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

Calibration

Governing requirement: 42 CFR 493.1255(a)

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 calibrate test systems at required intervals and document acceptability.

2. Scope

All nonwaived quantitative test systems that require calibration.

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

Calibrator: Material of known value used to set the measuring system's response.

5. Materials, equipment and records

- Calibrators **[Calibrator lot tracking]**

Calibrator lot tracking

- Calibration log or instrument records

6. Procedure

1. Calibrate per the manufacturer's instructions at least at the manufacturer's frequency **[Calibration frequency per manufacturer]**.

Calibration frequency per manufacturer

2. Use calibrators appropriate to the test system and traceable when possible.

3. Recalibrate after reagent lot change, major maintenance or QC failure when indicated.

4. Accept calibration only when it meets criteria **[Calibration acceptance criteria]**.

Calibration acceptance criteria	

5. Run QC after calibration before patient testing.

6. Recalibrate whenever calibration verification fails.

7. Document date, calibrator lot, results, acceptance and operator.

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

• Keep calibration records at least 2 years.

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

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

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

11. Calibration log

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

Date	Test	Calibrator lot	Reason	Acceptable (Y/N)	QC after cal OK	Tech

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.