

New York State Department of Health

Forensic Identity Standards

All laboratories shall comply with the applicable requirements contained in the *New York State Department of Health Clinical Laboratory Standards of Practice – General Systems*. Laboratories performing DNA analyses in forensic paternity cases shall also comply with applicable requirements in the NYS DOH Parentage/Identity Standards. NYS laboratories shall comply with the NYS DOH Laboratory Safety Standards. All other laboratories shall be in compliance with applicable state and federal (OSHA) safety standards. All permitted laboratories performing forensic DNA testing shall also be in compliance with the DNA Advisory Board (DAB) Standards (Quality Assurance Standards for Forensic DNA Testing Laboratories issued July 1998 and/or, as applicable, the Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories issued April 1999) and with current national forensic DNA testing standards as issued by the Director of the Federal Bureau of Investigation. In addition, the forensic identity laboratory shall meet the applicable NYS standards outlined below.

QUALITY ASSURANCE PROGRAM

- FI 1 The laboratory shall maintain a current, comprehensive quality system and a corresponding quality manual which, at a minimum, addresses all the DAB standards and the relevant NYS Forensic Identity Standards.
- FI 2 The laboratory shall have a quality assurance (QA) manager with the authority and responsibility to bring any significant quality issue to the highest levels of management.
- FI 3 The laboratory shall have appropriate quality control procedures designed to monitor the validity of tests undertaken. The resulting data shall be recorded in such a way as to reveal trends toward improving or diminishing quality of testing. There shall be a documented monitoring of this data, at a minimum interval of once a year.
- FI 4 The laboratory shall have a system to ensure maintenance and version control of policy and procedure documents. The laboratory shall keep current a list of all documentation relevant to these standards, including archived documents. The location of these documents and the period of time they are to be retained shall be indicated.

ORGANIZATION AND MANAGEMENT.....

- FI 5 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

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technical leader, the QA manager, the health and safety manager, where applicable an individual responsible for interacting with client CODIS managers, all analysts, all technicians and all laboratory support personnel.

Discussion: While the organization may choose to use other job titles, cross-reference to DAB-defined titles shall be made on this chart.

PERSONNEL.....

- FI 6 The laboratory shall maintain a current file on each employee. The file shall include:
 - o the date of employment
 - o a job description
 - o the requirements for this position, including any required background checks
 - o documentation of the individual’s required education (including transcripts or other documents demonstrating successful completion of the required course work and degree conferred)
 - o documentation of training
 - o a current list of all procedures and technical and/or administrative review the individual is qualified to perform and the date of qualification for each
 - o documentation of continuing education relevant to forensic DNA testing
 - o documentation of review of current literature
 - o documentation of court testimony (or lack thereof in any given calendar year)

Discussion: This 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.

FI 7 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.

FI 8 Continuing education of the laboratory director and/or the technical leader shall include one national DNA forensics meeting at least every three years. Laboratory management shall provide all staff involved in processing of samples and data interpretation with the opportunity to stay abreast of new developments and issues within the field of forensic DNA analysis, commensurate with their technical duties.

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- FI 9 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.
- FI 10 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.
- FI 11 The laboratory shall ensure the employment of an adequate number of qualified individuals to process samples and to satisfy requirements for technical and administrative review.

Discussion: If the laboratory is run with minimal staffing, the laboratory shall have a planned ability to expeditiously obtain additional qualified staff or consultants should the need arise.

FACILITIES AND SECURITY.....

- FI 12 The laboratory shall have a policy addressing maintenance of security when non-employees are required to have access to the laboratory (e.g. service people, auditors, legal staff or in an emergency).
- FI 13 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.
- FI 14 Equipment and personal protection items shall be dedicated to either the pre- or post-amplification area. There shall be no flow of paperwork from the post-amplification area.

Discussion: this includes permanent dedication of lab coats to either pre- or post-amplification areas. Lab coats are not to be interchangeable between these two areas and shall be laundered separately.

- FI 15 The laboratory shall secure the confidentiality and integrity of data (entry, amended corrections, storage, processing and transmission).

EVIDENCE OR SAMPLE CONTROL.....

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- FI 16 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.

Discussion: 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.

- FI 17 The laboratory shall examine specimens only at the request of licensed physicians or other persons authorized by law to use the findings of laboratory examinations in the performance of their official duties. (10NYCRR58-1.7) For samples not submitted by a law enforcement agency, verification of the identity of the tested individuals shall be documented by the laboratory.

Guidance: acceptable forms of identification include: A clear photocopy of a government-issued photo ID or a photo taken at the time of sample collection signed by the tested individual (or in the case of a minor, a parent or legal guardian) and an attestation from the collector of the sample that it came from the photographed individual.

- FI 18 No person shall report the result of any test, examination or analysis of a specimen except to a physician, the physician's agent, to law enforcement agencies or other person authorized by law to employ the results thereof in the conduct of his/her official duties. Results are not to be provided to the tested individual except with the written consent of the physician or an other authorized person. (10NYCRR58-1.8)

- FI 19 The laboratory shall comply with Section 79-1 of the NYS Civil Rights Law.

Discussion: The laboratory shall inform submitting agencies of the requirement to adhere to 79-1 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.

- FI 20 The laboratory shall provide written guidelines for sample acceptance to submitting agencies. The guidelines 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.

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Discussion: 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.

- FI 21 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.
- FI 22 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.
- FI 23 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.....

- FI 24 Validation of a procedure whether developmental or internal, shall be summarized and the laboratory director (or a delegated assistant Director with a CQ in Forensic Identity) and technical leader shall formally recognize the completion and approval of the validation study. Internal validation shall include an assessment of the procedure’s sensitivity. Validation shall lead to the establishment of documented quality assurance parameters including identification of critical reagents, the development of an appropriate qualifying exam and interpretation guidelines including, where applicable, threshold levels and match criteria. Modified procedures and procedures brought on-line at a different physical location shall also be validated. Validation of all standard operating procedures and interpretation guidelines shall be approved by the NYS DOH *prior* to their use in NYS casework.

Discussion: Validation documentation shall not include optimization studies. Only validation studies conducted utilizing the proposed SOP shall be submitted for review. Validation is performed to demonstrate that the procedure is suitable for its intended purpose and, where relevant, this includes a demonstration that the method is as reliable or more reliable than methods currently in use. The sensitivity limit shall be validated by the analysis of relevant samples known to be near the limit of detection.

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- FI 25 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.
- FI 26 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.....

- FI 27 The laboratory shall have a documented policy addressing the process for deviating from established and approved standard operating procedures or policies.
- FI 28 Analysis of the 13 core CODIS STR loci shall be performed using a National DNA Index System (NDIS)-approved PCR kit.
- FI 29 Laboratories performing mitochondrial DNA sequence analyses shall comply with standards for mtDNA analyses as defined by the current NDIS Data Acceptance Standards.
- FI 30 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.
- FI 31 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 FI 16 discussion)
- FI 32 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.....

- FI 33 The laboratory shall have a list of all critical equipment and instruments which require calibration. The list shall indicate the unique identifier and location of each piece of equipment, who calibrates the item and the frequency at which calibration is required.

Discussion: This document shall reference the manufacturer’s recommendation on frequency of calibration or shall reference the laboratory’s validation study showing a

different frequency is adequate.

- FI 34 The laboratory shall have a mechanism to protect critical equipment and computers from power surges and to deal with power outages.
- FI 35 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.

REPORTS.....

- FI 36 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.
- FI 37 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.

Discussion: 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.

- FI 38 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.....

- FI 39 A technical and administrative review of each case analysis, by a qualified individual(s)

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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.

Guidance: 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.

- FI 40 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.

PROFICIENCY TESTING.....

- FI 41 All staff involved with processing of samples shall participate in the NYS DOH proficiency testing program. Each staff member shall successfully participate in two proficiency tests per year and, at least once a year, shall be tested for each analytical method he/she is qualified to perform. The NYS proficiency test attestation statement provided by the Department shall be signed by the primary analyst, the technical reviewer and either the laboratory director or assistant director designated for the Forensic Identity category. When no relevant proficiency test is available from NYS DOH, the lab shall locate an alternate source of an external proficiency test or internally develop an appropriate proficiency test.

Discussion: Any lapse in proficiency testing due to temporary absence from laboratory activities such as for medical leave or military service shall be noted. Technical personnel shall be proficiency tested on each DNA technology to the full extent in which they perform casework examinations including any serological/presumptive/confirmatory tests the individual is qualified to perform.

- FI 42 The process for implementing the laboratory’s proficiency testing program shall be documented.

Guidance: 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.

- FI 43 The staff member directing proficiency testing shall be readily able to produce the

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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.....

- FI 44 The laboratory shall define non-conformities requiring corrective action. The laboratory shall have policies and procedures to ensure the monitoring, detection, investigation and correction of deviations from or failures to meet specified requirements. Such nonconformances shall include: failures of reagents, equipment, technical procedures, staff performance and any discrepancies in test results or any activity resulting in complaints from a submitting agency. The responsibility for addressing nonconformance issues shall be defined. All corrective actions shall be documented.
- FI 45 The laboratory shall have a process for the isolation and recall of nonconforming materials, and for identification of affected tests.
- FI 46 If it is suspected that the correctness or validity of reported results may have been affected by the nonconformance problem, the client(s) which submitted the associated specimens for analysis shall be contacted regarding the problem.
- FI 47 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.)
- FI 48 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.....

- FI 49 A list of all external and internal audits performed within the past 3 years, who conducted

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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.

SAFETY.....

- FI 50 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.
- FI 51 The laboratory shall address, in its safety manual, a description of its compliance with applicable state and federal safety standards. NYS laboratories shall comply with NYS DOH Safety Standards.

Discussion: The laboratory should also consult the current SWGDAM “Guide for the Laboratory Manager and Auditor during a DNA Laboratory Health and Safety Inspection”.

SUBCONTRACTORS.....

- FI 52 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 NYS DOH FI permit authorizing the test in question and this is agreed to in writing, in advance, by the submitting agency.

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