

FORENSIC BIOLOGY QUALITY ASSURANCE/QUALITY CONTROL MANUAL

Control of Reference Collections		
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Control of Reference Collections

1 Guiding Principles and Scope

- 1.1 Reference standards and reference materials shall be stored in a manner that ensures the prevention of contamination or deterioration in order to protect their integrity. Procedures for safe handling, transport, and use of reference standards are outlined below.

2 Reference Standards

- 2.1 Reference standards of measurement are to be used for calibrations only and for no other purpose. Since the laboratory does not conduct any calibrations, reference standards do not exist within the laboratory.

3 Reference Materials

- 3.1 Reference materials used to conduct intermediate performance checks of instruments and equipment are, where possible, traceable to certified reference materials such as those from the National Institute of Standards and Technology (NIST). Reference materials that cannot be traceable to certified reference materials must be certified according to original manufacturer's specification. Internal reference materials are checked as far as is technically and economically possible.
- 3.2 Where possible, reference materials are obtained from sources that can supply appropriate traceability information such as a Certificate of Analysis.
- 3.3 Reference materials are stored according to manufacturer's specifications. If the manufacturer's specification does not indicate storage conditions, the laboratory determines how similar materials are stored within the laboratory and applies those storage conditions to the reference materials.
- 3.4 Storage conditions must ensure the safe handling and safe transport of reference materials. Furthermore, storage conditions must minimize contamination or deterioration, where possible.
- 3.5 Checks needed to maintain confidence in the calibration status of the reference materials shall be carried out periodically. Where practical, reference materials must be re-certified on or before the expiration date or they must be removed from use. Any reference material that does not have an expiration date must be re-certified or removed from use after one (1) year of its first use.

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4 Standard Reference Materials (SRMs)

- 4.1 The use of standard reference materials is essential to reliable methodology. The laboratory will check its DNA typing procedures against an appropriate and available SRM as part of the validation of new DNA methods, typing kits, and instrument platforms or whenever substantial changes are made to a previously validated typing procedure. SRMs will be purchased from the National Institute of Standards and Technology (NIST) and shall have an associated Certificate of Analysis available. The laboratory may choose to use other SRMs to check any of its procedures, but it is not required to do so. SRMs must not be used beyond its expiration date unless a Certificate of Analysis is issued from NIST to document its recertification.
- 4.2 Secondary standards that are traceable to SRMs may be created by the laboratory for use in lieu of purchasing them directly from NIST. To create a secondary standard, a "lot" of DNA samples (such as a blood stain) must be run and analyzed in parallel with an appropriate NIST SRM. Documentation must be maintained to demonstrate that the results for the SRM are correct (as compared to the certificate of analysis) and the results of the secondary standard are consistent (as compared to a prior result).

5 Weights

- 5.1 The laboratory will conduct intermediate performance checks of balances using Class 1 weights that are traceable to NIST Standards. Only calibrated weights will be used. Any weights that are past expiration will be removed from service. Various companies exist that can calibrate weights traceable to NIST Standards. However, the Department of Forensic Biology will endeavor to select a company that is accredited in accordance with ISO 17025 standards for calibration laboratories.
- 5.2 Prior to each use, analysts should visually inspect the weights to ensure that there are no physical defects that would affect their performance.

6 Reference Collections

- 6.1 The laboratory uses a DNA "[LAB TYPES](#)" reference collection for comparison to casework DNA profiles to ensure that no exogenous DNA is present in samples and a "suspect database" to determine if there is an association between a named suspect and DNA profiles from previously tested cases. The use of these reference collections is outlined in the Forensic Biology CODIS Manual and the LAB-TYPES DATABASE procedure. These manuals identify these reference collections and describe how they are controlled.