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

Proficiency Testing Failure Investigation

Governing requirement: 42 CFR 493.803 and 493.1236

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 investigate unacceptable PT results and prevent recurrence.

2. Scope

Any unacceptable or ungraded PT result.

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

Unsatisfactory performance: Failure to attain the minimum score for an analyte in a single event.

Unsuccessful performance: Unsatisfactory performance for the same analyte in two consecutive or two of three events.

5. Materials, equipment and records

- PT evaluation report
- QC, calibration and maintenance records for the event

6. Procedure

1. Review the PT report as soon as it arrives.

2. For each unacceptable result, check clerical errors, method selection, units and transcription.

3. Review QC, calibration and maintenance around the testing date.

4. Retest the sample if available.

5. Classify the cause: clerical, methodology, equipment, technical, PT material, or no explanation.

6. Assess whether patient results were affected; review patient results from that period.

7. Take and document corrective action; director reviews and signs.

8. For ungraded results (no consensus, late return), verify accuracy by other means (493.1236(b)).

9. Track repeat failures; two unsatisfactory events in three is unsuccessful and may trigger sanctions.

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 Subpart H: Participation in proficiency testing
https://www.ecfr.gov/current/title-42/part-493/subpart-H

• 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 493.803 https://www.ecfr.gov/current/title-42/section-493.803

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

• eCFR, 42 CFR 493.1282 https://www.ecfr.gov/current/title-42/section-493.1282

11. PT investigation record

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

Event	Analyte	Result / target	Cause category	Patient impact	Corrective action	Director sign-off

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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