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.