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

Specimen Transport and Storage

Governing requirement: 42 CFR 493.1242(a)(4)

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 preserve specimen integrity during transport and storage.

2. Scope

Specimens transported within the facility, by courier and to referral laboratories.

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

Stability: The time a specimen remains acceptable for testing at a given temperature.

5. Materials, equipment and records

- Biohazard bags with separate document pocket
- Coolers, ice packs, frozen packs, temperature indicators
- Courier log

6. Procedure

1. Look up storage temperature and stability for each test **[Stability table location]**.

Stability table location	

2. Package specimens upright in sealed biohazard bags with requisitions in the outer pocket.

3. Maintain temperature: room temperature **[RT range]**, refrigerated 2-8 °C, frozen **[Frozen temperature]**.

RT range	

Frozen temperature	

4. Courier records pickup and delivery times and temperatures.
5. On receipt, check temperature and transit time; record deviations.
6. Separate serum or plasma from cells within **[Centrifugation time limit]** when required.

Centrifugation time limit	

7. Quality control

• Validate transport containers seasonally **[Validation frequency]**.

Validation frequency	

8. Interpretation, reporting and documentation

• Record the activity, date, result and initials on the form or log, and have the supervisor review records **[Review frequency]**.

Review frequency	

• Keep records per the record retention SOP (at least 2 years under 42 CFR 493.1105 unless a longer period applies).

9. Limitations and cautions

• Exceeding stability limits leads to rejection.

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

10. References

• eCFR, 42 CFR Part 493 Laboratory Requirements (CLIA)
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

• 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

• PHMSA, 49 CFR 173.199 Category B infectious substances (UN3373)
https://www.ecfr.gov/current/title-49/section-173.199

• CLSI guidelines relevant to this procedure (referenced by name only; obtain current editions from CLSI)

• eCFR, 42 CFR 493.1242 https://www.ecfr.gov/current/title-42/section-493.1242

11. Courier transport log

Fill in electronically or print. Keep completed forms per the record retention policy.

Date	Pickup site	Pickup time	Temp at pickup	Delivery time	Temp on arrival	Initials

12. Lab-specific notes

Notes and local requirements	

13. Revision history

Version	Date	Description of change	Author	Approved by

14. 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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