8.1 Purpose:

8.1.1 Documentation for reagent and chemical batches used in the laboratory.

8.1.2 Instructions for the in-house formulation of reagents for use in the laboratory.

8.2 Responsibility:

8.2.1 DNA Section personnel or those deemed responsible by TL.

8.3 Definitions:

8.3.1 Critical Reagent: A solution or chemical that requires routine practice on established samples before use on evidentiary samples to prevent unnecessary sample loss.

8.3.2 QA/QC: Quality Assurance/Quality Control are the actions performed to monitor and demonstrate that a product meets specific standards for use in casework.

8.3.3 Sub-component: An ingredient, constituent part that makes up a larger batch or bulk reagent.

8.3.4 Bulk: The final composition of sub-components in a homogeneous mixture. The final testable reagent is the bulk reagent.

8.3.5 Aseptic: A technique that is performed under sterile conditions.

8.3.6 Laminar flow: A workbench with a hood designed to prevent contamination.

8.4 Reagent and Chemical Log:

For chemicals that are received from an outside vendor, the identifying information (as supplied by each manufacturer) will be stored in the "Consumables" binder. Inside the binder is the worksheet for the following information to be recorded. See "Consumables Record" (see **DNA QR-272** Consumables Record).

Certain vendor supplied extraction kits, quantification kits, and amplification kits, have the reagent information recorded on a specific log QR and maintained in the DNA Section.

QR-5a Autosomal kit log (may also use QR-272 for separate components)
QR-10 YSTR kit log
QR-11 EZ1 consumables record
QR-17 Quantitation kit log

Upon receipt of all vendor supplied reagents, chemicals, and supplies, the packing slip will be checked for agreement with the items received according to GL-6: Purchasing. Once verified, a copy of the packing slip is made and the original and copy are given to thepurchasing coordinator in Administration..

MSDS: The MSDS received from the manufacturer from each chemical used in the laboratory can be found in the designated MSDS book. These data sheets are available in the laboratory.

8.4.1 Chemicals, reagents, standards, consumables exceeding the expiration date can no longer be used for casework. They may be used for research only purposes and will be appropriately labeled as such.

8.4.1.1 If no expiration date is available by vendor, then DNA laboratory will assign expiration date of **five years** from receipt of item or otherwise deemed by the QM or the TL.

8.4.2 Record the following information (if not already there) on the chemical container **as well as** on the "Consumables Record" worksheet:

8.4.2.1 date received at laboratory.

8.4.2.2 manufacturer lot number.

8.4.2.3 initials of receiving personnel.

8.4.2.4 date opened.

8.4.2.5 expiration date.

8.4.3 For reagents made in-house, refer to each individual Work Instruction/Quality Record. The following is maintained on the container of the reagent:

a). identity of the reagent

b). the date of preparation or lot number

c). expiration date

d). storage requirements

8.4.3.1 These records are kept in the "Reagent QC" binder. The work instructions for formulating the bulk reagent and the quality control result record are contained on the same worksheet. A new worksheet is used for each lot formulated and tested for quality. The results of all quality control tests will be maintained in a ring binder or properly labelled file.

8.5 Reagent Quality Testing:

8.5.1 All critical reagents must be quality control tested for reliable performance prior to being used in casework. All critical reagents are quarantined until passing quality control testing. Quarantined reagents will be identified by obvious visual markings. (See SOP-6 Section 4: Critical Reagents and Reagent Testing for a list of critical reagents).

8.5.2 The quality of all critical reagents is verified based on the performance of the appropriate control samples. The following shall be used at a minimum for QC experiment samples. See individual work instructions for additional specific details for quality testing.

8.5.2.1 Extraction Negative (Reagent Blank) (if QC is for an extraction reagent)

8.5.2.2 Extraction Positive Control (if QC is for an extraction reagent)

8.5.2.3 Amplification Negative

8.5.2.4 Amplification Positive

8.5.3 All quality experiment samples shall be analyzed and/or reviewed by at least one competent analyst.

8.5.4 For Critical Reagent QC, negative control samples and reagent blank samples should show no called alleles ≥ 50 rfu nor peaks used for contributor number estimation (25-49 rfu).

Negative controls and RBs should be amped and injected according to most sensitive conditions used for casework.

8.5.5 Documentation of quality test results is recorded on "Reagent bulk work instruction/QC worksheet" and shall be kept in the "Reagent QC Log" binder for that year.

8.6 Commercial Kits:

8.6.1 For Identifiler Plus™ amplification kits quality control testing, please see **DNA QR-250a** for quality testing work instructions and record.

8.6.2 For YFiler™ amplification kits quality control testing, please see **DNA QR-249** for quality testing. Amplification of a kit positive and a negative control will utilized for the QC testing of this kit.

8.6.3 For Quantifiler™ Trio, a set of standards will be made following DNA WI-07 using the lot of Quantifiler Trio Standard (100ng/ul) and the Quantifiler Trio DNA Dilution Buffer supplied with the kit. The standard dilutions used for amplification/quantitation are 50ng/ul, 5ng/ul, 0.5ng/ul, 0.05ng/ul, 0.005ng/ul.

Following the work instructions, a new set of standard dilutions will be QC'd. Please see **DNA QR-33** for quality testing work instructions and record.

8.6.4 Qiagen EZ1 kits will be quality control tested according to **DNA QR-279**.

8.6.5 For Promega Fusion 6C™ amplification kits quality control testing, please see **DNA QR-36 (Casework), DNA QR-298 (Direct Amp), or DNA QR-297 (Amp Solution)**.

8.7 Quality Control Test Results:

8.7.1 When results are verified by a competent analyst, the passing reagent or chemical shall then be released for use in the laboratory. Passing lots of reagents will be identified by obvious visual markings, such as a bright green "QC Pass" sticker or equivalent.

8.7.2 When results are verified, any reagent or chemical which fails the quality control procedures shall stay in quarantine. When quality control (QC) failure or non-conformance occurs: Inform the TL and if possible, determine the source of the problem.

8.7.2.1 Another sampling will be taken and re-tested. If results are again non-conforming the Technical Leader and the quality section (if needed) will examine the problem and make a decision whether to discard/reject the failed reagent or chemical.

8.7.2.2 If the re-tested material passes quality control after a re-test, then it may be released for use in the laboratory with TL approval, however, all documentation for both tests shall be maintained. Any issues regarding the quality of a reagent shall be reported to the technical leader.

8.8 Sub-Component Quality Control:

8.8.1 It is not necessary to quality control test a sub-component if it will be used in a bulk reagent formulation and thus will be quality tested at that point. It is noted on each individual work instruction whether a chemical or solution is a sub-component. It is important to note that the expiration date on the bulk reagent will be based off the soonest expiration date of the sub-components (if sooner than the expiration date of the bulk reagent).

8.9 Laboratory Extraction Positive Control Blood Aliquots and FTA Lots

8.9.1 When a new lot of the laboratory extraction positive control is drawn and dispensed for an internal extraction control, it must be quality controlled tested. All controls shall be used. See DNA WI-20 and **DNA QR-255 and DNA QR-256.**

8.10 NIST Annual Review

To annually verify that the entire PCR system is functioning within accepted criteria by the use of a standard that is traceable to the NIST Standard Reference Material (SRM) or a lab designated standard reference material. Please refer to **DNAWI-20**. The results and data will be documented on **DNA QR-266** and kept in the NIST Traceability Binder in the DNA Section.

8.11 Milli-Q System

The dH_2O dispensing system used for laboratory is called the Milli-Q® Integral Water Purification System. This system is on a service contract and will be annually checked by a service representative. Refer to "Millipore Users Manual Milli-Q® Integral Water Purification System" for more detailed information. Refer to **DNA WI-31** for operational guidance. For Quality testing of 50ml conical tube aliquots of dH_2O used for sampling evidence through amplification, refer to **DNA QR-268**. Filled containers of dH_2O will be lot tracked by fill date, but only the 50ml conical tube aliquots will be QC tested.

Documentation of the maintenance of the Milli-Q® will be kept in a binder next to the system. Besides an annual service visit, all other necessary maintenance will be prompted by an LCD message alert on the system. Documentation of this will be recorded on **DNA QR-269.**

8.12 Reagent Formulation

8.12.1 See individual quality record for each reagent formulation.

8.12.2 Listed solution volumes are a representative. Larger or smaller volumes may be generated as required by usage rates.

8.12.3 When necessary, proper aseptic procedures shall be followed for all reagent formulation.

8.12.3.1 Lab coat shall be worn.

8.12.3.2 Face mask shall be worn covering the mouth and nose.

8.12.3.3 Gloves shall be worn.

8.12.4 When necessary, reagents shall be made and dispensed under a laminar flow hood.

8.12.5 All containers and boxes with reagents shall be identified with description, lot number and expiration date.

8.12.6 Individual tubes shall have the identity of the reagent marked on the side or the top of the tube.

8.12.7 A sample from the finished product shall be taken and used for quality control purposes.

8.12.8 Reagent shall be quarantined following QC procedures until released for use.