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

Specimen Labeling

Governing requirement: 42 CFR 493.1232 and 493.1242(a)(3)

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 ensure specimens are labeled accurately so they can be traced to the patient throughout testing.

2. Scope

All primary specimen containers, aliquots and slides.

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

Primary container: The tube or container the specimen was collected into.

5. Materials, equipment and records

- LIS barcode labels or handwritten labels
- Slide labels / pencil

6. Procedure

1. Label the primary container, not the lid or bag.

2. Include at least two identifiers, collection date and time when required, and collector initials **[Additional required elements]**.

Additional required elements	

3. Label in the presence of the patient immediately after collection.

4. Apply barcode labels straight, lengthwise, without covering the fill window.

5. Label aliquots with the same identifiers plus aliquot type.

6. Label slides on the frosted end with pencil or solvent-resistant marker.

7. Mislabeled or unlabeled specimens: follow the rejection SOP; document any exceptions approved for irretrievable specimens.

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 labeling errors as occurrences.

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 493.1232 https://www.ecfr.gov/current/title-42/section-493.1232

• 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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