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

Calibration Verification and Reportable Range (AMR) Verification

Governing requirement: 42 CFR 493.1255(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 verify calibration throughout the reportable range at required intervals.

2. Scope

Quantitative nonwaived tests.

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

Calibration verification: Testing materials of known value as patient samples to confirm results stay accurate across the reportable range.

AMR: Analytical measurement range.

5. Materials, equipment and records

- Calibration verification materials **[Material and source]**

Material and source	

- Worksheet

6. Procedure

1. Test at least a minimal (or zero), mid-point and maximum value near the upper limit of the reportable range.

2. Perform at least every 6 months and after: complete reagent change (unless shown not to affect the range), major preventive maintenance or critical part replacement, unexplained QC trends or failures, or when the lab's schedule requires.

3. Compare results to assigned values with criteria **[Acceptance criteria per analyte]**.

Acceptance criteria per analyte	

4. If it fails, troubleshoot, recalibrate, repeat and evaluate patient results.

5. Document and have the technical consultant/supervisor review.

6. If the manufacturer's calibration includes three levels spanning the range, calibration every 6 months may meet the requirement; document the rationale.

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

• Report results outside the verified range only per dilution protocol.

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

• 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 493.1255 https://www.ecfr.gov/current/title-42/section-493.1255

11. Calibration verification worksheet

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

Analyte	Level	Expected	Observed	% / abs diff	Pass (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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