STANDARD OPERATING PROCEDURE TEMPLATE · PRE-ANALYTIC: ORDERING, COLLECTION AND SPECIMEN HANDLING

Specimen Processing and Centrifugation

Governing requirement: 42 CFR 493.1242(a)(4) and 493.1254

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 process blood specimens so they are suitable for testing.

2. Scope

Serum, plasma and whole blood specimens.

3. Responsibility

- Collectors (phlebotomists, nurses, medical assistants): follow this procedure and document collection.
- Specimen processing / accessioning staff: check acceptability and document problems.
- Supervisor: trains staff, monitors pre-analytic errors and reviews rejection logs.
- Laboratory director: approves the procedure and acceptance criteria.

4. Definitions

RCF: Relative centrifugal force, in x g.

5. Materials, equipment and records

- Centrifuge **[Centrifuge ID]**

Centrifuge ID	

- Pipettes and aliquot tubes

6. Procedure

1. Let serum tubes clot fully upright **[Clot time per tube manufacturer]** before centrifuging.

Clot time per tube manufacturer	

2. Balance the centrifuge; close lid.

3. Spin at **[RCF and time per tube manufacturer]**.

RCF and time per tube manufacturer	

4. Check for complete separation, hemolysis and fibrin.
5. Aliquot using labeled tubes and avoid disturbing the gel or cell layer.
6. Store per test stability.
7. Coagulation specimens: process to platelet-poor plasma per the coagulation SOP.

7. Quality control

• Verify centrifuge speed and timer per the equipment maintenance SOP.

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

• Re-spinning gel tubes can release analytes; do not re-centrifuge unless the tube manufacturer allows.

• 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 493.1242 https://www.ecfr.gov/current/title-42/section-493.1242

• eCFR, 42 CFR 493.1254 https://www.ecfr.gov/current/title-42/section-493.1254

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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