TRAINING UPDATE

Lab Location: Department: GEC, SGAH & WAH QA & Mgmt
 Date Distributed:
 11/3/2014

 Due Date:
 11/30/2014

 Implementation:
 12/1/2014

DESCRIPTION OF PROCEDURE

Name of procedure:

Performance Assessment of Technical Supervisor, Technical Consultant and General Supervisor Duties, Policy for GEC / SGAH / WAH.QDNQA734 v1.1

Technical Supervisor or Technical Consultant Performance Assessment Form (QDNQA318) **General Supervisor Performance Assessment Form** (QDNQA317)

Description of change(s):

New NQA policy that describes the performance assessment requirements for technical supervisors (TS), technical consultants (TC), and general supervisors (GS) for duties that have been delegated by the CLIA Laboratory Director.

CAP Checklist item: GEC.55525 Performance Assessment of Supervisors/Consultants The performance of section directors/technical supervisors, general supervisors, and technical consultants is assessed and satisfactory.

NOTE: All responsibilities of section directors (as technical supervisors in laboratories performing high complexity testing) and technical consultants (in laboratories performing moderate complexity testing, but not high complexity testing) must be delegated by the laboratory director in writing. Unsatisfactory performance must be addressed in a corrective action plan.

The assessment may take the form of a checklist or other written documentation of performance of responsibilities, as defined by the individual's job description.

This SOP will be implemented on December 1, 2014

TitlePolicy for Performance Assessment of Technical Supervisor,
Technical Consultant and General Supervisor Duties

Prepared byCorporate Quality AssessmentDate: 9/13/2014

Laboratory Approval	boratory 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:	10/6/2014
Print Name and Title	Signature		Date
Dianne Zorka, Director, Corporate			
Quality Assessment			
Owner	On file		10/1/2014
Lee Hilborne, M.D., MPH			
Corporate Medical Director,			
Clinical Pathology	On file		10/2/2014

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

TABLE OF CONTENTS

1.	PURPOSE	.2
2.	SCOPE	.2
3.	RESPONSIBILITY	.2
4.	DEFINITIONS	.3
5.	POLICY and PROCESS	.3
6.	RECORDS MAINTENANCE	.5
7.	RELATED DOCUMENTS	.5
8.	REFERENCES	.5
9.	DOCUMENT HISTORY	.5
10.	ADDENDA	.5

1. PURPOSE

This policy describes the performance assessment requirements for technical supervisors (TS), technical consultants (TC), and general supervisors (GS) for duties that have been delegated by the CLIA Laboratory Director.

2. SCOPE

- This policy applies to:
 - All Quest Diagnostics Clinical Pathology laboratories
 - All technical supervisors, technical consultants and general supervisors.
 - All duties and responsibilities delegated to these individuals by the CLIA Laboratory Director
- This policy does not apply to Quest Diagnostics Anatomic Pathology laboratories.

3. **RESPONSIBILITY**

- The **Laboratory Director** is responsible for:
 - Approval of the initial document and any subsequent revisions.
 - Ensuring compliance with this policy for technical supervisors and technical consultants.
 - If the Laboratory Director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.
- The **Laboratory Director or Designee** is responsible for the recurring review of this document.
- The **Technical Supervisor** is responsible for
 - Implementing this policy in the department for which he/she is responsible.
 - Ensuring compliance with this policy for general supervisor.

4. **DEFINITIONS**

- **General Supervisor:** Individual(s) qualified to provide day-to-day supervision of testing personnel and reporting of test results.
- **Laboratory Director:** Individual responsible for the overall operation and administration of the laboratory. This is the individual listed on the laboratory's CAP and/or CLIA certificate.
- **Technical Consultant:** Individual(s) qualified to provide technical consultation for each of the specialties and subspecialties of service in laboratories performing **moderate** complexity testing.
- **Technical Supervisor:** Individual(s) qualified to provide technical consultation for each of the specialties and subspecialties of service in laboratories performing **high** complexity testing

5. POLICY and PROCESS

The performance of delegated duties is assessed annually by the laboratory director.

A. <u>Technical Supervisor or Technical Consultant Assessment</u>

- 1. The laboratory director assesses the performance of the technical supervisor or technical consultant with respect to the following duties:
 - Provide technical and scientific oversight. Select test methodology that is appropriate for the clinical use of the test results.
 - Assure that method validation studies are completed and submitted to the Laboratory Director for approval.
 - Ensure that proficiency testing surveys or alternative performance assessments are performed appropriately, results reviewed and corrective action documented for PT failures and/or near miss evaluations.
 - Establishment and on-going review of department Quality Control and Quality Management programs. Review and approval of documentation of corrective actions for QC failures, failures to meet QM goals and major equipment failures.
 - Establishment of department training and competency programs. Assure that each individual performing testing receives regular in-service training and education appropriate for the services performed.
 - Assure approved procedures are available, complete and reflect current practice.
- 2. Assessments are documented on the Technical Supervisor or Technical Consultant Performance Assessment Form.
- 3. The Performance Assessment Form must be signed by the individual assessed and the laboratory director performing the assessment.

B. General Supervisor Assessment

- 1. The laboratory director or technical supervisor assesses the performance of the general supervisor with respect to the following duties:
 - Provide day-to-day supervision of testing personnel when performing testing and reporting test results.
 - Ensure acceptable levels of analytic performance are maintained for test analyses and specimen examinations.
 - All remedial actions are taken and documented when testing performance does not meet standards.
 - Ensure patient results are not reported until all corrective actions have been taken and test is performing according to specifications.
 - Provide departmental orientation to all new testing personnel.
 - Administer the departmental training program
 - Perform competency assessment on all testing personnel and non-testing personnel.
- 2. Assessments are documented on the General Supervisor Performance Assessment Form
- 3. The Performance Assessment Form must be signed by the individual assessed and the laboratory director or technical supervisor performing the assessment.

C. Corrective Action

- 1. Corrective action(s) taken in response to any deviation from the expected performance must be documented.
- 2. Ongoing performance must be monitored for a prescribed interval to ensure proper performance of delegated duties.
- 3. Specific (re)training and/or supplementary education may be required to ensure proper performance of delegated duties.
- 4. Reassignment of delegated duties, and / or removal from duty may be necessary as determined by the laboratory director in consultation with laboratory leadership and / or human resources

D. <u>New York State Requirements (if applicable)</u>

- Assessment of the ability of the supervisor to fulfill the responsibilities described under Human Resources Sustaining Standard of Practice 3 must be documented.
- Assessed responsibilities must include:
 - 1. Compliance with policies and procedures;
 - 2. Communication, including bringing problems and non-conformities to the attention of laboratory management;
 - 3. Leadership and problem-solving capabilities;
 - 4. Allocation of resources; and
 - 5. Personnel management

6. **RECORDS MAINTENANCE**

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

7. **RELATED DOCUMENTS**

- Quest Diagnostics *Training Verification* SOP (QDNQA600)
- Quest Diagnostics Authorization of Responsibilities and Job Duties SOP (QDNQA602)
- Quest Diagnostics *Competency Assessment* SOP (QDNQA601)
- Technical Supervisor or Technical Consultant Performance Assessment Form (QDNQA318)
- General Supervisor Performance Assessment Form (QDNQA317)

8. **REFERENCES**

- 1. Federal Register Code of Federal Regulations, Title 42, Part 493.xxxx
- 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, June 2014.

9. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1	10/14/14		Adopting corporate issued version 1.	L. Barrett	C. Bowman
		Cover	Add local Effective Date message		
		10	Remove table		

10. ADDENDA

None

TECHNICAL SUPERVISOR/TECHNICAL CONSULTANT ASSESSMENT

Employee Name:

Department/Specialty

Duties		ole?	
	Yes	No	N/A
Technical and Scientific Oversight: Provide on-site, telephone, or electronic			
consultation. Select test methodology that is appropriate for the clinical use of the test			
results.			
Method Validation Studies: 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.			
Proficiency Testing: Ensure that approved proficiency testing surveys or alternative			
performance assessments are performed appropriately and submitted on time. Review			
department PT or APA results and approve corrective actions to failures and near			
misses.			
Quality Control and Quality Management: Establish department Quality Control			
(QC) and Quality Management (QM) programs and ensure that they are maintained.			
Monthly QC/QM Review: Perform high level review of quality control performance			
and QM programs (at least monthly).			
Establish and maintain acceptable levels of analytical performance for each test system.			
Remedial/Corrective Action: Review and approve documentation of corrective			
actions for QC failures, QM goals misses, 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.			
Training: 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.			
Competency Assessment: Establish department competency program and ensure that it			
is maintained.			
Recurring Procedure Review: 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.
- Minor deviations reviewed. Employee meets job expectations. (Document corrective actions below).
- Does not meet expectations.

Laboratory Director: _____ Date: _____

Minor Deviations:

Expectation	Comment	Employee Initials

GENERAL SUPERVISOR ASSESSMENT

Employee Name:

Department/Specialty

Duties	Acceptal	ole?	
	Yes	No	N/A
Day to Day Oversight: 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.			
Analytic Performance Monitoring: Ensure acceptable levels of analytic performance			
are maintained for test analyses and specimen examinations.			
Record Review: 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 least monthly - more often if necessary).			
Corrective Actions: 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.			
Training: Administer the departmental training program and ensure all employees			
receive documented training from another trained individual. Approve and sign			
Training Verification forms for all employees at the completion of the training process.			
Competency Assessment: 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			
and sign competency assessment documentation.			

Employee Signature: ______ Date: _____

Assessment:

- Employee meets job expectations.
- Minor deviations reviewed. Employee meets job expectations. (Document corrective actions below).
- Does not meet expectations.

Technical Supervisor/Laboratory Director:_____ Date:

Minor Deviations:

Expectation	Supervisor Comment	Employee Initials