STANDARD OPERATING PROCEDURE TEMPLATE · FACILITY, EMERGENCY AND DOWNTIME

LIS Downtime

Governing requirement: 42 CFR 493.1291(a)

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 maintain safe testing and reporting during LIS outages.

2. Scope

Planned and unplanned LIS downtime.

3. Responsibility

- Laboratory director: approves the plan and authorizes downtime and recovery decisions.
- Supervisor on duty: activates the procedure and communicates with clients and staff.
- All staff: know their role, follow the checklist and document actions.

4. Definitions

Recovery: Entering downtime data after the system is restored.

5. Materials, equipment and records

- Downtime forms and labels
- Downtime log

6. Procedure

1. Activate downtime; notify clients.

2. Use downtime requisitions and labels.

3. Record results on downtime forms.

4. Report critical results by phone with read-back.

5. After recovery, enter data and verify with a second person.

6. Reconcile all specimens.

7. Quality control

• Test this plan with a drill or tabletop exercise at least **[Drill frequency]** and record lessons learned.

Drill frequency	

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

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

11. Lab-specific notes

Notes and local requirements	

12. Revision history

Version	Date	Description of change	Author	Approved by

13. 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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