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

Specimen Acceptance and Rejection Criteria

Governing requirement: 42 CFR 493.1242(a)(8) and 493.1291(c)(7)

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 define criteria for specimen acceptability and the handling of specimens that do not meet them.

2. Scope

All specimens received for testing.

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

Irretrievable specimen: A specimen that cannot be recollected (for example CSF, tissue, pre-treatment cultures).

5. Materials, equipment and records

- Rejection log
- Test-specific acceptability table

6. Procedure

1. Reject specimens that are unlabeled or mislabeled, have mismatched identifiers, wrong tube or preservative, insufficient volume, are clotted (for whole blood tests), hemolyzed/icteric/lipemic beyond test limits **[Index limits]**, leaking, expired stability or wrong temperature.

Index limits	

2. Notify the ordering location promptly and request recollection; document who was notified and when.

3. For irretrievable specimens, the director or designee may approve testing; the person who collected must correct identification and the report must note the problem.

4. Record the rejection in the LIS and rejection log.

5. Include information on condition and disposition of unacceptable specimens on the report (493.1291(c)(7)).

7. Quality control

• Review rejection rates monthly by location and reason.

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

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

• eCFR, 42 CFR 493.1291 https://www.ecfr.gov/current/title-42/section-493.1291

11. Specimen rejection log

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

Date	Accession	Source/location	Reason	Notified (name/time)	Recollect (Y/N)	Initials

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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