STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

Complaint Investigation

Governing requirement: 42 CFR 493.1233

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 make sure every complaint about laboratory services is documented, investigated and resolved, and that corrective action is taken when needed.

2. Scope

Complaints from providers, patients, staff and other parties about any laboratory service.

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

Complaint: Any expression of dissatisfaction about laboratory services, results, billing or staff.

5. Materials, equipment and records

- Complaint log

6. Procedure

1. Receive the complaint and record date, source, contact information and description.

2. Acknowledge receipt to the complainant within **[Acknowledgment time frame]**.

Acknowledgment time frame	

3. Assign an investigator; gather records (requisitions, QC, reports, audit trail).

4. Determine whether patient results were affected; if so follow the CAPA and corrected report procedures.

5. Document findings and corrective action.

6. Respond to the complainant (if appropriate) and record the date.

7. Review complaints at quality review and trend by type.

8. Post the process for staff to report concerns about quality or safety to **[Internal and accreditor contact]** without retaliation.

Internal and accreditor contact	

7. Quality control

• Unresolved complaints older than **[Days]** are escalated to the laboratory director.

Days	

8. Interpretation, reporting and documentation

• Keep complaint records at least 2 years.

9. Limitations and cautions

• Protect patient information in complaint files.

• 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 493.1233 https://www.ecfr.gov/current/title-42/section-493.1233

11. Complaint log

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

Date	Source	Complaint	Investigation summary	Action	Closed date	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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