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

Critical Value (Panic Value) Reporting

Governing requirement: 42 CFR 493.1291(g) and 493.1251(b)(11)

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 immediately notify responsible caregivers of life-threatening results.

2. Scope

All tests with defined critical values.

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

Critical value: A result indicating an imminently life-threatening condition.

Read-back: Receiver repeats the result to confirm accuracy.

5. Materials, equipment and records

- Critical value list **[Critical value list location]**

Critical value list location	

- Notification log

6. Procedure

1. Confirm the result (check specimen, repeat if appropriate per policy).

2. Notify the ordering provider or responsible licensed caregiver within **[Notification time target]**.

Notification time target	

3. Give patient name, two identifiers, test, result and units.

4. Require read-back; document name of receiver, date, time and read-back.

5. If unable to reach the provider within **[Escalation time]**, escalate per chain **[Escalation chain]**.

Escalation time	
Escalation chain	

6. Review the critical value list annually with medical staff.

7. Quality control

• Monitor notification time monthly.

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

• eCFR, 42 CFR 493.1251 https://www.ecfr.gov/current/title-42/section-493.1251

11. Critical value notification log

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

Date/time	Patient / accession	Test & result	Notified (name)	Read-back (Y/N)	Time	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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