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

Instrument Maintenance and Function Checks

Governing requirement: 42 CFR 493.1254

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 keep instruments in proper working order through scheduled maintenance and function checks.

2. Scope

All analytical instruments and equipment.

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

Function check: A check of critical operating characteristics (e.g. temperature, voltage, optics) before testing.

5. Materials, equipment and records

- Maintenance schedule **[Instrument list and schedules]**

Instrument list and schedules	

- Maintenance log

6. Procedure

1. Perform maintenance at least as often as the manufacturer specifies.

2. Perform function checks before patient testing as required.

3. Record date, task, results and initials.

4. Take instruments out of service when checks fail; label 'Out of service'.

5. Document service calls and repairs; perform required QC or calibration verification after repair.

6. For lab-developed or modified equipment, establish a maintenance schedule **[Schedule]**.

Schedule	

7. Supervisor reviews logs monthly.

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 logs at least 2 years and for the life of the instrument where practical.

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 493.1254 https://www.ecfr.gov/current/title-42/section-493.1254

11. Maintenance log

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

Date	Instrument	Daily	Weekly	Monthly	Problems / action	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

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