

FORENSIC BIOLOGY QUALITY ASSURANCE/QUALITY CONTROL MANUAL

Reagents		
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Reagents

1 Guiding Principles and Scope

- 1.1 A **reagent** is any substance used because of its chemical or biological activity. Reagents are used directly, or at a dilution, in a given analytical procedure. Reagents are different than *chemicals*, which are used in the preparation of in-house reagents.
- 1.2 Only reagents suitable for the methods employed may be used in the Department of Forensic Biology. This procedure describes in general terms the requirements for the documentation and quality control of commercial reagents and for the formulation, documentation, and quality control of in-house reagents. The last section in this document is a list of the reagents used by the Department.

2 Procedure

- 2.1 Reagents are classified into two general categories:
 - 2.1.1 A **critical reagent** is determined by empirical studies or routine practice to require testing on established samples before use on evidentiary or casework reference samples in order to prevent unnecessary or irreparable loss of sample. "Critical reagents" includes a variety of test kits or systems used in DNA testing.
 - 2.1.2 A **non-critical reagent** is a reagent whose failure to work properly will not cause irreparable loss of sample. Therefore, the use of a QC test procedure to check the reliability of the reagent prior to its use in casework is not an absolute requirement, but will be performed by the Department on a reagent-by-reagent basis.
- 2.2 Reagents are prepared **in-house** or are obtained **commercially**.
- 2.3 Personnel preparing reagents, and those who use reagents, are to exercise care at all times to ensure that no exogenous DNA will be introduced to a stock reagent.

3 Reagents Prepared In-House

- 3.1 Reagents are prepared in-house according to an approved formula or procedure. Reagent preparation is usually performed by a member of the Quality Assurance Unit.
- 3.2 A **reagent sheet** form (Reagent Lot Record in LIMS) exists for every reagent prepared in the laboratory and is used as a guide for the preparation of the reagent.
- 3.3 Each reagent record contains the following information:

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- the identity of the reagent
 - date of preparation
 - identity of individual preparing the reagent
 - standard batch size
 - ingredients of the reagent
 - data entry section
- 3.4 Some reagent records (such as critical reagents) may also include:
- lot numbers
 - expiration dates
 - quality control procedures (aka, “reliability checks”) to be performed and passed before the reagent is released for use in the laboratory.
- 3.5 Reagents prepared in the laboratory are labeled with, at a minimum:
- the identity of the reagent
 - the lot number
 - the expiration date
- 3.6 All Reagents prepared for casework use are labeled with a LIMS sticker. Scanning the barcode of the sticker in the LIMS will populate the reagent where all necessary records are kept. If a non-LIMS tracked reagent is aliquoted (such as for research) and the tubes are too small to be labeled with all of the required information, each tube is marked with the identity of the reagent and its lot number and stored in a “cryobox” that is labeled with the required identifying information listed above.
- 3.7 The expiration date given is usually one year from date of make/aliquot or the earliest expiration date of the reagents being used, whichever comes first. This may also be stated in each reagent form.
- 3.8 Staff is notified via email by the Quality Assurance Unit regarding reagents that are expiring.

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4 Commercial Reagents

- 4.1 Commercial reagents include, but are not limited to, kits for DNA quantitation and genetic typing.
- 4.2 A **Reagent type in the LIMS** exists for each commercial reagent that requires quality testing prior to use in casework. An applicable quality control procedure can be found in the Quality Control Procedures section of the Manual that will give directions on how to test these reagents before use.
- 4.3 Commercial reagents are labeled with, at a minimum:
- The identity of the reagent
 - The expiration date as provided by the manufacturer or as determined by the laboratory.
- 4.4 If identical reagents with the same lot number are assigned different expiration dates by the manufacturer, then the expiration date will be extended to the latest date provided that it passes quality control testing.
- For example, Lot #1234 of a reagent was received on June 1, 2011 (Bottle A) and has a manufacturer-assigned expiration date of June 1, 2012. A second bottle of Lot #1234 was received on December 1, 2011 (Bottle B) and has a manufacturer-assigned expiration date of December 1, 2012. Since the manufacturer supports the use of this particular lot of reagents until December 1, 2012, the expiration date of Bottle A can be extended to December 1, 2012 provided that Bottle B passes quality control testing.
- 4.5 Commercial reagents without an expiration date provided by the manufacturer shall expire two years *after receipt* unless otherwise indicated.
- 4.6 All commercial reagents received for casework use are labeled with a LIMS sticker. Scanning the barcode of the sticker in the LIMS will populate the reagent where all necessary records are kept. If a non-LIMS tracked commercial reagent is received (such as for research) and the tubes are too small to be labeled with all of the required information, each tube is stored in a “cryobox” that is labeled with the required identifying information listed above.
- 4.7 If applicable, a Certificate of Analysis should be downloaded or scanned and attached to the Reagent Record. If the certificate contains an expiration date for all of the reagents in a kit, (i.e.: amplification kits) use the expiration date on the certificate for the reagents rather than the dates that may be listed on the individual tubes within the kit.

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5 Reagent Quality Control Testing

5.1 Quality control (QC) tests are reliability checks and may be used by the Department to ensure that reagents are performing as expected. If needed, these tests must be completed prior to the reagent being used in actual casework. A reliability check may be a combination of several quality control tests and, for ease of classification, are assigned QC testing procedure numbers. If a reagent sheet lists a “procedure” for its quality control test, then the reagent must pass all the quality control tests listed below. If it only lists a specific “QC” number, then the reagent must pass that quality control test only.

	QC Tests Included	Analysis
Procedure 1	QC615 , QC616	Real Time Quantitative PCR
Procedure 2	QC240 , QC350	PCR Amplification and STRs
Procedure 3	QC145A , QC615 , QC350	Organic Extraction, Real Time Quantitative PCR, PCR Amplification, and STRs
Procedure 4	Retired	
Procedure 5	QC350	3130xl STRs

5.2 All QC Batches performed for testing, regardless if performed for reagents, instruments or other QC purposes, the witness steps are not required.

6 Reagent Records

6.1 Reagent records, such as reagent sheets are a form of Quality Record, and shall be stored in accordance with the guiding principles and procedures that govern such records. See [CONTROL OF RECORDS](#) in the Administrative Manual for further information.

7 Reagents Used by the Department

7.1 This section shows a list of reagents used in the Department of Forensic Biology. The list includes reagents prepared in-house as well as commercial reagents. Each reagent is classified as “Critical” or “Non-Critical” (See Section 2.1 for definitions).

REAGENT	CRITICAL
Agilent DNA 1000 Kits	N
Alpha Amylase Stock for Seratec Card Testing	N
AmpliTaq Gold DNA Polymerase Kit (all components)	Y
ANDE A-Chip (Rapid DNA cartridge)	Y
2800M Control DNA, 0.25ng/ul	Y

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REAGENT	CRITICAL
ATL Buffer	Y
BigDye Terminator Cycle Sequencing Kit	Y
Centrisep columns, strips, and plates	N
Conditioning Reagent	N
Deoxynucleotide Triphosphates, 2.5 mM (dNTPs)	Y
Dithiothreitol (DTT), 1M	Y
DNA IQ kit (all components)	Y
EDTA, 0.5 M (for organic extraction)	N
EDTA, 0.5M for WTC	Y
Ethanol 200Proof	N
Ethanol 200Proof (as used for extraction)	Y
ExoSAP-IT	Y
EZ1 DNA Investigator kit (all components)	Y
Fish Sperm DNA	Y
forensicGEM Sexcrime Kit	Y
Genetic Analyzer Buffers (Applied Biosystems®)	N
GeneScan™ LIZ 500 dye Size Standard	N
HiDi Formamide	N
Human Leukemia 60 (HL60)	Y
Hydrogen Peroxide, 3%	N
Isopropanol 99.9%	N
Isopropanol 99.9% (as used for extraction)	Y
Kastle-Meyer (KM) Reagent	Y
Matrix Standards for Genetic Analyzers (Promega and Applied Biosystems®)	N
MTL Buffer	Y
Nuclear Fast Red	Y
Organic Extraction Buffer	Y

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REAGENT	CRITICAL
PBS for Nail Extraction, 25mM EDTA	Y
PBS for Serology Testing	Y
Phase lock gel tubes	N
Phenol Chloroform Isoamyl Alcohol (PCIA)	Y
Picric Indigo Carmine (PIC)	Y
Potassium hydroxide (KOH)	N
POP-4	N
POP-6	N
Primer, FBI – A1, B1, C1, D1, C2, D2, A4, B4, HVIF, HVIR, HVIF, HVIR (mtDNA)	Y
PowerPlex® Fusion System	Y
PowerPlex® Y23 System	Y
Proteinase K Solution	Y
Quantifiler Trio DNA Quantification Kit	Y
RNase P Verification Plate	N
Roche Primer and Reaction Mix	Y
Saline (0.85% NaCl)	N
SDS, 2%	N
SDS, 20%	Y
SDS, 0.01%, and 1%	Y
Seratec α -Amylase card test cassettes	Y
Seratec PSA SemiQuant test cassettes	Y
Sequencing Loading Buffer	Y
Spectral Calibration Dye Plates (Applied Biosystems®)	N
SwabSolution Reagent	Y
Terg-a-zyme	N
TAE, 1X	Y

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REAGENT	CRITICAL
TBE buffer	N
Tris-EDTA, 0.1X	Y
Tris-HCl, 1M (pH 8.0)	N
UltraPure Water	Y
Xylene	N
XMAS Tree Stain A (Kernechtrot Solution)	Y
XMAS Tree Stain B (Picroindigocarmine Solution)	Y
Yfiler™ PCR Amplification Kit	Y

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