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

Temperature Monitoring (Refrigerators, Freezers, Incubators and Room)

Governing requirement: 42 CFR 493.1252(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 monitor and document temperatures that affect reagents, specimens and test performance.

2. Scope

Refrigerators, freezers, incubators, heat blocks, water baths and testing rooms.

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

Acceptable range: Range specified by the manufacturer for each item stored or test performed.

5. Materials, equipment and records

- Calibrated or certified thermometers or data loggers **[Thermometer IDs]**

Thermometer IDs	

- Temperature logs

6. Procedure

1. Record temperatures each day of use **[Time of reading]** (or continuous monitoring reviewed daily).

Time of reading	

2. Acceptable ranges: refrigerators 2-8 °C, freezers **[Freezer range]**, room **[Room range]**, incubators **[Incubator range]**, humidity **[Humidity range]** if required.

Freezer range	
Room range	
Incubator range	
Humidity range	

3. If out of range: recheck, adjust, move contents, quarantine reagents and evaluate their use.

4. Document corrective action and the impact on testing.

5. Verify thermometers against a certified thermometer annually **[Verification frequency]**.

Verification frequency	

6. Supervisor reviews logs weekly.

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

• Min/max thermometers capture excursions between readings.

• 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

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

11. Daily temperature log

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

Date	Time	Unit ID	Reading	In range (Y/N)	Corrective action	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

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