# *Forensic Identity*

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| The Forensic Identity Permit requires compliance with current Federal Bureau of Investigation Quality Assurance Standards for Forensic DNA Testing Laboratories and DNA Databasing Laboratories, as applicable. | |
| ***Quality Assurance Program*** | |
| **Forensic Identity Standard of Practice 1 (FI S1): Quality System**<br>The laboratory must maintain a current, comprehensive quality system and corresponding quality manual which, at a minimum, address all applicable FBI standards and all relevant New York State Clinical Laboratory Standards of Practice and Forensic Identity Standards. | |
| ***Organization and Management*** | |
| **Forensic Identity Standard of Practice 2 (FI S2): Organization Structure**<br>The organizational structure of the laboratory must be defined and the interrelationship of all individuals indicated on a current organization chart. The following individuals must be identified on this chart: the laboratory director, the assistant director, all other individuals with a current certificate of qualification in Forensic Identity, the technical leader, the QA manager, the health and safety manager, all analysts, all technicians and all laboratory support personnel. | While the organization may choose to use other job titles, cross-reference to FBI-defined titles must be made on this chart. |

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| **Forensic Identity Standard of Practice 3 (FI S3): Director and Technical Leader Continuing Education**<br>Continuing education of the laboratory director and/or the technical leader must include one national DNA forensics meeting at least every four years. | Please note, continuing education of staff is addressed in Human Resources Standard of Practice 10. |
| **Forensic Identity Standard of Practice 4 (FI S4): Technical Leader Responsibilities**<br>The technical leader must be readily available, must fulfill all the duties of a technical leader, and must have the authority to halt testing if quality is compromised. If the technical leader is on-site less than fifty (50) percent of the laboratory work week, on average, the laboratory must have documented policies and procedures indicating how the technical leader fulfills his/her duties while off-site. | |
| **Forensic Identity Standard of Practice 5 (FI S5): Databasing Services Staff**<br>Laboratories offering databasing services must have a staff member designated as the individual responsible for interacting with the client CODIS manager. This individual must maintain familiarity with CODIS requirements and procedures. This individual must have a working knowledge of computers, computer networks including network security, and computer database management, with an understanding of DNA profile interpretation. If this individual is responsible for actual data interpretation, he/she must be qualified as an analyst and must participate in proficiency testing. | |

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| ***Facilities and Security*** | |
| **Forensic Identity Standard of Practice 6 (FI S6): Laboratory Floor Plan**<br>The laboratory must have available a current floor plan of the laboratory indicating: major equipment, pre- and post-amplification areas, areas with controlled traffic flow, and areas maintained at different security levels. | |
| ***Evidence or Sample Control*** | |
| **Forensic Identity Standard of Practice 7 (FI S7): Low-copy DNA Specimen Processing**<br>Specimens expected to yield low-copy number DNA must be processed at separate times and/or in separate places in the laboratory than specimens expected to yield abundant DNA. Reference samples must be processed at separate times and/or in separate places in the laboratory relative to evidence samples. | The laboratory must make a good faith effort to identify those samples which may only provide enough DNA for one attempt at analysis. In these cases, the sample should be processed separately at each step for which there is not adequate material to allow a repeat of the process if a problem should occur |
| **Forensic Identity Standard of Practice 8 (FI S8): New York State Law Compliance**<br>The laboratory must comply with Section 79-L of the New York State Civil Rights Law. | Section 79-L of the Civil Rights Law is available at: www.wadsworth.org/regulatory/clep/laws.<br>The laboratory must inform submitting agencies of the requirement to adhere to 79-L of the New York State Civil Rights Law. Consent forms are recommended for voluntarily submitted specimens; however, an individual from the referring agency may provide a statement indicating that the sample was collected in a manner consistent with New York State Law. Samples submitted from convicted offenders, from a crime scene, or by court order, do not require informed consent. |

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| **Forensic Identity Standard of Practice 9 (FI S9): Submission Instructions**<br>In addition to the requirements in Specimen Processing Standard of Practice 1, the client instruction manual must include a requirement that only properly sealed packages will be accepted for analysis (packages sealed in a tamper-evident manner, with the identification of the individual packaging the specimens indicated). Improperly sealed packages must be returned to the submitting agency. | Each agency submitting New York State samples for analysis must be notified in writing at least once of the requirement that submitted packages be properly secured during transport to the laboratory. A copy of this notification should be maintained by the laboratory. It is acceptable to return an improperly sealed package to the submitting agency. The submitting agency can then reassess the integrity of the evidence and return the package, properly sealed, to the laboratory for analysis. |
| **Forensic Identity Standard of Practice 10 (FI S10): Internal Chain of Custody Procedures**<br>Internal chain of custody procedures must document that evidence is secured. All transfers of evidence must be documented. The use, storage and disposition of work product must be discernable from maintained case notes. | |
| **Forensic Identity Standard of Practice 11 (FI S11): Evidence Consumption Authorization**<br>Evidence must not be consumed in testing without prior written authorization by the submitting agency or authorized person. E-mail authorization is allowed, and must be retained with the case file. | Refer to Federal Bureau of Investigation Quality Assurance Standards (FBI QAS) for Forensic DNA Testing Laboratories - definition for evidence, standard 7.4, 7.4.1, and the FBI QAS Guidance Document – guidance for standard 7.4.1. |
| **Forensic Identity Standard of Practice 12 (FI S12): Evidence Integrity**<br>The laboratory must not destroy unconsumed forensic casework evidence, personal effects items, or the associated DNA extracts, without the prior written authorization of the submitting agency. An exception will be made for liquid blood provided as a | |

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| reference sample, as long as dried blood samples are preserved. | |
| ***Validation*** | |
| **Forensic Identity Standard of Practice 13 (FI S13): Validation Approval**<br>Non-DNA-based methods (e.g. serological methods) must also be validated and a summary of each validation study must be made available. Validation of these methods must be approved by the Department *prior* to their use in New York State casework. | |
| ***Analytical Procedures*** | |
| **Forensic Identity Standard of Practice 14 (FI S14): Test Deviation**<br>The laboratory must have a documented policy addressing the process for deviating from established and approved standard operating procedures or policies. | |
| **Forensic Identity Standard of Practice 15 (FI S15): National DNA Index System**<br>Analysis of the FBI-designated core CODIS STR loci must be performed using a National DNA Index System (NDIS)-approved PCR kit. | |

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| **Forensic Identity Standard of Practice 16 (FI S16): Mitochondrial DNA Nucleotide Sequence Interpretation**<br>Laboratories performing mitochondrial DNA sequence analyses must comply with the current Guidelines for Mitochondrial DNA (mtDNA) Nucleotide Sequence Interpretation as provided by the Scientific Working Group on DNA Analysis Methods (SWGDAM) and the data acceptance criteria as provided by the contracting laboratory or laboratory taking ownership of the profile(s). | |
| **Forensic Identity Standard of Practice 17 (FI S17): Limited Sample Reagent Testing**<br>In addition to routine quality control (QC) of critical reagents to ensure their proper functioning, QC testing must be performed on *all* reagents prior to their use in DNA testing or body fluid screening/identification tests of a sample which cannot be recollected or retested. | |
| **Forensic Identity Standard of Practice 18 (FI S18): PCR Inhibition Detection**<br>The laboratory must have available a method to detect inhibition of PCR amplification and must include a control for PCR inhibition when the state of the evidentiary material suggests inhibitors of the polymerase chain reaction might be present. | |
| ***Reports*** | |
| **Forensic Identity Standard of Practice 19 (FI S19): Case File Retrieval**<br>The laboratory must maintain case files according to Document and Specimen Retention Standard of Practice 9. The laboratory | |

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| must have a system for maintaining and retrieving each case file, including case notes not contained in the final case report. Such files must be adequately protected against modification or destruction either by using duplicated photographic or electronic medium with storage at a second secure site, by storage in secure fireproof file cabinets, or by other suitable means providing equivalent protection. | |
| **Forensic Identity Standard of Practice 20 (FI S20): Reports and Case Files**<br>In addition to the requirements in Reporting Standard of Practice 2, the signature of the analyst responsible for data interpretation must be included in the report and the analyst must indicate his/her review of each page of the case report and file. The case record must indicate the identities of the technical and administrative reviewers. The case identifier must be indicated on all pages of the case file. The final case file must indicate each page number and the total number of pages contained within the file. | A printed footer with the required information is acceptable if the cover page indicates that the analyst has reviewed and approved the entire file. At a minimum, the case file must contain: the request for analysis, accessioning information, chain of custody documentation, all relevant analyses, worksheets, results, interpretation, reports rendered and documentation of the disposition of evidence and derivative samples. All items contained within the case file (e.g. photographs) must be marked with the case identifier and secured to prevent their loss.<br>Mistakes in case notations must not be obliterated, and the correct information must be recorded with the date and initials of the person making the correction. Original electronic data must be maintained as long as the case file and must be protected from loss or modification. |
| ***Review*** | |
| **Forensic Identity Standard of Practice 21 (FI S21): Case Analysis Review**<br>A technical and administrative review of each case analysis, by a qualified individual(s) distinct from the primary analyst, must be conducted prior to the release of the results of the case to | Technical review must consist of a separate, independent analysis of all data associated with a case. This must include verification of run dates, an analysis of all raw data, including controls, as well as interpretation, calculations and conclusions |

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| the submitting agency. The laboratory must define the qualifications and training required to act as a technical or administrative reviewer. The elements of administrative and technical reviews must be defined in a review checklist. | reached. Raw data does not have to be printed out, but must be maintained electronically. |
| **Forensic Identity Standard of Practice 22 (FI S22): Data Review**<br>An NDIS-approved expert system can be used to replace the initial manual review of offender or known reference data by an analyst. A second technical review is still required.<br>Two independent NDIS-approved expert systems may be used for review of data where New York State approved validation studies, validated in accordance with applicable NDIS operational procedures, have demonstrated that such expert systems, used jointly, work as reliably as manual reviews by qualified analysts. | |
| ***Proficiency Testing*** | |
| **Forensic Identity Standard of Practice 23 (FI S23): Proficiency Testing Program Participation**<br>All staff processing samples/data from New York State must participate in an ANAB-approved proficiency testing (PT) program to the fullest extent that each staff member performs casework/databasing work.<br>When no relevant ANAB-approved proficiency test is available, the lab must participate in a proficiency testing program as available, or internally develop an equivalent internal system using material for which the result is known (e.g. for presumptive or confirmatory testing). | |

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| Each staff member performing screening, extraction, quantitation, amplification, analysis, interpretation and review, must successfully participate in two proficiency tests per year.<br><br>At least once a year, each staff member must be tested for each New York State-approved analytical method he/she is qualified to perform.<br><br>Any lapse in proficiency testing due to temporary absence from laboratory activities, such as for medical leave or military service, must be documented.<br><br>Any unsatisfactory PT performance must be reported to the Forensic Identity Section within two weeks of learning of the PT result. | |
| **Forensic Identity Standard of Practice 24 (FI S24): Proficiency Testing Activities**<br><br>Every six (6) months, each Forensic Identity-permitted laboratory must submit a brief summary of proficiency testing (PT) activities to the Forensic Identity Section.<br><br>The following information must be reported for each staff member participating in external or internal PT in the previous six (6) months:<br><br>a) name;<br><br>b) PT provider;<br><br>c) role of the PT participant, i.e., technical, technical review, administrative review;<br><br>d) analytes tested by this staff member; and | |

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| e) laboratory director or responsible assistant director signature verifying that the PT performance was completed satisfactorily. | |
| **Forensic Identity Standard of Practice 25 (FI S25): Documentation of Program Implementation**<br>The process for implementing the laboratory's proficiency testing program must be documented.<br>This must include information on who administers the program, how and where the testing documentation is maintained, how results are communicated to laboratory members, and the process for taking corrective action when appropriate. | |
| **Forensic Identity Standard of Practice 26 (FI S26): Proficiency Testing Documentation**<br>The laboratory must retain proficiency testing documentation according to Document and Specimen Retention Standard of Practice 9.<br>The staff member directing proficiency testing must be readily able to produce the following information pertaining to New York State Forensic Identity Program-required proficiency testing: a list of all technical personnel and all individuals involved in technical and/or administrative review of case results.<br>For each staff member, there must be a listing of the tests/activities the individual is qualified to perform and the associated dates of qualification.<br>The annual PT plan for each individual must be detailed (what tests will be performed on each PT). Dates of distribution and | |

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| submission of proficiency test results, the activities tested and test results for each tested staff member must be documented. | |
| ***Corrective Action*** | |
| **Forensic Identity Standard of Practice 27 (FI S27): Nonconformance Notification**<br>Within two (2) weeks of the discovery of a nonconformance having the potential to affect interpretation of case results or any incident involving staff misconduct affecting testing processes, documentation must be provided to the New York State Forensic Identity Section.<br>For non-New York State cases, notification need not reference the specific case. | |
| **Forensic Identity Standard of Practice 28 (FI S28): Corrective Action Documentation**<br>The laboratory must retain corrective action records according to Document and Specimen Retention Standard of Practice 1.<br>In situations where the investigation of the nonconformance and the corrective action taken led to an amended case(s) report, documentation must be retained for as long as the case documentation.<br>While the corrective action documentation may be kept in separate logs, a central listing of all incidents requiring corrective action must be available to auditors upon request. | |

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| ***Audits*** | |
| **Forensic Identity Standard of Practice 29 (FI S29): Audit Documentation**<br>The laboratory must retain audit documentation according to Document and Specimen Retention Standard of Practice 1. Documentation must include a list of all external and internal audits performed within the past three (3) years, who conducted the audit, and the dates of the audit must be available. The corresponding audit documents, the laboratory's response to any findings and any follow up documentation must be available for review during the on-site survey. | |