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

Specimen Packaging and Shipping (UN3373)

Governing requirement: 49 CFR 173.199 (Category B) and 42 CFR 493.1242(c)

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 package and ship patient specimens safely and legally.

2. Scope

Specimens shipped by courier or common carrier 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

Category B: Infectious substance not meeting Category A criteria; shipped as UN3373 Biological Substance, Category B.

Exempt human specimen: A specimen with minimal likelihood of pathogens, shipped as 'Exempt human specimen'.

5. Materials, equipment and records

- Leak-proof primary receptacle
- Leak-proof secondary packaging with absorbent
- Rigid outer packaging
- UN3373 label
- Dry ice labels (UN1845) if used

6. Procedure

1. Classify the specimen as Category B or exempt **[Classification guidance]**.

Classification guidance	

2. Place primary container in secondary packaging with enough absorbent for the entire contents.
3. Place itemized list of contents between secondary and outer packaging.
4. Mark outer package with UN3373 and 'Biological Substance, Category B' and shipper/consignee information.
5. If using dry ice, mark UN1845 and net weight and allow venting.
6. Ensure the person packaging has current training **[Training records location]**.

Training records location	

7. Record shipment and tracking number.

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

• 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

• Category A substances require specialized training and packaging; do not ship them under this SOP.

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

10. References

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

• CDC, Infectious diseases laboratory test directory: specimen collection and submission https://www.cdc.gov/laboratory/specimen-submission/index.html

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

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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