Guidance: Methods employing rapid DNA devices

FSR-GUI-0015

Issue 1

This document is issued by the Forensic Science Regulator in line with Section 9(1) of the Forensic Science Regulator Act 2021.

Contents

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 Portable instruments that can produce STR DNA profile results within two hours for a small number of samples per run have also been developed. 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 locations where PACE DNA samples are taken (for example, custody suites) 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 (incident scene, mass disasters e.g. terrorist attack) for processing samples in order to obtain investigative leads or to identify a deceased individual.
c. As part of laboratory casework.

1.1.4 A position for using rapid DNA devices was agreed 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 in 2020 [1]. The Regulator supports that position and the agreed areas that must be addressed before rapid DNA devices can be tested and considered for the analysis of casework samples.

2. Scope

2.1 General

2.1.1 This guidance document covers the use of rapid DNA devices employed to process the following sample types:

a. Buccal reference samples – these are good quality, high quantity DNA samples and can often be repeated if necessary.
b. Casework samples – (e.g., swabs, cigarette butts, body tissue, bone) these are sample types of variable composition, quality and quantity.

2.1.2 The guidance covers the process from sample preparation to profile designation for rapid DNA devices.

2.2 Terms and definitions

2.2.1 The terms and definitions set out in the statutory Code of Practice (the Code) [2] apply to this document.

2.3 Standards and regulation for DNA analysis

2.3.1 For a profile obtained using a rapid DNA device to be used in the criminal justice system in England and Wales it should be:

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

2.3.2 Manufacturers and suppliers of rapid DNA devices should understand the requirements set out in international standards ISO/IEC 17020 [3], ISO/IEC 17025 [4], and ILAC G19:06/2022 [5], for the testing and calibration requirements that the end users of the rapid DNA device need to demonstrate to their accreditation bodies.

2.3.3 The relevant requirements set out in the Code also apply.

3. Validation

3.1 Requirements

3.1.1 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.

3.2 DNA technology

3.2.1 The requirements set out in the Code and the relevant guidance documents should also be considered for the validation of the method, guidance documents can be found in the guidance collection on the Regulator's website [6].

3.2.2 Manufacturers and suppliers may also consider other appropriate international guidance [7], [8], [9]. Published material based on these guidance documents may be taken into account for validation or verification of the method.

3.2.3 Rapid DNA devices shall use validated methods for the extraction, amplification and profiling of DNA (Code, sec 103.6.3). rapid DNA devices are intended to be used in static and/or mobile environments and this shall be reflected in the validation and testing (Code, sec 30.2.3). As required by ILAC G19 (sec 3.10) the forensic unit shall review the validation records from the manufacturer/supplier and request information on the working environment parameters and limits of performance for the equipment and a summary of the supporting data. As required by the Code (sec 30.3.4) the end user shall verify the use of a rapid DNA device in their working environment, as defined by the user requirement and specification for the method.

3.2.4 As required by ILAC G19 (sec 3.10) 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 [10], [11].

3.2.5 As required by the Code (sec 103.7.1) validation studies shall include testing to ensure there is no cross-contamination between samples and, if appropriate, between runs.

3.2.6 The Regulator has published guidance on the use of casework material for validation [6].

3.3 Sample preparation

3.3.1 As required by the Code (sec 30.10.2) validation of the sample preparation and insertion method shall be conducted to demonstrate that as a minimum:

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.

3.3.2 As required by the Code (sec 30.10.2) 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.

3.4 Sample retrieval and reprocessing

3.4.1 As required by the Code (sec 30.2.10) 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.

3.5 Reference samples (buccal swabs)

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

3.5.2 A full, correctly designated profile is the expected result; failed alleles, dis-concordance and mutation differences are not classed as an error.

3.5.3 As required by the Code (sections 103.3.1 & 103.3.4), 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.

3.5.4 As required by the Code (sec 103.3.5) ongoing verification of the performance across batches shall be evidenced by quality control testing. In addition, the Code requires (sec 103.3.6) that any changes in the composition of the sampling material shall be risk assessed and either validated or verified to show that the performance is as good as or better than that previously validated.

3.5.5 The pass criteria include obtaining designated DNA profiles suitable for loading to and searching the National DNA Database® (NDNAD).

3.5.6 Single source DNA profiles do not need to be checked against an elimination database given the use of forensic DNA grade consumables and the high yield of DNA from buccal swabs.

3.6 Recovered biological material (casework samples)

3.6.1 Either quantification or a means to assess and address the effects of both degradation and inhibition for each sample type to be processed is required, as the samples are of variable composition, quality, and quantity and may not be repeatable.

3.6.2 As required by the Code (sec 30.2.3) the validation shall determine the limits of the rapid DNA device for various sample types and clearly identify what samples should and should not (for example, limited/ irreplaceable samples) be processed through the rapid DNA device.

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

a. Permit checking against an appropriate elimination database.
b. Carry out a speculative search that does not generate an unmanageable number of adventitious matches; or
c. Be suitable for loading to and searching the NDNAD.

3.7 Analysis interpretation software

3.7.1 The validation should analyse a complete range of alleles for the relevant loci, both simple and complex short tandem repeat primer sequences.

3.7.2 The allele data analysed should be of known designations and include rare alleles and anomalies such as tri-allelic variants.

3.7.3 As required by the Code (sec 103.8.1) manufacturers/suppliers shall provide evidence that the device can produce the expected correct profile (reference and casework) and obtain DNA profiles of the appropriate quality (predominantly casework). The profile mis-designation error rate for the final method should be provided; failed alleles, concordance and mutation differences are not classed as errors. As a minimum, analysis of 1,000 unique profiles and 200 more challenging DNA profiles of variable quality to represent casework is recommended; it is anticipated that some of this will have been completed as part of developmental validation studies.

3.8 The loading of DNA profiles from rapid DNA devices to the NDNAD

3.8.1 The approval for any forensic unit 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 purposes.

3.9 Verification by forensic unit

3.9.1 As required by ILAC G19 (sec 3.10) 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.

3.9.2 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.

4. Security

4.1 Data security and risk assessment

4.1.1 The Code covers 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 Code expects the forensic unit to identify key data and 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 as a result of information flow.

4.1.2 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 that a viable DNA profile has been obtained (or connected

to a database a ‘match’ or even a ‘non-match’), does not influence the impartiality of practitioners in their decision making.

4.1.3 Approaching all types of risk together allows the requirements in the Code to be addressed and ensures that a solution to one risk is not implemented if it inadvertently creates a second uncontrolled risk. For instance, if biometric and/or demographic data are stored on a device there is a risk that this information could be accessed by an unauthorised third party. The solution considered could be not to retain the data on the device. However, the process map should also show that there is a risk that data might 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.

4.1.4 The location where the rapid DNA device is to be used matters; from a security standpoint both in terms of its immediate physical environment, but also how the device is connected to the rest of the forensic unit’s network. If the intention is for the rapid DNA device to be used in a laboratory/examination area, then it may be appropriate to regard this simply as a normal laboratory instrument and the appropriate requirements in the Code for examination facilities shall be considered (section 29.1.2), the main requirement is the segregation of systems used for forensic science work from other networks.

4.1.5 If the operational requirement is to deploy the rapid DNA device in a non-traditional examination area, or 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 the Code (section 29.1.2) may still apply. Fulfilling the controls may require the device to have access controls including suitable controls for how the device is stored. Those setting the end user’s requirements for use of a Rapid DNA device need to recognise that the device is one part of a forensic unit’s process. Therefore,

the manufacturer should not be expected to include all of the required quality controls within the device.

4.1.6 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.

5. Quality assurance

5.1 Consumables

5.1.1 As required by the Code (sec 103.3.1 and 103.3.2) DNA consumables used shall be determined to be free from detectable levels of human DNA or shall be forensic DNA grade as demonstrated by compliance to ISO18385:2016 [13] or BSI PAS 377:2023 [14].

5.1.2 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.

5.2 Size standards and allelic ladders

5.2.1 As required by the Code (sec 103.9.2) the accuracy of the size standard to enable the correct allele designation shall be demonstrated.

5.2.2 As required by the Code (sec 103.9) the detection of allelic ladder leakage and a systematic contamination check shall be carried out. As a minimum this should include checks between samples and, where appropriate, between runs.

5.3 Pass criteria for reference (buccal) samples

5.3.1 The pass criteria should 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.

5.4 Pass criteria for recovered material (casework samples)

5.4.1 The pass criteria should 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 possible 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.

5.5 Ongoing monitoring

5.5.1 Process controls and ongoing monitoring of DNA analysis requirements are set out in section 103.9 of the Code.

5.6 Rapid DNA device

5.6.1 ISO/IEC 17025 requires laboratory equipment to have procedures for maintenance to ensure proper functioning (sec 6.4.3), therefore the rapid DNA device shall conduct routine system performance checks prior to and during the DNA process run that are recorded and retrievable by the end user for audit and troubleshooting purposes.

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

5.6.3 The manufacturer/supplier should provide the requirements for commissioning the equipment and routine maintenance for the rapid DNA device to operate at optimal conditions.

5.6.4 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 possible false negatives as a result of inhibition and/or degradation.

5.7 Environment and environmental controls

5.7.1 The end user shall carry out an assessment of the examination facility in which the rapid DNA device is operated that shall include consideration of the suitability of the location; power, IT requirements, operating surface (bench/table), suitability of the environment; temperature range, waste handling and consumable storage (Code, sec 29.1.2).

5.7.2 As described in section 48.2.2 of the Code, the end user shall ensure that sample preparation and use of the rapid DNA device is carried out in a suitable environment (i.e. the sample preparation is not conducted in the same location as the device and the device is not directly in contact with a scene environment).

5.7.3 The environment in which the rapid DNA device is placed should:

a. Have appropriate security (access control).
b. Have a schedule for maintaining suitable cleanliness, such as deep and routine cleaning of the operating environment and equipment.
c. Have environmental contamination monitoring of appropriate locations at a suitable frequency.
d. Not be a pre-PCR area used for preparing samples that are not intended for rapid DNA analysis.
e. Allow for the separation of casework and reference samples.
f. Minimise the risk of exposure to post-PCR products.

6. Competency and proficiency testing

6.1 Competency

6.1.1 As required in section 5.5(b) of ISO/IEC 17025, each role in the overall process shall be specified. The documented training and competency requirements for the overall process should 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.

6.2 Proficiency tests

6.2.1 Accredited DNA workflow(s) using rapid DNA devices should be included in the forensic unit's proficiency or interlaboratory comparisons (ILC) testing schedule for processing reference samples, recovered biological samples, or both, as applicable to the unit's specific deployment(s).

7. Modification

7.1.1 This is the first issue of this document.

7.1.2 The PDF is the primary version of this document.

7.1.3 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 three '#') indicate letters to describe the type of document and (b) (the second four '#') indicates a numerical code to identify the document. For example, this document is FSR-GUI-0015, and the 'GUI' indicates that it is a

guidance document. Combined with the issue number this ensures that each document is uniquely identified.

7.1.4 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 - ### - #### - #.

7.1.5 In the event of any discrepancy between the primary version and a modified version then the text of the primary version shall prevail.

8. Review

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

8.1.2 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@forensicscienceregulator.gov.uk

9. Acknowledgements

9.1.1 This guidance was adapted from the previous, non-statutory version of this document (FSR-G-229) and reviewed by the Forensic Information Databases Service.

10. References

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11. 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

12. Further Reading

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Published by:

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