

FDT.04890 Unique Specimen Labeling Phase II

The written accessioning procedure requires unique labeling of each specimen by the laboratory.

FDT.04950 Restricted Access Phase II

Access to specimens, aliquots and any extracts thereof is restricted to authorized laboratory personnel.

FDT.05000 Accessioning Procedure Phase II

The laboratory follows an accessioning procedure that defines criteria for determining the acceptability of specimens for analysis and the course of action when unacceptable specimens are identified.

NOTE: Evaluation criteria such as chain-of-custody failures, missing information, specimen leakage, etc. must be defined in the accessioning procedure, along with the required actions that laboratory personnel must take in reporting these problems to the client.

FDT.05020 Specimen Acceptability Phase II

The laboratory follows a written procedure for determining the quality of specimens received for analysis and course of action when unacceptable specimens are detected (eg, color, odor, volume, quantity, foreign material, etc.).

NOTE: This procedure must require the visual inspection of samples and assessment of the sample volume/quantity for acceptability for analysis, at minimum.

Evidence of Compliance:

- ✓ Records of specimen evaluation

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Toxicology and Drug Testing in the Medical Laboratory*. 3rd ed. CLSI guideline C52. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.

FDT.05045 Specimen Validity - Urine Phase II

All urine specimens are tested for validity.

NOTE: At a minimum, this requires a test for creatinine but may also include measurements of specific gravity, pH, etc. The laboratory is required to discuss the issue of excessively dilute specimens and potential adulteration with its clients.

Evidence of Compliance:

- ✓ Records of specimen validity testing

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Toxicology and Drug Testing in the Medical Laboratory*. 3rd ed. CLSI guideline C52. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.

FDT.05055 External Contamination - Hair and Nails Phase II

The laboratory follows validated procedures to control for potential external contamination of hair and nail specimens.

NOTE: This may include wash procedures and/or metabolite identification.

FDT.05095 Secured Specimen Storage Phase II



The original specimen (in the original container) and appropriately labeled aliquots are maintained in an appropriate manner when not in the possession of an authorized individual.

NOTE: The original specimens must always be maintained either in the direct custody of an authorized individual or be in a locked secured area accessible only to authorized individuals.

This locked and limited access area may be a refrigerator, freezer, or storage room within the laboratory.

Aliquots or extracts in the laboratory for testing must be in the possession of an authorized individual or be maintained with "line of sight" custody. If the laboratory is a secure, limited-access facility, custody of the aliquot may be assigned to an instrument or temporary storage area, as long as records of individual access and egress from the area are recorded

An authorized individual is considered a person with specific training and work responsibilities for chain-of-custody specimens. General personnel, such as custodians, or technologists not assigned to the chain-of-custody work, must not have unescorted access to secure areas.

Evidence of Compliance:

- ✓ Records for internal chain-of-custody reflecting limited-access storage **OR** record of direct custody of the specimen by an authorized person at all times

FDT.05110 Positive Specimen Retention

Phase II



All positive specimens are retained in their original containers frozen or per manufacturer's instructions for the collection device. Specimens are retained as defined in the specimen retention policy and for at least:

- **One year - all specimen types except blood**
- **30 days or longer at the discretion of the laboratory director - blood specimens**

NOTE: For hair, umbilical cord tissue, oral fluid, and nails, both the original specimen container and any residual sample, processed or not, must be retained.

Evidence of Compliance:

- ✓ Records of specimen disposition consistent with retention policy

FDT.05800 Negative Specimen Retention

Phase II



Negative specimens are retained under appropriate storage conditions as defined in the specimen retention policy.

NOTE: Negative specimens must be retained for sufficient time to complete the final reporting of all specimens within a batch, including confirmation testing, and for report receipt and review by clients.

Storage conditions must be appropriate for the specimen matrix as defined in laboratory policy, consistent with regulatory requirements and manufacturer's instructions for specialized collection devices if such requirements exist.

Evidence of Compliance:

- ✓ Records of specimen disposition consistent with retention policy

FDT.05805 Specimen Disposal

Phase II

Disposal of positive and negative specimens is recorded on a chain-of-custody form.