STANDARD OPERATING PROCEDURE TEMPLATE · SPECIALTY AND SUBSPECIALTY PROCEDURES

Coagulation Testing: PT/INR and aPTT

Governing requirement: 42 CFR 493.1269(b)-(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 perform PT/INR and aPTT testing.

2. Scope

Coagulation testing on **[Analyzer]**.

Analyzer	

3. Responsibility

- Testing personnel: perform the procedure as written and record QC and patient results.
- Technical supervisor / technical consultant: approves criteria, reviews QC and resolves problems.
- General supervisor (high complexity): provides day-to-day supervision and result review.
- Laboratory director: approves the procedure and is responsible for overall test quality.

4. Definitions

ISI: International Sensitivity Index of the thromboplastin lot.

Platelet-poor plasma: Plasma with fewer than 10,000 platelets/µL.

5. Materials, equipment and records

- 3.2% sodium citrate tubes
- Analyzer, reagents, controls

6. Procedure

1. Check tube fill (at least 90%) and hematocrit adjustments when Hct > 55%.

2. Centrifuge to platelet-poor plasma.

3. Test within stability: PT **[PT stability]**, aPTT **[aPTT stability]**.

PT stability	
aPTT stability	

4. Automated systems: two levels of control each 8 hours of operation and with each reagent change (493.1269(b)).

5. Manual methods: each person tests two control levels before patients and with reagent changes; test in duplicate (493.1269(c)).

6. Enter the current ISI and geometric mean normal PT for each new reagent lot **[ISI and mean]**.

ISI and mean	

7. Report and notify critical values.

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 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

• CLSI guidelines relevant to this procedure (referenced by name only; obtain current editions from CLSI)

• eCFR, 42 CFR 493.1269 https://www.ecfr.gov/current/title-42/section-493.1269

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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