Comparison between the Current Quality Assurance Standards for Forensic DNA Testing Laboratories (Forensic QAS) and the SWGDAM Proposed Revisions to the Forensic QAS

Current (eff. 7/1/2020) Forensic Standard	**Comparison between the Current Standard and the SWGDAM Proposed Revisions to the *Quality Assurance Standards for Forensic DNA Testing Laboratories***
NA	Added a Table of Contents with hyperlinks to each standard within the electronic document.
Standard 1. Scope	Added a statement about testing performed outside of the scope of the QAS being prohibited from entry into CODIS. Changed that testing begins "at sample extraction or direct amplification" to "at sample lysis or direct amplification" Added information pertaining to Forensic Rapid DNA Programs and the possible applications of a Forensic Rapid DNA program: • Operation of a Rapid DNA System or instrument in the laboratory, • Operation of a Rapid DNA System or instrument in a Rapid DNA partner agency facility that is recognized under the scope of accreditation of the laboratory, • Operation of a Rapid DNA System or instrument in a temporary/mobile facility that is recognized under the scope of accreditation of the laboratory. Described new Standards 18 and 19 and their applicability. Stated that a facility that has Rapid DNA as their only DNA capability does not satisfy the definition of a laboratory.
Standard 2. Definitions	**The following new definitions are added**: Advanced authentication Forensic Rapid DNA Lead Operator Forensic Rapid DNA Operator Forensic Rapid DNA Program Laboratory Rapid DNA Administrator Rapid DNA data Rapid DNA partner agency Sequencing Technical personnel (previously defined in QAS Guidance) **The following definitions are revised**: Accreditation – Added Rapid DNA partner agency's inclusion in the laboratory's scope of accreditation. Analyst – Clerical edit of "that" to "who" Casework reference sample – Removed blood draw examples CODIS – Added sentence about NDIS is the highest-level index of CODIS from DB definition Contract Employee – Added Laboratory Rapid DNA Administrator Coursework – Removed "and taught" to allow for AP/Dual Enrollment coursework DNA Type – Modernized examples to be specific to STRs and include SNPs Inconclusive – Removed sentence more defining uninformative Laboratory – Added accreditation requirement of federal law and having only Rapid DNA capability does not satisfy the definition of a laboratory Modified Rapid DNA analysis – Added forensic sample Negative amplification control – Changed focus from reagents to process

	Negative sequencing control – Changed focus from reagents to process; added allowance for a computational negative (for NGS) Ownership – Changed from passive to active acceptance; Changed reporting subclause to be specific to drawing conclusions on forensic samples to allow for use of another laboratory's reference profiles Positive amplification control – Deleted "the amplification reagents" to focus on the process Positive sequencing control – Deleted "the sequencing reagents" to focus on the process Rapid DNA cartridge – Changed to "cartridge/chip"; added requirements for use for forensic samples Rapid DNA System – Changed "cartridge" to "cartridge/chip", added forensic sample Technical reviewer – Deleted "is not an author of" the report wording and added similar wording to 12.1.1 Test kit – Moved specific methods to examples of method Updated referenced standard for Sensitivity studies and Specificity studies **The following definitions are deleted:** Binary method Biochemistry Genetics Integral component Molecular biology
Standard 3. Quality Assurance Program	No revision
Standard 4. Organization and Management	Clerical edit in 4.1.5: "interrelation" to "interrelationship"
Standard 5. Personnel	5.1: Added "technical" to personnel; replaced "the examination and testimony provided" with "their authorized responsibilities" 5.1.1: Simplified "a written job description … that may be augmented by additional documentation" to "documentation" that defines responsibilities, duties, and skills Technical Leader: 5.2.1: Revised TL education to require "at least 9 credit hours of coursework in biology- or chemistry-related areas that provide an understanding of the foundation of DNA analysis"; coursework "in statistics or population genetics"; and "at least one graduate level course" Eliminating the 3 specific course titles and subtracting 3 credit hours because the statistics/population genetics course was made a separate standard 5.2.1.5: Added allowance for a laboratory to accept a prior external audit approval of a TL's education 5.2.2: Deleted specific experience wording for a TL appointed prior to July 1, 2009 5.2.4: Added "current" for the FBI's DNA auditor training course within one year of TL appointment 5.2.5.2: Added Rapid DNA partner Agency to TL's required authority 5.2.5.4: Modified review of "academic transcripts" to "education and experience" 5.2.7.2: Modified "educational and training records" to "training records" and limited to those analysts and technical reviewers who have not been memorialized in an external audit

	CODIS Admin: Deleted specific wording for a CODIS Admin appointed prior to July 1, 2009. 5.3.1: Simplified to only a degree 5.3.3: Added "current" for the FBI-sponsored training in CODIS software and the FBI's DNA auditor training course within six months and one year of assuming duties, respectively 5.3.4: Added allowance for a Technical Leader to accept a prior external audit approval of a CODIS Admin's education Analyst: 5.4.1: Revised Analyst education to require "at least 9 credit hours of coursework in biology- or chemistry-related areas that provide an understanding of the foundation of DNA analysis." eliminating the 3 specific course titles. Clerical edits to coursework in statistics "or" population genetics for analysts after July 1, 2020 5.4.1.3: Added allowance for a Technical Leader to accept a prior external audit approval of an analyst's education 5.4.2: Changed 6 months experience to experience "commensurate with their authorized responsibilities" to allow for modular training programs 5.5: Simplified wording and eliminated specific reference to Standard 5.4. 5.5.1: Clerical edit of "current" to "currently"
Standard 6. Training	Clerical edits for all "his/her" to "their" 6.10: Added requirement to document the "authorized responsibilities" for personnel
Standard 7. Facilities and Evidence Control	Moved Rapid DNA to Standard(s) 18/19 Clerical edit to 7.3.1: "throughout processing" to "throughout the testing process"
Standard 8. Validation	Moved Rapid DNA to Standard(s) 18/19 Consolidated "The laboratory shall use validated methods for DNA analysis." and "Developmental validation shall precede the implementation of any new method used for forensic DNA analysis." into New Standard 8.1: "Validation shall precede the implementation of any method used for forensic DNA analysis." 8.1.1: Limited the Developmental validation studies to "for a new technology, typing test kit, or platform" 8.1.2: Changed wording from "internal validation of all manual and robotic methods" to "internal validation studies" shall be conducted by each laboratory. Listed studies remain the same Separated prior Standard 8.3.2 into 2 separate standards and changed from "internal validation data" to "validation data": 8.1.3: "Validation data shall be used to establish quality assurance parameters." 8.1.4: "Validation data shall be used to establish interpretation guidelines, mixture interpretation guidelines, and the application of appropriate statistical calculations, when applicable." 8.1.4.1: Changed from "Mixture interpretation validation studies" to "Validation studies for mixture interpretation" Deleted prior Standard 8.3.3 "Internal validation studies shall be conducted prior to implementing a change in platform instrument model or typing test kit." as no longer necessary to be a separate standard.

	8.2: Added exception for an NDIS approved Rapid DNA instrument/System and limited the requirement for the certified reference material to "a new technology, typing test kit, or platform instrument model" 8.3: Changed from "procedure" to "method" 8.4: Added validation of an Expert System in accordance with NDIS Operational Procedures 8.4.1: Added recertification in accordance with NDIS Operational Procedures 8.5: Revised software validation standards to remove requirement to evaluate and document what studies will and will not be conducted and removed developmental validation standards that mirrored internal validation standards. New 8.5.1: The laboratory shall use software suitable for the intended use in the laboratory and within the limitations established during the internal validation. 8.5.2: Added "or a major revision" 8.5.2.1, 8.5.2.2, 8.5.2.3: Consolidated requirement for regression testing of a major revisions with internal validation studies standards 8.5.3: Reworded minor revision wording to mirror 3 software categories "used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or statistical calculations" vs "that does not impact the analytical process, interpretation, or statistical calculations" 8.5.4: For a multi-lab system, shared software testing data must be available at each site 8.5.5: Testing removed from requiring TL approval 8.6: Changed from "procedure" to "method", and added software "validation and"
Standard 9. Analytical Procedures	Moved Rapid DNA to Standard(s) 18/19 Clerical edits to 9.5.3.1, 9.5.5, 9.6.5 9.3.1: Deleted systems since included in the definition of Test kit; added sequencing 9.4: Added additional 9.4.2 exception to quant of nDNA prior to amp New Standard 9.4.2 for the calculation of the amount of human DNA for laboratory defined forensic sample types to be performed after or simultaneously with nuclear DNA amplification and the requirements for the typing test kit and validation 9.6: Added allowance for use of Expert System 9.7: Moved specific conclusion terms to examples
Standard 10. Equipment Calibration and Maintenance	Moved Rapid DNA to Standard(s) 18/19 Removed "Thermal cycler temperature verification systems" from list requiring annual performance checks (10.3.2) to allow for use during entire calibration certification (typically 2 years). Similar to a thermometer, these are still required to be identified as critical in 10.2.1
Standard 11. Reports	No revision
Standard 12. Review	12.1.1: Added TR cannot review their own work that was removed from TR definition Added allowance for use of Expert Systems 12.2: added (s) to "Completion of the technical review(s) shall be documented…" 12.2.4: Changed conclusion words from "i.e." to "e.g." and changed terms from "inclusion"/ "exclusion" to "inclusionary"/"exclusionary" 12.2.7, 12.2.7.1, 12.2.7.2: Revised to allow for use of Expert System to review DNA types

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Standard 13. Proficiency Testing	Moved Rapid DNA to Standard(s) 18/19 13.1: Added allowance for when an external PT is not available or appropriate for a technology (e.g., SNPs) to be monitored in accordance with accreditation requirements
Standard 14. Corrective Action	No revision
Standard 15. Audits	15.2.1: Revision to change to one external audit review of education, experience, and training of personnel and addition of substandards 15.2.1.1 through 15.2.1.4 to allow for portability of prior external audit reviews 15.2.1.5: Clerical edits and added "interpretation software" to the additional qualifications that require external audit review
Standard 16. Professional Development	No revision
Standard 17. Outsourcing	Moved Rapid DNA to Standard(s) 18/19 17.1: Added clarification that Standard includes vendors doing modified Rapid DNA analysis New 17.2.3: Added Standard for an NDIS participating laboratory that permanently ceases operations and another NDIS participating laboratory will accept ownership of the laboratory's DNA data 17.3.2: Added allowance for use of Expert System
NA	New Standard 18 for Laboratory Use of Rapid DNA, including the relocation of Rapid DNA applicable standards previously imbedded in Standards 7 through 17. Requirements include: 18.1 Define the Rapid DNA applications to be used within the laboratory's Forensic Rapid DNA Program 18.2 Document the responsibility, authority, and interrelationship of all personnel who manage, perform, or review work relating to Rapid DNA applications 18.3 The training program for Rapid DNA 18.4 Locations of Rapid DNA instrument/System 18.5 A policy for Rapid DNA evidence consumption and sample selection. 18.6 Validation of modified Rapid DNA analysis prior to the use of a Rapid DNA instrument/System with forensic samples. 18.7 Performance check of an NDIS approved Rapid DNA System prior to its initial use. 18.8 Procedures for the use of Rapid DNA instruments/Systems 18.9 Rapid DNA instrument/Systems are critical equipment, and the laboratory shall have and follow a program to ensure they are properly maintained 18.10 Laboratory casework reports shall document the use of Rapid DNA to include the cartridge/chip type as well as loci tested or amplification system. 18.11 Verification of DNA types and technical review of the case file 18.12 Proficiency testing for modified Rapid DNA analysis 18.13 Procedures for addressing nonconformities 18.14 Outsourcing to a vendor laboratory performing Rapid DNA analysis and the ownership review for data generated by the Rapid DNA System

NA	New Standard 19 for Rapid DNA Partner Agency Forensic Rapid DNA Programs Requirements include: 19.1 An agreement between the Laboratory and Rapid DNA partner agency 19.2 A Laboratory Rapid DNA Administrator accountable for the administration and security of the laboratory's Rapid DNA partner agency Forensic Rapid DNA Program 19.3 A Forensic Rapid DNA Lead Operator accountable for the operation at the Rapid DNA partner agency and serves as the designated point of contact with the laboratory 19.4 Rapid DNA partner agency personnel shall successfully complete the laboratory's documented training program 19.5 A documented evidence control program to ensure the integrity of physical evidence 19.6 A facility that is designed to ensure the integrity of the evidence and the Forensic Rapid DNA processing 19.7 To maintain and operate the Rapid DNA instrument(s)/System(s) in accordance with manufacturer and/or laboratory requirements 19.8 For the Rapid DNA partner agency to provide case documentation to the NDIS participating laboratory 19.9 For the Rapid DNA partner agency Forensic Rapid DNA Program documentation to be available at the laboratory for inspection during the annual audit