STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

Corrective and Preventive Action (CAPA)

Governing requirement: 42 CFR 493.1282

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 ensure problems are investigated to root cause, corrected, prevented from recurring and documented, including evaluation of affected patient results.

2. Scope

Problems from QC failures, PT failures, complaints, audits, occurrences, survey deficiencies and quality indicators.

3. Responsibility

- Laboratory director: approves this policy, assigns responsibility for quality activities and reviews results.
- Technical consultant / technical supervisor: reviews technical aspects, investigates issues and signs off corrective actions.
- Quality lead (if assigned): coordinates records, tracking and reporting.
- All laboratory staff: follow this procedure and report problems promptly.

4. Definitions

Correction: Immediate action to contain a problem.

Corrective action: Action to remove the root cause and prevent recurrence.

Preventive action: Action to remove the cause of a potential problem.

5. Materials, equipment and records

- CAPA form / log
- Root cause tools (5 whys, fishbone)

6. Procedure

1. Open a CAPA record with a unique number and describe the problem, date found and who found it.

2. Contain the problem: stop testing, quarantine reagents or hold reports as needed.

3. Evaluate impact on patient results since the last acceptable run; decide whether corrected reports or provider notification are needed (493.1282(b)).

4. Determine root cause using **[Root cause method]**.

Root cause method	

5. Define corrective actions, owner and due date.

6. Implement actions and update procedures, training or equipment as required.

7. Verify effectiveness after **[Effectiveness check interval]** using objective data.

Effectiveness check interval	

8. Close the CAPA with technical supervisor or consultant review and laboratory director sign-off.

9. Trend CAPAs at management review to identify systemic issues.

7. Quality control

• CAPAs open past their due date are escalated to the laboratory director.

8. Interpretation, reporting and documentation

• Record all corrective actions taken; keep at least 2 years.

9. Limitations and cautions

• A CAPA is not closed until effectiveness has been verified.

• 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 Subpart K: Quality system for nonwaived testing
https://www.ecfr.gov/current/title-42/part-493/subpart-K

• 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 493.1282 https://www.ecfr.gov/current/title-42/section-493.1282

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

11. CAPA log

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

CAPA #	Date opened	Problem	Root cause	Action	Owner	Closed / verified

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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