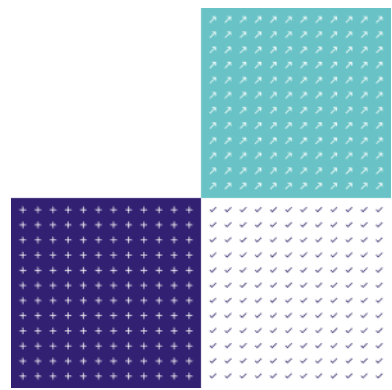


LAB 32

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Accreditation for suppliers to the UK National DNA Database



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Changes since last edition

Updated to reflect changes to the requirements of the Forensic Information Databases Service (FINDS) and changes to standards and frameworks.

1. Introduction

- 1.1 Laboratories that have been assessed by UKAS as meeting the requirements of ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories may be granted UKAS accreditation. Several publications providing guidance on the application of these requirements are listed on the UKAS website (www.ukas.com).
- 1.2 This publication has been prepared by UKAS in collaboration with the Home Office's Forensic Information Databases Service (FINDS), which is responsible for the delivery of the National DNA Database (NDNAD). It sets out how the requirements within ISO/IEC 17025:2017 shall be applied to organisations undertaking DNA analysis for the purpose of submitting data to the NDNAD and complies with the Forensic Science Regulator Code of Practice (the 'FSR Code'). It does not cover all the requirements of ISO/IEC 17025:2017, which remains the authoritative document.
- 1.3 An agreement between UKAS and FINDS defines the obligations of each party, and on laboratories that have been, or wish to be accredited to analyse samples and have been authorised to generate and load DNA profiles to the NDNAD. The agreement does not cover the search and recovery of body fluids. Requirements for laboratories are detailed in this publication.



2. Requirements for suppliers to the UK National DNA Database

- 2.1 The Criminal Justice and Public Order Act 1994 amends the Police and Criminal Evidence Act (PACE) 1984 and sets out the general conditions under which DNA samples can be taken, used, retained and speculatively searched against samples from unsolved crimes. Following on from this, the Home Office published circular 16/95, which set out the arrangements for the analysis of DNA samples, and the management and use of the NDNAD.
- 2.2 The amended PACE legislation allows for non-intimate samples to be taken for the purposes of DNA profiling from anyone suspected of involvement in a recordable offence, and for the profiles obtained to be checked against existing records of unsolved crime stains in a speculative search.
- 2.3 Custodianship of the NDNAD is established through the overall Governance arrangements for oversight of the Database. The Home Office, through FINDS, is accountable to the FIND Strategy Board for delivery of operational NDNAD services, the setting and maintenance of Forensic Supplier requirements, and maintenance of NDNAD quality and integrity.
- 2.4 All Forensic Suppliers that are accredited to load DNA profiles to the NDNAD are required to use documented protocols that are acceptable to FINDS.

Forensic Suppliers shall also: -

- demonstrate to FINDS that they are competent and able to produce profiles that are compatible with those on the NDNAD
 - adopt internal handling processes and procedures that conform to the rules of continuity and preservation of evidence
 - carry out an internal quality assurance program in accordance with the specification set by FINDS
 - be UKAS accredited for their DNA profiling services
 - comply with the FSR Code and
 - be present on the Information Commissioner's Office (ICO) 'Register of data protection fee payers' for the purposes of conforming to the Data Protection (Charges and Information) Regulations 2018.
- 2.5 The agreement that exists between FINDS and UKAS provides for UKAS to incorporate the additional requirements of FINDS, set out in the relevant FINDS Quality Management System (QMS) documents, into the assessment and accreditation process for laboratories acting as Forensic Suppliers or intending to apply for approval to act as Forensic Suppliers of DNA profiles to the NDNAD. The application process for new Forensic Suppliers shall be initiated in writing by each Forensic Supplier to both FINDS and UKAS. Copies of the FINDS QMS documents are available to prospective Forensic Suppliers by request to FINDS. The FINDS waiver needs to be in place for existing and applicant Forensic Supplier laboratories to enable UKAS to disclose relevant information relating to assessment and accreditation to FINDS who may then forward this information to the FIND Strategy Board and/or the Office of the Forensic Science Regulator if required.

3. Methods and procedures

3.1 General requirements

- (a) All laboratories supplying DNA profiles to the NDNAD shall meet the requirements of ISO/IEC 17025:2017 and the additional requirements given in the relevant FINDS QMS documents and the FSR Code. Compliance with these requirements will be assessed by UKAS through routine annual assessment and ad hoc assessment as required.
- (b) UKAS and FINDS shall be informed as soon as changes to a laboratory's activities are planned. This includes changes such as, but not limited to, accommodation, equipment, protocols and/or key staff. UKAS and FINDS shall then evaluate the proposed change and determine the type and extent of assessment required to ensure the continued accreditation status of the organisation.

3.2 Specific methodology

- (a) Laboratories must have fully documented and validated procedures for carrying out all activities involved in analysis of forensic DNA samples where the profile may be loaded to the NDNAD. These shall be documented in accordance with ISO/IEC 17025:2017 and the requirements of FINDS QMS documents. The documented procedures shall include sample receipt and handling, preparation of samples for DNA processing, laboratory techniques, and analysis and reporting of results.
- (b) A laboratory using accepted published methods shall have determined the performance characteristics of the method and shown its capability to meet the performance criteria described in the method before accreditation is granted. Additionally, in accordance with UKAS document TPS 47, laboratories preparing for accreditation are required to participate in Proficiency Testing or Interlaboratory Comparison schemes before accreditation can be granted.
- (c) Specific methods developed in the laboratory shall be fully validated as specified in ISO/IEC 17025:2017, and according to the specified FINDS QMS documents before use. Further guidelines on validation of techniques for use in Forensic laboratories are detailed in ILAC G19 Modules in a Forensic Science Process and the FSR Code.
- (d) After approval, any subsequent significant changes to methods and procedures (examples of which are included in FINDS QMS documents) shall be notified to both UKAS and FINDS before they can be used. The impact of any changes made to methods shall be fully assessed and the method revalidated as appropriate.

3.3 On-going quality control

- (a) As part of their quality systems, laboratories shall operate systematic quality control schemes to monitor day-to-day and batch-to-batch analytical performance of all the analysis undertaken.
- (b) Procedures shall incorporate the need to carry out repeat analysis in accordance with FINDS requirements. In the case of a Rapid DNA set-up, the rate (or actual presence) of allelic ladder usage would be considered based on the specific instrument used and set-up employed, with the laboratory providing details of what integrity checks/quality control could be applied to provide assurance that the set-up is fit for purpose.
- (c) Significant changes to location, equipment, process, software, materials used, or quality control/assurance processes, made after validation of the process approved for use must be assessed as to their impact on the DNA profiles obtained, and be validated accordingly. The

FSP should inform UKAS of Extensions to Scope and significant planned changes so that these can be reviewed by UKAS/FINDS to define the approach to be taken.

- (d) Procedures must also incorporate the requirement for validating/confirming prospective matches.

3.4 Retention of samples

Laboratories must operate a suitable system for the retention of samples (partial, or all remaining, where testing does not use the entire item), and for the destruction of samples as required by current legislation and guidance.

Similarly, laboratories shall operate a suitable system for the deletion of profiles as required by current legislation.

4. Assessment procedures

- 4.1 Assessment shall follow the standard UKAS procedure as detailed in relevant UKAS Publications and shall aim to establish the laboratory's compliance with all of the requirements of ISO/IEC 17025:2017, FINDS QMS documents, the FSR Code and any other relevant criteria of competence specified by UKAS.

- 4.2 In addition the assessment will include:

- (a) the laboratory's reporting arrangements for supply of profiles to the NDNAD;
- (b) arrangements for business continuity;
- (c) storage of samples and their associated data, including suitability of the facilities, access and security;
- (d) vertical audit of samples selected at random to cover all aspects of analysis and reporting;
- (e) confirmation that the organisation is present on the Information Commissioner's Office (ICO) 'Register of data protection fee payers' for the purposes of conforming to the Data Protection (Charges and Information) Regulations 2018;
- (f) issues identified through performance monitoring by FINDS in the proficiency testing programme, the repeat analysis programme and the reporting of unexpected results;
- (g) any aspect of the laboratory, its procedures, methods or staff that the assessment team considers necessary to confirm compliance with the requirements.

- 4.3 The granting and renewal of accreditation will be afforded only to a laboratory which continually complies with the above requirements.

- 4.4 The UKAS assessment team may include a member of staff from FINDS acting as a technical assessor. FINDS must make available sufficient resource to support the assessment of its requirements.

5. Monitoring of laboratory performance in proficiency testing schemes

- 5.1 FINDS has set out specific requirements for Forensic Suppliers of DNA profiles to the NDNAD to participate in a proficiency testing scheme as a condition of continued approval to load to the NDNAD. Laboratories are required to make available to UKAS the data and results associated with the specified monitoring scheme (e.g. declared, undeclared proficiency testing samples, and where applicable, methods of duplication process control). Laboratory management should take steps to ensure that, wherever possible, declared proficiency tests are allocated in such a way that all staff involved in DNA analysis will, over a period of time, be included in the analysis of proficiency test samples. Continuing satisfactory performance, as defined by the scheme organisers, will be a condition for maintenance of accreditation for suppliers to the NDNAD. Where satisfactory performance is not achieved, the laboratory shall investigate the cause of the apparent poor performance. If necessary, accreditation and permission to load to the NDNAD will be suspended until such time as satisfactory performance, as determined by FINDS and UKAS, has been resumed.
- 5.2 FINDS will inform the FIND Strategy Board where laboratories fail to satisfy the defined performance requirements. This may result in a removal of approval to load to the NDNAD.

6. Scope of accreditation

- 6.1 The Schedule of Accreditation for a laboratory will describe the scope of accreditation in terms of materials tested, or types of test and method of test. Forensic Suppliers accredited to load profiles to the NDNAD will be confirmed as such by the use of the phrase: 'for the purpose of supply of profiles to the National DNA Database'. The phrase will be applied to subject samples and/or crime stain samples as appropriate. Additionally, FINDS will hold a Statement of Unit Configuration (SoUC) for each individual unit within an organisation. Any changes that are required to the SoUC must be communicated to both FINDS and UKAS.

7. References

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

The Forensic Science Regulator Code of Practice

ILAC G19 Modules in a Forensic Science Process

UK General Data Protection Regulation (UK GDPR). For information on how UKAS protects data please see our privacy policy for Customers and Stakeholders on our website. For information on our respective obligations under UK GDPR please refer to our UKAS standard terms of business. For more information on UK GDPR, you can refer to the Information Commission Office.

Memorandum of Understanding between ACPO (now NPCC) and Custodian of the National DNA Database, September 2005 (superseded by the NPCC Statement of Requirements (SoR)).

FINDS QMS documents (available to applicant suppliers, on request, from FINDS)

8. Glossary of terms

ACPO (now NPCC)	Association of Chief Police Officers (now National Police Chiefs' Council)
APA (now APCC)	Association of Police Authorities (now Association of Police & Crime Commissioners)
FINDS	Forensic Information Databases Service
Custodian	Responsible organisation (in this case Home Office), for control, maintenance and delivery of NDNAD and related services
FSS	Forensic Science Service
ILAC	International Laboratory Accreditation Cooperation
FSR Code	The Forensic Science Regulator Code of Practice
Forensic Information Databases (FIND) Strategy Board	a tripartite board composed of NPCC, APCC and the Home Office responsible for overseeing and directing FINDS and NDNAD activities
NDNAD	National DNA Database
UK GDPR	Retained Regulation (EU) 2016/679 (United Kingdom General Data Protection Regulation (UK GDPR))
PACE sample	DNA sample taken from an individual under Police and Criminal Evidence Act 1984
QMS	Quality Management System
SoR	Statement of Requirements
SoUC	Statement of Unit Configuration
UKAS	United Kingdom Accreditation Service