

BIO: Standards

Introduction To determine that a procedure is working properly, appropriate standards are essential.

Sources Standards are obtained by

- purchasing from a reputable manufacturer
- using body fluids from laboratory staff

Testing to ensure reliability To ensure reliability, the standard is tested using the appropriate procedure before use. The results are recorded in the *Biology Quality Control Log Book* located in the Biology Laboratory.

Labeling-purchased standards Purchased standards will be labeled with the following information:

- identity of substance
- lot number
- date received
- initials of the person who received the standard
- date opened
- safety hazards, as appropriate

Labeling-prepared standards Prepared or collected standards will be labeled with the following information:

- identity of substance
- date prepared or collected
- initials of person who made or collected the standard
- safety information, as appropriate

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DNA procedure check The laboratory shall check its DNA procedures annually or whenever substantial changes are made. The procedures will be checked using a NIST standard reference material or a NIST-traceable standard

This will provide an annual performance check of the laboratory's robotic extraction instruments, Real-Time PCR quantitation instruments, PCR thermal cyclers, and genetic analyzers.

Records Records will be maintained for each standard and may include, as appropriate, the

- source
- lot number
- date standard was made or collected and by whom
- date purchased standard was received and by whom
- date reliability testing was performed and by whom
- certifications of purity from the manufacturer

These records will be located in the *Biology Quality Control Log Book*, located in the Biology Laboratory. The records will be kept a minimum of five years.
