

TRAINING UPDATE

Lab Location: GEC, SGMC & WAH
Department: All staff

Date Distributed: 7/1/2016
Due Date: 7/18/2016
Implementation: 7/18/2016

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

**Policy for Competency Assessment
GEC / SGAH / WAH. QDNQA737 v1.1
Competency Assessment Form for Field Ops (AG.F352)**

Description of change(s):

This is a new QD corporate policy that replaces current one.

Competencies for technical areas will be issued for each Test System (defined in the Training SOP)

ONE Competency Assessment form takes the place of the FOUR individual competency forms currently in use and clearly documents that the required elements have been assessed.

- The Testing Personnel Form covers the 6 required elements for assessing testing personnel
- The Non-Testing Personnel Form covers the 5 required method for assessing non-testing personnel – *this form will NOT be used by Field Ops*

Field Ops competency format will be similar to what is in use now

This revised SOP will be implemented on July 18, 2016

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	Policy for Competency Assessment	
Prepared by	Kathy Grimes	Date: 10/9/15

Laboratory Approval		Effective Date:
Print Name and Title	Signature	Date
<i>Refer to the electronic signature page for approval and approval dates.</i>		

Review		
Print Name and Title	Signature	Date

Corporate Approval	Corporate Issue Date: 12/7/15	
Print Name and Title	Signature	Date
Dianne Zorka, Director, Corporate Quality Assessment - CP Kathy Dwyer, Director, National Quality Assessment - AP Owners	<i>On file</i>	12/7/15
Ronald Kennedy, M.D. Sr. Medical Director Medical Quality	<i>On file</i>	12/7/15

Retirement Date:	<i>Refer to the SmartSolve EDCS.</i>
Reason for retirement/replacement:	

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1. PURPOSE

This document sets forth the policy and process for documentation of required competency assessment in Quest Diagnostics, AmeriPath and Dermpath Diagnostics laboratories.

2. SCOPE

- This policy and process applies to departments with personnel involved in any phase of the testing process (pre-analytic, analytic and post-analytic). This includes:
 - All testing departments
 - Specimen Processing
 - Referral Testing
 - Technical Operations
 - Point-Of-Care testing sites
- This policy defines competency assessment requirements for new and existing employees.
- The following departments are not covered by the specific requirements of this procedure. However, these departments must have policies and processes for assessing and documenting employee performance.
 - Warehouse/Materials Management
 - Logistics
 - Client Services
 - Patient Services
 - Information Technology (IT).

Notes: Quest Diagnostics at Germantown Emergency Center, Shady Grove Medical Center and Washington Adventist Hospitals, Client Service and Patient Services (Phlebotomy) adhere to this procedure. Point of Care follows the Adventist HealthCare training process.

3. RESPONSIBILITY

Responsible Party	Task
Laboratory Director	<ul style="list-style-type: none"> • Approves the initial document and any subsequent revisions.
Laboratory Director or Designee	<ul style="list-style-type: none"> • Recurring review of this document • Ensures that each person is competent and maintains competency in order to perform and report accurate and reliable test results.
Technical Supervisor	<ul style="list-style-type: none"> • Implements this policy and process in the area(s) for which he/she is responsible • Identifies Competency Assessment needs and assures that each individual performing any pre-analytic, analytic and/or post-analytic process is assessed at the required frequency • Ensures that Assessors for High Complexity testing meet qualifications as a General Supervisor and are currently trained and competent to perform the Test System • Ensures that Competency Assessment is documented according to this procedure
Technical Consultant or Pre-/Post-analytical Department Manager/Supervisor	<ul style="list-style-type: none"> • Implements this policy and process in the area(s) for which he/she is responsible • Identifies Competency Assessment needs and assures that each individual performing any pre-analytic, analytic and/or post-analytic process is assessed at the required frequency • Ensures that Competency Assessment is documented according to this procedure
General Supervisor	<ul style="list-style-type: none"> • Ensures compliance with this process in his/her department. • Manages the department competency program • Ensures that all employees are assessed • Signs the Competency Assessment Forms as supervisor
Delegated Assessor	<ul style="list-style-type: none"> • Observes employees as they perform all steps of procedure(s) and/or Test Systems • Reviews all records associated with procedure(s) and/or Test Systems • Evaluates Test Performance • Evaluates Problem Solving Skills • Documents evidence used to evaluate the employee's performance

Responsible Party	Task
Quality Assurance Department	<ul style="list-style-type: none">• Ensures that this document is available to all individuals responsible for Competency Assessment• Coordinates Internal Assessments (audits) of the Competency Assessment process to ensure compliance with this procedure.

4. DEFINITIONS

- **Assessor:** Trained, qualified, competent individual(s) who is/are delegated to perform competency assessment functions
- **Competency Assessment:** An objective evaluation that helps ensure a person continues to perform testing accurately, proficiently, and according to established processes and procedures
- **Competency:** The condition of having the essential knowledge, skills and ability to perform testing as trained and according to procedural specifications
- **Performance Assessment:** Evaluation of an employee that demonstrates they can perform all testing operations reliably to provide and report accurate results
- **Test System:** The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single-use and can include reagents, components, equipment or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.
- **Training Module:** A documented list of procedures associated with a single Test System. Training modules are supervisory tools used to document the contents of the training program for each Test System and are not required to be maintained as part of each individual's training record.

NOTE: The above definitions are derived from the CLIA regulations and/or CAP checklist requirements.

5. POLICY

5.1 Competency assessment must be performed on all employees involved in any phase of the testing process to ensure they perform assigned duties proficiently and in a manner that is consistent with standard operating procedures.

- Competency must be evaluated using objective, predefined criteria
- Competency assessment documents must correspond to Test Systems developed for training
- Competency assessment must be performed by individuals who are trained, qualified, and competent to perform the assigned duties.
 - For High Complexity testing the Assessor must meet the regulatory requirements as a General Supervisor and be delegated to perform the function by the Technical Supervisor.
 - For Moderate Complexity testing, the Assessor must meet the regulatory requirements as a Technical Consultant.
- Competency records must be readily available to demonstrate the organization and structure of the competency program

5.2 Competency assessment must be performed at the following frequency:

- At least semi-annually during the first year an employee tests patient specimens and
- At least annually thereafter.
- Refer to the following table for guidance:

New Employees (New to laboratory or new to department)	All Other Employees (in their job >1 year)
3 to 6 months after employee's start date, assess all Test Systems performed to date	Not required
10 to 12 months after start date, assess <u>all</u> test systems performed to date (includes those assessed in the first 6 month assessment)	Not required
Each subsequent calendar year, assess on an <u>annual</u> basis	Required each calendar year for each Test System performed

6. PROCESS

6.1. General Competency Assessment Requirements

6.1.1 Elements for Evaluating Testing Personnel

- For each Test System, evaluate all six CLIA required elements for competency assessment. The six elements are as follows:
 1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation, and specimen collection, handling, processing and testing
 2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
 4. Direct observation 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
- It is not necessary to use all six elements for each individual procedure associated with the test system (e.g., all six elements would be used to evaluate a test system designated “Olympus 5400”, but all six elements are not required for each individual procedure described in the test system (Glucose, BUN, Sodium, Potassium, etc.).

6.1.2 Elements/Methods for Non-Testing Personnel

- For all individuals who perform supportive tasks and tasks that are not technical in nature, the 5 following methods of assessment are required for each Test System:
 1. Direct observation of employee’s duties
 2. Observation of compliance with safety protocols
 3. Review of work product for compliance with standard operating procedures and applicable workload limits
 4. Monitoring the recording and reporting of test results, as applicable.
 5. Assessment of problem solving skills

6.2. Department Competency Assessment Program Components

- Create a Competency Assessment Form for each Test System/Training Module using the appropriate template for Testing Personnel and/or Non-Testing Personnel (QDNQA335 and QDNQA336) or local Field Ops Competency form (AG.F352).
- Include the Test System name used on the corresponding Training Plan and Training Verification documents.
- For each Test System, determine: 1) the specific key procedural steps to observe, 2) records for review, 3) method of test performance, and 4) process for evaluating problem solving skills, which will be used in order to assess and demonstrate that the employee performs the procedure(s)/Test Systems satisfactorily.
- Details of each element of assessment must be documented using batch numbers, dates, or other traceable information.

6.3 Process for Assessing Competency

Step	Action
1	Create a Competency Assessment Form for each employee, according to the appropriate interval being assessed (i.e., 6 month, Annual, or Reassessment) and for each Test System/Training Module on which they are trained.
2	Testing Personnel: Assessor(s) evaluates the employee's performance of all procedural steps associated with the Test System/Training Module using 1 or more of the 6 required elements listed on the Competency Assessment Form for Testing Personnel (QDNQA335). NOTE: All 6 elements are required but they may be performed by more than 1 assessor.
3	Non-Testing Personnel: Assessor(s) evaluates the employee's performance of all procedural steps associated with the Test System/Training Module using 1 or more of the 5 methods listed on the Competency Assessment Form for Non-Testing Personnel (QDNQA336) or local Field Ops Competency form (AG.F352).
4	Assessor documents the evidence used to evaluate the employee, result of the evaluation, and whether performance is Satisfactory (S), Unacceptable (U), or is Not Applicable (NA). NOTE: Additional documentation of evidence of completion is <u>optional</u> and may be attached to the Competency Assessment Form to be retained with the record.
5	The Assessor initials and dates each assessment as it is completed
6	Unacceptable performance must have corrective action(s) performed and documented in the appropriate field on the Competency Assessment Form.
7	Remedial training must be performed and documented whenever an employee fails to meet competency assessment expectations. Testing of patient samples must be suspended until retraining is complete.
8	The employee signs and dates the completed Competency Assessment form.
9	The Laboratory Director or Delegated Supervisor reviews, signs and dates the completed Competency Assessment Form. This signifies that the employee demonstrates satisfactory performance and is approved to perform the procedure(s) and/or Test System. NOTE: The Laboratory Director is not required to sign the Competency Assessment Form directly IF competency has been delegated to a qualified Supervisor.

6.4 Organization of Competency Assessment Documents

Step	Action
1	Each employee's records must contain documentation that all elements or methods have been assessed for each test system on which they are trained.
2	File completed Competency Assessment documents in a manner that is consistent and ensures that individual employee records can be readily retrieved. Forms may be sorted and filed in the following manner: <ul style="list-style-type: none"> • By employee name and then by job assignment or • By job assignment and then by employee name.
3	File completed competency documents separately from training documentation.

4	<p>File completed Competency Assessment documents according the year performed.</p> <ul style="list-style-type: none"> • Current and previous year’s competency assessment documents must be readily available in the laboratory. • Documents that predate the previous year may be stored offsite according to the record retention requirements outlined in the Quest Diagnostics Records Management Program.
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7. RECORDS MAINTENANCE

Records are maintained according to the requirements published in the Quest Diagnostics *Records Management Program Reference Guide*.

8. RELATED DOCUMENTS

- Policy for Training Verification (QDNQA736)
- Policy for Authorization Personnel (QDNQA739)
- Competency Assessment Form: Testing Personnel (QDNQA335)
- Competency Assessment Form: Non-Testing Personnel (QDNQA336)
- Competency Assessment Form for Field Ops (AG.F352)

9. REFERENCES

1. Clinical Laboratory Standards Institute (CLSI). Training and Competence Assessment Approved Guideline, GP21-A3. Wayne, PA.
2. Code of Federal Regulations CLIA Public Health 42 CFR Part 493
3. College of American Pathologists Commission of Laboratory Accreditation Checklist. Laboratory General Checklist, Northfield, IL: College of American Pathologists, current version.
4. New York State Department of Health Clinical Laboratory Standards of Practice

10. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1	5/18/16	Page 1	Add Local Effective Date message	L Barrett	C Bowman
1	5/18/16	2	Add note for local departments	L Barrett	C Bowman
1	5/18/16	6.2,6.3,8	Add local form	L Barrett	C Bowman

11. ADDENDA

Addendum	Title
A	Assessment Tools

ADDENDUM A

ASSESSMENT TOOLS

Common methods used to assess learning comprehension include, but are not limited to:

1. **Problem Solving Skills**
 - a. Evaluation of responses to situational problems or calculations related to a procedure - Using this approach, the employee's written or verbal responses to a specified situation are evaluated. This tool can be used to measure an employee's ability to resolve procedural problems, perform calculations related to a specific procedure, or take appropriate actions consistent with laboratory policies
 - b. Administration of a Written Test - Written tests can be used when verification of an employee's knowledge is desired. This tool can assess knowledge of all testing phases and can evaluate understanding of theory or principle, problem-solving ability or decision-making processes. All employees can be assessed with the same questions. However, this tool does not emulate actual working conditions and time must be allocated for test development and compilation of results.
2. **Observation of performance** - The supervisor, assessor or other reviewer observes the employee performing a specific activity and documents performance using a checklist or descriptive document.
3. **Testing blind specimens** - When using this tool, the employee is not aware that the blind specimens are submitted. This assessment method provides a reliable measure of routine performance and can identify problems in the pre-analytic, analytic and post-analytic phases.
4. **Testing previously analyzed specimens** - This tool is limited to an assessment of the analytic testing phase. Replicate testing of previously tested patient specimens or proficiency testing specimens for which results have been reported provides verification of training for the analytic process.
5. **Verbal Queries** - Oral questions and responses are used to evaluate specific knowledge about a procedure. Phrasing of questions must be managed to avoid ambiguity.

COMPETENCY ASSESSMENT TESTING PERSONNEL			
Employee (print name):		Year:	
Employee ID Number:			
Department:		Position:	
Interval (check one): <input type="checkbox"/> 6 month (Semiannual) <input type="checkbox"/> Annual <input type="checkbox"/> Reassessment			
Test System Name:			
Instructions: Assess the competency of the employee using each of the elements specified below. For the assessed test system, the assessor's response will indicate if performance is Satisfactory (S) , Unacceptable*(U*) , or Not Applicable (NA) . Attach documentation, as applicable.			
Required Element	Evidence	Evaluation (S, U*, NA)	Assessor and Assessment Date
1. Direct observation of routine patient test performance, including, as applicable, patient identification and preparation; specimen collection, handling, processing and testing. NOTE: Includes compliance with all applicable Safety protocols.			
2. Monitoring the recording and reporting of test results, including as applicable, reporting critical results.			
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records. NOTE: Includes compliance with the Documentation Technique Policy.			
4. Direct observation of performance of instrument maintenance and function checks.			
5. Assessment of performance through testing previously analyzed specimens, internal blind testing samples or external proficiency samples.			
6. Evaluation of problem solving skills.			
If unacceptable (U) is marked, explain corrective action(s) to be taken. Attach additional documentation (as applicable):			
Employee Signature:		Date:	
Laboratory Director or Delegated Supervisor:		Date:	

COMPETENCY ASSESSMENT DIRECT OBSERVATION CHECKLIST

Employee Name: _____ **Training Module:** _____

Step Observed:	Acceptable?		
	YES	NO	N/A

Employee Signature: _____ Date: _____

Observer Signature: _____ Date: _____

Supervisor Assessment:

- Employee demonstrates competency
- Minor deviations reviewed. Employee demonstrates competency. (Document corrective actions below).
- Remedial training required. Employee can not perform test until retraining is complete. Review employee’s previous work to see if patient results were affected.

Supervisor/Designee: _____ **Date:** _____

Minor Deviations:

Step #	Comment	Employee Initial

COMPETENCY ASSESSMENT RECORD REVIEW CHECKLIST

Employee Name: _____ **Training Module:** _____

Records Reviewed:	ID or Date	Acceptable?		
		YES	NO	N/A

Employee Signature: _____ Date: _____

Reviewer Signature: _____ Date: _____

Supervisor Assessment:

- Employee demonstrates competency
- Minor deviations reviewed. Employee demonstrates competency. (Document corrective actions below).
- Remedial training required. Employee can not perform test until retraining is complete. Review employee’s previous work to see if patient results were affected.

Supervisor/Designee: _____ **Date:** _____

Minor Deviations:

Step #	Comment	Employee Initial

Note: Log into the MTS (Medical Training Solutions) website to take the quiz.