

DNA: Reagents

Introduction

High quality chemicals are used in the preparation of reagents. When possible, reagents and materials are sterilized by autoclaving.

All reagent preparation QC information is recorded in the appropriate section of the *Reagent Preparation Logbook* located in the reagent preparation area of the Biology laboratory.

Refer to [*AQR: Chemicals Used in Testing*](#) in the *Quality Manual* for general information regarding labeling and testing. Additional requirements specific to testing in the DNA section are listed below.

Reagent preparation

A *Reagent Preparation* logbook contains a list of reagents, their formulas, notes on the method of preparation, and the appropriate container.

The amount prepared may be increased or decreased according to need.

In addition to the requirements listed in [*AQR: Chemicals Used in Testing*](#) in the *Quality Manual*, the *Reagent Preparation* logbook will include the expiration date.

Color-coded reagent containers

Reagent containers are color-coded for their usage area.

- **Green tape** is used for reagents in the extraction area
 - **Red tape** is used for marking reagents in the amplification/typing room.
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Single use containers

Single-use reagent containers that are discarded each day of use need only to be labeled with the reagent name and lot number or date of preparation. Results for the positive and negative controls are recorded in the examination documentation.

Continued on next page

DNA: Reagents, Continued

Batch number These laboratory-prepared critical reagents are assigned a batch number:

- digest buffer
- dithiothreitol (DTT)
- proteinase K
- TE buffer
- sterile water

The current batch of reagents can be used with any of the commercially prepared reagents and kits that have passed quality control testing.

Critical commercial reagents and kits

Critical commercial reagents and kits are assigned the manufacturer's lot number or kit expiration date for purposes of tracking in quality control testing. The manufacturer's lot number, kit control date, and lot numbers/control dates of the kit components are recorded, as applicable, in the QC binders in the Biology Unit Conference room. The packaging of commercial kits and supplies will be marked with the date received.

Kits may be used until they reach the manufacturer's expiration date if they have passed quality control testing.

The following critical commercial reagents and kits are used:

- phenol/chloroform
- EZ1 DNA Investigator Robot Kit
 - EZ1 cartridges are the only critical component
- Quantifiler[®] Trio Human DNA Quantification Kit
- Promega PowerPlex[®] Fusion 6C PCR Amplification Kit
- AmpF ℓ STR[®] Yfiler[™] PCR Amplification Kit.

NOTE: Bovine Serum Albumin (BSA) solution is a laboratory-prepared optional additive that can be used to enhance the amplification of DNA. It may be used for two years after the date of preparation once it has passed quality control testing. BSA will be assigned a lot number based on the expiration date for purposes of tracking in quality control testing. Bovine Serum Albumin is a critical reagent.

Continued on next page

DNA: Reagents, Continued

Kit quality control testing

Each new batch of PCR amplification kits should be quality control tested with the following samples:

- positive PCR control
- negative PCR control
- two previously typed reference samples

The amplified samples are typed according to the kit typing procedure. Each sample must demonstrate expected relative intensities and match the assigned type within the current interpretation guideline. The negative PCR control must show no evidence of contamination. Refer to [DNA: Contamination Control](#) for additional information.

Results of QC testing of kits are documented in the *QC* logbook. At the conclusion of testing, the Technical Lead will review the *QC* logbook and will certify the new QC batch and lot numbers for use if all samples, including those containing no DNA, type as expected.

Absence of human DNA

Laboratory and commercially-prepared reagents require quality control testing for the absence of human DNA contamination before they are approved for use.

Quality control tests used are appropriate to the reagent under study. This may include testing the reagent through all four steps (extraction, quantitation, amplification, and typing) of a DNA typing method.

Results of QC testing are documented in the *QC* logbook.

Commercial reagents

Commercial reagents are stored in accordance with the manufacturer's recommendations. Commercial reagents with no expiration date will be discarded or designated as training reagents five years after the date it was received or opened whichever date is later.
