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

Test Result Reporting

Governing requirement: 42 CFR 493.1291

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 report results accurately, promptly and only to authorized persons.

2. Scope

All patient test reports, paper and electronic.

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

Authorized person: Individual authorized by state law to order or receive results.

5. Materials, equipment and records

- LIS / EHR
- Report templates

6. Procedure

1. Verify the report includes: patient name and ID number (or unique identifier and ID number); lab name and address; report date; test performed; specimen source when appropriate; result with units or interpretation; specimen condition/disposition when unacceptable.

2. Make reference intervals available to the ordering provider.

3. Review results before release (or via validated autoverification).

4. Notify providers when results will be delayed beyond the established time frame, based on urgency.

5. Release results only to authorized persons, the person responsible for using results, and the referring lab.

6. Provide patients access to completed reports on request after verifying identity (493.1291(l)) **[Patient access process]**.

Patient access process	

7. Verify electronic interfaces deliver results accurately (see LIS validation SOP).

7. Quality control

• Audit **[Number]** reports per month for accuracy and completeness.

Number	

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

• HHS, Individuals' right to access health information (including lab reports)
https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html

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

11. Report audit log

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

Date	Accession	Elements complete	Result matches	Units/ref range	Issue	Reviewer

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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