Personnel Competency Assessment Form (Six Elements)

Laboratory name: _____

CLIA #: _____

Location / department: _____

Month / Year: _____

Employee name: _____

Position / role: _____

Test or test system assessed: _____

Assessment type: [ ] 6-month (first year) [ ] Second 6-month (first year) [ ] Annual [ ] New method/instrument

Assessor name & role (e.g., TC/TS/GS as applicable): _____

Element	**Method / evidence reviewed (e.g., accession #, QC date, PT event)**	**Date**	**Acceptable? Y/N**	**Assessor initials**
1. Direct observation of routine patient test performance (patient prep if applicable, specimen handling, processing, testing)				
2. Monitoring recording and reporting of test results				
3. Review of intermediate results/worksheets, QC records, PT results, preventive maintenance records				
4. Direct observation of instrument maintenance and function checks				
5. Testing of previously analyzed specimens, internal blind samples, or external PT samples				
6. Assessment of problem-solving skills (e.g., written case, verbal scenario)				

Overall outcome: [ ] Competent [ ] Remediation required

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Remediation plan & retraining date: _____

Re-assessment date and result: _____

Employee signature / date: _____

Assessor signature / date: _____

Laboratory director or designee review / date: _____

Regulatory reference (verify against current eCFR): 42 CFR 493.1413(b)(8)–(9) (moderate complexity) and 42 CFR 493.1451(b)(8)–(9) (high complexity) list six procedures for competency evaluation and set frequency at least semiannually during the first year an individual tests patient specimens, then at least annually, and again before reporting results after a methodology or instrumentation change.

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