STANDARD OPERATING PROCEDURE TEMPLATE · WAIVED TESTING AND POINT-OF-CARE TESTING

Point-of-Care Testing (POCT) Program

Governing requirement: 42 CFR 493.1256, 493.1281 and 493.15

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 manage point-of-care testing across sites so it meets CLIA and facility requirements.

2. Scope

All POCT devices and operators under **[CLIA number(s)]**.

CLIA number(s)	

3. Responsibility

- Testing personnel: follow the manufacturer's instructions exactly and document QC and results.
- Site supervisor / testing coordinator: trains staff, reviews logs and orders supplies.
- Laboratory director: approves the procedure and holds responsibility for the certificate.

4. Definitions

POCT coordinator: Person who manages devices, operators, QC and records **[Coordinator name]**.

5. Materials, equipment and records

- Device inventory
- Operator list with certification dates
- Connectivity / data management system

6. Procedure

1. Approve new POCT tests through the lab director; verify categorization.

2. Train and certify operators; lock out uncertified operators in devices where possible.

3. Ensure QC per manufacturer (waived) or per CLIA/IQCP (nonwaived).

4. Ensure results are documented in the patient record.

5. Compare POCT results with the main lab at least twice a year when the same analyte is tested (493.1281).

6. Review QC lockouts, operator activity and errors monthly.

7. Recertify operators **[Recertification interval]**.

Recertification interval	

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

• 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

• CDC, Ready? Set? Test! Patient testing is important (waived testing booklet) https://www.cdc.gov/clia/php/waived-tests/index.html

• eCFR, 42 CFR 493.15 https://www.ecfr.gov/current/title-42/section-493.15

• eCFR, 42 CFR 493.1256 https://www.ecfr.gov/current/title-42/section-493.1256

• eCFR, 42 CFR 493.1281 https://www.ecfr.gov/current/title-42/section-493.1281

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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