**TITLE: Competency Assessment of Laboratory Personnel**

**PRINCIPLE:**  Once hired all new employees complete a training period that covers the methods, procedures, and instruments applicable to a designated area. Once training is completed in a specific area and the appropriate CLIA qualified designee has reviewed and found the employee competent, the CLIA qualified designee will sign off that the employee is deemed competent to perform patient testing. At the 6-month and 12-month marks from training completion, the appropriate CLIA qualified designee such as the Technical Supervisor for high complexity testing will review and complete a competency assessment for that employee. After 2 successful competencies in the first year, the staff member will have competency assessed on an annual basis.

* Assess training/competency of each person performing patient testing or managing patient samples.
  1. Every employee is trained and competency is assessed prior to handling specimens, starting patient testing and prior to reporting patient results on any new method/procedure or instrument.
  2. Competency assessment involves all technical staff including the Clinical Lab Technical Specialists and Lead phlebotomists in each department and Yorkville.
  3. At the completion of training, at the 6-month mark and at 1 year, the Technical Supervisor, for high complexity testing and the technical consultant, for moderate complex testing, assess and reviews competency.
  4. If proper performance is not verified, retraining and reassessment of competency must occur along with appropriate documentation.
* For CLIA Waived Testing:
  1. Once training is complete in a specific area and at the 6-month mark and 12-month mark from training completion, all staff undergoes a competency assessment.
  2. After the 6 month and 12-month competency in the first year, competency is assessed on an annual basis.
* For POC CLIA Waived Testing:

1. Competency assessment must be performed annually
2. The laboratory can select which competency elements are evaluated.

* For CLIA Nonwaived Testing:

1. During the first year on employment, competency is assessed at the end of the training period/initial, at six-month orientation and again at the annual competency by the Technical Supervisor for high complexity testing and technical consultant for moderate complexity testing.
2. After the first year of employment, competency may be assessed annually and reviewed by a General Supervisor for high complexity testing.
3. If test methods or instrumentation changes, prior to reporting test results, the employees’ performance must be reevaluated to include the new methodology or instrument.

* Competencies assess individuals on the six elements listed below, unless one of the elements does not apply to the test system.

1. Direct observation of patient testing, including patient identification and preparation; specimen collection and sample processing.
2. Monitoring the recording and reporting of test results, including critical test result reporting and documentation.
3. Review of results, quality control records, proficiency testing results and preventative maintenance records.
4. Direct observation of performing instrument maintenance and necessary system/function checks.
5. Assessment of test performance through proficiency samples, blind testing of specimens or testing of previously analyzed samples.
6. Evaluate Critical Thinking Skills.

* Competency must be evaluated and documented for all testing personnel for each test system. Systems include pre-analytical, analytical, and post-analytical steps used to produce a result.
* The CLTS, Lead Phlebotomists, technical consultant and Technical Supervisor ensures that the individual performing the competency assessments are qualified through education and experience.
* Testing personnel performing high complexity testing must be assessed by the director, or individual meeting technical supervisor requirements for the first year of employment. Subsequent years may be assessed by an individual meeting general supervisor requirement.
* Testing personnel performing moderately complex training is assessed by an individual meeting the qualifications of a technical consultant.
* Records of competency assessments for new and existing personnel reflecting the specific skills assessed are kept in each personnel file.
* The performance of the technical consultants, general supervisors and technical supervisor is the responsibility of the medical director. The responsibilities related to competency assessment are delegated in writing. Any unsatisfactory performance is addressed in a corrective action plan. See Technical Consultant (4840-G/LAB-304F), General Supervisor (4840-G/LAB-304E), Technical Supervisor (4840-G/LAB-304A) responsibilities.

**PERSONNEL:**

All Laboratory Staff including clinical laboratory technical specialist and lead phlebotomists

**STEPWISE PROCEDURE: TRAINING**

1. Employee training methods include the following as a minimum:
2. Reading the procedure(s) and review the checklist.
3. Observed demonstration of the procedure by a qualified trainer.
4. Practice of the procedure, under observation of a qualified trainer.
5. Assessment of test performance through proficiency samples, blind testing of specimens or testing of previously analyzed samples.
6. The checklist is signed off by the trainee and trainer once the employee has demonstrated competency. The designated trainer or qualified person meeting CLIA requirements will assess the trainee for competence and sign off that the employee is fit to perform the job requirements to ensure quality testing.
7. The trainee and trainer will review what was accomplished and set a plan for the next training day.
8. Documentation
9. New employees may have multiple training checklists reviewed and signed off by the Clinical Laboratory Technical Specialist/Lead Phlebotomist in each respective department/area once the trainee and trainer feel confident in the new skill.
10. Checklists for employees performing high complexity testing are signed off by an individual meeting the requirements of technical supervisor.
11. Maintain paper checklists in the laboratory.
12. Store electronic copies of checklists during the first 90 days in HR
13. When re-training is necessary, additional documentation is included in the employee file.
14. Establish dates for 6 month and 12-month competency.
15. Verification Tools
16. Direct observation of patient testing, including patient identification and preparation; specimen collection and sample processing.
17. Monitoring the recording and reporting of test results, including critical test result reporting and documentation.
18. Review of results, quality control records, proficiency testing results and preventative maintenance records.
19. Direct observation of performing instrument maintenance and necessary system/function checks.
20. Assessment of test performance through proficiency samples, blind testing of specimens or testing of previously analyzed samples.
21. Evaluate Critical Thinking Skills.
22. Retraining
23. If an employee fails to demonstrate satisfactory performance on the competency assessment, the employee will be re-educated and allowed to retake the portion of the assessment in question.
24. If, after re-education and training, the employee is unable to satisfactorily pass the assessments, the individual will not be able to perform the work in question without supervision. The employee will be placed on a performance improvement plan (PIP) and HR informed.
25. Retraining and reassessment of employee competency may also occur when problems are identified with employee’s performance. This process is part of the laboratory Quality Management Program and identified by Quality Assurance/Improvement form which is designed to assesses how the error occurred and what next steps.
26. Errors
27. When an analytical error is discovered, the process is analyzed to determine:
28. Procedure was followed, but an error occurred.
29. Procedure was not followed, and an error occurred.
30. Unable to determine if the procedure was followed or not, and an error occurred.
31. Upon error discovery, document the action taken:
32. No action taken
33. Discuss procedure with employee
34. Procedure modified, if necessary.
35. Employee must re-read the procedure and discuss to clarify.
36. Employee must observe another trained employee.
37. Employee must practice procedure with known specimens.
38. Employee must correctly retest same specimen.
39. Review problem with Clinical Laboratory Technical Specialist/Lead phlebotomist.
40. Repeat original or similar exercise.
41. Formal retraining instituted along with a performance improvement plan.
42. Progressive discipline initiated.
43. Failure to achieve competency
44. The lead phlebotomist, Clinical Laboratory Technical Specialist in the department where competency is in question will meet with lab administration and the employee to draft an action plan.
45. The staff member is told they will not be performing the testing in question, or if more extensive, will not be scheduled in that department.
46. Action plan will have a reassessment date.
47. Upon successful completion of the test/task, the action plan, training checklist the competency form will document successful completion of retraining.

**REFERENCES:**

1. Training Verification for Laboratory Personnel: Approved Guideline, GP21-A, Vol. 15 No. 21 NCCLS.
2. ASCP Computerized Ongoing Monitoring Program to Evaluate Competency

(COMPTEC)