STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

Writing and Formatting SOPs (SOP on SOPs)

Governing requirement: 42 CFR 493.1251(b)

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 set a single format and minimum content for laboratory standard operating procedures so they are complete, consistent and meet CLIA procedure manual requirements.

2. Scope

All new and revised technical and administrative procedures written in the laboratory.

3. Responsibility

- Laboratory director: approves this policy, assigns responsibility for quality activities and reviews results.
- Technical consultant / technical supervisor: reviews technical aspects, investigates issues and signs off corrective actions.
- Quality lead (if assigned): coordinates records, tracking and reporting.
- All laboratory staff: follow this procedure and report problems promptly.

4. Definitions

SOP: A written, director-approved instruction for performing a task the same way every time.

Procedure manual: The complete set of current SOPs for all tests and examinations the lab performs (42 CFR 493.1251(a)).

5. Materials, equipment and records

- SOP template (this library)
- Style guide **[Style guide location]**

Style guide location	

- Manufacturer package inserts and operator manuals

6. Procedure

1. Use the standard header: laboratory name, CLIA number, document number, version, effective date, author, approval signature and date.

2. Write each test procedure with these sections, as applicable: principle, patient preparation, specimen collection, labeling, storage, preservation, transport, processing and referral, and specimen acceptability and rejection criteria.

3. Include microscopic examination steps and how to detect inadequately prepared slides, when applicable.

4. Write step-by-step performance of the test, including calculations and interpretation.

5. Describe preparation of slides, solutions, calibrators, controls, reagents and stains.

6. Include calibration and calibration verification, the reportable range, and control procedures with acceptance criteria.

7. State corrective action when calibration or controls fail, limitations and interfering substances, reference intervals, and critical (panic or alert) values.

8. Describe how results are entered and reported, including critical value reporting, and what to do if the test system becomes inoperable.

9. List pertinent literature references.

10. You may reference the manufacturer's package insert or operator manual for items it covers; add anything it does not cover (42 CFR 493.1251(c)). Record the insert version: **[Package insert version tracking method]**.

Package insert version tracking method	

11. Use numbered steps, one action per step, active voice, and units for every value. Put lab-specific values in the template's fill-in fields.

12. Submit the draft through document control for review and director approval before use.

7. Quality control

• Reviewers check each draft against the 493.1251(b) checklist before approval.

8. Interpretation, reporting and documentation

• A procedure is incomplete if any applicable 493.1251(b) element is missing.

9. Limitations and cautions

• Textbooks may supplement but not replace written procedures (42 CFR 493.1251(a)).

• 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 493.1251 https://www.ecfr.gov/current/title-42/section-493.1251

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

Free template from Sound Lab Consultants, soundlabconsult.com. Download more free templates at soundlabconsult.com/laboratory-sop-library.