**Competency Assessment Procedure**

1. **PRINCIPLE:** 
   1. 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.
   2. Documented competency assessment is required for individuals who perform testing on patient specimens.
   3. Newly hired personnel or current staff members learning a new test method or instrument must demonstrate competency in accordance with the following schedule:
      1. Initial training and competency must be documented prior to the reporting of any patient results.
      2. Semiannually:
         1. First assessment within seven months from the start of testing
         2. Second assessment no later than 12 months from the start of testing during the first year an individual tests patient specimen (new employees).
      3. At least annually after an individual has performed assigned duties for one year.
         1. The annual assessment of competency can be performed throughout the entire year to minimize impact on workload.
      4. When problems are identified with an individual's performance.
      5. Whenever a new test method is added or an existing procedure is modified substantially, all testing personnel must demonstrate competency in performing the new or altered test procedures.
   4. Elements of Competency: Competency assessment records must include all six elements described below for each individual on each test system they are trained on during each assessment period, unless an element is not applicable to the test system. Elements of competency assessment include but are not limited to:
      1. Direct observations of routine patient test performance, including 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 preventative 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.
      6. Evaluation of problem-solving skills.
2. **QUALIFICATIONS OF COMPETENCY ASSESSORS:**
   1. Per CAP, the person to perform competency in a Molecular Pathology Lab must meet the following criteria:
      1. Person who qualifies as a section director/technical supervisor (pathologist, board certified physician in a specialty other than pathology, or doctoral scientist in a chemical, physical, or biologic science, with specialized training and/or appropriate experience in molecular pathology) \*or
      2. Bachelor's degree in a chemical, physical, biological, or clinical laboratory science or medical technology with at least four years of experience (at least one of which is in molecular pathology methods) under a qualified sectiondirector.
      3. This individual will be assessed annually by the Manager, who qualifies as a Molecular Pathology General Supervisor.
3. **PROCEDURE:**
   1. Initial training:
      1. Any technologist who is competent in each assay may train another technologist.
      2. The trainee will review the procedure before training.
      3. The trainer will review the procedure with the trainee during training.
      4. The trainee will observe the trainer performing the assay and then when the trainee is comfortable, they will perform the assay with the trainer observing.
      5. Final documentation of training completion will be performed by a Senior Tech who was not the original trainer (if possible).
      6. All documentation will be recorded on the individual assay competency forms.
   2. Competency assessments
      1. During the assessment, a qualified assessor must critically observe the individual being signed off to determine that all procedures are followed, and proper technique is used in the performance of the assay.
      2. Some elements of assessment can be performed during routine review of personnel throughout the year. These may include instrument maintenance, recording of QC and taking appropriate corrective actions. These can be documented on the Competency Assessment Form by the individual responsible for competency assessment.
   3. The laboratory will maintain documentation of training and competency for each employee, including:
      1. Initial and 6-month Competency Forms
      2. Yearly Competency Assessment Form
      3. Yearly Multiple-Choice Test (Score of 80% needed to pass)
   4. The employee must successfully complete all six Elements of Competency to be considered Competent. If an employee fails to meet the competency requirement for a particular test, the employee will need to be retrained and allowed to retake the competency test. If a second competency test is not successfully completed, the employee will receive appropriate counseling and an action plan will be developed by the manager to assist the employee in becoming successful and competent.
4. **REFERENCES:**
   1. [www.cms.gov/clia Brochure #10](http://www.cms.gov/clia%20Brochure%20#10)
5. **REVISIONS:**
   1. 3/6/2018: Addition of yearly test score requirement
   2. 1/13/2020: Updated with revised footer, representing the new laboratory name.
   3. 1/16/2024: Added section on how the competency assessors are assessed.