Competency Assessment (both of employees and of the laboratory as a whole)

I. Purpose:
   A. The CLIA'88 legislation requires a mechanism to evaluate and demonstrate competency in test performance for each person who performs a clinical diagnostic test. This means that the laboratory director, site supervisor, or other designated person must critically observe the individual being checked to determine that procedural methods and protocols are followed correctly, technique is adequate and safety guidelines are followed.
   B. In contrast, "internal proficiency testing" is a process evaluating a remote location's ability to correctly generate a result from an unknown test sample; the process is operated by the central regional laboratory. "External proficiency testing" is similar to internal proficiency testing, except that the process is operated and evaluated by an independent agency and the reports are sent to the U.S. CMS. In all cases, actual test performance must be validated by the site supervisor.

II. Personnel:
   A. These guidelines apply to personnel who perform clinical tests on human specimens. Persons performing clinical tests are required to exercise good judgment in protecting themselves, their patients and co-workers.
   B. It is the site supervisor's responsibility to monitor compliance and assure that competency evaluations are performed according to the schedule outlined below.

III. Interval:
   Competency evaluation must be performed according to the following schedules:
   1. New personnel must demonstrate competency in performing each test procedure prior to reporting patient results.
   2. New personnel must demonstrate competency in performing each test procedure twice during the first year in which they begin to perform the procedure.
   3. After the first year of testing, each person must demonstrate test proficiency on an annual basis. If a new test method is added, or existing procedures substantially changed, all testing personnel must demonstrate competency (prior to the testing of clinical samples, 6 months later, and annually thereafter) in performing the new (or altered) test procedure.

IV. Specimen:
   A. Competency evaluation will be performed using clinical specimens or training materials. Serum, whole blood, urine or other clinical specimens or quality control material appropriate for the procedure in question may be used. Refer to the specific written procedure in the laboratory manual.
   B. SAFETY NOTICE: Reagents developed from human blood or body fluids may be infectious. Standard (Universal) precautions are required when working with reagents of human origin.
V. Materials:
   A. Instruments:
      All instruments must be in working order and of the same type as used for routine clinical determinations.
   B. Supplies, Reagents and Standards:
      All reagents and Q.C. materials must be in date and of the same type as used for routine clinical determinations.

VI. Evaluation:
   A. The evaluator, usually the site supervisor, will directly observe the entire testing procedure with special emphasis on the following:
      1. Specimen accession, handling and processing.
      2. Test performance according to written protocols.
      3. Appropriate QA checks must be performed and recorded.
      4. Monitoring and recording of results according to written protocols.
      5. Instrument maintenance and function checks are properly performed.
      6. Assessment of problem solving skills.
      7. Adherence to appropriate safety guidelines.
   B. All samples are to be tested in the same manner as routine clinical materials.

VII. Results:
   A. Individual Competency Evaluation Worksheet
      1. Make as many copies of the Individual Competency Worksheet as needed so that each person has their own evaluation form.
      2. Record the name of the individual and site location on each form.
      3. Indicate the approved test complexity level for the individual.
      4. The evaluator, site supervisor or designee, will observe the person performing each clinical procedure.
      5. For each test evaluated, each of the criteria, listed in Evaluation (VI, A.) above, will be scored as pass or fail. Acceptable test performance requires a “pass” score in all of the seven criteria.
      6. The evaluator will note the date, individual criteria and overall pass or fail. If an individual fails any portion of the assessment, any corrective action or retraining initiated must be documented.
      7. The evaluator must initial the box opposite the test evaluated.
      8. The site supervisor will review each person’s individual Competency Evaluation form, sign and date the form.
      9. The Laboratory Director must also sign the Individual Competency Evaluation on a yearly basis.
      10. The Individual Competency Evaluation form will be maintained by the site supervisor.
B. Annual Site Competency Record; (a summary of all individuals and the procedures that they may perform)
   1. Make as many copies of the "Annual Site Competency Record" as needed.
   2. Record all of the indicated information as appropriate.
   3. It is the site supervisor's responsibility to maintain up to date copies of both the Individual Competency Evaluation and Annual Site Competency Record forms on site.
   4. The Annual Site Competency Record will be sent to the Laboratory Director for review and signature on a scheduled basis once a year. Alternatively, the Laboratory Director may sign the form(s) during a site visit.
   5. File the Annual Site Competency Record with the quality control records.

VIII. Corrective Action:
   A. The following remedial actions will be taken whenever an individual fails to generate acceptable results against sample unknowns. "Acceptable Results" are defined as at least 80% correct test performance (100% correct test performance for ABO/RH testing) as evidenced by test results when five or more unknown (blind) samples are tested. If fewer than five samples tested, "Acceptable Results" will be defined as 100% correct test performance.
   B. The site supervisor will review the competency test results with the individual.
   C. An individual that fails any portion of the competency assessment should review the written test procedure and quality control guidelines with the site supervisor.
   D. The site supervisor will observe the individual while they repeat the test procedure.
   E. Consult with the Laboratory Director as the need warrants, especially if there seems to be a problem with the competency sample itself.
   F. If competency assessment issues cannot be resolved on-site by the site supervisor, the Laboratory Director will arrange for remedial training and/or additional testing materials as appropriate.
   G. The individual will not perform the test for any clinical purposes until they have satisfactorily passed their competency evaluation.
   H. A corrective action report will be completed and attached to or included on the annual competency evaluation form.

IX. Records:
   A. File all records for two years on site. All records must be signed by the site supervisor and reviewed by the Laboratory Director on an annual basis.
   B. Individual annual competency evaluation forms should be kept at the testing site.

X. References:
   A. Federal Register, 42 CFR Part 74, Wednesday March 14, 1990: Revision of Laboratory Regulations, (Clinical Laboratory Improvement Amendments of 1988). Section 493.1451 (b) (8) and Section 493.1501 (h) (1 & 2).

XI. Authors:

Source: Strengthening Laboratory Management towards Accreditation
William S Sottile, Ph.D., D(ABMM), Laboratory Director, Northern Michigan Regional Laboratory, Houghton, MI.

Ken Terpstra, Laboratory Manager, Kent County Department of Public Health, Grand Rapids, MI.

**XI. Procedure Review:**

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Date installed or replaced _____/_____/_____    Date removed _____/_____/_____

Supervisor: ___________________    Director: ___________________

# Individual Competency Evaluation

Employee: ________________________________________   Year ___________

Emp. ID# or SSN: _____________________  Evaluator:________________

Health Dept: __________________________________ , ________________

Approved Test Complexity Level: ( ) waived, ( ) moderately complex ( ) highly complex

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<tr>
<th>Test Procedure</th>
<th>Criteria (Pass/Fail)</th>
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Overall Rating (Pass / Fail)

Criteria: A = Specimen handling and processing  
          B = Test procedure  
          C = Quality Control testing and recording  
          D = Results recording and interpretation  
          E = Instrument maintenance and function checks  
          F = Assessment of problem solving skills  
          G = Safety guidelines  
          H = Problem solving skills

Corrective Action (if any):

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Review:

Supervisor: ___________________________  Medical Director: ________________________

Date: ________________________________
# Annual Site Competency Record

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P = passed, F = failed, N/A = Test not performed by employee

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**Review:**

Supervisor: ___________________________ Lab Director: ___________________________

Date: _______________________________