- What previously used procedures are available for reference purposes?

FDT.03200 Procedure Revision Review **Phase II**

All changes are dated and initialed by the laboratory director.

FDT.03300 Retained Procedures **Phase II**

Copies of all procedures (paper or electronic) and the effective dates are retained for reference.

FDT.03400 Procedure Manual **Phase II**

There is a complete procedure written for each analytical test.

NOTE: Information must include, where appropriate:

1. *Principles of each test*
2. *Preparation of reagents, standards/calibrators, and controls*
3. *Protocol for performing the analysis*
4. *Directions for calibration and calibration verification*
5. *Derivation of results (ie, direct readout, calibration from a standard or against a multi-point curve, definitions for semi-quantitative readout)*
6. *LOQ, linearity of quantitative methods and the course of action taken if results exceed this linearity*
7. *Limit of detection (LOD)*
8. *Specificity of the method (ie, interferences)*
9. *Cutoff values used for screening and confirmation*
10. *How to report when the result is below the cutoff value*
11. *Controls used in the assay*
12. *Criteria for unacceptable result*
13. *Notes, special requirements, safety precautions, etc.*
14. *Carryover potential and the actions to take when carryover is detected*
15. *Pharmacokinetic information about the drug or drug group*
16. *References*

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Developing and Managing Laboratory Documents*. 7th ed. CLSI guideline QMS02. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.

FDT.04700 Procedure Manual Index **Phase II**

The procedure manual has an index or it is organized in a fashion that allows for quick retrieval of information.

SPECIMEN HANDLING

Review the written procedures and thoroughly inspect the specimen handling in the laboratory. This may require a prearranged inspection during the evening or night shifts in some laboratories. Particular attention should be paid to specimen receipt, verification of identity, accessioning, external and internal chain-of-custody, labeling, specimen examination, evaluation of sample volume, any adulteration and dilution checks, evaluation of integrity

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

Inspector Instructions:

	• 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
	• Sampling of specimens (unique labeling) • Locked limited-access secured area (contains original specimen/containers) • Locked limited-access secured area (contains forensic records)
	• 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?
	• 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:

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