STANDARD OPERATING PROCEDURE TEMPLATE · PRE-ANALYTIC: ORDERING, COLLECTION AND SPECIMEN HANDLING

Test Ordering and Requisitions

Governing requirement: 42 CFR 493.1241

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 make sure testing is performed only on the order of an authorized person and that requisitions contain required information.

2. Scope

All test orders received by the laboratory: paper, electronic and verbal.

3. Responsibility

- Collectors (phlebotomists, nurses, medical assistants): follow this procedure and document collection.
- Specimen processing / accessioning staff: check acceptability and document problems.
- Supervisor: trains staff, monitors pre-analytic errors and reviews rejection logs.
- Laboratory director: approves the procedure and acceptance criteria.

4. Definitions

Authorized person: An individual authorized under state law to order or receive test results **[State rules on who may order]**.

5. Materials, equipment and records

- Requisition form **[Form number]**

Form number	

- LIS / EHR order entry

6. Procedure

1. Accept orders only from authorized persons.

2. Check the requisition for: ordering provider name and address or identifier and contact for critical values; patient name or unique identifier; sex and age or date of birth; tests ordered; specimen source when appropriate; date and, if appropriate, time of collection; for Pap smears, LMP and history of abnormal results; any other

information needed for accurate testing.

3. Resolve missing or unclear information before testing by contacting the ordering office; document the contact.

4. When the chart or EHR is used as the requisition, make sure it is available to the lab at the time of testing.

5. Enter orders into the LIS accurately; verify transcription **[Verification method]**.

Verification method	

6. Standing orders: accept only with a written standing order signed by the provider, reviewed **[Review frequency]**.

Review frequency	

7. Quality control

• Audit **[Number]** requisitions per month for completeness.

Number	

8. Interpretation, reporting and documentation

• Keep requisitions or authorizations at least 2 years (493.1105(a)(1)).

9. Limitations and cautions

• Do not add tests without authorization.

• 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 493.1241 https://www.ecfr.gov/current/title-42/section-493.1241

• eCFR, 42 CFR 493.1105 https://www.ecfr.gov/current/title-42/section-493.1105

11. Requisition audit

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

Date	Accession #	Provider info	Patient ID x2	DOB/sex	Tests	Collection date/time

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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