

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 Training Verification GEC / SGAH / WAH. QDNQA736 v1.1

Description of change(s):

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

Training for technical areas will now be broken down by Test System (not by bench), refer to definition in SOP and section 6.1

The **basic** form is the same. Changes to the form include:

- There is a form for Testing Personnel and a form for Non-Testing Personnel
- Some additional fields are provided on the new forms
- There is 1 form for all types of training (initial, remedial and for previously trained employees)
- Verbiage for the Initial Performance Assessment is modified
- An employee (trainee) attestation and signature are new fields
- A Trainer attestation has been added
- The Laboratory Director/Designee signature includes verbiage that the employee demonstrates satisfactory performance after training.
- The form includes a field to document if the trainee requires supervision.

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 Training Verification	
Prepared by	Kathy Grimes	Date: 10/8/15

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 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
 - Point-Of-Care testing sites
- 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
 - Client Services
 - Patient Services
 - Information Technology (IT).

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: 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 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 training is documented according to this policy • Signs Training Verification forms
Delegated 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 is capable of performing and understands 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

- **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.
- **Electronic Document Control System (EDCS):** A computer system used to track and store electronic documents, such as SOPs. Medical Training Solutions (MTS)
- **EDCS or SmartSolve or Medical Training Solutions (MTS) Assessment:** Electronic documentation that an employee has knowledge of changes or revisions to a procedure. The assessment is in the form of a question or attestation statement.
- **Learning Objectives:** 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 measurable outcomes that are desired when training is complete.
- **Performance Assessment:** Evaluation of the trainee that demonstrates they can perform all testing operations reliably to provide and report accurate results.
- **Previously Trained Employee:** An employee without documentation of initial training or 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.
- **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.
- **Training Plan:** A documented list all of the Training Modules and their associated Test Systems that exist in a department. It serves as a "Table of Contents" for the more detailed 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 Verification Form:** Written documentation that training objectives have been met and that the training process for a specific Test System is complete.

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

5. POLICY

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

- Training on all applicable procedures must be completed and documented prior to the performance of 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.
 - 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.
 - Revisions are made to existing procedures. Prior to performing the 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.
 - Documentation of training is not available for a currently trained employee

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 Training Verification forms.
- 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. NOTE: The delegated Technical Supervisor, Technical Consultant, or Pre-/Post-Analytical Manager for this individual may sign the Training Verification form as both Trainer and Supervisor.
 - An individual who developed or validated the new method or process. NOTE: The delegated Technical Supervisor, Technical Consultant, or Pre-/Post-Analytical Manager for this individual may sign the Training Verification form as both Trainer and Supervisor.
 - 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). NOTE: Training Verification forms and Competency Assessment are not required for the delegated individual unless he/she actually performs all or part of the Test System.

6. PROCESS

6.1. General Training Program Requirements

6.1.1. Define Test Systems in each department

- Group all pre-analytic, analytic, and post-analytic tasks and processes used to produce a test result or set of results.

6.1.2 Create a Training Module for each Test System

- List all procedures required to perform the Test System on the applicable/appropriate standard template for Testing Personnel or Non-Testing Personnel (QDNQA330 or QDNQA332). Include the title and SOP identifier on this form.
- Name each Training Module using terminology that clearly describes the Test System. The Test System/ Training Module may be numbered to facilitate tracking. This is optional.
- Use the name of the Test System/Training Module consistently on all Training and Competency documents.
- 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.
- It is acceptable to create special Training Modules to cover general or advanced training requirements, such as general quality control requirements, advanced maintenance procedures, or common procedures that are used across multiple Test Systems (e.g., microbial identification/susceptibility procedures).

6.1.3 Create a Training Plan that lists all the Test Systems/Training Modules in a department

6.1.4 Create a Training Verification Form for each Test System/Training Module using the appropriate template for Testing Personnel and/or Non-Testing Personnel (QDNQA331 and QDNQA333)

- List specific learning objectives for the Test System/Training Module
- The first learning objective must always document that the trainee “Reads and understands procedures associated with the Test System”
- The second learning objective must always document that the trainee “Understands and adheres to applicable safety policies”
- The document must always include assessment of the trainee/employee’s initial training
- The form must also specify if the trainee requires supervision for specimen processing, test performance or result reporting.

6.1.5 Initial Training Assessment

- Determine which of the following training assessment tools are most appropriate for ensuring that each learning objective is met:
 - 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)
- It is not necessary to use all assessment tools for each individual learning objective.
- Define which tools will be used to assess and demonstrate that the trainee can perform all tasks and testing operations reliably such that he/she can provide and report accurate results.
- Details of successfully completed test runs or tasks must be documented using batch numbers, dates, or other traceable information.
Note: 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 form.

6.1.6 Previously Trained Employees

- 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

6.1.7 Remedial Training

- 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

6.1.8 Updates to Procedures

- Create an EDCS/ SmartSolve Assessment or Training Update Form (QDNQA334) to document training for revisions or changes to procedures (e.g., added, deleted, reformatted or moved information).
 - **SmartSolve Assessment:** Develop questions to test the employee's knowledge of the revisions. Refer to SmartSolve process documents for using the Assessment tool.
 - **Training Update Form:** Specify the applicable Test System and describe or list the change(s) to an SOP based on revisions listed in the Document History.
- These changes typically do not require complete retraining, and usually involve only a quick in-service or brief explanation.
- 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
- Other documentation, such as an email communication, is an acceptable format provided a copy is retained with other department training records.

6.2 Process for Initial Training

Step	Action
1	The Trainee must read all procedures listed in the Training Module for the Test System.
2	The Trainee observes the performance of all procedural steps associated with the training module as performed by a qualified Trainer.
3	The Trainee practices the Test System while being observed and instructed by a qualified Trainer.
4	The Trainee and Trainer initial and date each Learning Objective as it is completed.
5	The Trainer uses training assessment tools to evaluate the trainee's progress toward completing all required learning objectives.
6	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 the Training Verification Form(s) is complete.
7	The Trainee signs and dates the completed Training Verification Form to indicate they have had sufficient training and are confident to perform the procedure(s) and/or the Test System.
8	The Trainer signs and dates the completed Training Verification Form to indicate that 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 Laboratory Director or delegated Supervisor reviews the training documentation and Assessment of Initial Training. Indicate on the Training Verification Form if supervision is required for any phase of the testing process (i.e., (specimen processing, test performance and/or result reporting)).
10	The Laboratory Director or delegated Supervisor signs and dates the completed Training Verification Form(s) as verification 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 Employee

Step	Action
1	The Trainer or delegated Supervisor ensures that previously trained employees have met all learning objectives described on the Training Verification Form(s) by reviewing the procedures and current learning objectives with the previously trained employees.
2	The Trainer or delegated Supervisor must use the training assessment tools to evaluate the previously trained employee's understanding of current learning objectives based on current performance of the Test System.
3	Perform and document supplemental training if gaps in previous training are identified.
4	The Trainee and Trainer or delegated Supervisor initial and date each Learning Objective as it is completed.
5	The delegated Supervisor documents the outcome of the Performance Assessment and ensures that all learning objectives have been successfully completed and documented on the Training Verification Form(s) for Previously Trained Employees.
6	The Trainee signs and dates the completed Training Verification Form to indicate they have had sufficient training and are confident to perform the procedure(s) and/or the Test System.
7	When applicable, the Trainer signs and dates the completed Training Verification Form to indicate that 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 training documentation and Assessment of Initial Training. They then sign and date the completed Training Verification Form(s) to signify that the trainee is fully trained, demonstrates satisfactory performance, and is approved to perform the procedure and/or Test System.

6.4 Process for Remedial Training

Step	Action
1	The Trainer or delegated Supervisor ensures that the employee meets all of the learning objectives described on the Training Verification Form(s) by reviewing the procedure(s) and current learning objectives with the employee.
2	The Trainer or delegated Supervisor documents specific areas that address the deficiencies identified during competency assessment or other reasons for 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 training assessment tools.
4	The Trainee and Trainer initial and date each Learning Objective as it is completed.

Step	Action
5	The delegated Supervisor documents the outcome of the Performance Assessment and ensures that all learning objectives have been successfully completed and documented on the Training Verification Form(s) for Previously Trained Employees.
6	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.
7	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.
8	The delegated Supervisor reviews the training documentation and Performance Assessment and signs and dates the completed Training Verification Form(s) to signify that the trainee is fully re-trained and meets current learning objectives for the Test System.

6.5 Process for Procedure Updates

Step	Action
1	<p>The Trainer or delegated Supervisor reviews procedural changes or revisions with all trained employees. For most changes this may be accomplished during department meetings, a quick in-service or brief explanation with trained employees. Documentation of this can be accomplished using an EDCS/SmartSolve/MTS Assessment or Training Update Form.</p> <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>
2	<p>SmartSolve Assessment:</p> <ul style="list-style-type: none"> • Trained employees are notified that an Assessment has been assigned. • 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. • If a passing grade is not obtained, the Supervisor must evaluate the employee's understanding of the changes and then initiate a new Assessment.
3	<p>MTS Assessment:</p> <ul style="list-style-type: none"> • Trained employees are notified that an Assessment has been assigned. • Employees complete the assigned MTS procedure review and quiz, and results are evaluated by MTS. • If a passing grade is not obtained, the Supervisor must evaluate the employee's understanding of the changes and then initiate a new Assessment. Refer to MTS procedure for details.
4	<p>Training Update:</p> <ul style="list-style-type: none"> • Trained employees read the procedural revisions • Trained employees sign and date the Training Update Form, acknowledging they have read and understand the changes in the specified procedure(s).

6.6 Organization of Training Documents

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. 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).
3	File completed Training Verification documents separately from competency assessment documentation.
4	File Training Updates chronologically.
5	Current Training records must be readily available in the laboratory
6	File inactive/outdated Training records separately from the current/active records.

7. RECORDS MAINTENACE

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

8. RELATED DOCUMENTS

- Quest Diagnostics Policy for Authorization of Job Duties
- Quest Diagnostics Policy for Competency Assessment
- Training Plan: Non-Testing Personnel (QDNQA332)
- Training Plan: Testing Personnel (QDNQA330)
- Training Update Form (QDNQA334)
- Training Verification Form: Non-Testing Personnel (QDNQA333)
- Training Verification Form: Testing Personnel (QDNQA331)
- SmartSolve Training Documents for Users
- Medical Training Solutions (MTS), local QA procedure

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 Laboratory Accreditation Checklists

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	4, 6.5, 8	Add MTS	L Barrett	C Bowman
1	5/18/16	6.3,6.4	Correct step numbering	L Barrett	C Bowman

11. ADDENDA

Addendum	Title

