STANDARD OPERATING PROCEDURE TEMPLATE · PRE-ANALYTIC: ORDERING, COLLECTION AND SPECIMEN HANDLING

Chain of Custody Specimen Collection

Governing requirement: 49 CFR Part 40 (DOT) / SAMHSA guidelines; forensic practice

Applies to: ☐ Waived ☑ Moderate complexity ☑ High complexity

Laboratory name		**CLIA number**	
Document number		**Version**	
Effective date		**Next review due**	
Author		**Department / section**	
Approved by (laboratory director)		**Director signature**	
Approval date		**Supersedes document**	

Important: Template only. Before use, this document must be reviewed, adapted to your laboratory's instruments, test systems and the manufacturer's instructions, and approved, signed and dated by the laboratory director. Check current federal, state and accreditation requirements. Not legal advice. Sound Lab Consultants is not affiliated with or endorsed by CMS, CDC, FDA, OSHA, CAP, COLA, The Joint Commission, CLSI or any manufacturer.

1. Purpose

To collect and handle specimens so their identity and integrity are documented from collection to testing.

2. Scope

Workplace, legal and forensic urine or oral fluid drug testing that requires chain of custody. Federally regulated DOT testing must follow 49 CFR Part 40 exactly.

3. Responsibility

- Collectors (phlebotomists, nurses, medical assistants): follow this procedure and document collection.
- Specimen processing / accessioning staff: check acceptability and document problems.
- Supervisor: trains staff, monitors pre-analytic errors and reviews rejection logs.
- Laboratory director: approves the procedure and acceptance criteria.

4. Definitions

Custody and control form (CCF): The form that records specimen identity and each transfer of custody.

5. Materials, equipment and records

- Custody and control forms
- Tamper-evident seals
- Collection kit with temperature strip
- Bluing agent for toilet, secured water sources

6. Procedure

1. Secure the collection site: bluing in toilet, no running water, remove soap and cleaning agents.

2. Verify donor photo ID and explain the process.

3. Have the donor empty pockets and wash hands.

4. Provide sealed collection container; donor provides at least **[Required volume]**.

Required volume	

5. Read the temperature strip within 4 minutes; acceptable range 32-38 °C (90-100 °F).

6. Inspect for signs of tampering.

7. Split if required, seal bottles in front of the donor, donor initials seals.

8. Complete the CCF; every transfer is signed, dated and timed.

9. Package and ship to the testing lab in sealed bags.

7. Quality control

• Follow the laboratory's QC policy and the manufacturer's instructions; record QC before reporting patient results.

• Stop patient testing and take corrective action when QC or acceptance criteria are not met.

8. Interpretation, reporting and documentation

• Any break in custody documentation must be recorded and may invalidate the specimen for legal use.

9. Limitations and cautions

• Non-regulated testing may use a simplified chain of custody approved by the director.

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

10. References

• eCFR, 49 CFR Part 40 Procedures for transportation workplace drug and alcohol testing
https://www.ecfr.gov/current/title-49/subtitle-A/part-40

• HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (referenced by name)

• CMS, State Operations Manual Appendix C: Survey procedures and interpretive guidelines for laboratories
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_lab.pdf

11. Lab-specific notes

Notes and local requirements	

12. Revision history

Version	Date	Description of change	Author	Approved by

13. Annual review log

Procedures and changes must be approved, signed and dated by the current laboratory director before use (42 CFR 493.1251(d)).

Review date	Reviewed by	Signature	Changes needed (Y/N)	Comments

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