Forensic Science Regulator

Overseeing Quality

Codes of Practice and Conduct

Appendix: DNA Analysis

FSR-C-108-001

Consultation Draft

This is a consultation draft and therefore should not be regarded or used as a standard. This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. Comments should be sent to FSRConsultation1@homeoffice.gsi.gov.uk using the form available from http://www.homeoffice.gov.uk/agencies-public-bodies/fsr/ and should be submitted by 10 MARCH 2013. This mailbox is not for general correspondence and is not routinely monitored, so no acknowledgement will normally be sent.
THIS DRAFT IS NOT CURRENT BEYOND 10 MARCH 2013.

1. INTRODUCTION

1.1.1 This appendix provides further explanation of some of the requirements of the Codes specifically pertaining to the provision of DNA analysis.

1.1.2 This appendix should be read alongside with the Codes, BS EN ISO/IEC 17025:2005 and ILAC-G19 and will generally follow the heading titles used in the Codes with cross references to ISO 17025:2005 given in parentheses where appropriate.

2. SCOPE

2.1.1 This appendix provides further explanation of some of the requirements of the application of the Codes specifically pertaining to the detection, recovery and examination of DNA and the use of DNA evidence.

2.1.2 The requirements are for all STR based analyses and where appropriate other chromosomal or mitochondrial DNA analyses conducted for the Criminal Justice System, whether performed in a conventional laboratory or by an alternative analysis method elsewhere.

3. PACKAGING AND GENERAL CHEMICALS AND MATERIALS (ISO 17025:2005, 4.6)

3.1.1 Where it is critical for consumables and reagents to have an absence of detectable human DNA, testing may be in the form of batch testing to demonstrate successful clean production standards, a validated technique of post production treatment or both.[1]

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

3.1.3 All testing must be traceable and available for disclosure. The use of potentially misleading phrases such as ‘DNA-free’ and ‘DNA-clean’ should be avoided,

[1] This can be demonstrated by consumable manufacturers and kit assemblers meeting the requirements set out in the Publically Available Specification (PAS) 377 “Specification for consumables used in the collection, preservation and processing of material for forensic analysis - Requirements for product, manufacturing and forensic kit assembly”.

phrases such as Forensic Science Grade or PCR Grade would be acceptable alternatives provided the exact nature of the test is disclosed.

3.1.4 Any detected or reported problems with packaging or materials already in the evidential chain will require an appropriate risk or case assessment.

4. CONTAMINATION AVOIDANCE, MONITORING AND DETECTION (ISO 17025:2005, 5.3.3, 5.8)

4.1.1 The provider should have policies and procedures to ensure access to laboratory areas are restricted to individuals covered by an adequate staff and visitor elimination database. This database may be locally or remotely maintained.

4.1.2 Elimination databases should include as far as is practical, all those that are associated with the collection/recovery of evidence, its analysis, and the processing environment, including staff, visitors and sub-contractors.

4.1.3 Policies and procedures for elimination databases of laboratory staff, visitors and equipment suppliers should include, but are not limited to:

a. Reporting policies;

b. Data formats;

c. Searching procedures & algorithms;

d. Retention periods;

e. Sharing agreements (i.e. Between laboratories/providers);

f. Agreements/consents; and

g. Release forms.

4.1.4 Casework DNA laboratories should maintain a log of negative control results to record drop-in and gross contamination events. The purpose will be to act as a monitoring tool and also to provide data that may be used in probabilistic models for reporting purposes

4.1.5 Any detected or reported contamination problems with packaging or materials already in the evidential chain will require an appropriate risk or case assessment.

5. SELECTION OF METHODS (CODES, 17; ISO 17025:2005, 5.4.2)

5.1.1 It is expected that all providers to the Criminal Justice System will routinely use a validated quantification technique[2] 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:

a. 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, when a partial or no profile has been obtained, then the possibility of inhibition should be explored.[3]

b. 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, reworking considered and recorded.

c. Exceptional instances where in the professional opinion of the scientist a separate quantification step normally required in a protocol is not advisable or not required this should be clearly communicated to the customer and recorded.[4]

5.1.2 The interpretation method using qualitative or probabilistic techniques (or a combination of the two) should include consideration of:

a. Allele drop-in;

b. Allele drop-out;

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[2] Validated methodologies such as direct PCR are also acceptable; however such methodologies should also cover the issue of potential inhibition etc. covered in 5.1.1a-c.

[3] Policies may require this routinely or only when the quantification value indicates an unexpected profiling result.

[4] Such instances include where the amount of available evidential material is considered in the professional opinion of the scientist to be so low that using some of the material risks the ability to obtain an interpretable profile.

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; and

g. Methodology for reporting a single test result or replicate analyses as a single figure e.g. likelihood ratio.

6. VALIDATION OF METHODS (CODES, 20.2; ISO 17025:2005, 5.4.5)

6.1.1 The validation procedure contained in the Codes will be followed whether this is an adopted method which has been developed and validated elsewhere or developed at a laboratory of the provider. The Codes allow for tailoring of the validation procedure through verification of the extent and scope of supporting external validation studies.

6.1.2 The validation procedure shall generally be expected to include, but is not limited to:

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

b. Risk assessment of the method;

c. A review of the end-user's requirements and specification;

d. The acceptance criteria;

e. Development plan;

f. The validation plan;

g. The outcomes of the validation exercise;

h. Assessment of acceptance criteria compliance;

i. Validation report;

j. Statement of validation completion; and

k. Implementation plan.

6.2 Validation of Measurement Based Methods (CODES, 20.8)

6.2.1 For DNA methods, the parameters/characteristics in the validation plan shall include, as appropriate;[5]

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 (e.g. 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 (e.g. To environmental and chemical factors);

i. Repeatability and reproducibility;

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;

[5] See SWGDAM Revised Validation Guidelines, July 2004

r. 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.

7. DATABASES (CODES, 20.18.4; ISO 17025:2005, 5.4.7)

7.1.1 Laboratories shall maintain local databases of profiles detected from batch testing reagents and negative controls as a way of detecting contamination events as part of an integrated elimination database.

7.1.2 Elimination databases may be locally or remotely maintained. Laboratories may maintain local DNA databases of volunteers for staff, visitors, suppliers and sub contractors.

7.1.3 Laboratories shall utilise, as required, DNA allele frequency and haplotype (e.g. 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. Any limitations on their use shall be documented and revealed alongside any interpretation or opinion provided.

7.1.4 Other databases may be held as directed by the customer (such as for intelligence led screens).