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

Referral Laboratory (Send-Out) Testing

Governing requirement: 42 CFR 493.1242(c) and 493.1291(i)

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 refer specimens appropriately and report results correctly.

2. Scope

Tests sent to outside laboratories.

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

Referral laboratory: CLIA-certified lab that performs referred tests.

5. Materials, equipment and records

- Reference lab manual
- Send-out log

6. Procedure

1. Refer specimens only to CLIA-certified labs (or labs meeting equivalent requirements) **[Approved reference labs]**.

Approved reference labs	

2. Package and ship per specimen requirements.

3. Track specimens and pending results.

4. Do not revise results or interpretation from the testing lab.

5. Notify the ordering provider of the name and address of each lab that performed tests.

6. Keep an exact duplicate of each reference lab report.

7. Quality control

• Follow the laboratory's QC policy and the manufacturer's instructions; record QC before reporting patient results.

• Stop patient testing and take corrective action when QC or acceptance criteria are not met.

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 493.1242 https://www.ecfr.gov/current/title-42/section-493.1242

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

11. Send-out log

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

Date	Patient / accession	Test	Reference lab	Shipped	Result received	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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