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

Alternative Performance Assessment (Tests Without PT)

Governing requirement: 42 CFR 493.1236(c)

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 accuracy of tests not covered by required PT at least twice annually.

2. Scope

Non-regulated analytes and tests with no available PT.

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

Split-sample comparison: Testing the same specimens at another lab or method and comparing results.

5. Materials, equipment and records

- Split samples, external materials, chart review or other approved method

6. Procedure

1. List tests needing alternative assessment **[Test list]**.

Test list	

2. Choose a method: split samples with another lab, assayed materials, ungraded PT, clinical correlation or other approved approach.

3. Test **[Number]** samples at least twice a year.

Number	

4. Compare to criteria **[Acceptance criteria]**.

Acceptance criteria	

5. Document results, investigate failures and obtain director review.

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

• 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 493.1236 https://www.ecfr.gov/current/title-42/section-493.1236

11. Alternative assessment record

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

Test	Date	Method	Samples	Agreement	Acceptable (Y/N)	Reviewer

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

Free template from Sound Lab Consultants, soundlabconsult.com. Download more free templates at soundlabconsult.com/laboratory-sop-library.