STANDARD OPERATING PROCEDURE TEMPLATE · WAIVED TESTING AND POINT-OF-CARE TESTING

Waived Testing Program Policy (Certificate of Waiver)

Governing requirement: 42 CFR 493.15 and 493.35-493.39

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 establish how the site performs waived tests correctly and stays within its Certificate of Waiver.

2. Scope

All waived tests performed at **[Site name]** under CLIA number **[CLIA number]**.

Site name	
CLIA number	

3. Responsibility

- Testing personnel: follow the manufacturer's instructions exactly and document QC and results.
- Site supervisor / testing coordinator: trains staff, reviews logs and orders supplies.
- Laboratory director: approves the procedure and holds responsibility for the certificate.

4. Definitions

Waived test: A test categorized as waived by FDA (cleared for home use or approved for waiver).

Off-label use: Any departure from instructions (specimen type, timing, steps); this makes the test high complexity.

5. Materials, equipment and records

- Current test list with manufacturer and kit names **[Waived test list]**

Waived test list	

- Package inserts (current versions)
- Training records

6. Procedure

1. Keep a current list of waived tests and verify each is waived in the FDA CLIA database before use.

2. Follow the current manufacturer's instructions exactly; any change makes the test nonwaived.

3. Keep current package inserts and check for changes with each new kit lot.

4. Train each tester before testing and document training; check competency **[Competency frequency]** (recommended practice).

Competency frequency	

5. Run QC as the manufacturer requires and document results.

6. Record patient results in the medical record with test name and date.

7. Do not test patients if QC fails or kits are expired.

8. Notify CMS/state agency within 30 days of changes in ownership, name, location or director (493.39).

9. Pay certificate fees and renew the Certificate of Waiver every two years.

10. Allow announced or unannounced CMS inspections (493.1775).

7. Quality control

• Review QC and testing logs **[Review frequency]**.

Review frequency	

8. Interpretation, reporting and documentation

• Keep test records at least 2 years.

9. Limitations and cautions

• Adding a nonwaived test requires a different certificate before testing.

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

10. References

• CDC, Ready? Set? Test! Patient testing is important (waived testing booklet) https://www.cdc.gov/clia/php/waived-tests/index.html

• CDC, Clinical Laboratory Improvement Amendments (CLIA) https://www.cdc.gov/clia/php/about/index.html

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

• Manufacturer's package insert, operator manual and safety data sheets for each test system in use

• CMS, Form CMS-116 CLIA application https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms116.pdf

• eCFR, 42 CFR 493.15 https://www.ecfr.gov/current/title-42/section-493.15

• eCFR, 42 CFR 493.35 https://www.ecfr.gov/current/title-42/section-493.35

• eCFR, 42 CFR 493.37 https://www.ecfr.gov/current/title-42/section-493.37

• eCFR, 42 CFR 493.39 https://www.ecfr.gov/current/title-42/section-493.39

• eCFR, 42 CFR 493.1775 https://www.ecfr.gov/current/title-42/section-493.1775

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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