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

Laboratory Water Quality (CLRW) Testing

Governing requirement: 42 CFR 493.1252(b) and manufacturer requirements

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 ensure reagent water meets the quality needed by test systems.

2. Scope

Water purification systems and instruments with onboard water.

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

CLRW: Clinical laboratory reagent water.

Resistivity: Measured in megohm-cm at 25 °C.

5. Materials, equipment and records

- Water system **[System ID]**

System ID	

- Resistivity meter
- Culture media or kits

6. Procedure

1. Check resistivity daily **[Specification, e.g. >10 MΩ·cm]**.

Specification, e.g. >10 MΩ·cm	

2. Test microbial counts **[Frequency]** with limit **[CFU/mL limit]**.

Frequency	
CFU/mL limit	

3. Check TOC if required by the instrument manufacturer.

4. Change filters and cartridges per schedule.

5. Record results and act on failures; stop testing if water affects results.

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

• 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)

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

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

11. Water quality log

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

Date	Resistivity	Bacterial count	Filter change	Acceptable	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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