Lab Location:	All AHC Labs	**Date Implemented:**	12/6/23
Department:	All Departments	**Due Date:**	12/31/23

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:		
Competency Assessment		
Description of change(s):		

The following process was added to this procedure:

If an employee doe not meet competency expectations,
   A. The employee's supervisor must assess and document patient impact that resulted from the failed competency assessment.
   B. The employee will not be allowed to perform testing for the test system in which competency did not meet expectations.
   C. The employee will be retrained in the test areas for which competency did not meet expectations. The retraining must be documented.
   D. The employee must complete a competency assess after retraining and before patient testing is resumed.
        a. If competence is demonstrated, the employee may resume testing.
        b. If the employee cannot demonstrate competence after retraining, the employee will not be allowed to resume testing in the test area and may be terminated.

AHC.QA 3003 Competency Assessment

Copy of version 3.0 (approved and current)

Last Approval or Periodic Review Completed	11/16/2023	
Next Periodic Review Needed On or Before	11/16/2025	
Effective Date	11/16/2023	

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	11/16/2023	3.0	*Nicolas Cacciabeve MD* Nicolas Cacciabeve	
Approval	QA Leader approval	11/16/2023	3.0	Cynthia Bowman-Gholston MT(ASCP) (104987)	
Periodic review	QA Leader approval	8/3/2023	2.0	Cynthia Bowman-Gholston MT(ASCP) (104987)	
Periodic review	QA approval	5/22/2023	2.0	Demetra Collier (110199)	
Approval	Lab Director	5/18/2021	2.0	Nicolas Cacciabeve	
Approval	QA Leader approval	5/18/2021	2.0	Cynthia Bowman-Gholston	
Approval	QA review	5/14/2021	2.0	Leslie Barrett	
Approval	Lab Director	6/21/2019	1.0	Nicolas Cacciabeve	
Approval	QA Leader approval	6/20/2019	1.0	Cynthia Bowman-Gholston	
Approval	QA review	6/14/2019	1.0	Leslie Barrett	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
3.0	Approved and Current	Major revision	11/15/2023	11/16/2023	Indefinite
2.0	Retired	Major revision	5/14/2021	6/2/2021	11/16/2023
1.0	Retired	Initial version	6/13/2019	7/23/2019	6/2/2021

Linked Documents

- AG.F352 Competency Assessment Form for Field Ops
- AG.F392 Competency Assessment Form for Technical Staff

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Non-Technical SOP

Title	Competency Assessment	
Prepared by	Leslie Barrett	Date: 6/13/2019
Owner	Cynthia Bowman-Gholston	Date: 6/13/2019

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

TABLE OF CONTENTS

1. PURPOSE

This document describes the policy and process for documentation of required competency assessment for laboratory staff.

2. SCOPE

This policy and process applies to laboratory personnel that perform any pre-analytic, analytic and/or post-analytic process.

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3. RESPONSIBILITY

Responsible Party	Task
Laboratory Director	• Approves the initial document and any revisions.
Laboratory Director or Designee	• Recurring review of this document • Ensures that each person is competent and maintains competency in order to perform assigned duties

Technical Supervisor	• Implements this policy and process in the areas for which he/she is responsible
	• Identifies competency assessment needs and assures that each individual is assessed at the required frequency
	• Ensures that Assessors meet the qualifications:
	  o as a General Supervisor for High complexity testing
	  o as a Technical Consultant for Moderate complexity testing
	• Ensures Assessors are currently trained and competent to perform the Test System
	• Ensures that competency assessment is appropriately documented

Technical Consultant / Pre-/Post-analytical Department Manager/Supervisor	• Implements this policy and process in the areas for which he/she is responsible • Identifies competency assessment needs and assures that each individual 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 employees are assessed, as applicable • Approves completed competency assessments
Assessor (Must be delegated in writing)	• Observes employees as they perform all steps of procedures and/or Test Systems / Module • Reviews all records associated with procedures and/or Test Systems / Module • Evaluates Test Performance • Evaluates Problem Solving Skills • Documents evidence used to evaluate the employee's performance
Quality Assurance Department	• Coordinates Internal Assessments (audits) of the competency assessment process to ensure compliance with this procedure.

4. DEFINITIONS

Term	Definition
Assessor	Qualified individual who is delegated to perform competency assessment functions.
Competency	The condition of having the essential knowledge, skills and ability to perform testing as trained and according to procedural specifications

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Term	Definition
Competency Assessment	An objective evaluation that helps ensure a person continues to perform testing accurately, proficiently, and according to established processes and procedures
Performance Assessment	Evaluation of an employee that demonstrates they can perform all 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. o 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. o 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 procedure *Training Verification* for specific requirements and instructions.
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.

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.
  - Competency must be evaluated using objective, defined criteria
  - Competency assessment must correspond to Test Systems/ Modules developed for training
  - Competency assessment must be performed by individuals who are qualified and delegated.
    - For High Complexity testing, the Assessor must meet the regulatory requirements as a General 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.
  - o 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
Annual Competency Assessment	Each subsequent calendar year, annually assess each Test System/Training Module the employee performs.	Required each calendar year for each Test 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

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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 <u>must</u> 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
  4. 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. This 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.

6.1.3 Competency Assessment Components
Create a Competency Assessment Form for each Test System / Training Module.
- Include the name of the Test System / Training Module from the department Training Plan and/or training documents.
- 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.

6.2 Process for Assessing Competency

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.
2	The Assessors evaluates the employee's performance of all procedural steps associated with the Training Module using the methods listed on the form.

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Step	Action
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 <u>optional</u> 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 actions performed and documented in the appropriate field on the Competency Assessment Form.
6	If an employee does not meet competency expectations, a. The employee's supervisor must assess and document and patient impact that resulted from the failed competency assessment. b. The employee will not be allowed to perform testing for the test system in which competency did not meet expectations. c. The employee must be retrained in the test area for which competency did not meet expectations. The retraining must be documented. d. The employee must complete a competency assessment after retraining and before patient testing is resumed. a. If competence is demonstrated, the employee may resume testing. b. If the employee cannot demonstrate competence after retraining, the employee will not be allowed to resume testing in the test area and may be terminated.
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.

6.3 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.
2	File completed Competency Assessment documents in the employee's competency file / folder to ensure that records can be readily retrieved.
3	File completed competency documents separately from training documentation.
4	File completed Competency Assessment documents according to 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 policy.

7. RELATED DOCUMENTS

- Authorization of Personnel and Delegation of Responsibilities, QA procedure
- Training Verification, QA procedure
- Medical Training Solutions (MTS), Laboratory procedure
- Competency Assessment Form for Field Ops (AG.F352)
- Competency Assessment Form for Technical Staff (AG.F392)

8. 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 Laboratory Accreditation Checklists
4. Quest Diagnostics *Policy for Competency Assessment* QDNQA737

9. DOCUMENT HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAHQDNQA737v3.1		
1	5/14/21	Header: changed WAH to WOMC, added FWMC	L Barrett	C Bowman-Ghloston
2	11/15/23	Added section 6.2, step 6, the steps that will be taken if an employee fails competency assessment to meet GEN.57000. Changed SOP prefix to AHC	SCodina	C Bowman-Ghloston

10. APPENDICES

A. Assessment Tools

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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.