TRAINING UPDATE

Lab Location: Department:

GEC, SGMC & WAH Supervisors & QA staff

 Date Distributed:
 8/16/2017

 Due Date:
 8/28/2017

 Implementation:
 8/28/2017

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Policy for Competency Assessment SGAHQDNQA737 v2.1

Description of change(s):

Adopting new CQA revision with the following edits:

Section	Description	
	Remove references to MediaLab throughout	
2	Add note for local departments	
6.1	Add local process for quiz	
6.2	Include Test System	
6.3	Add note for local forms	
9	Add local SOP and forms	

The revised SOP & forms will be implemented on August 28, 2017

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

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

Review			
Print Name and Title	Signature	Date	

Corporate Approval	Corporate Issue Date:	6/5/2017
Print Name and Title	Signature	Date
Dianne Zorka, Director ,		
Corporate Quality Assessment -		
CP		
Kathy Dwyer, Director , National		
Quality Assessment - AP		
Owners	On file	6/1/2017
Ronald Kennedy, M.D.	MM O (100 T	
Sr. Medical Director Medical	(11) plumes I blue !	6/1/2017
Quality	d d	

Retirement Date:	Refer to the SmartSolve EDCS.
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
- 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

Notes: At Quest Diagnostics at Germantown Emergency Center, Shady Grove Medical Center and Washington Adventist Hospitals, Information Technology (IT), 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	Approves the initial document and any subsequent revisions.	
Laboratory Director or	Recurring review of this document	
Designee	Ensures that each person is competent and maintains	
	competency in order to perform assigned duties	
Technical Supervisor	• 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 appropriately documented	
Technical Consultant	Implements this policy and process in the area(s) for which	
Technical Consultant	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 appropriately	
	documented	
Pre-/Post-analytical	Implements this policy and process in the area(s) for which	
Department	he/she is responsible	
Manager/Supervisor	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 appropriately	
	documented	
General Supervisor	• Ensures compliance with this process in his/her department.	
	Manages the department competency program Ensures that all applement agreement as applicable.	
	• Ensures that all employees are assessed, as applicable	
Assessor (Must be	 Approves completed competency assessment(s) Observes employees as they perform all steps of procedure(s) 	
delegated in writing)	and/or Test Systems / Module	
delegated in writing)	Reviews all records associated with procedure(s) and/or Test	
	Systems / Module	
	Evaluates Test Performance	
	Evaluates Problem Solving Skills	
	Documents evidence used to evaluate the employee's	
	performance	
Quality Assurance	Ensures that this document is available to all individuals	
Department	responsible for Competency Assessment	
	Coordinates Internal Assessments (audits) of the Competency	
	Assessment process to ensure compliance with this procedure.	

4. **DEFINITIONS**

Term	Definition		
Assessor	 Qualified individual(s) who is/are delegated to perform competency assessment functions. In laboratories that perform both moderate and high complexity testing, the individual(s) must meet the qualifications of 4 years of education and 4 years of experience in the specialty. In laboratories that perform only moderate complexity testing the individual(s) must meet the qualifications of a technical consultant. 		
Competency	The condition of having the essential knowledge, skills and ability to perform testing as trained and according to procedural specifications		
Competency Assessment	An objective evaluation that helps ensure a person continues to perform testing accurately, proficiently, and according to established processes and procedures		
Performance	Evaluation of an employee that demonstrates they can perform all		
Assessment	testing operations reliably to provide and report accurate results		
Post-analytic Process	A process that occurs after testing is complete, such as result reporting.		
Pre-analytic Process	A process that occurs prior to testing, such as patient preparation, specimen collection, identification, preservation, transportation and specimen processing		
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	 Supervisory tools used to organize the contents of the department's training program and are not required to be maintained as part of each individual's training record. For Testing Personnel - A Module is a documented list of procedures associated with a single Test System. Training on all applicable procedures must be completed prior to the performance of the Test System. For Non-testing personnel - A Module is a documented list of procedures associated with a specific process, workstation or job assignment. Training on all applicable procedures must be completed prior to the performance of the job assignment. Refer to the Policy for Training Verification for specific requirements and instructions. 		

Germantown Emergency Center

Term	Definition	
Training Plan	A documented list of all Training Modules in a department. It	
	serves as a "Table of Contents" for the department's Training	
	Modules. Refer to the Policy for Training Verification for specific	
	requirements and instructions.	

5. POLICY

5.1 Competency assessment intention

- 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 records must be readily available.
 - o Competency must be evaluated using objective, defined criteria
 - o Competency assessment must correspond to Test Systems/ Modules developed for training
 - o Competency assessment must be performed by individuals who are qualified and delegated.
 - For High Complexity testing the Assessor must meet the qualifications of 4 years of education and 4 years of experience in the specialty 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.

5.2 Competency assessment frequency

- During the first year of hire, performance of an individual's assigned duties must be evaluated least semi-annually.
- When an individual has completed the first 2 semi-annual assessments, performance must be assessed at least annually (per calendar year), thereafter.
 - The date for annual assessment can occur anytime in the calendar year and is not dependent upon the date of the previous assessment.

• Refer to the following table for guidance:

Frequency	New Employees	Employees >1 year
First Semi-Annual Competency Assessment	 Within 6 months from the date the first training verification checklist is completed perform the first competency assessment. Assessment must be completed for ALL Test Systems/Training Modules on which the employee is trained. 	Not required
Second Semi-Annual Competency Assessment	 6 months after the date of the first semi-annual assessment perform the second competency assessment for ALL Test Systems/Training Modules on which the employee has been trained to date. This must include those previously assessed in the first 6 month assessment 	Not required

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Annual Competency	Each subsequent calendar year, annually	Required each calendar
Assessment	assess each Test System/Training Module	year for each Test
	the employee performs.	System/Training Module
		the employee performs

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. The Adventist hospital sites may include a quiz on the competency form or utilize an electronic system to administer tests. Refer to the policy Medical Training Solutions (MTS) for specific details.
- For Test Systems in which one of the six elements does not exist, such as direct observation of performance of instrument maintenance and function checks, the reason why the element is not applicable must be documented.
- Record review must include observation of compliance with the Documentation Technique Policy.

6.1.2 Elements/Methods for Evaluating Non-Testing Personnel

- For all individuals who perform supportive tasks that are not technical in nature, the 5 following methods of assessment are required for each Test System / Module:
 - 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
 - Monitoring the recording and reporting of test results (as applicable)
 NOTE: Includes observation of compliance with the Documentation Technique Policy.
 - 5. Assessment of problem solving skills. The Adventist hospital sites may include a quiz on the competency form or utilize an electronic system to administer tests. Refer to the policy Medical Training Solutions (MTS) for specific details.

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6.2 Department Competency Assessment Program Components

For departments using manual or paper methods

Create a Competency Assessment Form for each Test System / Training Module (refer to the template for Non-Testing Personnel QDNQA336).

- Include the name of the Test System / Training Module from the department Training Plan.
- For each Test System / Training Module determine: 1) the specific key procedural steps to observe, 2) records and other work products for review, and 3) process for evaluating problem solving skills, which will be used in order to assess and demonstrate that the employee performs the procedure(s) satisfactorily.
- Details of each method of assessment must be documented using document identifiers, dates, or other traceable information.

6.3 Process for Assessing Competency

6.3.1 For departments using manual or paper methods:

Step	Action
1	Create a Competency Assessment Form for each employee, according to the
	appropriate interval being assessed (i.e., first semi-annual at 6 months, second
	semi-annual at 12 months, Annual, or Reassessment) and for each Test System /
	Training Module on which they are trained.
	NOTE: Use Competency Assessment Form for Non-Testing Personnel
	(QDNQA336). The Adventist system uses local forms, see Related Documents.
2	The Assessor(s) evaluates the employee's performance of all procedural steps associated with the Training Module using the methods listed on the form.
3	The Assessor documents the evidence used to evaluate the employee, the 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 optional and may be attached to the Competency Assessment
	Form to be retained with the record.
4	The Assessor initials and dates each assessment as it is completed
5	Unacceptable performance must have corrective action(s) performed and
	documented in the appropriate field on the Competency Assessment Form.
6	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.
7	The employee signs and dates the completed Competency Assessment form.
8	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.

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6.4 Organization of Competency Assessment Records

Step	Action
1	Each employee's records must contain documentation that <u>all</u> elements or
	methods have been assessed for each Test System or Training Module on which
	they are trained.
For dep	artments using manual or paper methods:
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:
	By employee name and then by Training Module
	OR
	By Training Module and then by employee name.
3	File completed competency documents separately from training documentation.
4	File completed Competency Assessment documents according the year
	performed.
	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.

7. PROCEDURE NOTES

None

8. RECORDS MANAGEMENT

Records generated as a result of this policy/process/procedure may have different retention requirements. Refer to the Quest Diagnostics *Records Management Program Reference Guide*. http://questnet1.qdx.com/Business_Groups/legal/records/schedule.htm

9. RELATED DOCUMENTS

- Quest Diagnostics Competency Assessment Form: Non-Testing Personnel (QDNQA336)
- Quest Diagnostics Policy for Authorization Personnel (QDNQA739)
- Quest Diagnostics Policy for Delegation of Responsibilities (QDNQA738)
- Quest Diagnostics Policy for Training Verification (QDNQA736)
- Medical Training Solutions (MTS), Laboratory procedure
- Competency Assessment Form for Field Ops (AG.F352)
- Competency Assessment Form for Technical Staff (AG.F392)

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10. 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

11. DOCUMENT HISTORY

Version	Date	Revision (Immediate retired and prior two versions)	Revised By
2	4/25/17	Updated entire document:	K. Grimes/
		To include MediaLab for electronic documentation of competency	G. Troutman
		 Included changes to the Policy for Delegation of Responsibilities 	
		 Included changes to the Policy for Training Verification. 	
2	7/5/17	Remove references to MediaLab throughout	L Barrett
		Page 1: Add Local Effective Date message	
		2: Add note for local departments	
		6.1: Add local process for quiz	
		6.2: Include Test System	
		6.3: Add note for local forms	
		9: Add local SOP and forms	

12. APPENDICES

Appendices	Title		
1	Assessment Tools		

APPENDIX 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 DIRECT OBSERVATION CHECKLIST

Emplo	yee Name:				Em	ployee ID:				
	Module:					Date:				
	Interval:	☐ New employee/test	□ 6 month		1 Year	□ Annua	ıl		Reasses	sment
							Λ.		+abla2	
Ctor O	haamiadi.								table?	NI/A
Step O	bserved:						YE	:5	NO	N/A
Emp	loyee Signa	nture:				Date:				
Obse	Observer Signature:				Date:					
Supe	ervisor Asse	essment:								
	Employee d	demonstrates competency								
		ations reviewed. Employe	e demonstrates	compe	tency. (De	ocument cor	rectiv	ve ac	tions be	elow).
		raining required. Employe								, .
		previous work to see if p				· ·	•			
Sup	ervisor/Des	ignee:				Date	:			
Mino	r Deviations:									
Step#	Comment							Emp	oloyee Init	tial



COMPETENCY ASSESSMENT RECORD REVIEW CHECKLIST

Employee Name:				Em	ployee ID:			
Module:					Date:			
Interval:	☐ New employee/test	□ 6 month		1 Year	□ Annu	al	□ Reass	essmen
							eptable	
Records Reviewed	<u>: t</u>			ID or D	ate	YES	NO	N/A
					_			
Employee Signa	ature:				Date	:		
Daviassas Ciana	42240				Doto			
Reviewer Signature: Date:								
Supervisor Asse	ecement:							
Supervisor Asse	ASSITION.							
□ Employee	demonstrates competency							
	tations reviewed. Employe		compe	tency. (Do	ocument con	rrective	actions	below).
	raining required. Employe							,
employee's	s previous work to see if p	patient results we	re affe	cted.				
G					- .			
Supervisor/Des	signee:				Date	e:		_
Minon Donieti								
Minor Deviations: Step # Comment						Emp	loyee Initi	al
F							. ,	
1								



Employee (print name):		Employee ID:			
Department:	Position:			Year:	
Interval:		□ 6 month	□ 1 Year	□ Annual	□ Reassessment
Instructions: Assess the competency of the employee usin	g each of the elements:	specified below. For the	e assessed test system, the	assessor's response will	indicate if performance is
Satisfactory (S), Unacceptable* (U), or Not Applicable (NA	-	•	• •	·	·
Required Element	add system/test				
Direct observation of routine patient test performance, including as applicable, patient identification and preparation; specimen	Evidence:	Evidence:	Evidence:	Evidence:	Evidence:
collection, handling, processing and testing. Note: Includes	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA
compliance with all applicable safety protocols. (Evidence = FIN	Assessor:	Assessor:	Assessor:	Assessor:	Assessor:
# & Date)	Date:	Date:	Date:	Date:	Date:
	Evidence:	Evidence:	Evidence:	Evidence:	Evidence:
Monitoring the recording and reporting of test results, including					
as applicable, reporting critical results. (Evidence = FIN & Date)	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA
as applicable, reporting critical results. (Evidence Title & Dute)	Assessor:	Assessor:	Assessor:	Assessor:	Assessor:
	Date:	Date:	Date:	Date:	Date:
	Evidence:	Evidence:	Evidence:	Evidence:	Evidence:
Review of quality control records, proficiency testing results, and preventive maintenance records.					
NOTE: Includes compliance with the Documentation Technique	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA
Policy. (Evidence = Date)	Assessor:	Assessor:	Assessor:	Assessor:	Assessor:
	Date:	Date:	Date:	Date:	Date:
	Evidence:	Evidence:	Evidence:	Evidence:	Evidence:
Direct observation of performance of instrument maintenance					
and function checks. (Evidence = Date)	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA
	Assessor:	Assessor:	Assessor:	Assessor:	Assessor:
	Date:	Date:	Date:	Date:	Date:
Assessment of performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency	Evidence:	Evidence:	Evidence:	Evidence:	Evidence:
samples.	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA
(Evidence = FIN & Date)	Assessor:	Assessor:	Assessor:	Assessor:	Assessor:
,	Date:	Date:	Date:	Date:	Date:
	Evidence:	Evidence:	Evidence:	Evidence:	Evidence:
Evaluation of problem solving skills.					
(Evidence = Response to Questions on Sheet)	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA	Evaluation: S, U*, NA
Levidence - Response to Questions on sheetj	Assessor:	Assessor:	Assessor:	Assessor:	Assessor:
	Date:	Date:	Date:	Date:	Date:
		15000	- 310.		
Employee signature:			Da	te:	
Laboratory Director or Delegated Supervisor:			Da	te:	

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Problem Solving Skill Questions: insert system/test:	[insert section/bench]				
moert system, testi					
insert system/test:					
insert system/test:					
Employee signature:	Date:				
*Action taken for unsatisfactory responses:					
Laboratory Director or Delegated Supervisor:	Date:				

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