
	<b>Competency Testing Procedure</b> <b>Critical Care Labs</b>  <b>CCL-011</b>	<b>Dept: 324318</b>	<b>Critical Care Labs</b>
		<b>Effective Date:</b>	<b>Jan 2013</b>
		<b>Revised Date:</b>	<b>Feb 2019</b>
		<b>Contact:</b>	<b>Jane Houska</b>
<b>Name &amp; Title: Gregory Pomper, MD</b> <b>CLIA Laboratory Director</b>		<b>Date:</b>	<b>2/25/19</b>
<b>Signature:</b> 			

**1) General Procedure Statement:**

- a. **Purpose:** 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.
- b. **Principle:** All employees beginning work in the Critical Care Labs will receive orientation and job training before they begin working independently. A written competency quiz will be given at the end of new employee training. Competency assessments will occur at six month intervals within the first year of employment. Competency assessments will occur annually thereafter.
- c. **Responsible Department/Party/Parties:**
  - i. Procedure owner: Ann Shoffner
  - ii. Procedure: Critical Care Lab (CCL) Staff
  - iii. Supervision: Ann Shoffner
  - iv. Implementation: Ann Shoffner and Critical Care Lab (CCL) Staff

**2) Definitions:**

**Competency Assessment Testing** – Defined activities to assess and document the ability of each person to perform his/her assigned duties.

**Competency Corrective Action** – Defined and documented plan of action to address employee’s failure to demonstrate satisfactory performance to include retraining and reassessment of the employee’s competency.

**3) Procedure:**

**A. Annual Competency Assessment:**

1. Competency assessment occurs every six months within the first year of employment and annually thereafter. Competency assessment is performed prior to the performance evaluation.
2. A section competency checklist assessing pre-analytical, analytical and post analytical activities will be used which include: employee name, competency skills being assessed, observer's name, date of observation, method of evaluation, task competency assessment follow-up action for unsatisfactory performance and other competency assessment comments.
3. A written competency quiz will be given at the end of new employee training, every six months within the first year of employment and annually thereafter. This quiz contains QA, QC, testing and problem solving questions for each test system. The employee must score 80% or better on each test system section in order to be considered competent and able to perform testing independently for that respective test system.
4. All employees are required to read and sign: procedure manuals, lab safety manual, exposure control plan, etc.
5. Employees will perform tests on proficiency samples, unknowns or previously tested samples.

6. The Section Manager or their qualified designate will observe testing procedures being performed by each employee.

7. Employees will take the patient safety goal test annually.

Per CLIA, the following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing.

- Direct observations of routine patient test performance including pre-analytical, analytical and post analytical processes.
- Monitoring the recording and reporting of test results
- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
- Direct observation of performance of instrument maintenance and function checks.
- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
- Evaluation of problem solving skills via review of instrument problem/troubleshooting logs, QC review and or written competency quiz.

Competency assessment, which includes the six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform.

7. Competency activities will also include continuing education and training. Documentation of continuing education and training will be maintained by each section.

**B. Competency Assessment Analysis and Corrective Action and Improvement Process:**

1. Successful completion of orientation and/or annual competency assessment requires no follow-up.
2. Unsuccessful completion of orientation can result in an extension of the probation period to include retraining with reassessment or dismissal during probation.
3. Unsuccessful completion of any part of the written quiz, 6 month or annual competency assessment will result in a corrective action plan for improvement that may include retraining, continuing education or other remedial activities.
4. A reassessment should follow with an action plan to monitor performance.
5. Continuous unsuccessful competency assessment results will lead to the disciplinary process and/or dismissal.

**C. Competency assessment records:**

Competency Assessment records will be maintained in the lab section and a summary will be submitted to Human Resources with the Annual Performance Evaluation.

**4) Related Procedures:**

Department of Pathology – Orientation and Competency Procedure for Pathology

**5) Attachments:** none

**6) Related Forms:** Training and Competency forms can be found under G:\Houska\_Shoffner\  
PolProcGuidCHkLst\Checklist\_Competency\Critical Care Labs\Training and Observation Competency.

CCL-F055 Annual Competency Assessment Summary

CCL-F056 OR/ICU CCL 6 Month and Yearly Competency Assessment - RapidLab 1265

CCL-F058 OR CCL 6 Month and Yearly Competency Assessment - SPREG

CCL-F059 OR/ICU CCL 6 Month and Yearly Competency Assessment - Hemochron Response

CCL-F060 OR CCL 6 Month and Yearly Competency Assessment - iSTAT

CCL-F096 OR/ICU 6 month and Yearly Competency Assessment – Cobas e411

CCL-F062 OR/ICU Labs Initial Training Check List

CCL-F044 Continuing Education Log

**7) Related CLIA/CAP Standards:**

GEN.55000, GEN.57000

CLIA Regulations Section 493.1413(b)(8)(9) & 1451(b)(8)(9) Competency Evaluation

**8) References: none**

**9) Review/Revision/Implementation:**

- Review Cycle: All procedures must be reviewed at least every 2 years.
- Office of Record: Department of Pathology, Critical Care Laboratory

**10) Previous Revision Date(s): 1/13, 6/14, 6/15, 8/15, 12/16**

**11) Revised/Reviewed Dates and Signatures:**

Reviewed/Revision Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Reviewed/Revision Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Reviewed/Revision Date: \_\_\_\_\_

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