STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

Purchasing, Inventory and Supplier Qualification

Governing requirement: 42 CFR 493.1252

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 reagents, controls, calibrators and supplies meet requirements, are received in acceptable condition and are used before expiration.

2. Scope

All critical supplies and services that affect test quality.

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

Critical supply: Any material or service whose failure could affect test results.

5. Materials, equipment and records

- Approved supplier list
- Receiving log
- Inventory system **[Inventory system]**

Inventory system	

6. Procedure

1. Maintain an approved supplier list; evaluate suppliers on quality, delivery and support **[Evaluation frequency]**.

Evaluation frequency	

2. Set par levels for each critical item **[Par level list location]**.

Par level list location	

3. On receipt, check the packing list, lot number, expiration date, shipping temperature indicator and package integrity.

4. Record receipt date, lot and expiration; label with date received and date opened as required.

5. Store per the manufacturer's instructions; segregate new lots until verified when lot-to-lot checks are required.

6. Use first-expiring first (FEFO); remove expired materials and document disposal.

7. Report supplier problems as occurrences.

7. Quality control

• Reject shipments that arrive outside required temperature and notify the supplier.

8. Interpretation, reporting and documentation

• Keep receiving records at least 2 years.

9. Limitations and cautions

• Do not mix components from different kit lots unless the manufacturer allows it (493.1252(d)).

• 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

• Manufacturer's package insert, operator manual and safety data sheets for each test system in use

• eCFR, 42 CFR 493.1252 https://www.ecfr.gov/current/title-42/section-493.1252

11. Reagent receiving log

Fill in electronically or print. Keep completed forms per the record retention policy.

Date received	Item	Lot #	Expiration	Condition OK (Y/N)	Storage	Initials

12. Lab-specific notes

Notes and local requirements	

13. Revision history

Version	Date	Description of change	Author	Approved by

14. 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.