STANDARD OPERATING PROCEDURE TEMPLATE · PERSONNEL, TRAINING AND COMPETENCY

Competency Assessment (Six Required Elements)

Governing requirement: 42 CFR 493.1413(b)(8)-(9) and 493.1451(b)(8)-(9)

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 evaluate and document the competency of testing personnel and others with CLIA roles on each test system they use.

2. Scope

All testing personnel performing moderate or high complexity tests, and others with CLIA roles (technical consultant, supervisors) for their duties.

3. Responsibility

- Laboratory director: ensures staff are qualified, trained and competent before testing and signs delegations.
- Technical consultant / technical supervisor: performs or delegates training and competency assessment.
- Supervisor / manager: maintains personnel records and schedules training and assessments.
- Employee: completes training, keeps credentials current and reports changes.

4. Definitions

Six elements: (1) direct observation of routine patient test performance; (2) monitoring recording and reporting of results; (3) review of worksheets, QC, PT and maintenance records; (4) direct observation of maintenance and function checks; (5) testing previously analyzed specimens, blind samples or PT samples; (6) assessment of problem-solving skills.

Assessor: The technical consultant (moderate), technical supervisor (high) or a qualified general supervisor delegated in writing.

5. Materials, equipment and records

- Competency checklist per test system
- Previously tested or blind samples
- Problem-solving quiz or case

6. Procedure

1. List each test system each employee performs **[Test system list]**.

Test system list	

2. Schedule assessments: before patient testing for new hires, at 6 months and 12 months in the first year, and annually after; and before reporting results on a new method or instrument.

3. Element 1: observe routine patient testing including patient prep, specimen handling and processing.

4. Element 2: monitor recording and reporting of results.

5. Element 3: review the employee's worksheets, QC records, PT results and maintenance records.

6. Element 4: observe instrument maintenance and function checks.

7. Element 5: have the employee test **[Number and type of samples]** previously analyzed or blind samples with acceptance criteria **[Acceptance criteria]**.

Number and type of samples	
Acceptance criteria	

8. Element 6: assess problem-solving with a scenario, quiz or documented troubleshooting.

9. Document results, assessor, date; retrain and reassess if unacceptable.

10. Laboratory director or designee reviews and signs completed assessments.

7. Quality control

• Tests on the same test system with the same skills may be assessed together if documented as such; each test system must be covered.

8. Interpretation, reporting and documentation

• Keep assessments in personnel files.

9. Limitations and cautions

• Competency is test-system specific; a new instrument requires reassessment before reporting results.

• 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 Subpart M: Personnel for nonwaived testing
https://www.ecfr.gov/current/title-42/part-493/subpart-M

• 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

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

• eCFR, 42 CFR 493.1235 https://www.ecfr.gov/current/title-42/section-493.1235

• eCFR, 42 CFR 493.1413 https://www.ecfr.gov/current/title-42/section-493.1413

• eCFR, 42 CFR 493.1451 https://www.ecfr.gov/current/title-42/section-493.1451

11. Competency assessment record

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

Test system	1 Observe testing	2 Recording/reporting	3 Records review	4 Maintenance	5 Samples	6 Problem solving

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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