Parentage/Identity Testing

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Revised and effective July 14, 2014	During the on-site visit, a litigation package for a randomly selected patient sample shall be prepared and submitted for Departmental review.
GENERAL REQUIREMENTS	
Paternity/Identity Standard 1 (PIT S1)	Standard has been deleted. Number reserved for future use
Paternity/Identity Standard 2 (PIT S2) Analysis of all test subject specimens in a paternity/ identity case shall be performed in the same laboratory using the same methods and techniques.	Samples from mother, child(ren), and alleged father(s) should all be analyzed in the same laboratory and for DNA procedures, in the same test run.
INDIVIDUAL IDENTIFICATION	
Paternity/Identity Standard 3 (PIT S3) The laboratory shall establish procedures to ensure the verification of the identity of all individuals who present themselves for testing; and such verification shall: a) include photographs, fingerprints or similar evidence of identity; and, b) be documented and retained as part of the record.	
Paternity/Identity Standard 4 (PIT S4) The date of birth of the child shall be recorded.	

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Paternity/Identity Standard 5 (PIT S5) A transfusion history for the preceding three months shall be recorded for each individual.	
Paternity/Identity Standard 6 (PIT S6) A history of a bone marrow transplant shall be recorded for each individual.	
Paternity/Identity Standard 7 (PIT S7) The laboratory shall keep a record of all identifying information including, but not limited to: name, relationship, race, and place and date of the collection of the specimen.	
Paternity/Identity Standard 8 (PIT S8) Identifying information regarding each individual to be tested shall be affirmed by the signature of that person or the guardian.	

SPECIMEN COLLECTION, HANDLING, AND IDENTIFICATION

Parentage/Identity Testing

Standard	Guidance
Paternity/Identity Standard 9 (PIT S9) A paternity/identity standard operating procedure manual shall be developed, adopted, and maintained as part of the laboratory's SOPM and shall minimally include, in addition to applicable SOPM requirements stated in the Operating Procedures and Compliance Standards, the following: a) algorithms used for the calculation and computation of the paternity index, the probability of paternity and the determination of exclusion, including documentation of software program logic; b) frequency tables for each marker and method, including the source of the frequency data; c) protocols for the maintenance of chain-of-custody; d) policies for resolution of discrepancy between duplicate test runs and/or interpretations; e) the methods used for determining the racial background of test subjects and for assigning race for purposes of calculation; and, f) literature references used to document loci, probes, and/or primers and conditions of their use.	
Paternity/Identity Standard 10 (PIT S10) Specimens shall be collected, received, handled, sampled and stored so as to preserve their identity, integrity, and security.	
Paternity/Identity Standard 11 (PIT S11) The name of the phlebotomist or specimen collector shall be documented in the record.	

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Standard	**Guidance**
Paternity/Identity Standard 12 (PIT S12) The laboratory shall develop and implement chain-of-custody procedures.	
Paternity/Identity Standard 13 (PIT S13) The chain-of-custody for each specimen shall be maintained and documented in the record.	
Paternity/Identity Standard 14 (PIT S14) Each specimen shall be identified with a firmly attached label bearing the subject's full name, the date of specimen collection, and initials of the person who collected the specimen, as well as any other information required for unique identification of each specimen.	
Paternity/Identity Standard 15 (PIT S15) The accuracy of the labeling process and the information on the labels shall be verified by the test subject or guardian before the specimens are removed from his or her presence.	In situations where the subject or guardian is incapable of verifying the labeling, a responsible witness may do so.

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Standard	Guidance
Paternity/Identity Standard 16 (PIT S16) Any laboratory accepting specimens collected outside its premises or those of its patient service center shall develop and implement a system which: a) establishes the positive identification of all individuals to be tested and includes with the specimen evidence of such identification; b) establishes and maintains a chain of custody in accordance with pre-established protocols for chain of custody which meet or exceed criteria recognized by the NYS Family Court System; c) rejects the specimen(s) if the external chain of custody does not meet the laboratory's pre-established acceptance criteria; and d) includes a written agreement with the collector when the specimen collector is other than a *bone fide* employee of the paternity testing laboratory, which may be another laboratory under permit, that defines the testing laboratory's procedures and requirements for chain of custody, and the testing laboratory shall verify and monitor the collector's compliance with such requirements.	It is the responsibility of the laboratory to maintain chain of custody, and such responsibility may not be relegated. The director must be able to certify that the test result was prepared in a manner intended to insure acceptance into evidence in a court. Therefore, all paternity testing performed under NYS permit shall meet the standards for court admissibility, regardless of whether the test order source is the court, with or without under a Child Protective Services contract; a physician in private practice; or any other individual or entity authorized by law. Third-party cases (i.e., "brokers") may, in the eyes of the court, be uncertifiable because the laboratory can not reasonably be expected to maintain complete control of chain of custody when using brokers as independent agents.
Paternity/Identity Standard 17 (PIT S17) Results shall be read and interpreted independently by at least two individuals prior to reporting.	Observations and interpretations from both individuals should be documented as independent events.
Paternity/Identity Standard 18 (PIT S18) The director shall be responsible for verifying that the duplicate observed results are in agreement and are correctly interpreted as phenotypes on the report form.	
DNA-BASED PATERNITY/IDENTITY TESTING	

Parentage/Identity Testing	
Standard	**Guidance**
Paternity/Identity Standard 19 (PIT S19)	Standard has been deleted. Number reserved for future use
Paternity/Identity Standard 20 (PIT S20)	Standard has been deleted. Number reserved for future use
Paternity/Identity Standard 21 (PIT S21) All polymorphic loci shall: a) be validated by family studies demonstrating Mendelian inheritance and a frequency of mutation and/or recombination of 0.5 percent or less; b) have a chromosomal location recorded by the International Human Gene Mapping Workshop; and, c) be documented in the literature, including identification of the restriction endonucleases and probes used to detect the polymorphism.	
Paternity/Identity Standard 22 (PIT S22)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 23 (PIT S23) All records demonstrating polymorphisms including autoradiographs, computer-generated images and recordings shall be retained as part of the record.	The laboratory should have a system for maintaining and retrieving original image. This also applies to image analysis software.

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Standard	Guidance
Paternity/Identity Standard 24 (PIT S24) In addition to the requirements of Part 58, the report shall contain: a) name of the test DNA locus as defined by the International Human Gene Mapping Workshop; b) name of the probe, where applicable; c) name of the restriction endonuclease, where applicable; and, d) size or alphanumeric description of reported alleles.	
Paternity/Identity Standard 25 (PIT S25) The SOPM shall contain the criteria employed for determining that two bands represent the same allele, including the protocols used to determine acceptable inter- and intra-gel variations in band size and mobility.	See Operating Procedures and Compliance Standards for additional SOPM requirements.
DNA-BASED TESTING USING RESTRICTION ENZYMES	
Paternity/Identity Standard 26 (PIT S26)	Standard has been deleted. Number reserved for future use
Paternity/Identity Standard 27 (PIT S27)	Standard has been deleted. Number reserved for future use
Paternity/Identity Standard 28 (PIT S28) The laboratory shall use a known human DNA control and, where appropriate, test gels in every run to monitor restriction enzyme activity, fragment production and electrophoretic separation.	The cell line K562 is commonly used as the human DNA control.
DNA-BASED TESTING USING PROBES	

Parentage/Identity Testing	
Standard	**Guidance**
Paternity/Identity Standard 29 (PIT S29) Probes that are developed in-house shall be validated by family studies demonstrating Mendelian inheritance of the detected polymorphism and by extensive population studies.	
Paternity/Identity Standard 30 (PIT S30) For in-house developed methods, pre-hybridization, hybridization and autoradiography shall be carried out under empirically determined, and documented conditions of concentration and temperature determined by the nature of the probe as determined during the initial validation studies; Hybridization conditions shall minimize the possibility of cross-hybridization and maximize the specificity of binding between probe and test DNA; and, These studies shall be periodically verified	
Paternity/Identity Standard 31 (PITS 31)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 32 (PIT S32)	Standard has been deleted. Number reserved for future use.
DNA-BASED TESTING USING AMPLIFICATION	
Paternity/Identity Standard 33 (PIT S33)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 34 (PIT S34)	Standard has been deleted. Number reserved for future use.

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Standard	**Guidance**
Paternity/Identity Standard 35 (PIT S35) Primers shall be of known specificity and sequence. Conditions of time, temperature and concentration which optimize amplification product specificity or quantity shall be empirically determined, periodically verified and documented for each set of primers.	
Paternity/Identity Standard 36 (PIT S36)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 37 (PIT S37)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 38 (PIT S38)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 39 (PIT S39) For in-house developed methods, the number of amplification cycles determined during the initial validation studies shall be set at a level that minimizes the synthesis of extraneous DNA, but is sufficient to synthesize detectable levels of test DNA.	
Paternity/Identity Standard 40 (PIT S40)	Standard has been deleted. Number reserved for future use.
Human Leukocyte Antigen (HLA) Paternity/Identity Testing Standards 41 – 51)	Testing no longer being performed by laboratories and category deleted.
Blood Genetic Marker Paternity/Identity Testing (Standards 52-59)	Testing no longer being performed by laboratories and category deleted.
PROBABILITY, CALCULATIONS AND REPORTS	

Parentage/Identity Testing

Standard	Guidance
Paternity/Identity Standard 60 (PIT S60) Each laboratory shall establish an advisory committee on population statistics and calculation of probability of paternity, composed of persons with training and experience in statistics, population genetics, immunology and genetics.	
Paternity/Identity Standard 61 (PIT S61) The committee shall establish the procedures for computation of probability. Such procedures shall be reviewed at least annually.	
Paternity/Identity Standard 62 (PIT S62) The committee shall establish procedures to assure that gene and haplotype frequencies are obtained from examination of population of adequate size.	
Paternity/Identity Standard 63 (PIT S63) Computer assisted analyses shall be reviewed, verified and signed by a supervisor and/or laboratory director before issuance.	
Paternity/Identity Standard 64 (PIT S64) The method of calculation shall be validated.	
Paternity/Identity Standard 65 (PIT S65) If only manual calculations are performed, they shall be performed in duplicate.	

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Standard	Guidance
Paternity/Identity Standard 66 (PIT S66) The report shall minimally contain the following information: a) the date(s) the samples were collected; b) the name of each individual tested and the relationship to the child; c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation; d) the phenotypes established for each individual in each genetic marker system examined; e) a statement as to whether or not the alleged father can be excluded; f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided; g) if there is a failure to exclude, the report shall include: i. the paternity index for each genetic marker system reported; ii. the combined paternity index; and, iii. the probability of paternity, including the prior probability used to calculate the probability of paternity; h) an explanation of the nature of the problem, if the results are inconclusive; and, i) the signature of the qualified person who reviewed, approved, and interpreted the test results.	g) iii) Most laboratories use a prior probability of 0.5. i) A qualified person is an individual holding a valid New York State certificate of qualification in the Parentage / Identity Testing category. i) Laboratories using electronic signatures should have a procedure in place that ensures and documents the qualified person's authorization for each signature occurrence (such as access limited by password).