STANDARD OPERATING PROCEDURE TEMPLATE · PERSONNEL, TRAINING AND COMPETENCY

Phlebotomy Training and Competency

Governing requirement: 42 CFR 493.1242 and 493.1235

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 specimen collectors are trained and competent in patient identification, safe venipuncture and capillary collection, and labeling.

2. Scope

All employees who collect blood specimens for the laboratory.

3. Responsibility

- Laboratory director: ensures staff are qualified, trained and competent before testing and signs delegations.
- Technical consultant / technical supervisor: performs or delegates training and competency assessment.
- Supervisor / manager: maintains personnel records and schedules training and assessments.
- Employee: completes training, keeps credentials current and reports changes.

4. Definitions

Successful collection: A collection with correct ID, correct tubes and order of draw, adequate volume, proper labeling and no adverse events.

5. Materials, equipment and records

- Phlebotomy checklist
- Practice arm (if used)
- State certification, if required **[State phlebotomy certification]**

State phlebotomy certification	

6. Procedure

1. Complete didactic training: anatomy, order of draw, infection control, patient ID, labeling, complications.

2. Observe **[Number]** collections by a trainer.

Number	

3. Perform **[Number]** supervised successful venipunctures and **[Number]** capillary collections.

Number	
Number	

4. Trainer signs off; supervisor releases to independent collection.

5. Assess competency annually by direct observation and review of collection errors (mislabels, hemolysis, recollects).

6. Retrain when error rates exceed **[Error rate threshold]**.

Error rate threshold	

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

• File checklists in personnel records.

9. Limitations and cautions

• Some states (CA, NV, LA, WA) license or certify phlebotomists.

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

10. References

• 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

• OSHA, 29 CFR 1910.1030 Bloodborne pathogens https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030

• 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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