

of seals or secured containers and leakage, recording of exceptions, aliquoting, placing into batches, storing, and completion of records.

Inspector Instructions:

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|  | <ul style="list-style-type: none"> Sampling of specimen handling policies and procedures for completeness (includes collection, accessioning, specimen retention/storage, record retention) Sampling of records/logs for completeness (includes specimen rejection, security seal records, specimen validity, collection monitoring) Sampling of external and internal chain-of-custody records for completeness (includes specimen disposition) Sampling of specimen rejection records/log |
|  | <ul style="list-style-type: none"> Sampling of specimens (unique labeling) Locked limited-access secured area (contains original specimen/containers) Locked limited-access secured area (contains forensic records) |
|  | <ul style="list-style-type: none"> What is your course of action when unacceptable specimens are received? What procedure does your laboratory follow when dilutions are made from the primary specimen? What process does your laboratory follow for retention of positive specimens? How do you ensure the validity of all specimen types? Who has access to the secure area where the original specimens are stored? |
|  | <ul style="list-style-type: none"> If problems are identified during the review of specimen handling processes, or when asking questions, further evaluate the laboratory's responses, corrective actions and resolutions |

FDT.04800 Receiving/Accessioning Procedure

Phase II



The receiving and/or accessioning procedure requires a record of verification of:

- Specimen identification adequacy
- Specimen security seal condition or secured specimen container integrity
- External chain-of-custody completeness upon receipt

FDT.04850 Chain-of-Custody Records

Phase II



The laboratory properly completes appropriate sections of external and internal chain-of-custody records to include the following:

- Type of specimen collected
- Verification of donor and/or specimen identity
- Identification of laboratory-generated aliquots
- Verification of the integrity (tamper-evident) of the specimen container
- Identity of individuals handling the specimens
- Storage location when not in the possession of an authorized individual, including aliquots
- Reason for the transfer of custody and date of transfer

Evidence of Compliance:

- Completed chain-of-custody records with required elements