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

Corrected Reports

Governing requirement: 42 CFR 493.1291(k)

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 correct reporting errors promptly and transparently.

2. Scope

Any error in a released report.

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

Corrected report: A revised report marked as corrected that replaces an erroneous one.

5. Materials, equipment and records

- LIS correction function

6. Procedure

1. Verify the error and correct result.

2. Promptly notify the ordering provider (and the person using results) and document.

3. Issue a corrected report clearly marked 'Corrected' with the date and reason.

4. Keep the original and corrected reports.

5. Record an occurrence and investigate cause.

7. Quality control

- Track corrected report rate as a quality indicator.

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 493.1291 https://www.ecfr.gov/current/title-42/section-493.1291

11. Corrected report log

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

Date	Accession	Original result	Corrected result	Provider notified	Reason	Tech

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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