

NOTE: The laboratory must retain the following records for at least two years:

1. Laboratory security access logs
2. Laboratory accessioning logs
3. Chain-of-custody records and requisitions
4. Analytical data from screening and confirmation analyses
5. Specimen reports
6. QC program records
7. Instrument maintenance/service records
8. Instrument calibration records
9. Reagent/standard/calibrator/control preparation and verification records
10. Method performance validation records (at least two years after retirement of procedure)
11. Personnel files on all laboratory personnel involved with the forensic drug testing performed by the laboratory
12. Proficiency testing survey results, reports, and corrective actions
13. Previous CAP FDT on-site inspection records and corrective actions
14. Previous CAP FDT self-inspection records and corrective actions
15. Previous CAP general on-site inspection records and corrective actions appropriate to the FDT laboratory

FDT.07100 Secured Storage Phase II



Records are stored in a secured area that is only accessible to authorized personnel.

FDT.07200 Record Availability Phase II

Records for the last two years are available at the time of the inspection.

REAGENTS/STANDARDS/CALIBRATORS/CONTROLS

The verification of reagents/standards/calibrators/controls (RSCC) is required and must be recorded. Several methods are acceptable, such as direct analysis with reference materials, other standards, or checking against previously validated controls. The intent is for new RSCC to be verified by an appropriate method and recorded before the RSCC is placed in service.

Inspector Instructions:

 READ	<ul style="list-style-type: none"> • Sampling of verification of reagents/standards/calibrators/controls policies and procedures • Sampling of RSCC verification records (includes certification/verification of calibrator purity) • Sampling of control range verification records • Current DEA license (for US laboratories that handle pure controlled substances)
 OBSERVE	<ul style="list-style-type: none"> • Sampling of RSCC materials (labeling, storage, quality of calibration standards)