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

Procedure Manual (42 CFR 493.1251 Format)

Governing requirement: 42 CFR 493.1251

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 provide a test procedure in the format required for the CLIA procedure manual.

2. Scope

Test: **[Test name]** on **[Instrument / test system]** in **[Department]**.

Test name	
Instrument / test system	
Department	

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

Reportable range: The span of results the lab verified it can report without dilution or concentration.

5. Materials, equipment and records

- Instrument **[Instrument and model]**

Instrument and model	

- Reagents **[Reagent names and catalog numbers]**

Reagent names and catalog numbers	

- Calibrators **[Calibrator material]**

Calibrator material	

- Controls **[Control material and levels]**

Control material and levels	

6. Procedure

1. Principle: **[Test principle in one paragraph]**.

Test principle in one paragraph	

2. Patient preparation: **[Patient preparation]**.

Patient preparation	

3. Specimen: type **[Specimen type]**, container **[Container]**, minimum volume **[Minimum volume]**, stability **[Stability]**, rejection criteria **[Rejection criteria]**.

Specimen type	
Container	
Minimum volume	
Stability	
Rejection criteria	

4. Reagent preparation and storage: **[Reagent preparation steps]**.

Reagent preparation steps	

5. Calibration: frequency **[Calibration frequency per manufacturer]** and acceptance **[Calibration acceptance criteria]**.

Calibration frequency per manufacturer	
Calibration acceptance criteria	

6. Calibration verification: at least every 6 months and after major maintenance or reagent changes per 493.1255.

7. Quality control: **[QC levels and frequency]**; acceptable ranges per lab-established limits.

QC levels and frequency	

8. Step-by-step procedure: **[Test steps]**.

Test steps	

9. Calculations: **[Calculations]**.

Calculations	

10. Reportable range: **[Reportable range]**; results outside are diluted **[Dilution protocol]** or reported as < or >.

Reportable range	
Dilution protocol	

11. Reference intervals: **[Reference intervals]**.

Reference intervals	

12. Critical values: **[Critical values]**; report per the critical value SOP.

Critical values	

13. Interferences and limitations: **[Interfering substances]**.

Interfering substances	

14. Result entry and reporting: **[Reporting steps]**.

Reporting steps	

15. If the test system is inoperable: **[Backup method or referral laboratory]** and notify clients of delays.

Backup method or referral laboratory	

7. Quality control

• Corrective action when QC or calibration fails: stop patient testing, troubleshoot, repeat, and evaluate patient results since the last acceptable QC.

8. Interpretation, reporting and documentation

• Report units: **[Units]**.

Units	

9. Limitations and cautions

• The manufacturer's package insert may be referenced for items it covers; add the rest.

• 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 493.1251 https://www.ecfr.gov/current/title-42/section-493.1251

• eCFR, 42 CFR 493.1253 https://www.ecfr.gov/current/title-42/section-493.1253

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

• eCFR, 42 CFR 493.1256 https://www.ecfr.gov/current/title-42/section-493.1256

11. Lab-specific notes

Notes and local requirements	

12. Revision history

Version	Date	Description of change	Author	Approved by

13. 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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