STANDARD OPERATING PROCEDURE TEMPLATE · REGULATORY, CERTIFICATES AND SURVEYS

New Test Implementation and Test Menu Changes

Governing requirement: 42 CFR 493.1253 and 493.51

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 implement new tests in a controlled way.

2. Scope

New or changed tests.

3. Responsibility

- Laboratory director: signs regulatory submissions and plans of correction and is accountable for compliance.
- Laboratory manager / compliance lead: tracks certificates, deadlines and notifications.
- Technical consultant / technical supervisor: provides technical evidence for submissions.

4. Definitions

Go-live: First patient reporting.

5. Materials, equipment and records

- Implementation checklist

6. Procedure

1. Confirm FDA categorization and certificate coverage.

2. Perform verification or validation.

3. Write procedure; train staff; assess competency.

4. Enroll in PT or plan alternative assessment.

5. Build LIS; validate.

6. Director approves go-live.

7. Notify clients and update test directory.

7. Quality control

• Review this process at least annually and after any survey or regulatory change.

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

• FDA, CLIA test categorization database https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/search.cfm

• 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 493.1253 https://www.ecfr.gov/current/title-42/section-493.1253

• eCFR, 42 CFR 493.51 https://www.ecfr.gov/current/title-42/section-493.51

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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