TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/1/2016
Department:	All staff	**Due Date:**	7/18/2016
		Implementation:	**7/18/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Policy for Authorization of Personnel GEC / SGAH / WAH. QDNQA739 v1.1

Description of change(s):

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

Authorization forms are used for Dr Cacciabeve to authorize lab staff to perform their assigned duties.

Current process:

We use a Job Authorization chart that lists all employees who work in a specific section. It is updated every 3 months. Chart is signed by the supervisor and Dr Cacciabeve after every change.

New process:

An Authorization Form is required for testing personnel (techs) and for Non-Testing Personnel who perform pre-analytic or post-analytic duties related to testing.

- It is signed once (upon employee hire) and anytime the employee's job duties or responsibilities change
- Both employee and Dr C must sign

Our lab will continue to use a Job Authorization chart as a quick reference to identify employees who are trained & competent to perform which tests / section / department area.

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 Authorization of Personnel**
Prepared by	Kathy Grimes **Date:** 11/19/15

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:** 12/7/15	
Print Name and Title	**Signature**	**Date**
Dianne Zorka Director, Corporate Quality Assessment **Kathleen Dwyer** Director, National Quality Assessment	*On file*	12/7/15
Ronald Kennedy, M.D. Sr Medical Director Medical Quality	*On file*	12/7/15

Retirement Date:	*Refer to the SmartSolve EDCS.*
Reason for retirement/replacement:	

Form ID: QDNQA305 v1 issued 8/05/13

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1. PURPOSE

This document sets forth the policy and process for the CLIA Laboratory Director to authorize individuals to perform their current duties and job responsibilities.

2. SCOPE

- This policy and process applies to personnel in departments under each CLIA license involved in any phase of the testing process (pre-analytic, analytic and post-analytic). This includes:
  - All Anatomic and Clinical testing departments including AmeriPath and Dermpath Diagnostics laboratories.
  - Specimen Processing
  - Referral Testing
  - Technical Operations
  - Point of Care Testing
- This policy and process does not apply to the following:
  - Warehouse/Materials Management
  - Logistics
  - Client Services
  - Patient Services
  - Information Technology

  Notes: At 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	• Approves the initial document and any subsequent revisions. • Authorizes appropriately trained and qualified individuals to perform pre-analytic, analytic, and post-analytic duties. • Ensures test systems and associated records of employee Training and Competency are maintained by delegated individuals • Signs Authorization Documents. • Ensures adequate continuing clinical laboratory education programs are available for all personnel.
Laboratory Director or Designee	• Recurring review of this SOP
Technical Supervisor	• Implements this process in the area(s) for which he/she is responsible. • Ensures applicable documentation of education, experience, and certification is on file according to standard practice. • Ensures that each authorized individual successfully completes the appropriate training • Ensures employee training records include the level of supervision required, when applicable. • Ensures each authorized individual demonstrates competency to perform the applicable test systems.
Pre-analytical/Post-analytical Department Manager	• Implements this process in the area(s) for which he/she is responsible. • Ensures applicable documentation of education, experience, and certification is on file according to standard practice. • Ensures that each authorized individual has successfully completed the appropriate training and demonstrates competency to perform the applicable job assignments for pre-analytical or post-analytical processes.
Quality Assurance Department	• Ensures that all Authorization Documents have Laboratory Director approval signature • Ensures the original signed Authorization Document is retained according to local document control practice • Ensures retired (inactive) Authorization Documents are archived according to record retention policy

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4. DEFINITIONS

- **Laboratory Director:** An individual qualified to manage and direct laboratory personnel and the performance of moderate complexity or high complexity test performance. The individual who is responsible for the overall operation and administration of the laboratory, including provision of timely, reliable and clinically relevant test results and compliance with applicable regulations and accreditation requirements. This individual is listed on the laboratory's CAP and CLIA certificate (as applicable).
- **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
- **Testing Personnel**: Individuals responsible for performing laboratory assays and reporting laboratory results
- **High Complexity Testing:** Rating given by the FDA to commercially marketed in vitro diagnostic tests based on their risks to public health. Tests in this category are seen to have the highest risks to public health
- **Moderate Complexity Testing:** Rating given by the FDA to commercially marketed in vitro diagnostic tests based on their risks to public health
- **Non-testing Personnel:** Individuals responsible for performing pre-analytic and/or post-analytic tasks which are not technical in nature.

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

5. POLICY FOR AUTHORIZATION OF PERSONNEL

The laboratory director is responsible for the overall operation and administration of the laboratory. This includes the employment of personnel who are competent to perform test procedures, record and report test results, and for assuring compliance with all applicable regulations.

The laboratory director ensures sufficient numbers of personnel with appropriate educational qualifications, experience, training and competency to meet the needs of the laboratory.

- Each Laboratory Director must document that testing and non-testing personnel involved in pre-analytic, analytic, and post-analytic phases of testing are authorized to perform their assigned duties and responsibilities in the laboratory for which he/she holds a CLIA license and/or CAP certificate.

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6. PROCESS FOR AUTHORIZATION OF PERSONNEL DUTIES

6.1 Testing Personnel

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>According to standard practice, file and maintain documentation of education, experience, certification (if applicable) and training for each employee involved in pre-analytic, analytic or post-analytic processes.</td></tr>
<tr><td>2</td><td>Choose the appropriate Authorization Form according to level of test complexity. Refer to Related Documents.</td></tr>
<tr><td>3</td><td>Enter the printed name of the employee and the printed name of the Laboratory Director on the form.</td></tr>
<tr><td>4</td><td>The Laboratory Director evaluates and verifies that each employee has appropriate education, experience, training, and certification (if applicable) for the level of testing.</td></tr>
<tr><td>5</td><td>The Laboratory Director signs and dates the Authorization Form, indicating the employee is authorized to perform the duties and responsibilities of testing personnel.
NOTE: This is a one time approval by the Laboratory Director and it may be completed at the time of hire.</td></tr>
<tr><td>6</td><td>Employee signs and dates the Authorization Form as confirmation that they understand their duties and responsibilities as testing personnel.</td></tr>
<tr><td>7</td><td>Place the original signed and dated Authorization Form under document control according to local practice (place in employee personnel file). Controlled copies specific to the applicable department must be available to each department.</td></tr>
<tr><td>8</td><td>Update the form <u>only</u> when or if an employee’s responsibilities and/or duties change Example:

<table><tr><th>If</th><th>Then</th></tr><tr><td>The employee is authorized to perform high complexity testing and is trained on a new test / bench</td><td>No new authorization is required</td></tr><tr><td>The employee is authorized to perform moderate complexity testing and is trained on a new high complexity test / bench</td><td>A new authorization is required</td></tr></table></td></tr>
<tr><td>9</td><td>Retire Authorization forms:
When an employee form is updated (see step 8)
When an employee leaves the company</td></tr>
<tr><td>10</td><td>Archive retired delegation documents according to standard record retention guidelines.</td></tr>
</table>

6.2 Non-Testing Personnel

Step	Action
1	According to standard practice, file and maintain documentation of training and any applicable experience and/or educational certification (if applicable) for each employee involved in pre-analytic or post-analytic processes.
2	Complete an appropriate Authorization Form for each employee. Refer to Related Documents.
3	Enter the printed name of the employee and the printed name of the Laboratory Director on the form.
4	The Laboratory Director evaluates and verifies that each employee has appropriate training, and education or certification (if applicable).
5	The Laboratory Director signs and dates the Authorization Form, indicating the employee is authorized to perform the pre-analytic or post-analytic duties associated with their job. NOTE: This one time approval by the Laboratory Director may be completed at the time of hire.
6	Employee signs and dates the Authorization Form as confirmation that they understand their duties and responsibilities.
7	Place the original signed and dated Authorization Form under document control according to local practice (place in employee personnel file). Controlled copies specific to the applicable department must be available to each department.
8	Update form only when or if an employee's responsibilities and/or duties change.
9	Retire Authorization Forms: • When an employee form is updated (see step 8) • When an employee leaves the company
10	Archive retired delegation documents according to standard record retention guidelines.

6.3 Job Authorization Summary (Local Process)

Step	Action
1	The Job Authorization Summary is a tool used as a quick aid to track which staff are trained for benches or areas. The summary includes • Employee names • Test systems / Training modules (must match the Training Plan) • Key for performance levels • Signature space for supervisor / manager and medical director
2	The summary is updated at least quarterly
3	Signed and dated Job Authorization Summaries are scanned and retained electronically on a shared drive.

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7. RECORDS MAINTENANCE

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

8. RELATED DOCUMENTS

- Authorization To Perform High Complexity Testing Form (QDNQA337)
- Authorization To Perform Histology or POC Testing Form (QDNQA339)
- Authorization To Perform Moderate Complexity Testing Form (QDNQA338)
- Authorization For Non-Testing Personnel (QDNQA340)
- Quest Diagnostics Policy for Competency Assessment (QDNQA737)
- Quest Diagnostics Policy for Delegation (QDNQA738)
- Quest Diagnostics Policy for Training Verification (QDNQA736)
- Job Authorization Summary (AG.F353)

9. REFERENCES

1. Code of Federal Regulations CLIA Public Health 42 CFR Part 493
2. 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	6.1,6.2	Add local filing process	L Barrett	C Bowman
1	5/18/16	6.3	Add local process for authorization summary	L Barrett	C Bowman
1	5/18/16	8	Add local form	L Barrett	C Bowman

11. ADDENDA

Addendum	Title

AUTHORIZATION TO PERFORM HIGH COMPLEXITY TESTING

As Laboratory Director, I authorize the following qualified, individual to perform the duties of Testing Personnel as specified in CLIA CFR 493.1495 for High Complexity Testing (below*). The individual is approved to assume duties and responsibilities associated with test systems on which they are trained and competent.

- Test systems and associated records of Training and Competency are on file in the testing department. When applicable, the level of supervision required is maintained with these records.
- Records of Continuing Education are on file according to standard to standard laboratory or departmental practice.
- Quest Diagnostics Standard Job Description for this employee specifies current duties and responsibilities.
- All other required personnel records are on file according to standard Quest Diagnostics HR practices

Laboratory Director Name (*print*)**:** _____

Laboratory Director Signature: _____ **Date:** _____

I understand and will fulfill the responsibilities of Testing Personnel as established by CLIA standard CFR 493.1495 (below*):

Employee Name (*print*)**:** _____

Employee Signature: _____ **Date:** _____

***493.1495 STANDARD; TESTING PERSONNEL RESPONSIBILITIES.**

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing high complexity testing must-(b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(b)(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(b)(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(b)(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

(b)(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and

(b)(7) Except as specified in paragraph (c) of this section, if qualified under §493.1489(b)(5), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under §493.1461.

(c) Exception. For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

AUTHORIZATION FOR NON-TESTING PERSONNEL

As Laboratory Director, I authorize the following qualified, trained individual to perform pre-analytic and/or post-analytic tasks that are not technical in nature. They are approved to assume duties and responsibilities associated with tasks and/or test systems on which they are trained and competent.

- Quest Diagnostics Standard Job Description for this employee specifies current duties and responsibilities.
- Records of Training, Competency Assessment, and Continuing Education are on file in the testing department or with other required personnel records according to standard Quest Diagnostics HR practices

Laboratory Director Name: _____

Laboratory Director Signature: _____ **Date:** _____

I know and will fulfill the duties and responsibilities associated with tests and tasks on which I am trained.

Employee Name: _____

Employee Signature: _____ **Date:** _____

Job Authorization Summary

Laboratory: Adventist Hospitals
Shady Grove and Washington Adventist Hospitals

Department: Technical Lab

1 of

Module #	Test System	Employees																							

Performance Level

1. Specimen collection, transport, labeling, processing
2. Test set-up, basic testing processes. Cannot make decisions regarding result release.
3. Performs all phases of testing, makes decisions regarding result release.
4. Performs duties of Group Lead in his/her absence
5. Makes supervisory decisions, monitors results, oversees remedial actions, explains test information using official sources

T = Training: Supervision required during job performance

The employees listed above have been trained and are competent to perform job assignments at the level indicated:

Technical Supervisor Signature _____ Date _____

Blood Bank Supervisor Signature _____ Date _____

The employees listed above are authorized to perform the duties and assume responsibilities as indicated:

Laboratory Director Signature _____ Date _____

Job Authorization Summary

Laboratory: Adventist Hospitals **Department:** Phlebotomy

Shady Grove and Washington Adventist Hospitals 1 of

		Employees																						
Module #	**Training Module Name**																							

1- Specimen collection, transport, labeling, processing, ordering

2- Test set-up, basic testing processes. Cannot make decisions regarding result release.

3- Performs all phases of testing, evaluates test integrity and takes appropriate action, documents results.

4- Performs duties of Group Lead in his/her absence.

5- Makes supervisory decisions, monitors outcomes and oversees remedial actions

The employees listed above have been trained and are competent to perform job assignments at the level indicated:

Supervisor Signature _____ Date _____

The employees listed above are authorized to perform the duties and assume responsibilities as indicated:

Laboratory Director Signature _____ Date _____

Job Authorization Summary

Laboratory: Adventist Hospitals **Department:** Client Services / Specimen Processing
Shady Grove and Washington Adventist Hospitals 1 of

Module #	Training Module Name	Employees																							

Performance Level

1- Performs ordering and all phases of report-processing

2- Specimen collection, transport, labeling, processing, communicating orders & results.

3- Processes specimen for testing, prepares aliquots and send outs

4- Performs duties of Group Lead in his/her absence.

5- Makes supervisory decisions, monitors results, oversees remedial actions

T - Training: Supervision required during job performance.

The employees listed above have been trained and are competent to perform job assignments at the level indicated:

Supervisor Signature _____ Date _____

The employees listed above are authorized to perform the duties and assume responsibilities as indicated:

Laboratory Director Signature _____ _____