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

Proficiency Testing Handling

Governing requirement: 42 CFR 493.801

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 PT samples are handled, tested and reported per CLIA and results are reviewed.

2. Scope

All regulated analytes and specialties for which PT is required, plus voluntary 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

PT referral: Sending PT samples to another lab, which is prohibited and can lead to certificate revocation.

5. Materials, equipment and records

- PT provider **[CMS-approved PT program]**

CMS-approved PT program	

- PT calendar

6. Procedure

1. Enroll each year in CMS-approved PT for each regulated analyte; designate the PT program to CMS.

2. Log PT samples on receipt and store per instructions.

3. Test PT samples with the regular workload, by personnel who routinely test patients, using routine methods.

4. Do not test PT samples more times than patient samples are routinely tested.

5. Never send PT samples or portions to another laboratory and never discuss PT results with other labs before the deadline.

6. If a PT sample is accidentally referred, report it to CMS/accreditor as required.

7. Testing personnel and the laboratory director sign the attestation statements.

8. Submit results before the deadline; keep copies.

9. Review graded results with staff; investigate all unacceptable results.

10. Keep PT records at least 2 years.

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

• Unsatisfactory or unsuccessful performance is investigated per the PT failure SOP.

9. Limitations and cautions

• Results must be treated exactly like patient specimens.

• 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

• eCFR, 42 CFR Part 493 Subpart I: Proficiency testing programs
https://www.ecfr.gov/current/title-42/part-493/subpart-I

• 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 493.801 https://www.ecfr.gov/current/title-42/section-493.801

• 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

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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