STANDARD OPERATING PROCEDURE TEMPLATE · ANALYTIC: QC, CALIBRATION, VERIFICATION AND EQUIPMENT

Reagent Lot-to-Lot Verification

Governing requirement: 42 CFR 493.1256(e)-(f) and 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 confirm new reagent lots and shipments give comparable results before patient use.

2. Scope

Quantitative and qualitative reagents, test kits and media.

3. Responsibility

- Testing personnel: perform the procedure, record results and stop patient testing when criteria are not met.
- Technical consultant / technical supervisor: sets acceptance criteria, reviews records and approves corrective action.
- Supervisor: ensures schedules are met and records are reviewed on time.
- Laboratory director: approves the procedure and any change to criteria.

4. Definitions

New lot: Reagent with a different lot number from the lot in use.

5. Materials, equipment and records

- Patient specimens, controls

6. Procedure

1. Before using a new lot or shipment, test controls (and patient samples when appropriate).

2. Quantitative: test **[Number]** patient samples on old and new lots; compare to criteria **[Acceptance criteria]**.

Number	
Acceptance criteria	

3. Qualitative: test known positive and negative samples, including weak positives.

4. Do not use the new lot until acceptable; document.

5. Record lot numbers, dates opened and expiration.

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

• Controls alone may not detect lot differences because of matrix effects.

• 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

• CLSI guidelines relevant to this procedure (referenced by name only; obtain current editions from CLSI)

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

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

11. Lot-to-lot log

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

Test	Old lot	New lot	Samples	Result summary	Acceptable (Y/N)	Reviewer

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

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