

TRAINING UPDATE

Lab Location: GEC, SGMC & WAH
Department: Supervisors & QA staff

Date Distributed: 8/16/2017
Due Date: 8/28/2017
Implementation: 8/28/2017

DESCRIPTION OF PROCEDURE REVISION

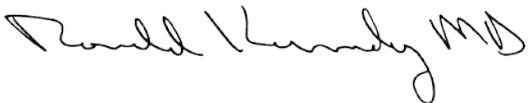
Name of procedure:	
Policy for Training Verification SGAHQDNQA736 v2.1	
Description of change(s):	
Adopting new CQA revision with the following edits:	
Section	Description
	Remove references to MediaLab throughout
2	Add note for local departments
3	Delete Cytology
4, 6.6, 9	Add MTS
6.1, 12	Add local forms
9	Add local SOP
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.

Title	Policy for Training Verification
Prepared by	Kathy Grimes

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: 6/5/17
Print Name and Title	Signature	Date
Dianne Zorka Director, Corporate Quality Assessment - CP		
Kathy Dwyer Director, National Quality Assessment - AP	<i>On file</i>	6/1/2017
Ronald Kennedy, M.D. Sr. Medical Director Medical Quality		6/1/2017

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 training 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

- It defines training requirements for new employees, new methods, procedure revisions and retraining, as needed.

- This policy and process does not apply to:

- Warehouse/Materials Management
- Logistics

The above departments must have policies for training and evidence of appropriate employee training. These departments are not covered by the specific requirements of this procedure.

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	<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 personnel have satisfactorily completed initial training on all aspects related to their designated Test System
Technical Supervisor, 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 training needs and develops training materials Ensures that each individual has successfully completed the appropriate training Regularly evaluates the trainee's progress Ensures that completed training is documented appropriately.
General Supervisor with training responsibilities	<ul style="list-style-type: none"> Ensures compliance with this process in his/her department Ensures that trainers are currently trained and competent on the applicable Test Systems Develops training materials, as needed
Trainer	<ul style="list-style-type: none"> Provides training and ensures that all learning objectives are understood and complete Ensures that each trainee understands and is capable of performing the learning objectives covered in the training. Makes suggestions for training materials, as applicable.
Quality Assurance Department	<ul style="list-style-type: none"> Ensures that this document is available to all individuals responsible for employee training Coordinates Internal Assessments (audits) of the training process to ensure compliance with this procedure.

4. DEFINITIONS

Term	Definition
Authorization to Perform Testing	Documentation that a Laboratory Director has authorized an employee to perform responsibilities and job duties on which they have been trained.
Competency Assessment Profile	<p>Specific activities used for documenting initial training and periodic competency assessment of a given test system, platform or procedure(s). Profiles are assigned to new or currently trained employees, depending on the person's status for that test system, platform, or procedure(s).</p> <p>The standard Profile format includes 3 intervals or phases, each with associated activities:</p> <ul style="list-style-type: none"> • Training and the initial assessment • The first-year semi-annual (6-month) assessment • Annual assessment
Electronic Document Control System (EDCS)	A computer system used to track and store electronic documents, such as SOPs.
EDCS, SmartSolve or Medical Training Solutions (MTS) Assessment	Electronic documentation that an employee has knowledge of and understands changes or revisions to a procedure. The assessment is in the form of questions or attestation statement.
Initial Performance Assessment	Evaluation that demonstrates a trainee can perform all testing operations reliably in order to provide and report accurate results.
Learning Objectives	<ul style="list-style-type: none"> • Observable or measurable outcomes from a training exercise. • Learning objectives use action verbs and measure either cognitive or psychomotor skills. • They are key components of the procedures that describe the desired measurable outcomes when training is complete. <p>NOTE: In MediaLab, each learning objective is identified as a Task on a Training Verification Checklist.</p>
Previously Trained Employee	An employee without documentation of initial training or with documentation of previous training that does not meet current learning objectives.
Procedure	A description of a sequence of steps leading to a defined outcome or product. A procedure can be technical (analytical, pre-analytical, or post-analytical) or non-technical (administrative).
SmartSolve	Quest Diagnostics standard electronic document control software.

Term	Definition
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. NOTE: The above definition is derived from the CLIA regulations and/or CAP checklist requirements.
Training	A procedural based exercise of ensuring an employee can perform all objectives associated with a test system.
Training Module	Training modules are 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. <ul style="list-style-type: none"> • 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.
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.
Training Update	A form (or equivalent record) used to document knowledge of changes or revisions to procedures. For EDCS sites, this form is not required.
Training/Initial Assessment	Documentation that training objectives have been met and that the training process for a specific Test System or procedure is complete.
Training Verification Form	Written documentation that training objectives have been met and that the training process for a specific Test System/Training Module is complete.

5. POLICY

5.1 Training must be performed on all employees involved in any phase of the testing process.

- Training must cover all applicable procedures for each individual.
- Training must be completed and documented prior to performing the Test System or any job-related task.
- Training must be performed when:
 - A new employee learns to perform a specific Test System. This includes individuals who are new to the company or have transferred from another department.
 - An existing employee requires remedial training due to unsuccessful competency assessment or has demonstrated inadequate test performance.
 - An existing employee learns to perform a procedure or Test System that he/she has not previously performed.

- A new procedure or Test System is introduced in the department.
- Retraining must occur when problems are identified with personnel performance.
- Training records must be maintained for a minimum of two years (five years for transfusion medicine).
 - After the initial two-year (or five-year) period, records of successful ongoing competency assessment may be used to demonstrate compliance with this requirement.
- Employees working in more than one laboratory (CLIA number), must have documentation of training with approval by each Laboratory Director or delegated Supervisor.
 - Comprehensive, duplicate training is not required as long as the Test System is identical at each location.
 - All differences must be addressed in CLIA laboratory specific training documents.

5.2 Trainers must have successfully completed training for the specific Test System and be currently competent to perform that Test System

- Laboratory Director delegation is not required for this responsibility unless the Trainer is specifically responsible for the Training Plan and signing/approving Training Verification.
- If a new Test System is created that involves a new laboratory method or process, the following individuals may assume responsibility for the initial training:
 - An individual trained by a manufacturer/vendor of a system or by an outside user of the system.
 - An individual who developed or validated the new method or process.
 - An individual delegated as responsible for SOP review and/or laboratory method validations in the department (i.e., Technical Supervisor, Technical Consultant, or Pre-/Post-analytical Department Manager)

5.3 Employees must be knowledgeable about the content of procedures and policies relevant to their scope of testing, including change to existing procedures.

- Prior to performing a changed procedure or Test System, the employee must acknowledge that they have read and understand the revision(s). This acknowledgment must be documented and dated.

6. PROCESS

6.1 General Training Program Requirements

6.1.1 For Testing Personnel

- Define **Test Systems** in each testing department
- Group all pre-analytic, analytic, and post-analytic tasks and processes used to produce a test result or set of results.
NOTE: The term Test System does not apply to non-technical tasks or processes
- Create a Training Plan for the department using the Training Plan for Testing Personnel (QDNQA330). **The Adventist system uses a local Training Plan.**
- Using the Training Module form (page 2 of the Training Plan document), list all procedures required to perform each Test System.
NOTE: Each Test System must be listed on a separate Training Module page.
- Include the title and document identifier for each SOP on the form.

- Name each Test System/Training Module using terminology that clearly describes the Test System. **Optional:** The Test System/ Training Module may be numbered to facilitate tracking.
- Administrative procedures do not need to be included
- It is acceptable to create a limited number of sub-categories for a Test System if tasks are restricted due to experience level, shift, or other reasons. If Test Systems have sub-categories, the Training Module must clearly show which procedures are included for each sub-category.

6.1.2 For Non-Testing Personnel

- Group all procedures and tasks related to a specific process, workstation, bench, or assignment.
- Create a Training Plan for the department using the Training Plan for Non-Testing Personnel (QDNQA332). **The Adventist system uses a local Training Plan.**
- Using the Training Module form (page 2 of the Training Plan document), list all procedures required to perform each process, workstation, bench, or assignment. **NOTE:** Each one must be listed on a separate Training Module page.
- Include the title and identifier for each SOP on this form
- Name each Training Module using terminology that clearly describes the process, workstation, bench, or assignment.

6.1.3 Create Training Verification Forms For Each Test System/Training Module

- **For departments using manual or paper methods** for documentation:
 - Use the standard template for Non-Testing Personnel (QDNQA333). **The Adventist system uses a local Training Verification template.**
 - Forms must specify if the trainee requires supervision for specimen processing, test performance or result reporting.

6.1.4 Initial Training Assessment

- An assessment of the trainee/employee's initial training must always be performed and documented
 - Determine which of the following tools are most appropriate for ensuring that each learning objective is met for each test system or module:
 - Direct observation of task performance
 - Reporting of test results
 - Review of associated records
 - Assessment of analytical test performance (where applicable)
 - Performance and documentation of instrument maintenance and function checks
 - Problem solving skills (observed, written, or responses to verbal queries)
- NOTE:** It is not necessary to use all assessment tools for each individual learning objective.
- Define which of the above tools will be used to assess and demonstrate that the trainee can perform all tasks, testing operations, and/or procedural steps reliably.
 - For Testing Personnel, this demonstrates that he/she can provide and report accurate results.

- Document details of successfully completed test runs or tasks must be documented using batch numbers, dates, or other traceable information.
- **For departments using manual or paper methods**
 If special documents are created as part of the Performance Assessment, such as a written quiz, these documents must be attached to the Training Verification record.

6.1.5 Previously Trained Employees

- **For departments using manual or paper methods** for documentation:
 - Use a Training Verification Form when documentation of initial training is missing, previous training documentation does not meet the requirements of the current SOP, or initial training does not meet current learning objectives.
 - Learning objectives must be the same as those used for newly trained employees

6.1.6 Remedial Training

- **For departments using manual or paper methods** for documentation:
 - Use a Training Verification Form for employees who require additional training due to unsuccessful competency assessment or other reasons
 - Learning objectives may be the same as those used for newly trained employees

6.2 Process for Initial Training

Step	Action
1	The Trainee must read all procedures listed in the Test System/Training Module for the Test System.
2	The Trainee observes the performance of all procedural steps associated with the Test System/Training Module as performed by a qualified Trainer.
3	The Trainee practices performing procedural steps while observed and instructed by a qualified Trainer.
4	The Trainer uses assessment tools to evaluate the trainee’s progress toward completing all required learning objectives.
For departments using manual or paper methods:	
5	On the Training Verification Form, the Trainee and Trainer initial and date, each Learning Objective as they are completed, indicating the trainee has had sufficient training and has demonstrated mastery of the knowledge, skills and abilities required to perform the procedure(s) and/or the Test System.
6	The Trainee signs and dates the completed Training Verification Form, indicating they have had sufficient training and are confident to perform the procedure(s) and/or the Test System.
7	The delegated Supervisor documents the outcome of the Initial Performance Assessment and ensures that all learning objectives are understood by the trainee, all learning objective have been completed successfully, and that training is complete.
8	The Laboratory Director or delegated Supervisor reviews the training documentation and Assessment of Initial Training and indicates if supervision is required for any phase of the testing process (i.e., specimen processing, test performance and/or result reporting).

Form ID: QDNQA305 v2 issued 2017

Step	Action
9	The Laboratory Director or delegated Supervisor reviews the completed Training Verification Form. He/she signs the document indicating that the trainee is fully trained, demonstrates satisfactory performance, and is approved to perform the procedure and/or Test System. NOTE: The Laboratory Director is not required to sign the Training Verification Form directly IF training has been delegated to a qualified Supervisor.

6.3 Process for Previously Trained Employees

Step	Action
1	The Trainer or delegated Supervisor reviews applicable procedures and current learning objectives with the previously trained employee to ensure they meet all learning objectives as described on the current Training Verification Form.
2	The Trainer or delegated Supervisor must use the assessment tools to evaluate the previously trained employee's understanding of current learning objectives based on current performance of the Test System.
3	If gaps in previous training are identified supplemental training must be performed and documented.
For departments using manual or paper methods:	
4	The Trainer or delegated Supervisor Check ensures that Previously Trained Employee is recorded on the Training Verification Form.
5	The Trainee and Trainer or delegated Supervisor initial and date each Learning Objective on the Training Verification Form, as it is completed.
6	The delegated Supervisor documents the outcome of the Assessment of Training and ensures that all learning objectives have been successfully completed.
7	The Trainee signs and dates the completed Training Verification Form, indicating they have had sufficient training and are confident to perform the procedure(s) and/or the Test System. <ul style="list-style-type: none"> When applicable, the Trainer signs and dates the completed Training Verification indicating that supplemental training has been completed successfully and the trainee has demonstrated mastery of the knowledge, skills and abilities required to perform the procedure(s) and/or Test System.
8	The Laboratory Director or delegated Supervisor reviews the completed Training Verification Form. He/she signs the document, indicating that the trainee is fully trained, demonstrates satisfactory performance, and is approved to perform the procedure(s) and/or Test System. NOTE: The Laboratory Director is not required to sign-off/approve IF training has been delegated to a qualified Supervisor.

6.4 Process for Remedial Training

Step	Action
1	The Trainer or delegated Supervisor ensures that the employee meets all of the current learning objectives described on the Training Verification Form by reviewing the procedure(s) and current learning objectives with the employee.

Step	Action
2	The Trainer or delegated Supervisor documents the specific area(s) that address the deficiencies identified during competency assessment or other reasons for the remedial training.
3	The Trainer or delegated Supervisor evaluates the employee's understanding of current learning objectives based on current performance of the Test System using applicable assessment tools.
For departments using manual or paper methods:	
4	The delegated Supervisor documents the reason for remedial training on the Training Verification form.
5	The Trainee and Trainer initial and date each Learning Objective as it is completed.
6	The delegated Supervisor documents the outcome of the Assessment of Remedial Training and ensures that all learning objectives have been successfully completed.
7	The Employee signs and dates the completed Training Verification Form to indicate they have had sufficient remedial training and are confident to perform the procedure(s) and/or the Test System.
8	When applicable, the Trainer signs and dates the completed Training Verification Form to indicate that remedial training has been completed successfully and the trainee has demonstrated mastery of the knowledge, skills and abilities required to perform the procedure(s) and/or Test System.
9	The delegated Supervisor reviews the training documentation and Assessment of Remedial Training and signs and dates the completed Training Verification Form signifying that the trainee is fully re-trained and meets current learning objectives for the Test System.

6.5 Organization of Manual or Paper Training Records

Step	Action
1	File the department Training Plan and Training Modules separately from individual employee training records.
2	File completed Training Verification documents in a manner that is consistent and ensures that individual employee records can be readily retrieved. <ul style="list-style-type: none"> • Completed Training Verification records may be sorted and filed in the following manner: <ul style="list-style-type: none"> • By employee name and then by Training Module (Test System) or • By Training Module and then by employee name. <p>NOTE: It is not necessary to keep copies of routine records used to evaluate the initial performance assessment as long as the details of successfully completed runs or tasks are traceable to the original source document (i.e., documented using batch numbers, dates, or other traceable information).</p>
3	File completed Training Verification documents separately from competency assessment documentation.
4	File Training Updates chronologically.

Step	Action
5	Current Training records must be readily available in the laboratory
6	File inactive/outdated Training records separately from the current/active records and retain according to the Quest Diagnostics Retention Policy

6.6 Process for Revised or Updated Procedures

Step	Action
1	The Trainer or delegated Supervisor reviews procedural changes or revisions with all trained employees. <ul style="list-style-type: none"> For most changes this may be accomplished during department meetings, a quick in-service or brief explanation with trained employees. Documentation can be accomplished using an EDCS/SmartSolve/MTS Assessment or Training Update Form. <p>NOTE: When/if extensive changes to a procedure or Test System necessitate re-training, new Training Verifications must be completed for all previously trained employees. Do not use the Assessment or Training Update Form.</p>
For departments using manual or paper methods:	
2	Trained employees must read the procedural revisions
3	Trained employees sign and date the Training Update Form, acknowledging they have read and understand the changes in the specified procedure(s).
4	A single Training Update may be used for processes that affect multiple SOPs on an on-going basis (e.g., all department SOPs are renumbered or reformatted but content is not changed). In these cases, it is not necessary to issue a Training Update for each individual SOP.
5	Other documentation, such as an email communication, is an acceptable format provided a copy is retained with other department training records.
For departments using EDCS/SmartSolve:	
6	Create an EDCS/ SmartSolve Assessment for revisions or changes to procedures (e.g., added, deleted, reformatted or moved information).
7	Develop questions to test the employee's knowledge of the revisions. Refer to SmartSolve process documents for using the Assessment tool.
8	Trained employees are notified that an Assessment has been assigned.
9	Employees complete the assigned SmartSolve quiz, results are evaluated by SmartSolve, and notification is sent to the applicable Supervisor. Refer to SmartSolve process documents for details.
10	If a passing grade is not obtained, the Supervisor must evaluate the employee's understanding of the changes and then initiate a new Assessment.
Local MTS Process:	
11	Create an MTS Update/Assessment for revisions or changes to procedures (e.g., added, deleted, reformatted or moved information).
12	Develop questions to test the employee's knowledge of the revisions.
13	Trained employees are notified that an Update has been assigned.
14	Employees complete the assigned MTS procedure review and quiz, and results are evaluated by MTS.

Step	Action
15	If a passing grade is not obtained, the Supervisor must evaluate the employee's understanding of the changes and then re-assign the Assessment. Refer to MTS procedure for details.

7. PROCEDURE NOTES

N/A

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 Policy for Authorization of Job Duties (QDNQA738)
- Quest Diagnostics Policy for Competency Assessment (QDNQA737)
- Quest Diagnostics Training Plan: Non-Testing Personnel Form (QDNQA332)
- Quest Diagnostics Training Plan: Testing Personnel Form (QDNQA330)
- Training Update Form (QDNQA334)
- Training Verification Form: Non-Testing Personnel (QDNQA333)
- SmartSolve Training Documents for Users
- Medical Training Solutions (MTS), local Laboratory procedure

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 Laboratory Accreditation Checklists

11. DOCUMENT HISTORY

Version	Date	Revision (Immediate retired and prior two versions)	Revised By
2	4/19/17	Updated entire document: <ul style="list-style-type: none"> • To include MediaLab for electronic documentation of competency • To be consistent with changes to the Policy for Delegation of Responsibilities • To be consistent with changes to the Policy for Competency Assessment 	K. Grimes/ G. Troutman
2	6/20/17	Remove references to MediaLab throughout Page 1: Add Local Effective Date message 2: Add note for local departments 3: Delete Cytology 4,6.6, 9: Add MTS 6.1: Add local forms 9: Add local SOP 12: Add local forms	L Barrett

12. APPENDICES

Appendices	Title
A	Training Plan template (see Attachment Pane in SmartSolve)
B	Training Verification template (see Attachment Pane in SmartSolve)

