STANDARD OPERATING PROCEDURE TEMPLATE · POST-ANALYTIC: REPORTING AND RECORDS

Record and Specimen Retention

Governing requirement: 42 CFR 493.1105

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 retain records, slides, blocks and tissues for required periods.

2. Scope

All laboratory records and pathology materials.

3. Responsibility

- Testing personnel: review results before release and follow reporting rules.
- Supervisor: monitors reporting timeliness and errors.
- Laboratory director: approves reporting policies and report formats.

4. Definitions

Retention period: Minimum time a record must be kept.

5. Materials, equipment and records

- Retention schedule
- Storage / archive **[Location]**

Location	

6. Procedure

1. Requisitions and authorizations: at least 2 years.

2. Test procedures: at least 2 years after discontinued, with dates of use.

3. QC, patient test records, instrument printouts and analytic records: at least 2 years; performance specification records for as long as the test is used, at least 2 years.

4. Immunohematology, blood and transfusion records: as specified in 21 CFR 606.160.

5. Proficiency testing and quality assessment records: at least 2 years.

6. Test reports: at least 2 years; pathology reports at least 10 years.

7. Cytology slides: at least 5 years; histopathology slides 10 years; blocks 2 years; tissue until diagnosis is made.

8. Apply longer state, accreditor or payer requirements **[State and accreditor periods]**.

State and accreditor periods	

9. If the lab closes, arrange retention and access **[Closure custodian]**.

Closure custodian	

10. Destroy records after the period securely.

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

• eCFR, 21 CFR 606.160 Records (blood and blood components)
https://www.ecfr.gov/current/title-21/section-606.160

• eCFR, 42 CFR 493.1105 https://www.ecfr.gov/current/title-42/section-493.1105

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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