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

Specimen Receiving and Accessioning

Governing requirement: 42 CFR 493.1242 and 493.1283

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 receive and register specimens accurately and promptly.

2. Scope

All specimens arriving at the laboratory.

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

Accession number: Unique laboratory number linking the specimen to the order and results.

5. Materials, equipment and records

- LIS
- Barcode printer
- Receiving log

6. Procedure

1. Check specimen against requisition: identifiers, tests, container, temperature, volume.

2. Record date and time of receipt.

3. Assign accession number and apply labels without covering original identifiers.

4. Prioritize STAT specimens **[STAT handling]**.

STAT handling	

5. Route specimens to sections or storage.

6. Document problems and follow the rejection SOP.

7. Reconcile courier manifests with specimens received **[Reconciliation method]**.

Reconciliation method	

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

• 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

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

• eCFR, 42 CFR 493.1283 https://www.ecfr.gov/current/title-42/section-493.1283

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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