Forensic Identity

Standard	Guidance
All laboratories shall comply with the applicable requirements contained in the NYS DOH General Systems standards. Laboratories performing DNA analyses in forensic paternity cases shall also comply with applicable requirements in the NYS DOH Paternity/Identity Standards. All permitted laboratories performing forensic DNA testing shall also be in compliance with the most recent version of the Federal Bureau of Investigation Quality Assurance Standards for Forensic DNA Testing Laboratories and, as applicable, DNA Databasing Laboratories. In addition, the forensic identity laboratory shall meet the applicable Forensic Identity NYS standards outlined below. Revised and effective September 13, 2018	
QUALITY ASSURANCE PROGRAM	
Forensic Identity Standard 1 (FOID S1) The laboratory shall maintain a current, comprehensive quality system and corresponding quality manual which, at a minimum, address all the FBI standards and all relevant NYS General and Forensic Identity Standards.	
ORGANIZATION AND MANAGEMENT	
Forensic Identity Standard 2 (FOID S2) The organizational structure of the laboratory shall be defined and the interrelationship of all individuals indicated on a current organization chart. The following individuals shall be identified on this chart: the laboratory director, the assistant director, all other individuals with a current NYS 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 shall be made on this chart.

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PERSONNEL	
Forensic Identity Standard 3 (FOID S3) In addition to the requirements set forth in General Systems Human Resources Sustaining Standards, the laboratory must maintain records of the following for each employee: • documentation of review of current literature; • documentation of court testimony (or lack thereof) in any given calendar year.	Human resources information may be maintained in different on-site locations provided that a master list is developed which indicates the locations of all the information and all the information is readily available to auditors.
Forensic Identity Standard 4 (FOID S4) The laboratory shall have a documented training program for qualifying all technical and support staff participating in processing of evidentiary materials, sample analysis, technical or administrative review and/or reporting of results. Documentation of training shall be maintained. Successful completion of a competency exam shall mark the end of a training module and shall be formally recognized in writing by the laboratory director or an individual authorized by the laboratory director. All individuals, regardless of previous training and experience, shall successfully complete a qualifying test for the specific DNA technology to be used at the current laboratory prior to assuming casework responsibilities.	

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Forensic Identity Standard 5 (FOID S5) Continuing education of the laboratory director and/or the technical leader shall include one national DNA forensics meeting at least every four years.	Please note; continuing education of staff is addressed in proposed Human Resources Sustaining Standard of Practice 10: Continuing Education.
Forensic Identity Standard 6 (FOID S6) The technical leader shall be readily available to fulfill all the duties of a technical leader and shall have the authority to halt testing if quality is compromised. If the technical leader is on-site less than 50% of the laboratory work week, on average, the laboratory shall have documented policies and procedures indicating how the technical leader fulfills his/her duties while off-site.	
Forensic Identity Standard 7 (FOID S7) Laboratories offering databasing services shall have a staff member designated as the individual responsible for interacting with the client CODIS manager. This individual shall maintain familiarity with CODIS requirements and procedures. This individual shall 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 shall be qualified as an analyst and shall participate in proficiency testing.	
FACILITIES AND SECURITY	

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Standard	**Guidance**
Forensic Identity Standard 8 (FOID S8) The laboratory shall have available a current floor plan of the laboratory with major equipment and pre-amplification and post-amplification areas indicated and with any relevant controlled flow of traffic. Areas maintained at different levels of security shall be indicated.	
EVIDENCE OR SAMPLE CONTROL	
Forensic Identity Standard 9 (FOID S9) Specimens expected to yield low-copy number DNA shall be processed at separate times and/or in separate places in the laboratory than specimens expected to yield abundant DNA. Reference samples shall 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 10 (FOID S10) The laboratory shall comply with Section 79-l of the NYS Civil Rights Law.	The laboratory shall inform submitting agencies of the requirement to adhere to 79-l of the NYS 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 NY 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 11 (FOID S11) The client instruction manual shall 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 shall be returned to the submitting agency.	Each agency submitting NYS 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 12 (FOID S12) Internal chain of custody procedures shall document that evidence is secured. All transfers of evidence shall be documented. The use, storage and disposition of derivative evidence shall be discernable from maintained case notes.	
Forensic Identity Standard 13 (FOID S13) The integrity of the original specimen shall be maintained by storage in a secured space with access limited to authorized staff. Evidence shall not be consumed in testing without prior written authorization by the submitting agency or authorized person. E-mail authorization is allowed. A printed copy of the e-mail communication should be included in the case file. A reasonable attempt shall be made to protect evidence from fire or water damage.	

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Standard	Guidance
Forensic Identity Standard 14 (FOID S14) The laboratory shall have a policy on disposition of samples. However, in no case shall the laboratory 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 reference sample as long as dried blood samples are preserved.	
VALIDATION	
Forensic Identity Standard 15 (FOID S15) Non-DNA-based methods (e.g. serological methods) which are used to evaluate biological specimens for their suitability for DNA analysis shall also be validated and a summary of each validation study shall be made available. Validation of these methods shall be approved by the NYS DOH *prior* to their use in NYS casework.	
Forensic Identity Standard 16 (FOID S16) Software customized for the laboratory and software developed by the laboratory or modified in-house shall be validated prior to use for casework or databasing.	
ANALYTICAL PROCEDURES	

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Standard	**Guidance**
Forensic Identity Standard 17 (FOID S17) The laboratory shall have a documented policy addressing the process for deviating from established and approved standard operating procedures or policies.	
Forensic Identity Standard 18 (FOID S18) Analysis of the FBI-designated core CODIS STR loci shall be performed using a National DNA Index System (NDIS)-approved PCR kit.	
Forensic Identity Standard 19 (FOID S19) Laboratories performing mitochondrial DNA sequence analyses shall 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 20 (FOID S20) If automation is used, the laboratory shall demonstrate that it can maintain the same high standards for and control over sample processing as with individual casework samples.	

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Standard	**Guidance**
Forensic Identity Standard 21 (FOID S21) In addition to routine quality control (QC) of critical reagents to ensure their proper functioning, QC testing shall be performed on *all* reagents prior to their use on a limited sample. (See FOID S16 discussion)	
Forensic Identity Standard 22 (FOID S22) The laboratory shall have available a method to detect inhibition of PCR amplification and shall include a control for PCR inhibition when the state of the evidentiary material suggests inhibitors of the polymerase chain reaction might be present.	
EQUIPMENT CALIBRATION AND MAINTENANCE	
Forensic Identity Standard 23 (FOID S23) Systems shall be in place to prevent critical analytical equipment (both hardware and software) from being modified in any way that would invalidate test results.	

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Standard	Guidance
REPORTS	
Forensic Identity Standard 24 (FOID S24) The laboratory shall have a system for maintaining and retrieving each case file, including case notes not contained in the final case report. Such files shall 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. Case files shall be maintained for a minimum of 15 years.	
Forensic Identity Standard 25 (FOID S25) The contents of a case file shall be defined. The signature of the analyst responsible for data interpretation shall be included in the report and the analyst shall indicate his/her review of each page of the case report and file. The case record shall indicate the identities of the technical and administrative reviewers. The case identifier shall be indicated on all pages of the case file. The final case file shall 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 shall contain: the request for analysis, accessioning information, chain of custody documentation, all relevant analyses and 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) shall be marked with the case identifier and secured to prevent their loss. Mistakes in case notations shall not be obliterated but shall be crossed out and the correct information entered alongside with the date and the initials of the person making the correction. Original electronic data shall be maintained as long as the case file and shall be protected from loss or modification.

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Forensic Identity Standard 26 (FOID S26) When utilizing high throughput systems, the laboratory shall maintain the ability to access and document the specific results of an individual DNA analysis and all associated controls and processing information.	
REVIEW	
Forensic Identity Standard 27 (FOID S27) A technical and administrative review of each case analysis, by a qualified individual(s) distinct from the primary analyst, shall be conducted prior to the release of the results of the case to the submitting agency. The laboratory shall define the qualifications and training required to act as a technical or administrative reviewer. The elements of administrative and technical reviews shall be defined in a review checklist.	Technical review shall consist of a separate, independent analysis of all data associated with a case. This shall include verification of run dates, an analysis of all raw data, including controls, as well as interpretation, calculations and conclusions reached. Raw data does not have to be printed out but must be maintained electronically.
Forensic Identity Standard 28 (FOID S28) For databasing only, an expert system, approved by NDIS, can be used to replace the initial manual review of high quality data by an analyst. A second technical review is still required. Two independent NDIS-approved expert systems may be used for review of high quality data for databasing where NYSDOH approved validation studies have demonstrated that such expert systems, used jointly, work as reliably as manual reviews by qualified analysts.	

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Standard	Guidance
PROFICIENCY TESTING	
Forensic Identity Standard 29 (FOID S29) All staff involved with processing of samples from New York shall participate in an ANAB-approved proficiency testing (PT) program. Each of these staff members participating in activities including screening, extraction, quantitation, amplification, analysis, interpretation and review, shall successfully participate in two proficiency tests per year. At least once a year, each staff member shall be tested for each New York State Forensic Identity Section-approved analytical method he/she is qualified to perform. Testing must be performed to the fullest extent that each staff member participates in casework/databasing. When no relevant ANAB-approved proficiency test is available, the lab shall participate in a proficiency testing program as available or internally develop an appropriate proficiency test using material for which the result is known (e.g. for presumptive or confirmatory testing). Every six months, each Forensic Identity-permitted laboratory must submit a brief summary of PT activities to the Forensic Identity Section. The following information should be reported for each staff member participating in external or internal proficiency testing in the previous six months: • name; • PT provider; • role of the PT participant, i.e., technical, technical review, administrative review; • analytes tested by this staff member; and • Laboratory Director or responsible Assistant Director signature verifying that the PT performance was completed satisfactorily. Any unsatisfactory PT performance must be reported to the Forensic Identity Section within two weeks of learning of the PT result.	Any lapse in proficiency testing due to temporary absence from laboratory activities such as for medical leave or military service shall be documented.

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Standard	**Guidance**
Forensic Identity Standard 30 (FOID S30) The process for implementing the laboratory's proficiency testing program shall be documented.	This shall 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 31 (FOID S31) The staff member directing proficiency testing shall be readily able to produce the following information pertaining to NYS DOH proficiency testing: a list of all technical personnel and all individuals involved in technical and/or administrative review of case results. For each staff member, there shall be a listing of what tests/activities the individual is qualified to perform and the associated dates of qualification. The annual PT plan for each individual shall be detailed (what tests will be performed on each PT). Dates of distribution and submission of proficiency test results, what activities were tested and test results for each tested staff member shall be documented.	
CORRECTIVE ACTION	
Forensic Identity Standard 32 (FOID S32) The laboratory shall have a process for the isolation and recall of nonconforming materials, and for identification of affected tests.	

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Standard	Guidance
Forensic Identity Standard 33 (FOID S33) Any incident that has the potential to affect interpretation of the case results (e.g. phenotype reported, statistical interpretation, conclusions drawn) or any incident involving staff misconduct affecting testing processes shall be reported to the NYS DOH Forensic Identity section within two weeks of the discovery of the nonconformance. (For non-NYS cases involved, the report can be made without reference to the specific case.)	
Forensic Identity Standard 34 (FOID S34) The laboratory shall retain records on corrective action for a minimum of 3 years. In situations where the investigation of the nonconformance and the corrective action taken led to an amended case(s) report, documentation shall be retained for as long as the case documentation. While the corrective action documentation may be kept in separate logs, a central listing of all incidents requiring corrective action shall be available to auditors upon request.	
AUDITS	
Forensic Identity Standard 35 (FOID S35) A list of all external and internal audits performed within the past 3 years, who conducted the audit, and the dates of the audit shall be available. The corresponding audit reports, the laboratory's response to any findings and any follow up documentation shall be available, on-site, for review.	

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Standard	Guidance
SAFETY	
Forensic Identity Standard 36 (FOID S36) The laboratory shall have a designated health and safety manager and shall regularly monitor and annually review its health and safety program. At a minimum, this safety program shall address exposure to blood borne pathogens, chemical hygiene and emergency response plans in the event of staff injury or fire.	
SUBCONTRACTORS	
Forensic Identity Standard 37 (FOID S37) No laboratory shall subcontract any portion of the testing of evidence or reference material associated with a case to a different laboratory or to another part of its own laboratory located at a different location, unless that laboratory has a New York State Forensic Identity permit authorizing the test in question and this is agreed to in writing, in advance, by the submitting agency.	