





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

## Inspector Instructions:

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

### FDT.04800 Receiving/Accessioning Procedure

Phase II



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

1. Specimen identification adequacy
2. Specimen security seal condition or secured specimen container integrity
3. 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