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

| **Current (eff. 7/1/2020) DNA Databasing Standard** | **Comparison between the Current Standard and the SWGDAM Proposed Revisions to the *Quality Assurance Standards for DNA Databasing Laboratories*** |
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| **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.<br>Changed that testing begins "at sample extraction or direct amplification" to "at sample lysis or direct amplification"<br><br>Added clarification that Booking Station implementation of Rapid DNA on qualifying arrestees are covered under a separate set of national Standards and Procedures with reference to the Standards for the Operation of Rapid DNA Booking Systems by Law Enforcement Agencies and National Rapid DNA Booking Operational Procedures Manual. |
| **Standard 2. Definitions** | **The following new definitions are added**:<br>Rapid DNA data<br>Sequencing<br>Technical personnel (previously defined in QAS Guidance)<br><br>**The following definitions are revised**:<br>Accreditation – Added Rapid DNA partner agency's inclusion in the laboratory's scope of accreditation.<br>Analyst – Clerical edit of "that" to "who"<br>Casework reference sample – Removed blood draw examples<br>Coursework – Removed "and taught" to allow for AP/Dual Enrollment coursework<br>DNA Type – Modernized examples to be specific to STRs and include SNPs<br>Laboratory – Added accreditation requirement of federal law and having only Rapid DNA capability does not satisfy the definition of a laboratory<br>Negative amplification control – Changed focus from reagents to process<br>Negative sequencing control – Changed focus from reagents to process; added allowance for a computational negative (for NGS)<br>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<br>Positive amplification control – Deleted "the amplification reagents" to focus on the process<br>Positive sequencing control – Deleted "the sequencing reagents" to focus on the process<br>Rapid DNA cartridge – Changed to "cartridge/chip"; added requirements for use for forensic samples<br>Rapid DNA System – Changed "cartridge" to "cartridge/chip"<br>Technical reviewer – Deleted "of analytical documentation which he/she did not create" and added similar wording to 12.1.1<br>Test kit – Moved specific methods to examples of method<br>Updated referenced standard for Sensitivity studies and Specificity studies |

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| | **The following definitions are deleted:**<br>Biochemistry<br>Genetics<br>Integral component<br>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"<br>5.1.1: Simplified "a written job description … that may be augmented by additional documentation" to "documentation" that defines responsibilities, duties, and skills<br>Technical Leader:<br>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<br>5.2.1.5: Added allowance for a laboratory to accept a prior external audit approval of a TL's education<br>5.2.2: Deleted specific experience wording for a TL appointed prior to July 1, 2009.<br>5.2.4: Added "current" for the FBI's DNA auditor training course within one year of TL appointment<br>5.2.5.4: Modified review of "academic transcripts" to "education and experience"<br>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<br>CODIS Admin:<br>Deleted specific wording for a CODIS Admin appointed prior to July 1, 2009.<br>5.3.1: Simplified to only a degree<br>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<br>5.3.4: Added allowance for a Technical Leader to accept a prior external audit approval of a CODIS Admin's education<br>Analyst:<br>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 |

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| | 5.4.1.3: Added allowance for a Technical Leader to accept a prior external audit approval of an analyst's education<br>5.4.2: Changed "six months human DNA laboratory experience with at least 3 months in a forensic or database DNA laboratory" to "human DNA laboratory experience in a forensic or database DNA laboratory commensurate with their authorized responsibilities" to allow for modular training programs<br>5.5: Simplified wording and eliminated specific reference to Standard 5.4.<br>5.5.1: Clerical edit of "current" to "currently" |
| **Standard 6. Training** | Clerical edits for all "his/her" to "their"<br>6.10: Added requirement to document the "authorized responsibilities" for personnel |
| **Standard 7. Facilities and Sample Control** | Moved Rapid DNA to Standard(s) 18/19<br>Clerical edit to 7.3.1: "throughout processing" to "throughout the testing process" |
| **Standard 8. Validation** | Moved Rapid DNA to Standard(s) 18/19<br>Consolidated "The laboratory shall use validated methods for DNA analysis." and "Developmental validation shall precede the implementation of any new method used for DNA database analysis." into New Standard 8.1: "Validation shall precede the implementation of any method used for DNA database analysis."<br>8.1.1: Limited the Developmental validation studies to "for a new technology, typing test kit, or platform"<br>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<br>Separated prior Standard 8.3.2 into 2 separate standards and changed from "internal validation data" to "validation data":<br>8.1.3: "Validation data shall be used to establish quality assurance parameters."<br>8.1.4: "Validation data shall be used to establish interpretation guidelines."<br>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.<br>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"<br>8.3: Changed from "procedure" to "method"<br>8.4: Deleted "applicable"; Clerical edits for formalize title of the NDIS Operational Procedures Manual, also in 8.4.1.<br>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.<br>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.<br>8.5.2: Added "or a major revision"<br>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 |

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| | 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"<br>8.5.4: For a multi-lab system, shared software testing data must be available at each site<br>8.5.5: Testing removed from requiring TL approval<br>8.6: Changed from "procedure" to "method", and added software "validation and" |
| **Standard 9. Analytical Procedures** | Moved Rapid DNA to Standard(s) 18/19<br>Clerical edits to 9.4.5, 9.5.5<br>9.3.1: Deleted systems since included in the definition of Test kit; added sequencing<br>9.5: Changed "the data interpretation process" to "some or all of the data interpretation steps defined in Standards 9.5.1 through 9.5.4." |
| **Standard 10. Equipment Calibration and Maintenance** | Moved Rapid DNA to Standard(s) 18/19<br>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. Documentation** | No revision |
| **Standard 12. Review** | 12.1.1: Added TR cannot review their own work that was removed from TR definition<br>12.2: added (s) to "Completion of the technical review(s) shall be documented…" |
| **Standard 13. Proficiency Testing** | Moved Rapid DNA to Standard(s) 18/19<br>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<br>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<br>17.1: Added clarification that Standard includes vendors doing modified Rapid DNA analysis<br>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 |

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| **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.<br><br>Requirements include:<br>18.1 Use of Rapid DNA must be in the laboratory's scope of accreditation<br>18.2 Document the responsibility, authority, and interrelationship of all personnel who manage, perform, or verify work relating to Rapid DNA<br>18.3 The training program for Rapid DNA<br>18.4 Locations of Rapid DNA instrument/System<br>18.5 Validation of modified Rapid DNA analysis if it will be used<br>18.6 Performance check of an NDIS approved Rapid DNA System prior to its initial use.<br>18.7 Procedures for the use of Rapid DNA instruments/Systems<br>18.8 Rapid DNA instrument/Systems are critical equipment, and the laboratory shall have and follow a program to ensure they are properly maintained<br>18.9 Technical review of modified Rapid DNA analysis.<br>18.10 Proficiency testing for modified Rapid DNA analysis<br>18.11 Procedures for addressing nonconformities<br>18.12 Outsourcing to a vendor laboratory performing Rapid DNA analysis and the ownership review for data generated by the Rapid DNA System |