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Reagents

GUIDING PRINCIPLES AND SCOPE

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.

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.

PROCEDURE

Reagents are classified into two general categories:

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.
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.

Reagents are prepared **in-house** or are obtained **commercially.**

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.

A. Reagents Prepared In-House

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.

2) A **reagent sheet** form exists for every reagent prepared in the laboratory and is used as a guide for the preparation of the reagent.

3) Each reagent record contains the following information:
   i. the identity of the reagent
   ii. date of preparation
   iii. identity of individual preparing the reagent
   iv. standard batch size
   v. ingredients of the reagent
   vi. data entry section

4. Some reagent records (such as critical reagents) may also include:
   i. lot numbers
   ii. expiration dates (see step 6)
   iii. quality control procedures (aka, "reliability checks") to be performed and passed before the reagent is released for use in the laboratory.

5. Reagents prepared in the laboratory are labeled with, at a minimum:
   i. the identity of the reagent
   ii. the lot number
   iii. the expiration date (see step 6)

   When a reagent is aliquotted into tubes that 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.

6. 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 forms.

7. Staff is notified via email by the Quality Assurance Unit regarding reagents that are expiring.

B. Commercial Reagents

2. Commercial reagents include, but are not limited to, kits for DNA quantitation and genetic typing.

3. A **Raw Materials** form exists for each commercial reagent that requires quality testing prior to use in casework. The applicable quality control procedure is contained on the form.

4. Commercial reagents are labeled with, at a minimum:
   i. The identity of the reagent
   ii. The expiration date as provided by the manufacturer or as determined by the laboratory.
      1) 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 regent 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 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 will be extended to December 1, 2012 provided that Bottle B passes quality control testing.

      2) Commercial reagents without an expiration date provided by the manufacturer shall expire two years *after receipt* unless otherwise indicated**.**

C. Reagent Quality Control Testing

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 or QC620	Real Time Quantitative PCR
Procedure 2	QC240, QC350	PCR Amplification and STRs
Procedure 3	QC145A, QC615/620, QC350	Organic Extraction, Real Time Quantitative PCR, PCR Amplification, and STRs
Procedure 4	QC145/165, QC160, QC615/620, QC350	Chelex/M48 Extraction, Real Time Quantitative PCR, PCR Amplification, and STRs
Procedure 5	QC350	3130xl STRs

D. Reagent Records

Reagent records, such as reagent sheets and Raw Materials Forms are a form of Quality Record, and shall be stored in accordance to the guiding principles and procedures that govern such records. See CONTROL OF RECORDS in the Administrative Manual for further information.

E. REAGENTS USED BY THE DEPARTMENT

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".

REAGENT	CRITICAL
a-Amylase powder from Human Saliva	N
Acid Phosphatase Test Reagent	Y
Alkaline Substrate Buffer	Y
Agilent DNA 1000 Kits	N
AmpFlSTR Identifiler PCR Amplification Kit	Y
AmpFlSTR MiniFiler PCR Amplification Kit	Y
AmpliTaq Gold DNA Polymerase Kit (all components)	Y
BigDye Terminator Cycle Sequencing Kit	Y
Centrisep columns, strips, and plates	N
Chelex, 20%	Y
Chelex, 5%	Y
Deoxynucleotide Triphosphates, 2.5 mM (dNTPs)	Y
Digest Buffer	Y
Dithiothreitol (DTT), 1M	Y
EDTA, 0.5 M	N
EDTA, 0.5M for WTC	Y
ExoSAP-IT	Y
Fish Sperm DNA	Y
Genetic Analyzer Buffer (ABI)	N
HiDi Formamide	N
Human Leukemia 60 (HL60)	Y
Hydrogen Peroxide, 3%	N

REAGENT	CRITICAL
Kastle-Meyer (KM) Reagent	Y
MagAttract DNA Mini M48 Kit (Qiagen)	Y
Magnesium Chloride (MgCl2)	N
Nuclear Fast Red	Y
Organic Extraction Buffer	Y
PBS for Chelex Extraction	Y
PBS for Nail Extraction, 25mM EDTA	Y
PBS Solution for Seratec (PBS tablets)	Y
PBS Solution, Irradiated (LCN DNA)	Y
Phase lock gel tubes	N
Phenol Chloroform Isoamyl Alcohol (PCIA)	Y
Picric Indigo Carmine (PIC)	Y
POP-4	N
POP-6	N
Poly A RNA	Y
Primer, FBI – A1, B1, C1, D1, C2, D2, A4, B4, HVIF, HVIR, HVIIF, HVIIR (mtDNA)	Y
PowerPlex Fusion System	Y
Proteinase K solution	Y
Quantifiler Trio DNA Quantification Kit	Y
Roche Primer and Reaction Mix	Y
Saline (0.85% NaCl)	N
SDS, 2%	N
SDS, 20%	Y
SDS, 0.01%, 0.05%, and 1% (LCN DNA)	Y
Seratec PSA Semiquant Kits	Y
Seratec Amylase Forensic Test	Y

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REAGENT	CRITICAL
Sequencing Loading Buffer	Y
Sodium Acetate, 0.1 M	N
Sterile Deionized Water	Y
Terg-a-zyme	N
TAE, 1X	Y
TBE buffer	N
Tris-EDTA, 1X	Y
Tris-HCl, 1M (pH 8.0)	N
UltraPure Water	Y
Xylene	N
Yfiler™ PCR Amplification Kit	Y