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

Method Verification for FDA-Cleared or Approved Tests

Governing requirement: 42 CFR 493.1253(b)(1)

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 verify the manufacturer's performance specifications for an unmodified FDA-cleared or approved nonwaived test before patient testing.

2. Scope

New tests and new instruments for unmodified moderate or high complexity FDA-cleared/approved test systems.

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

Accuracy: Agreement with a comparative method or known values.

Precision: Agreement of repeated measurements.

Reportable range: The range of results verified as reliable.

5. Materials, equipment and records

- Patient samples, PT or reference materials
- Comparative method **[Comparative method]**

Comparative method	

- Statistics software **[Software]**

Software	

6. Procedure

1. Write a verification plan with acceptance criteria approved by the director before starting **[Acceptance criteria]**.

Acceptance criteria	

2. Accuracy: test **[Number]** specimens spanning the reportable range by the new and comparative method; evaluate bias and agreement.

Number	

3. Precision: run **[Number]** replicates of at least two levels within run and across **[Number of days]** days.

Number	
Number of days	

4. Reportable range: test at least low, mid and high materials near the limits.

5. Reference intervals: verify the manufacturer's or published intervals are appropriate for the lab's population (for example with 20 healthy-donor samples).

6. Qualitative tests: test known positives and negatives, including near the cutoff.

7. Summarize data, compare to criteria and document conclusions.

8. Laboratory director signs approval before reporting patient 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

• Keep verification records as long as the test is in use, at least 2 years (493.1105(a)(3)(i)).

9. Limitations and cautions

• Any modification to an FDA-cleared test makes it a validation under 493.1253(b)(2).

• 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)

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

• eCFR, 42 CFR 493.1105 https://www.ecfr.gov/current/title-42/section-493.1105

11. Verification summary

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

Characteristic	Samples / replicates	Acceptance criterion	Result	Pass (Y/N)	Reviewed by

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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