

Laboratory Personnel Competency Assessment Program

PURPOSE

The intent of this document is to provide a clear and thorough description of the Canton City Health Department Laboratory's requirements and procedures for clinical laboratory personnel competency assessment.

POLICY

Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by federal regulation and local policies.

BACKGROUND

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing competency standards for all laboratory testing personnel to ensure the accuracy, reliability, and timeliness of patient test results regardless of whom the tester was. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April 24, 2003. Together these documents provide a history of a movement toward a process of continuous improvement. Throughout the legislative process an emphasis has been placed on the need for an evaluation process to ensure a competent and reliable workforce.

RESPONSIBILITIES

It is the responsibility of all laboratory personnel to adhere to the guidelines and requirements set forth in this document.

The Employer is responsible for maintaining all PT records for at least 90 days post-employment.

The Laboratory Director is responsible for:

1. evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens,
2. for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually after the first year unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the

individual's performance must be reevaluated to include the use of the new test methodology or instrumentation,

3. if deemed appropriate to delegate, in writing, to the Technical Consultant (TC) the responsibility for- Annually evaluating and documenting the performance of all testing personnel as well as a detailed list of the assessment responsibilities, and
4. perform a competency assessment of the individual serving as the TC based on their regulatory responsibilities.

Laboratory Testing Personnel (TP) are responsible for:

1. maintaining their own personal copies of training materials to be available on request to the Laboratory Director (LD) or designee,
2. ensure individual competency is maintained, and
3. notify LD or designee if additional training needs are identified through self-analysis.

PROCEDURES & STANDARD OPERATING GUIDELINES

Below are six (6) points which describe the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing.

1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing,
2. Monitoring the recording and reporting of test results,
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records,
4. Direct observations of performance of instrument maintenance and function checks,
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples, and
6. Assessment of problem-solving skills.

Examples of testing laboratory staff competencies using the six procedures described above can be found in Example Assessment Points below.

Competency assessment can be done throughout the entire year. The laboratory may coordinate the competency assessment with its routine practices and procedures to minimize impact on workload. Additionally, PT performance may be used as part of your competency assessment; however, use of PT performance alone is not sufficient to meet all six required procedures.

Additional assessment tools can and should be created as situations arise, retraining is necessary or the LD or their designee deems appropriate.

Document the assessment of all 6 points above, for all personnel performing testing utilizing the Competency Assessment Form. Assessment must be repeated for each individual test performed.

An example of the form is attached as Sample Personnel Competency Form (400-004-08-A). The original forms are in an excel document that can be found on the shared network in the Competency Assessment Documentation folder. This checklist can be summarized for all tests utilizing the Training Checklist Summary.

Example Assessment Points

Testing Personnel

- Collect sufficient patient sample and correctly process the specimen used for the testing?
- Complete the test report correctly, using the appropriate test units of measurement?
- Perform the test correctly by adding the proper amount of patient specimen and reagent(s) and in the correct order?
- Add the testing solutions in the proper amount and order?
- Collect sufficient patient sample and add it to the testing system correctly?
- Use test solutions and reagents from the same test kit and lot number?
- Maintain records of the patient testing results?
- Treat PT samples in the same manner as patient specimens and maintain records indicating such?
- Adhere to the laboratory's Quality Control (QC) policies and document QC activities?
- Adhere to the laboratory's policies for instrument calibrations and maintenance activities?
- Follow the laboratory's corrective action policies and procedures when a test system fails to meet the laboratory's acceptable level of performance?
- Identify problems that may affect test performance or reporting test results and either correct the problem or notify the TC or director?
- Document all corrective action taken when there is a test system failure?

If the LD delegates authority for assessment to a TC, the LD must include assessment of the TC's ability to perform the additional duties required to perform thorough and completed employee assessment.

The following is a list of items you may consider when assessing the competency of the TC , assuming that all dual responsibilities have been delegated.

Technical Consultant

- Is the TC available to provide consultation to the laboratory?
- Does the TC select test methods that are appropriate for the laboratory's patient population?

- Does the TC assure that performance specifications are established or verified for necessary tests?
- Does the TC ensure that the laboratory is enrolled and participating in an approved HHS approved proficiency testing program for each test requiring PT? How well does the laboratory perform PT? Are the appropriate staff reviews conducted when PT results are received from the provider?
- Does the TC ensure that a Quality Control (QC) program is in effect and is adequate for the laboratory's testing performance?
- Does the TC resolve technical problems and insure remedial actions are taken whenever there is a test system failure?
- Does the TC ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly?
- Does the TC identify training needs and assure that each individual performing tests receives regular in-service training and education appropriate for the tests they are performing?
- Does the TC evaluate the competency of the testing personnel and assure that all staff members maintain their competency to perform tests accurately, report results promptly, accurately and proficiently.
- Does the TC use the following techniques, as well as any additional techniques determined by the laboratory to be appropriate for evaluating the competency of the testing personnel? Directly observe test performance, including patient preparation, specimen handling, processing and testing.
- Monitor the recording and reporting of test results.
- Review worksheets, QC records, PT results and preventive maintenance records.
- Directly observe performance of instrument maintenance and function checks.
- Assess test performance using previously analyzed samples.
- Assessment of problem solving skills.
- Evaluate and document testing personnel performance at least semiannually for the first year and annually thereafter.

CITATIONS & REFERENCES

Department of Health and Human Services, Health Care Financing Administration, Clinical Laboratory Improvements of 1988; Final Rule. Federal Register 42 CFR 493.1713, Feb 28 1992.

What Do I Need to Do to Assess Personnel Competency? http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf, accessed 11-02-2014.

400-004-01-P_Personnel Competency Program.docx, Revised 04/23/2024

National Committee for Clinical Laboratory Standards. Training Verification for Laboratory Personnel: Approved Guideline GP21-A, 1996. NCCLS, Wayne, Pa.

CLIA Training Checklist, Canton City Health Department Network, P:\private\bactlab\Lab Procedures\Lab Forms\CLIA Training Checklist

CONTRIBUTORS

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REFERENCE FORMS

400-004-01-P-A_Sample Personnel Competency Form