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<td><strong>Jo Shim</strong></td>
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SMILE Comments: This document is provided as an example only. It must be revised to accurately reflect your lab’s specific processes and/or specific protocol requirements. Users are directed to countercheck facts when considering their use in other applications. If you have any questions contact SMILE.
PERSONNEL COMPETENCY TESTING PROGRAM

CLIA’88 requires the laboratory to document the competency of all testing personnel before they begin working, every 6 months during the first year of employment and annually thereafter. The process is designed to be finished within a 30 day period from the date it is started/due. (Example: For a staff member who started on June 1, 2001, the demonstration of competency associated with the first year of employment should be finished by June 30, 2002.) An individual serving as the Director, Technical Supervisor or General Supervisor may perform this documentation. Initial demonstration of competency is handled via the Orientation checklist. Afterward, demonstration of competency is handled using the following methods and is documented on the Competency Documentation form.

1. Direct observation of specimen handling, processing and testing. While under direct observation the staff member must perform a test using the procedures described in the method manual.

2. Monitoring of results recording/reporting. The Director of the laboratory tracks corrected reports issued. The information collected on corrected reports is used by the Director to determine if an individual is appropriately recording/reporting results. Competency is considered to be demonstrated unless a staff member has a higher than average number of corrected reports. Corrective action will be taken if a staff member is repeatedly making the same error or if a staff member’s error is related to gross negligence.

3. Review of QC and Maintenance records, Proficiency testing and Worksheets. The Director of the laboratory reviews all QC and Maintenance records and selected worksheets at least once a month. During this review, if substandard performance is found, it is documented and corrective action taken immediately.

4. Direct observation of the performance of maintenance and function checks. While under direct observation the staff member must perform maintenance and function checks as per the written protocol.

5. Assessment of test performance via analysis of samples with known concentrations such as previously assayed patient samples or pooled samples, Proficiency testing material or control material. Staff members are given a sample in a blinded manner for analysis. They must analyze the sample and obtain a value within a range determined by the Director of the laboratory in order to demonstrate competency.

6. Assessment of problem solving skills. This will be handled via written questions provided by the Director. The staff member being tested must provide a written response that is judged to be acceptable by the Director.
COMPETENCY DOCUMENTATION FORM

Staff Member: ____________________________________________

Review type: ( ) 6 months ( ) annual Process started on: _______________________

SECTION 1: DIRECT OBSERVATION OF SPECIMEN HANDLING, PROCESSING AND TESTING

Briefly describe the specimen handling, processing and testing process that you observed being performed by the staff member listed above:

Signature: ______________________________________ Date: ____________________

SECTION 2: MONITORING OF RESULTS RECORDING/REPORTING

I certify that my monitoring of corrected reports during the last ( ) 6 months ( ) 12 months indicate that the staff member listed above has demonstrated competency in the results recording/reporting process.

Signature: ______________________________________ Date: ____________________

SECTION 3: REVIEW OF QC AND MAINTENANCE RECORDS, PROFICIENCY TESTING AND WORKSHEETS

I certify that my monitoring of maintenance records, proficiency testing reports and worksheets during the last ( ) 6 months ( ) 12 months indicate that the staff member listed above has demonstrated competency in this area.

Signature: ______________________________________ Date: ____________________

SECTION 4: DIRECT OBSERVATION OF THE PERFORMANCE OF MAINTENANCE AND FUNCTION CHECKS

Briefly describe the maintenance and function checks that you observed being performed by the staff member listed above:

Signature: ______________________________________ Date: ____________________
SECTION 5: DIRECT ANALYSIS OF SAMPLE

List the sample tested, test(s) performed and results obtained. The Director will fill in the acceptable range and grade the results.

SECTION 6: ASSESSMENT OF PROBLEM SOLVING SKILLS

Please write in your answer to question number ______ from the attached Competency Questions list.

Review of answer to question by Director:

Having reviewed this document, I certify that the above listed staff member has demonstrated competency as defined in CLIA'88.

Signature: ___________________________ Date: __________________

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COMPETENCY TESTING PROGRAM QUESTIONS

1. What actions would take if you had a hemolyzed sample with an order for potassium?

2. What actions would you take if you received an unlabeled sample from the Outpatient lab?

3. A potassium of 6.5 meq/l is obtained on a sample from a patient located in an inpatient unit. What action would you take?

4. A glucose of 43 mg/dl is obtained on a sample from an outreach account. What action would you take?

5. The Axsym has just gone down with a bad power supply about 30 minutes ago. You receive an order for a STAT digoxin. What action would you take?

6. You are working on the LX20 and the last 5 samples with electrolytes have anion gaps <5. Is any action needed on your part? If yes, what would you do?

7. You run a blood gas sample and the pH values on the two instruments are different by 0.06. Do you report the results? If not, what action would you take?

8. You get a blood lead value on a sample of 33 ug/dl. What actions do you take?

9. You get an order for an HCG (test code 4943) on a 63 year old woman. What do you do?

10. You get a calcium value of 2.0 mg/dl. What actions do you take? What are the possible causes of the results?

11. A caller requests the sample requirements for a test you never heard of. How do you handle that call?

12. You receive an unlabeled sample on a patient that was drawn during a code. How do you handle this situation?

13. You receive a grossly lipemic sample for a cardiac risk profile. What actions do you take?

14. Before the beginning of a Glucose Tolerance, a patient as a fasting glucose of 315 mg/dl. What actions do you take?

15. At the 21/2-hour mark of a Glucose Tolerance a patient reports feeling faint. What actions do you take?

EFFECTIVE DATE

June 3, 1993

WRITTEN BY

James Dohnal, PhD