

## TRAINING UPDATE

**Lab Location:** SGMC, WAH & GEC  
**Department:** Mgmt & QA

**Date Distributed:** 12/17/2018  
**Due Date:** 12/31/2018  
**Implementation:** 12/20/2018

### DESCRIPTION OF REVISION

#### Name of procedure:

**Performance Assessment of Delegated Duties SGAH.QA1022 v0**  
**Clinical Consultant Performance Assessment Form AG.F246**  
**General Supervisor Performance Assessment Form AG.F247**  
**Technical Supervisor / Technical Consultant Performance Assessment Form AG.F248**

#### Description of change(s):

This is a 'new' SOP that replaces our previous NQA version. It is very similar to the old SOP but has been converted to our local SOP format. The biggest changes:

- Frequency has been changed from annual to every 2 years
- Added requirement to assess clinical consultants (pathologists)

The assessment form for General Supervisor and Technical Supervisor/Consultant were given our document control numbers (no change to content). QA will continue to coordinate assuring these get completed by tracking on the recurring calendar.

The Clinical Consultant Assessment Form is new; Dr C will have to complete these for pathologists.

**These documents will be implemented on December 20, 2018**

**Document your compliance with this training update by taking the quiz in the MTS system.**

Non-Technical SOP

<b>Title</b>	<b>Performance Assessment of Delegated Duties</b>	
<b>Prepared by</b>	Leslie Barrett	Date: 11/30/2018
<b>Owner</b>	Cynthia Bowman-Gholston	Date: 11/30/2018

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

<b>Review:</b>		
<b>Print Name</b>	<b>Signature</b>	<b>Date</b>

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**1. PURPOSE**

This document sets forth the policy for assessment of duties delegated by the CLIA Laboratory Director in Quest Diagnostics laboratories. This document also specifies the processes required for performing this assessment.

**2. SCOPE**

This policy applies to:

- Designated personnel in Clinical testing departments
- All Clinical Consultants, Technical Supervisors, Technical Consultants and General Supervisors
- Assessors delegated to perform competency
- All duties and responsibilities delegated to these individuals by the CLIA Laboratory Director

**3. RESPONSIBILITY**

Responsible Party	Task
<b>Laboratory Director</b>	<ul style="list-style-type: none"> <li>• Approval of the initial document and any subsequent revisions</li> <li>• Ensuring compliance with this policy in his/her laboratory</li> <li>• Ensuring all delegated duties are properly performed</li> <li>• Assessment of duties and responsibilities delegated to any of the following qualified individuals:                             <ul style="list-style-type: none"> <li>• Clinical Consultant</li> <li>• Technical Supervisor</li> <li>• General Supervisor</li> </ul> </li> </ul>
<b>Technical Supervisor or Technical Consultant</b>	<ul style="list-style-type: none"> <li>• Implementing this policy in the department for which he/she is responsible</li> <li>• Ensuring General Supervisor and Assessor compliance with this policy</li> </ul>

Responsible Party	Task
Department Manager/Supervisor	<ul style="list-style-type: none"> <li>• Periodic review of records as specified</li> <li>• Ensuring compliance with this policy in their department</li> </ul>
Quality Assurance Department	Ensuring that all assessments are completed

#### 4. DEFINITIONS

Term	Definition
<b>Assessor (technical)</b>	<p>Qualified individuals who are delegated to perform competency assessment functions.</p> <ul style="list-style-type: none"> <li>• In laboratories that perform <u>only</u> moderate complexity testing the individuals must meet the qualifications of a Technical Consultant (i.e., 4 years of education and 2 years of experience in the specialty)</li> <li>• In laboratories that perform high complexity testing the individual must meet the qualifications of a General Supervisor (i.e., 2 years of education and 2 years of experience in the specialty)                             <ul style="list-style-type: none"> <li>• If the same laboratory also performs moderate complexity testing, the Assessor for only these tests must qualify as a Technical Consultant</li> </ul> </li> </ul>
<b>Clinical Consultant</b>	Qualified individuals who are delegated to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment, and management of patient care.
<b>General Supervisor</b>	Qualified individual( who, under the direction of the Laboratory Director and supervision of the Technical Supervisor, are delegated to provides day-to-day supervision of testing personnel and reporting of test results for <b>high</b> complexity testing
<b>High Complexity Testing</b>	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
<b>Laboratory Director</b>	An individual qualified to manage and direct laboratory personnel and the performance of <b>moderate complexity or high complexity test</b> performance. This individual 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 CLIA and CAP certificate (as applicable).
<b>Moderate Complexity Testing</b>	Rating given by the FDA to commercially marketed in vitro diagnostic tests based on their risks to public health.
<b>Technical Consultant</b>	Qualified individuals who are delegated to provide technical consultation for each of the specialties and subspecialties of service in laboratories performing <b>moderate</b> complexity tests or procedures.
<b>Technical Supervisor</b>	Qualified individuals who are delegated to provide technical consultation for each of the specialties and subspecialties of service in laboratories performing <b>high</b> complexity tests or procedures.

## 5. POLICY

The Laboratory Director must ensure that delegated functions or responsibilities are properly performed and satisfactory.

- If the laboratory director has delegated any duties he/she remains responsible for ensuring that all duties are properly performed
- Delegated duties and responsibilities must be assessed at least every two years.
- Unsatisfactory performance must be addressed in a corrective action plan.
- Corrective action(s) taken in response to any deviation from the expected performance must be documented.
- Ongoing performance must be monitored for a prescribed interval to ensure proper performance of delegated duties.
- In addition to assessment of delegated duties, Clinical Consultants, Technical Consultants, Technical Supervisors, and General Supervisors who perform testing on patient specimens must also have competency assessment on each test system and it must include all six required elements.

## 6. PROCESS

### 6.1 CLINICAL CONSULTANT

Step	Action
1.	<b>Laboratory Director</b> evaluates the performance of the <b>Clinical Consultant</b> on each of the following delegated duties, as applicable for the individual: <ul style="list-style-type: none"><li>• Ensure that test reports include all pertinent information required for specific patient interpretation.</li><li>• Provide availability for consultation and ensure that the appropriate tests are ordered to meet the clinical expectations.</li><li>• Provide communication with laboratory clients on quality of test results reported and their interpretation concerning specific patient conditions.</li></ul>
2.	Document the assessment on the Clinical Consultant Performance Assessment Form (AG.F426). Documentation must include deviations, if indicated.
3.	The Laboratory Director and the assessed individual sign and date the Performance Assessment Form.

## 6.2 TECHNICAL SUPERVISOR

Step	Action
1.	<p><b>Laboratory Director</b> evaluates the performance of the <b>Technical Supervisor</b> on each the following delegated duties, as applicable for the individual:</p> <ul style="list-style-type: none"> <li>• Ensuring technical and scientific oversight. Selects test methodology and equipment that is appropriate for the clinical use of test results.</li> <li>• Ensuring method validations are complete and submitted to the laboratory director for approval.</li> <li>• Ensuring enrollment in proficiency testing surveys and that alternative performance assessment is performed, as needed.                             <ul style="list-style-type: none"> <li>○ Ensuring these are performed appropriately and submitted on time.</li> <li>○ Reviews proficiency testing or alternative assessment results and approves corrective actions for failures.</li> </ul> </li> <li>• Establishing department Quality Control (QC) and Quality Management (QM) programs with documentation of on-going review.                             <ul style="list-style-type: none"> <li>○ Ensures implementation, documentation and review of corrective actions for failures in QC, major equipment and/or failures to meet QM goals.</li> </ul> </li> <li>• Ensuring department training and competency programs are established and maintained.</li> <li>• Ensuring that each individual performing testing receives regular in-service training and education appropriate for the services performed.</li> <li>• Ensuring procedures are complete, reflect current practices and have been approved by the Laboratory Director.</li> </ul>
2.	Document the assessment on the Technical Supervisor / Technical Consultant Performance Assessment Form (AG.F428). Documentation must include deviations, if indicated.
3.	The Laboratory Director and the assessed individual must sign and date the Performance Assessment Form.

## 6.3 TECHNICAL CONSULTANT

Step	Action
1.	<p><b>Laboratory Director</b> evaluates the performance of the <b>Technical Consultant</b> on each the following delegated duties, as applicable for the individual:</p> <ul style="list-style-type: none"> <li>• Ensuring technical and scientific oversight. Selects test methodology and equipment that is appropriate for the clinical use of test results.</li> <li>• Ensuring method validations are complete and submitted to the laboratory director for approval.</li> <li>• Ensuring enrollment in proficiency testing surveys and that alternative performance assessment is performed, as needed.                             <ul style="list-style-type: none"> <li>○ Ensuring these are performed appropriately and submitted on time.</li> <li>○ Reviews proficiency testing or alternative assessment results and approves corrective actions for failures.</li> </ul> </li> </ul>

Step	Action
	<ul style="list-style-type: none"> <li>• Establishing department Quality Control (QC) and Quality Management (QM) programs with documentation of on-going review.                             <ul style="list-style-type: none"> <li>○ Ensures implementation, documentation and review of corrective actions for failures in QC, major equipment and/or failures to meet QM goals.</li> </ul> </li> <li>• Ensuring department training and competency programs are established and maintained.</li> <li>• Performs competency assessment for testing personnel.</li> <li>• Ensuring that each individual performing testing receives regular in-service training and education appropriate for the services performed.</li> <li>• Ensuring procedures are complete, reflect current practices and have been approved by the Laboratory Director.</li> </ul>
2.	Document the assessment on the Technical Supervisor / Technical Consultant Performance Assessment Form (AG.F428). Documentation must include deviations, if indicated.
3.	The Laboratory Director and the assessed individual sign and date the Performance Assessment Form.

#### 6.4 GENERAL SUPERVISOR

Step	Action
1.	<p><b>Laboratory Director or Technical Supervisor</b> evaluates the performance of the <b>General Supervisor</b> on each the following delegated duties, as applicable for the individual:</p> <ul style="list-style-type: none"> <li>• Day to day operation of the department and supervision of testing personnel when performing testing and reporting test results.</li> <li>• Ensuring acceptable levels of pre-analytic, analytic and post-analytic performance are maintained for test analyses and specimen examinations.</li> <li>• All remedial actions are taken and documented when testing does not meet performance standards.</li> <li>• Ensuring that patient results are not reported until all corrective actions have been taken and testing is performed according to specifications.</li> <li>• Providing and documenting departmental orientation to all personnel.</li> <li>• Ensuring employees receive documented training from another individual (trainer) prior to performing patient testing.                             <ul style="list-style-type: none"> <li>○ The trainer must have completed training for the specific test/test system and be currently competent.</li> <li>○ The trainer does not have to be a supervisor.</li> </ul> </li> <li>• Managing and administering the department competency program and ensuring assessment of testing personnel.</li> </ul>
2.	Laboratory Director or Technical Supervisor documents assessment results on the General Supervisor Performance Assessment Form (AG.F427). Documentation must include deviations, if indicated.

Step	Action
3.	The Laboratory Director <u>or</u> Technical Supervisor and the assessed individual must sign and date the Performance Assessment Form.

## 6.5 ASSESSOR

Step	Action
1.	<p>The <b>Laboratory Director <u>or</u> Technical Supervisor</b> evaluates the performance of the <b>technical Assessor</b>. The <b>General Supervisor</b> evaluates the performance of the <b>non-technical Assessor</b>. Assess the following delegated duties, as applicable for the individual:</p> <p>Appropriately evaluates and documents competency assessment of personnel using the following:</p> <ol style="list-style-type: none"> <li>1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation, and specimen collection, handling, processing and testing</li> <li>2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results</li> <li>3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records</li> <li>4. Direct observation of performance of instrument maintenance and function checks</li> <li>5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples</li> <li>6. Evaluation of problem-solving skills</li> </ol>
2.	Assessment results are documented on the department's annual competency assessment forms. Documentation must include deviations, if indicated.
3.	The Laboratory Director <u>or</u> Technical Supervisor (technical staff) or General Supervisor (non-technical staff) and the assessed individual must sign and date the competency forms.

## 6.6 CORRECTIVE ACTION

- Corrective action(s) taken in response to any deviation from the expected performance must be documented.
- Ongoing performance must be monitored for a prescribed interval to ensure proper performance of delegated duties.

Step	Action
1.	<p>Document deviations from acceptable performance in the Corrective Actions section of the appropriate Assessment Form.</p> <p>Documentation must include:</p> <ul style="list-style-type: none"> <li>• Corrective action(s)</li> <li>• Training or supplementary education as required</li> </ul>



Step	Action
2.	Restrict/Limit the individual from performing specific delegated duties until competency of the specific task(s) is deemed acceptable.
3.	Provide specific (re)training &/or supplementary education to ensure proper performance of delegated duties. <ul style="list-style-type: none"> <li>• If an individual’s performance after retraining is deemed acceptable                             <ul style="list-style-type: none"> <li>○ Document acceptability</li> <li>○ Have individual resume delegated duties</li> <li>○ Monitor ongoing performance for a prescribed and specified interval to ensure proper performance of delegated duties.</li> </ul> </li> <li>• If an individual’s performance remains unacceptable after retraining then reappportion delegated duties that remain unacceptable to another qualified and competent individual</li> </ul>

**7. PROCEDURE NOTES**

Delegation of duties and responsibilities must be made to qualified individuals, but these individuals are not required to hold the job titles of Technical Supervisor, General Supervisor, and so forth.

**8. RELATED DOCUMENTS**

- *Policy for CLIA Personnel Qualifications*
- *Policy for Competency Assessment*
- *Policy for Delegation of Responsibilities*
- *Policy for Training Verification*
- Clinical Consultant Performance Assessment Form (AG.F426)
- General Supervisor Performance Assessment Form (AG.F427)
- Technical Supervisor / Technical Consultant Performance Assessment Form (AG.F428)

**9. REFERENCES**

1. Federal Register Code of Federal Regulations, Title 42, Part 493.
2. Laboratory General. College of American Pathologists, Laboratory Accreditation Program, Northfield, IL 60093.
3. New York State Department of Health Clinical Laboratory Standards of Practice. Part 1 General Systems.
4. Quest Diagnostics *Policy for Performance Assessment of Delegated Duties* (QDMOQ722)

**10. DOCUMENT HISTORY**

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAHQDNQA734v1.2		

**11. ADDENDA**

None

- Germantown Emergency Center
- Shady Grove Medical Center
- Washington Adventist Hospital

**GENERAL SUPERVISOR PERFORMANCE ASSESSMENT**

**Employee Name:** \_\_\_\_\_ **Department/Specialty** \_\_\_\_\_

Duties	Acceptable?		
	Yes	No	N/A
<b>Day to Day Oversight:</b> Provide day-to-day supervision of testing personnel when performing testing and reporting test results. Provide on-site, telephone, or electronic consultation to resolve technical problems.			
<b>Analytic Performance Monitoring:</b> Ensure acceptable levels of analytic performance are maintained for test analyses and specimen examinations.			
<b>Record Review:</b> Assure that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; Review (as delegated) weekly quality control, instrument function, preventive maintenance, and other laboratory records at least monthly and more often if required.			
<b>Corrective Actions:</b> Ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. Initially review and approve corrective action documentation to ensure it is complete and in accordance with laboratory and department policies.			
<b>Training:</b> Administer the departmental training program and ensure all employees receive documented training from another trained individual. Approve Training for all employees at the completion of the training process.			
<b>Competency Assessment:</b> Administer the department competency program and ensure that all employees are assessed by another trained individual using direct observation, record review, test performance, and assessment of problem-solving skills. Approve competency assessment documentation.			

**Employee Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Assessment:

- Employee meets job expectations.
- Employee meets job expectations with correctable deviations as documented below
- Employee does not meet expectations.

**Technical Supervisor/Laboratory Director:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Corrective Actions for Observed Deviations:**

Expectation	Corrective Action	Employee Initials

- Germantown Emergency Center
- Shady Grove Medical Center
- Washington Adventist Hospital

**TECHNICAL SUPERVISOR / TECHNICAL CONSULTANT PERFORMANCE ASSESSMENT**

**Employee Name:** \_\_\_\_\_ **Department/Specialty** \_\_\_\_\_

Duties	Acceptable?		
	Yes	No	N/A
<b>Technical and Scientific Oversight:</b> Provide on-site, telephone, or electronic consultation. Select test methodology that is appropriate for the clinical use of the test results.			
<b>Method Validation Studies:</b> Ensure that method validation studies are completed and submitted to Laboratory Director for approval. Ensure that laboratory personnel are appropriately trained prior to method implementation.			
<b>Proficiency Testing:</b> Ensure that approved proficiency testing surveys (PT) or alternative performance assessments (APA) are performed appropriately and submitted on time. Review department PT or APA results and approve corrective actions to failures and near misses.			
<b>Quality Control and Quality Management:</b> Establish department Quality Control (QC) and Quality Management (QM) programs and ensure that they are maintained.			
<b>Monthly QC/QM Review:</b> Perform high level review of quality control performance and QM programs. Establish and maintain acceptable levels of analytical performance for each test system.			
<b>Remedial/Corrective Action:</b> Review and approve documentation of corrective actions for QC failures, failure to meet established QM goals, Reportable Quality Issues (RQIs), and major equipment failures. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified; and that patient test results are reported only when the system is functioning properly.			
<b>Training:</b> Establish department training program and ensure that it is maintained. Assure that each individual performing testing receives regular in-service training and education appropriate for the services performed.			
<b>Competency Assessment:</b> Establish department competency program and ensure that it is maintained.			
<b>Recurring Procedure Review:</b> Ensure that approved procedures are available, complete, and reflect current practice. Submit SOPs to Laboratory Director for approval. Review SOPs at least annually/biennially.			

**Employee Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Assessment:

- Employee meets job expectations.
- Employee meets job expectations with correctable deviations as documented below
- Employee does not meet expectations.

**Laboratory Director:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Corrective Actions for Observed Deviations:**

Expectation	Corrective Action	Employee Initials

- Germantown Emergency Center
- Shady Grove Medical Center
- Washington Adventist Hospital

## CLINICAL CONSULTANT PERFORMANCE ASSESSMENT

**Employee Name:** \_\_\_\_\_ **Laboratory** *Indicate above* \_\_\_\_\_

Duties	Acceptable?		
	Yes	No	N/A
<b>Interpretation of Test Results:</b> Ensure that test reports include all pertinent information required for specific patient interpretation. These include explanatory medical interpretations added to the patient report.			
<b>Client Consultation:</b> Assist clients in ordering appropriate tests to meet clinical expectations, communicate with clients regarding the quality of test results and their interpretation concerning specific patient conditions.			

**Employee Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Assessment:

- Employee meets job expectations.
- Employee meets job expectations with correctable deviations as documented below
- Employee does not meet expectations.

**Laboratory Director:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Corrective Actions for Observed Deviations::**

Expectation	Corrective Action	Employee Initials