 [1] to meet the EU Council Framework Decision 2009/905/JHA [2] as set out as a legal requirement in The Accreditation of Forensic Service Providers Regulations 2018 (UK Statutory Instrument 1276/2018) [3] and the standards set out in theFSR-C-100 the Forensic Science Regulator's Codes of Practice and Conduct (the Codes) [4].

1.1.4 An agreed position for using Rapid DNA devices by the Scientific Working Group on DNA Analysis Method (SWGDAM) in the USA and the European Network of Forensic Science Institutes (ENFSI) in Europe for crime scene samples is set out in a letter to the editor of the journal Forensic Science

International: Genetics (Hares et al., 2020) [5]. For the current (2021) maturity of the technology that position is supported by the Regulator for use within the CJS and is reflected in the provisions set out in this guidance.

2. Scope

2.1.1 Requirements that apply to the use of DNA Rapid devices employed to process the following sample types.

a. Buccal reference samples – these are good quality, high quantity DNA samples and not an irreplaceable sample.

b. Recovered biological samples (crime stains, casework) – these are sample types of variable composition, quality and quantity; some samples are irreplaceable. Samples may include blood, cigarette butts, trace/touch DNA, body fluids from sexual assaults, burnt tissue and bone.

2.1.2 The requirements cover the process from sample preparation to profile designation for Rapid DNA devices.

3. Modification

3.1.1 This is the first issue of this document.

3.1.2 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-G-229, and the 'G' indicates that it is a guidance document. Combined with the issue number this ensures that each document is uniquely identified.

3.1.3 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-#-####.

3.1.4 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.

4. Implementation

4.1.1 This guidance is available for incorporation into a forensic unit's quality management system from the date of publication. The Forensic Science Regulator (FSR) required that Codes of Practice and Conduct, FSR-C-100 (the Codes) [4] were included in a provider's schedule of accreditation from October 2017. The requirements in this guidance are effective from 01 October 2021.

5. Terms and Definitions

5.1.1 The terms and definitions set out in FSR-C-100 the Codes of Practice and Conduct (the Codes) [4], FSR-C-108 DNA Analysis [6], FSR-G-222 DNA Mixture interpretation [7] apply to this document.

6. Forensic Science Regulator Guidance

6.1.1 The Forensic Science Regulator's Codes of Practice and Conduct, FSR-C-100 (the Codes) and guidance relevant to this topic include:

a. FSR-C-108 DNA Analysis [6];
b. FSR-G-201 Validation [8];
c. FSR-G-202 The interpretation of DNA evidence (including low-template DNA) [9];
d. FSR-G-208 The control and avoidance of contamination in laboratory activities involving DNA evidence recovery and analysis [10];
e. FSR-G-222 DNA mixture interpretation [7];
f. FSR-G-223 Software validation for DNA mixture interpretation [11]; and
g. FSR-P-302 DNA contamination detection: The management and use of staff elimination DNA databases [12].

7. Standards and Regulation for DNA Analysis

7.1.1 The Accreditation of Forensic Service Providers Regulations 2018 (UK Statutory Instrument 1276/2018) [3] introduced the requirement for commissioners of fingerprint and DNA services in England and Wales to use providers accredited to the standard BS EN ISO/IEC 17025 [1].

7.1.2 For a profile obtained using a Rapid DNA device to be used in the criminal justice system in England and Wales it shall be:

a. from a validated DNA method; and
b. included in the forensic unit's scope of accreditation.

7.1.3 Manufacturers and suppliers of Rapid DNA devices should understand the requirements set out in international standards BS EN ISO/IEC 17020 [13] BS EN ISO/IEC 17025 [1] ILAC G19:08/2014 [14] for testing and calibration that the end users of the Rapid DNA device are required to demonstrate to their accreditation bodies.

7.1.4 The requirements set out in the Forensic Science Regulator's Codes of Practice and Conduct, FSR-C-100 (the Codes) [4] and FSR-C-108 DNA Analysis [6] apply.

8. Validation

8.1.1 Manufacturers, suppliers and forensic units should understand the requirements for validation. Forensic units should provide evidence that the Rapid DNA method is validated for the specific use to which it is being applied, including the range and limitations of the method, prior to its use in the criminal justice system.

8.2 DNA Technology

8.2.1 The requirements set out in the Forensic Science Regulator's Codes of Practice and Conduct, FSR-C-100 (the Codes) [4], FSR-C-108 DNA Analysis [6], FSR-G-201 Validation [8] and FSR-G-223 Software validation for DNA mixture interpretation [11] apply for the validation of the method.

8.2.2 Manufacturers and suppliers may also consider other appropriate international guidance (Scientific Working Group on DNA Analysis Methods [SWAGDAM]) [15]; [16]; European Network of Forensic Science Institutes [17]. Published material based on these guidance documents can be taken into account for validation or verification of the method, although it is not a requirement to do so.

8.2.3 As Rapid DNA devices are intended to be used in static and/or mobile environments the validation and testing shall include elements expected to be encountered in whichever environment(s) are appropriate to the specific deployment. The manufacturer/supplier shall determine the working environment parameters and limits of performance for the equipment and consumables and make this information, and a summary of the supporting data, available to the end user. The end user shall independently verify the use of the appropriate Rapid DNA device in their working environment, as defined by the user requirement and specification for the method.

8.2.4 Validation samples and data of known characteristics shall be used for comparison against the new or upgraded system. These generally include:

a. previously processed samples and data;

b. internally produced positive controls of specific quantitated value and profile; or

c. externally provided reference standards/materials such the Standard Reference Material PCR-Based DNA Profiling Standard (ATCC® NIST-2391d™ [18] [19].

8.2.5 Validation studies shall include testing to ensure that no contamination is carried forward from one run into another, for example, by running increased polymerase chain reaction (PCR) (5-10) cycles of strong positive DNA samples followed by negative samples to check for carry-over.

8.2.6 In England and Wales, the guidance set out in FSR-P-300 Validation – Use of casework material validation [20] apply to organisations wishing to use previously processed casework material.

8.3 Sample Preparation

8.3.1 Validation of the sample preparation and insertion method shall be conducted to demonstrate as a minimum that:

a. the materials and method minimise contamination from the user, environment and internal system processing;

b. the procedure avoids sample and demographic switches; and

c. the samples (quality, quantity and material size) used do not compromise the quality of the profile obtained.

8.3.2 If the end user intends to use sample types not covered by the validation studies performed by the manufacturer/supplier, then they shall validate that sample preparation and insertion method on the appropriate Rapid DNA device in their working environment.

8.4 Sample Retrieval and Reprocessing

8.4.1 Any method to retrieve part-processed samples, for example, the material or extracted fluid from the Rapid DNA device, shall be validated as specified above (8.3).

8.5 Reference Samples (Buccal)

8.5.1 Quantification and addressing inhibition are not required as these are good quality DNA rich samples that can be retaken, or multiple samples are available.

8.5.2 A full, correctly designated profile is the expected result; failed alleles, dis-concordance and mutation differences are not classed as an error. The profile error rate shall be calculated and disclosed (8.7.3).

8.6 Recovered Biological Samples (Casework Stains)

8.6.1 Either quantification or a means to assess and address the effects of both degradation and inhibition for each of sample types is required as the samples are of variable composition, quality and quantity. Some samples are irreplaceable.

8.6.2 The validation shall determine the limits of the Rapid DNA device for sample types and clearly identify what samples should and should not (for example, limited/ irreplaceable samples) be processed through the Rapid DNA device.

8.6.3 The pass criteria include obtaining designated DNA profiles of sufficient discriminating power to enable:

a. checking against an appropriate elimination database;
b. a speculative search that does not generate an unmanageable number of adventitious matches; or
c. the load criteria for the National DNA Database® (NDNAD) being met.

8.7 Analysis Interpretation Software

8.7.1 Guidance on profile interpretation can be found in FSR-G-202 The interpretation of DNA evidence (including low-template DNA) [9] and FSR-G-223 Software validation for DNA mixture interpretation [11].

8.7.2 The validation should analyse a complete range of alleles for the relevant loci, both simple and complex short tandem repeat primer sequences. The allele data analysed shall have known designations from previous profiling and include rare alleles and anomalies such as tri-allelic variants.

8.7.3 Manufacturers/suppliers shall provide evidence of the profile mis-designation error rate for the final method; failed alleles, concordance and mutation differences are not classed as errors. As a minimum 1,000 unique profiles and 200 profiles of variable quality to represent casework type stains and challenging profiles shall have been analysed; it is anticipated that some of this will have been completed as part of developmental validation studies (FBI Laboratory, NDIS Operational Procedures Manual, Section 4.5 – 4.6) [21].

8.8 The Loading of DNA Profiles from Rapid DNA Devices to The NDNAD

8.8.1 The approval for any organisation to submit DNA profiles to the NDNAD is dependent on meeting the NDNAD technical requirements administered by

the Home Office Forensic Information Databases Service (FINDS). The NDNAD technical requirements define:

a. PCR chemistry approval;

b. DNA sample processing requirements;

c. profile requirements for retention or searching; and

d. the format for DNA profile acceptance for NDNAD[1] purposes.

9. Security

9.1.1 The Forensic Science Regulator's Codes of Practice and Conduct, FSR-C-100 (the Codes) [4] cover sample handling and related physical and information security. Methods or procedures should be based on assessed business and security requirements. In relation to data, the Codes expect the forensic unit to identify key data and identify the critical control points (i.e. places where data are entered, transferred, stored or processed in a manner where they may be vulnerable to risks such as data corruption, errors or unauthorised manipulation). This critical control point approach is advocated for assessing contamination, data integrity and in guidance issued by the Regulator for assessing the risk of cognitive bias[2] as a result of information flow.

9.1.2 Approaching all types of risk together allows the various Codes' [4] requirements to be addressed together and ensures that a solution to one risk is not implemented if it inadvertently creates a second uncontrolled risk. For instance, there is a risk if biometric and/or demographic data are stored on the device in a manner that could be accessed by an unauthorised third

---

1 For details of the polices and requirements manufacturers or suppliers should contact FINDS at: FINDS_Quality_Management@homeoffice.pnn.police.uk.

2 The cognitive bias issue should be borne in mind in designing the overall method including but not limited to the reporting of results. The rapid availability of a DNA profile carries some risk if introduced to decision making without the correct caveats. For instance, obtaining a profile might influence the decision maker to consider releasing a scene earlier than a properly formed forensic strategy would suggest. The requirement at its simplest level is to ensure that reporting a viable DNA profile has been obtained (or connected to a database a 'match' or even a 'non-match' is achieved), does not influence the impartiality of the incident scene examiner or the crime scene manager in their decision making.

party; the solution considered could be to not retain the data on the device. However, the process map should also show that there is a risk that data become corrupted during transit and/or are not correctly received, which might favour a period of retention on the device. So dealing with the whole set of risks together should ensure a properly designed system. It is for the forensic unit to determine the end user's requirements for method development and/or validation; critical control point analysis should assist in this activity.

9.1.3 The location where the Rapid DNA instrument is to be used matters; from a security standpoint both in terms of its immediate physical environment but also how the instrument is connected to the rest of the forensic unit's network. If the intention is for the Rapid DNA instrument to be used in a laboratory/examination area, then it may be appropriate to regard this simply as a normal laboratory instrument. In this case the Codes [4] chapter on 'Laboratory/examination facilities' dealing with access controls is appropriate, and the main requirement is the segregation of systems used for forensic science work from other networks.

9.1.4 If the operational requirement is to deploy the Rapid DNA instrument in a non-traditional examination area, or even a near-scene environment (it is assumed that the anti-contamination risk assessment would favour the instrument not being within the inner perimeter of the scene), then the controls detailed in 'Laboratory/examination facilities' may still apply; how they are fulfilled may require the instrument to have 'access controls' including suitable controls for how the device is stored (see the Codes [4]). Those setting the end user's requirements for the method using the Rapid DNA device need to recognise that the device is part of a bigger method and not all quality controls are best implemented within the device; expecting the manufacturer to include them may be a false expectation.

9.1.5 Irrespective of the deployment environment, the data being processed are biometric data and adequate protection during storage and transit of such data is required. This includes, but is not limited to, any access that the manufacturer may have during servicing, software and firmware updates and

management of any security issues within the forensic unit's change procedures, which should manage any potential impact to the forensic examination process or validation status.

10. Verification

10.1.1 Evidence of relevant validation studies and data shall be available to forensic units to enable them to review their suitability and conduct an appropriate verification study for their deployment method, with the range of samples that will be used on the Rapid DNA device.

10.1.2 Verification that the Rapid DNA device operates as required can be conducted centrally as part of commissioning the deployment of Rapid DNA devices. However, this does not absolve the end user from verifying the performance and ongoing monitoring of the Rapid DNA device on site.

11. Profile Requirement (FSR-C-108)

11.1.1 The validation and verification of a Rapid DNA device shall demonstrate that it can achieve the correct profile (reference and casework) and obtain profiles of the appropriate quality (predominantly casework). The requirements are set out in FSR-C-108 DNA Analysis (section 9.3) [6].

12. Buccal Swab Requirement (FSR-C-108)

12.1.1 Validation to demonstrate consistency in the recovery and release of DNA with no leaching of substances that could interfere with downstream processing shall be conducted; this is likely to be part of the developmental validation undertaken by the manufacturer. Ongoing verification of the performance across batches shall be evidenced by quality control testing. Any changes in the composition of the sampling material shall be risk assessed and either validated or verified that the performance is as good as or better than the previously validated swab.

13. Quality Assurance

13.1.1 The requirements to provide quality assurance for processing DNA samples are set out in FSR-C-108 DNA Analysis (section 10) [6].

13.2 Consumables

13.2.1 DNA consumables used shall be determined to be free from detectable levels of human DNA[3] or shall be forensic DNA grade as demonstrated by compliance to ISO18385:2016 [22].

13.3 Size Standards and Allelic Ladders

13.3.1 The accuracy of the size standard to enable the correct allele designation shall be demonstrated.

13.4 Contamination Checks

13.4.1 The detection of allelic ladder leakage and a systematic contamination check shall be carried out. As a minimum this shall include between-run checks for single sample processing or between runs and samples processed simultaneously, i.e. two or more samples.

13.5 Pass Criteria for Reference (Buccal) Samples

13.5.1 The pass criteria shall include, as a minimum, the following elements.

a. The profile is not a mixture.
b. The contamination check against simultaneously processed samples is clear.
c. A fully designated profile meeting all loci, allele and threshold values set from the validation of the profiling system has been obtained.

[3] Human DNA is not detectable by the most sensitive DNA profiling techniques available or, as minimum, by the profiling system in use on the Rapid DNA device.

13.6 Pass Criteria for Recovered Biological Samples (Casework Stains)

13.6.1 The pass criteria shall include, as a minimum, the following elements.

a. Designation of alleles meeting all loci, allele and threshold values set from the validation of the profiling system.

b. Either an alert is triggered to indicate a false negative result for reprocessing considerations; or confirmation that there are no significant degradation nor inhibition effects present that will affect obtaining and accurately designating the profile.

c. For direct searching or loading from the device, the profile is not a mixture where an unambiguous single source profile cannot be determined.

14. Ongoing Monitoring

14.1.1 Process controls and ongoing monitoring of DNA analysis requirements are set out in FSR-C-108 DNA Analysis (section 10.2) [6].

14.2 Consumables

14.2.1 Verification of the performance and DNA status of all consumables used should be undertaken in advance of use. These may include batch tested and/or ethylene oxide treated items.

14.3 Rapid DNA Devices

14.3.1 The Rapid DNA device shall conduct routine system performance checks prior to and during the DNA process run. The data for these checks shall be recorded and retrievable by the end user for audit and troubleshooting purposes.

14.3.2 Any fault or failures shall alert the end user in an easily understood format so that they can take the appropriate action.

14.3.3 The manufacturer/supplier shall provide the requirements for commissioning the equipment and routine maintenance for the Rapid DNA device to operate at optimal conditions.

14.3.4 The Rapid DNA device should incorporate internal quality controls that as minimum will verify accurate profile designation and will alert the user to quality issues concerning contamination and/or false negatives as a result of inhibition and/or degradation.

14.4 Environment and Environmental Controls

14.4.1 The end user shall:

a. conduct a risk assessment of the environment(s) that the Rapid DNA device will be employed in; and
b. determine and implement conditions for operating the Rapid DNA device as specified by the manufacturer/supplier.

14.4.2 The risk assessment shall include consideration of the location, power, IT requirements, operating surface (bench/table), temperature range, waste handling and consumable storage.

14.4.3 The end user shall carry out sample preparation and operate the Rapid DNA device within a controlled enclosed environment (i.e. the device is not directly in contact with a scene environment). This shall include:

a. access control;
b. schedule for deep and routine cleaning of the operating environment and equipment; and
c. the frequency and locations for environmental contamination monitoring.

15. Staff Competency

15.1.1 Each role in the overall process shall be specified. The documented training and competency requirements for the overall process shall include the following, which may be split between different roles:

a. sampling;

b. sample and consumable handling;

c. commissioning and use of the Rapid DNA device;

d. identification of faults/errors and escalation routes;

e. routine maintenance and monitoring of the Rapid DNA device and consumables;

f. environment management and monitoring; and

g. profile interpretation if profile data from the device is analysed by a practitioner.

16. Proficiency Tests

16.1.1 Accredited DNA work flow(s) using Rapid DNA devices should be included in the organisation's proficiency or interorganisational testing schedule for processing reference, recovered biological samples or both, as applicable to the organisation's specific deployment(s).

17. Acknowledgements

17.1.1 This guidance was produced by the Forensic Science Regulator's DNA Analysis Specialist Group. The FSR would like to thank Cellmark Forensic Services, Defence Science and Technology Laboratory (Dstl), Eurofins Forensic Services, Forensic Information Databases Service (FINDS), Forensic Science Ireland, Forensic Science Northern Ireland, Metropolitan Police Service, Scottish Police Authority Forensic Services, United Kingdom Accreditation Service (UKAS) and the Forensic Science Regulation Unit (FSRU).

18. Review

18.1.1 This published guidance will form part of the review cycle as determined by the Forensic Science Regulator.

18.1.2 The Forensic Science Regulator welcomes comments. Please send them to the address as set out at: www.gov.uk/government/organisations/forensic-science-regulator, or email: FSREnquiries@homeoffice.gov.uk

19. References

[1] British Standard, BS EN ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.

[2] The Council of The European Union, 'Council Framework Decision 2009/905/JHA of 30 November 2009 on accreditation of forensic service providers carrying out laboratory activities', [online]. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009F0905. [Accessed 14 03 2021].

[3] The Accreditation of Forensic Service Providers Regulations 2018 and The Accreditation of Forensic Service Providers (Amendment) Regulations 2019, (UK Statutory Instrument 2018 No. 1276, [online]. Available at: www.legislation.gov.uk/uksi/2018/1276. [Accessed 10 03 2021].

[4] Forensic Science Regulator, 'Codes of Practice and Conduct for Forensic Science Providers and Practitioners in the Criminal Justice System', FSR-C-100. [online]. Available at: www.gov.uk/government/collections/forensic-science-providers-codes-of-practice-and-conduct. [Accessed 10 03 2021].

[5] Hares, D. R., Kneppers, A., Onorato, A. J. and Kahn, S. (2020) 'Rapid DNA for crime scene use: Enhancements and data needed to consider use on forensic evidence for State and National DNA Databasing – An agreed position statement by ENFSI, SWGDAM and the Rapid DNA Crime Scene Technology Advancement Task Group', Forensic Science International: Genetics, Sept vol. 48, p 102349. Doi: 10.1016/j.fsigen.2020.

[6] Forensic Science Regulator, 'DNA Analysis', FSR-C-108, [online]. Available at: www.gov.uk/government/collections/forensic-science-providers-codes-of-practice-and-conduct#appendices. [Accessed 10 03 2021].

[7] Forensic Science Regulator, 'DNA mixture interpretation', FSR-G-222, [online]. Available at: www.gov.uk/government/publications/dna-mixture-interpretation-fsr-g-222. [Accessed 10 03 2021].

[8] Forensic Science Regulator, 'Validation', FSR-G-201, [online]. Available at: www.gov.uk/government/publications/forensic-science-providers-validation

. [Accessed 10 03 2021].

[9] Forensic Science Regulator, 'The interpretation of DNA evidence (including low-template DNA)', FSR-G-202, [Online]. Available: www.gov.uk/government/publications/the-interpretation-of-dna-evidence. [Accessed 14 03 2021].

[10] Forensic Science Regulator, 'The control and avoidance of contamination in laboratory activities, involving DNA evidence recovery and analysis', FSR-G-208. [online]. Available at: www.gov.uk/government/publications/laboratory-dna-anti-contamination-guidance. [Accessed 03 05 2021].

[11] Forensic Science Regulator, 'Software validation for DNA mixture interpretation', FSR-G-223, [online]. Available at: www.gov.uk/government/publications/software-validation-for-dna-mixture-interpretation-fsr-g-223. [Accessed 10 03 2021].

[12] Forensic Science Regulator, 'DNA contamination detection: The management and use of staff elimination DNA databases', FSR-P-302, [online]. Available at: www.gov.uk/government/publications/dna-contamination-detection. [Accessed 10 03 2021].

[13] British Standard, BS EN ISO/IEC 17020:2012, General criteria for the operation of various types of bodies performing inspection.

[14] International Laboratory Accreditation Cooperation, ILAC G19:08/2014 'Modules in a Forensic Science Process', [online]. Available at: http://ilac.org/news/ilac-g19082014-published/. [Accessed 10 03 2021].

[15] Scientific Working Group on DNA Analysis Methods 'Validation Guidelines for DNA Analysis Methods', [online]. Available at: www.swgdam.org/publications. [Accessed 10 03 2021].

[16] Scientific Working Group on DNA Analysis Methods 'Interpretation Guidelines for Autosomal STR Typing by Forensic DNA Testing Laboratories', [online]. Available at: www.swgdam.org/publications. [Accessed 14 03 2021].

[17] European Network of Forensic Science Institutes (ENFSI) 'Recommended Minimum Criteria for the Validation of Various Aspects of the DNA Profiling Process, [online]. Available at: enfsi.eu/documents/forensic-guidelines/ . [Accessed 14 03 2021].

[18] Steffen, C. R., Kline, M. C., Duewer, D. L. and Vallone, P. M. (2015) 'Establishing traceability to NIST SRM 2391c: PCR-Based DNA Profiling Standard', Forensic Science International: Genetics Supplement Series, vol. 5, pp e112–113. doi.org/10.1016/J.FSIGSS.2015.09.045.

[19] National Institute of Standards and Technology 'NIST SRM 2391d – PCR-Based DNA Profiling Standard', [online]. Available at: https://www-s.nist.gov/srmors/view_datafiles.cfm?srm=2391d. [Accessed 14 03 2021].

[20] Forensic Science Regulator, 'Validation – Use of casework material validation', FSR-P-300, [online]. Available at: www.gov.uk/government/publications/protocol-using-casework-material-for-validation-purposes. [Accessed 14 03 2021].

[21] FBI Laboratory 'National DNA Index System (NDIS) Operational Procedures Manual., [online]. Available at: www.fbi.gov/file-repository/ndis-operational-procedures-manual.pdf/view. [Accessed 14 03 2021].

[22] International Organization for Standardization, ISO 18385:2016 'Minimizing the risk of human DNA contamination in products used to collect, store and analyse biological material for forensic purposes'.

[23] The Equality Act 2010, [online]. Available at: www.legislation.gov.uk/ukpga/2010/15/contents. [Accessed 10 03 2021].

20. Abbreviations and Acronyms

Abbreviation	Meaning
BS EN	British Standard European Norm
CJS	Criminal justice system
DNA	Deoxyribonucleic acid

ENFSI	European Network of Forensic Science Institutes
FBI	Federal Bureau of Investigation
FINDS	Forensic Information Databases Service
FSR	Forensic Science Regulator
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
NDNAD	National DNA Database®
NDIS	National DNA Index System
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 Methods
UK	United Kingdom
UKAS	United Kingdom Accreditation Service
USA	United States of America

21. Further Reading

Forensic Science Regulator, 'The control and avoidance of contamination in crime scene examination involving DNA evidence recovery', FSR-G-206. [online]. Available at: www.gov.uk/government/publications/crime-scene-dna-anti-contamination-guidance. [Accessed 14 03 2021].

Human Tissue Act 2004, [online]. Available at: www.legislation.gov.uk/ukpga/2004/30/contents. [Accessed 14 03 2021].

The Council of The European Union, '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', [online]. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1481187358403&uri=CELEX:32008D0616. [Accessed 14 03 2021].

The Royal Society and the Royal Society of Edinburgh (2017) 'Forensic DNA Analysis – A primer for courts'. [online]. Available at: www.royalsociety.org/~/media/about-us/programmes/science-and-law/royal-society-forensic-dna-analysis-primer-for-courts.pdf. [Accessed 14 03 2021].

United Kingdom Accreditation Service (2016, updated 2020) 'UKAS Policy on Participation in Proficiency Testing', TPS 47, edition 4, issued 4 February 2020, [online]. Available at: www.ukas.com/download/publications/Technical%20Policy%20Statements/TPS-47-Participation-in-PT-Edition-4-February-2020.pdf. [Accessed 14 03 2021].

Published by:

The Forensic Science Regulator

5 St Philip's Place

Colmore Row

Birmingham

B3 2PW

www.gov.uk/government/organisations/forensic-science-regulator