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

Patient Identification

Governing requirement: 42 CFR 493.1232 and 493.1242(a)

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 positively identify patients and specimens using two identifiers throughout the testing process.

2. Scope

All specimen collections and point-of-care tests.

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

Two identifiers: Two person-specific identifiers such as full name and date of birth **[Approved identifiers]**. Room number is not an identifier.

5. Materials, equipment and records

- ID band or photo ID
- Requisition / order

6. Procedure

1. Ask the patient to state full name and date of birth; do not ask yes/no questions.

2. Compare with the requisition and ID band (inpatients) or ID document.

3. Resolve discrepancies before collection; do not collect until identity is confirmed.

4. For unconscious or unidentified patients use the facility's temporary ID system **[Temporary ID process]**.

Temporary ID process	

5. For pediatric or non-verbal patients, verify identity with the caregiver and record who verified.

6. Label specimens in the presence of the patient immediately after collection.

7. Quality control

• Track mislabel and misidentification events as occurrences.

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

• Never relabel a specimen without supervisor approval and documentation; irretrievable specimens follow the rejection SOP.

• 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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