TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	10/16/2017
Department:	Supervisors & QA staff	**Due Date:**	10/24/2017
		Implementation:	**10/24/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Policy for Delegation of Responsibilities SGAHQDNQA738 v4.1

Description of change(s):

Adopting new CQA revision with the local following edits:

Section	Description
2	Add note for local departments
4,5,8,11	Delete Cytology
11	Add attachments 1-4

Corporate changes are highlighted in sections 5.3.1 and 5.3.6

The revised SOP will be implemented on October 24, 2017

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

Non-Technical SOP

Title	**Policy for Delegation of Responsibilities**
Prepared by	Kathy Grimes and Georgiann Troutman **Date:** 4/24/2017

Laboratory Approval	**Effective Date:**	
Print Name and Title	**Signature**	**Date**

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval	**Corporate Issue Date:** 9/11/2017	
Print Name and Title	**Signature**	**Date**
Dianne Zorka Director, Corporate Quality Assessment **Kathleen Dwyer** Director, National Quality Assessment	*On file*	9/8/2017
Ronald Kennedy, M.D. Sr Medical Director Medical Quality	*On file*	9/8/2017

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

Form ID: QDNQA305 v1 issued 8/05/13

TABLE OF CONTENTS

1. PURPOSE

This document sets forth the policy for the CLIA Laboratory Director to delegate and reapportion certain responsibilities and duties in Quest Diagnostics laboratories on their behalf. This document also provides a standard process that defines, in writing, the authorized designee's responsibilities and duties.

2. SCOPE

- This policy applies to Quest Diagnostics designated personnel in:
  - Anatomic and Clinical testing departments including AmeriPath and Dermpath Diagnostics laboratories.
  - Referral Testing
  - Specimen Processing
  - Tech Ops
- This policy does not apply to:
  - Client Services
  - Logistics
  - Phlebotomy/specimen collection.
  - Materials management
  - Information Technology

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.

3. RESPONSIBILITY

Responsible Party	Task
Laboratory Director	• Approves the initial document and any subsequent revisions. • Ensures that delegated responsibilities are assigned to qualified individuals. • Signs Delegation Documents. • Periodically reviews Delegation Documents
Laboratory Director or Designee	• Recurring review of this SOP
Technical Supervisor	• Complies with this process in the area(s) for which he/she is responsible.
Pre-analytical/Post-analytical Department Manager	• Complies with this process in the area(s) for which he/she is responsible.
Quality Assurance Department	• Ensures that all Delegation Documents have Laboratory Director approval signature • Maintains the original signed Delegation Documents according to local document control procedure • Archives retired (inactive) Delegation Documents according to record retention policy

4. DEFINITIONS

Term	Definition
Assessor	Qualified individual(s) who is/are delegated to perform competency assessment functions.
Clinical Consultant	Individual(s) qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment, and management of patient care.
General Supervisor	Qualified individual(s) who, under the direction of the Laboratory Director and supervision of the Technical Supervisor, provides day-to-day supervision of testing personnel and reporting of test results for **high** complexity testing.
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
Laboratory Director	An individual qualified to manage and direct laboratory personnel and the performance of **moderate complexity or high complexity test** performance. This is 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 CLIA and CAP certificate (as applicable).

Form ID: QDNQA305 v1 issued 8/05/13

Term	Definition
Moderate Complexity Testing	Rating given by the FDA to commercially marketed in vitro diagnostic tests based on their risks to public health
Pre-analytical/Post-analytical Department Manager	An individual who, under the direction of the Laboratory Director, is primarily responsible for a pre-analytic or post-analytic area or department. The Quest Diagnostics job title may vary and does not have to include the word "manager."
Pre-analytical/Post-analytical Department Supervisor	An individual who, under the direction of the Laboratory Director and/or Pre-analytic/Post-analytic Department Manager, provides day-to-day supervision of personnel performing pre-analytic and post-analytic processes. The Quest Diagnostics job title may vary and does not have to include the word "supervisor."
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
Technical Consultant	Individual(s) qualified to provide technical consultation for each of the specialties and subspecialties of service in laboratories performing **moderate** complexity tests or procedures.
Technical Supervisor	Individual(s) qualified to provide technical consultation for each of the specialties and subspecialties of service in laboratories performing **high** complexity tests or procedures.

5. POLICY

5.1. The Laboratory Director is responsible for ensuring all persons performing delegated functions are qualified to do so and that the delegated functions are properly performed.

5.2. The Laboratory Director may NOT delegate the following responsibilities:

Responsibility	Duties That May NOT Be Delegated
Quality Management	Ensures that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic, and post-analytic phases of testing. Examples include but are not limited to: o Signature approval of new method validation packages o Signature approval of pre-analytical, analytical, and post-analytical SOPs and revisions to those SOPs o Signature approval of Individual Quality Control Plans (IQCP) o Participation in Quality Management meetings o Documented annual review of the Quality Management program for effectiveness, including determination and/or approval of quality monitors and improvement activities

Responsibility	Duties That May NOT Be Delegated
	o Selection and approval of referral testing laboratories o Interacting with government and other agencies as appropriate o Provides for intra-laboratory consultations and clinical consultations regarding the ordering of appropriate tests and the medical significance of laboratory data o Documented review and approval of the content and format of patient reports according to regulatory requirements and Quest Diagnostics policies. * o Documented system for reviewing, approving, and authorizing the use of specimen collection/handling procedures (written or electronic) o For part-time Laboratory Directors, there must be an agreement defining the frequency of on-site visits and documentation of activities performed during the visits. * This function may be performed by a Laboratory Director-qualified designee. The laboratory must develop an appropriate Delegation Document describing how this function is delegated.
Safety	Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biologic hazards. Examples include but are not limited to: o Signature approval of safety procedures o Evidence of involvement in the laboratory's safety program (may include: participation in safety meetings, consultation on safety policies and issues, review of incident investigations) o Documented review/approval of corrective actions taken for safety issues.
On-Site Supervision	Ensure that a qualified general supervisor provides on-site supervision of high complexity test performance by testing personnel.
Personnel	Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, proper supervision, accurate performance of tests, and to report test results in accordance with the personnel responsibilities described elsewhere. Examples include but are not limited to: o Establish systems to ensure consultants, supervisors, managers, and testing personnel are qualified to perform their assigned duties o Ensure staffing levels are sufficient for the workload o Ensure that all applicable credentials and certifications are documented and on file.

Responsibility	Duties That May NOT Be Delegated
Responsibilities	Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the pre-analytic, analytic, and post-analytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. Examples include but are not limited to: o Delegating, in writing, the specific responsibilities and duties that are delegated to qualified Technical Consultants, Clinical Consultants, Technical Supervisors, General Supervisors, and Pre-analytical/Post-analytical Department Managers using this standard operating procedure. NOTE: The Laboratory Director or Technical Supervisor or Pre-analytical/Post-analytical Department Manager may delegate to General Supervisors or Pre-analytical/Post-analytical Department Supervisors, as appropriate.
Approval Of Standard Operating Procedures (SOP)	Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic and post-analytic phases of testing. Approval of procedures and changes to procedures must be performed by the director named on the laboratory's CLIA certificate. If the Laboratory Director does not meet the qualifications of Technical Supervisor for a specialty or subspecialty, the Technical Supervisor must also sign and approve new and changed procedures. Recurring review of procedures may be delegated to the appropriate Technical Supervisor or Pre-analytic and Post-analytic Department Manager. Examples include but are not limited to: o Signing and approving all testing procedures when initially placed in use. This includes all analytic procedures, as well as procedures that contain pre-analytic and post-analytic processes, such as specimen collection, specimen transport, specimen processing, and reporting of patient results o Signing and approving procedures whenever revisions are made. o If there is a change in Laboratory Director, the new director must review and sign all procedures within a reasonable period of time, not to exceed 6 months.

5.3. The Laboratory Director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, OR delegate the following responsibilities to personnel meeting the qualifications:

5.3.1. The Laboratory Director may delegate responsibilities to the **Technical Consultant** (moderate complexity testing) or to the **Technical Supervisor** (high complexity testing).

- The Laboratory Director must ensure that these responsibilities are delegated to qualified individuals.
- The Laboratory Director may delegate all of the responsibilities, a single duty, or a combination of duties.
- Delegations must not be ambiguous and must clearly indicate who is responsible for each duty in a particular area.
- Delegations may be restricted by department, shift, or discipline.
- The Laboratory Director may elect to retain (personally perform) any of these responsibilities if appropriately licensed and qualified in the specialty.

Responsibility	Duties That May Be Delegated To Technical Supervisor or Technical Consultant
Test Methodology	• Ensure that the test methodologies selected have the capability of providing the quality of results required for patient care • Ensure verification procedures are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method • Ensure Laboratory personnel perform tests, as required, for accurate and reliable test results. Examples include but are not limited to: o Timely and accurate implementation of Best Practice Team (BPT) initiatives o Submission of complete method validation studies to the Laboratory Director for approval prior to patient testing o Preparation and submission of a complete Standard Operating Procedure for all new or changed test methods, including submission to the Laboratory Director for review and approval signature o Documented training, prior to performing the test, for all testing personnel for any new or changed test methods. o Ensuring that the CAP Activity Menu is correct and changes are appropriately communicated to the quality assurance department and/or CAP
Proficiency Testing (PT)	• Ensure that the laboratory is enrolled in CMS approved PT programs for the testing performed • Ensure PT samples are tested as required • Sign PT survey attestation statement

Responsibility	Duties That May Be Delegated To Technical Supervisor or Technical Consultant
	• Ensure PT results are returned within the timeframes established by the PT program • Ensure all PT results received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action, including analysis of trends and bias as applicable. • Ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory. Examples include but are not limited to: o Documentation that all tests are covered by PT or alternative performance assessment (APA) o Timely and accurate submission of PT results o Documented review of PT results and performance, including documented approval of corrective actions taken in response to PT failures and/or near miss evaluations o Documented steps taken to prevent inappropriate referral of PT samples or inappropriate communication of PT results.
Quality Management/Quality Control	Ensure that quality control and quality management programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Examples include but are not limited to: o Documented review of Quality Control data, Quality Assurance monitors, and Quality Improvement activities o Ongoing assessment of the department's IQCP (s) o Timely and effective responses to quality failures identified through the laboratory's problem tracking process.
Analytic Performance	Ensure the establishment and maintenance of acceptable levels of analytic performance for each test system. Examples include but are not limited to: o Ensuring appropriate QC frequency is defined in each SOP o Establishing appropriate QC ranges prior to performing each test system o Documented monthly review of QC data to monitor analytic bias and/or imprecision.

Responsibility	Duties That May Be Delegated To Technical Supervisor or Technical Consultant
Corrective Action	Ensure that all necessary corrective 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. Examples include but are not limited to: o Review and approval of corrective actions taken in response to QC failures, revised reports, and Reportable Quality Issues (RQIs) o Review and approval of corrective actions taken in response to quality issues identified through the laboratory's problem tracking process and department Quality Management activities o Review of corrective actions taken in response to major instrument or test system failures.
Training	Ensure that, prior to testing patient specimens, all personnel have the appropriate training for the type and complexities of the services offered and have demonstrated that they can reliably perform all testing operations and report accurate results. Examples include but are not limited to: o Ensuring a complete and documented training program is established for all staff
Competency	Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytic, analytic, and post-analytic phases of testing to assure that they are competent and maintain competency to process specimens, perform test procedures and report test results promptly and proficiently. Whenever necessary, identify needs for remedial training. Examples include but are not limited to: o Establishing a complete and documented competency assessment program for all staff o Ensuring that all employees are assessed by a trained appropriately delegated individual using all applicable tools: direct observation, record review, test performance, and assessment of problem-solving skills. o Ensuring that remedial training is provided (as appropriate).
SOPs	Ensure that approved procedures are available to all personnel for all aspect of the testing process. Examples include but are not limited to: o Recurring review of approved SOPs to ensure they are complete, readily available, and reflect current practice.

5.3.2. The Laboratory Director may delegate responsibilities to the **Clinical Consultant.**

- The Laboratory Director must ensure that these responsibilities are delegated to qualified individuals.
- The Laboratory Director may delegate one or both of the responsibilities,
- Delegation may be restricted by department, shift or discipline.
- The Laboratory Director may elect to retain (personally perform) any of these responsibilities.

Responsibility	Duties That May Be Delegated To Clinical Consultant
Laboratory Reports	Ensure that reports of test results include pertinent information required for interpretation. Example includes but is not limited to: Explanatory medical interpretations added to laboratory reports.
Consultation	Ensure that consultation is available to laboratory clients on matters relating to the quality of test results and their interpretation concerning specific patient conditions. Example includes but is not limited to: Conversations with clients to discuss test results and possible clinical implications for specific patients or types of patients.

5.3.3. The Laboratory Director may delegate responsibilities to one or more **General Supervisors**.

- The Laboratory Director must ensure that these responsibilities are delegated to qualified individuals.
- The Laboratory Director may delegate all of the responsibilities, a single duty, or combination of duties.
- If the Laboratory Director delegates responsibilities to one or more General Supervisors, the Delegation Document(s) must be maintained under document control and maintained with other Delegation Documents.
- Overlap in the assignment of General Supervisor duties is acceptable in order to provide adequate supervision.
- The Laboratory Director or Technical Supervisor may reapportion Competency assessment activities to an Assessor.
- Delegation may be restricted by department, shift, or discipline.
- The Laboratory Director may elect to retain (personally perform) any of these responsibilities.

Responsibility	Duties That May Be Delegated To General Supervisor
Corrective Action	Assure that all corrective actions are taken whenever test systems deviate from the laboratory's established performance specifications.

Responsibility	Duties That May Be Delegated To General Supervisor
	Examples include but are not limited to: o Advise testing personnel on appropriate corrective actions when problems occur o Ensure that corrective action documentation is complete o Consult with and obtain approval of the Technical Supervisor for process improvements implemented in response to major or frequently recurring problems o Document review of quality control, instrument function, preventative maintenance and other laboratory records (monitor QC weekly, other records at least monthly - more often if necessary).
Patient Reporting	Ensures that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. Examples include but are not limited to: o Supervisory review of workflow, work practices and test records, as necessary. (It is not required that all test records be reviewed.) o Initial review and approval of corrective action documentation o Advise testing personnel on daily QC practice o Documented weekly review of QC data to monitor analytic bias and/or imprecision.
Orientation/Training	Provides orientation to all testing personnel. Examples include but are not limited to: o Ensures that orientation of all testing personnel is completed and documented (as applicable) o Ensures that employees receive documented training from another trained individual (does not have to be a supervisor) prior to performing patient testing.
Competency	Annually evaluates and documents the performance of all testing personnel. Examples include but are not limited to: o Manage and administer the department competency program o Review and approve completed documentation of competency assessment activities o Address identified performance issues and provide documented follow-up on corrective action.

5.3.4. Quest Diagnostics policy allows certain Laboratory Director responsibilities for pre-analytic and post-analytic phases of testing to be delegated to **Pre-analytic/Post-analytic Department Managers.** These individuals are not required to hold a job title of manager, but must be supervisory level staff members who are primarily responsible for oversight of these departments.

- The Laboratory Director may delegate all of the responsibilities, a single duty, or a combination of duties.
- Delegations must not be ambiguous and must clearly indicate who is responsible for each duty in a particular area.
- Delegation may be restricted by shift or department.

Responsibility	Duties That May Be Delegated To Pre-Analytic/Post-Analytic Department Managers
Quality Management	Ensures that quality management programs are established and maintained to assure that quality pre-analytic and/or post-analytic laboratory services are provided and to identify failures in quality as they occur. Examples include but are not limited to: o Documented monthly review of Quality Assurance monitors and Quality Improvement activities o Timely and effective responses to quality failures identified through the laboratory's problem tracking process and department Quality Management program.
Corrective Action	Ensures that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's pre-analytic and/or post-analytic processes are identified. Examples include but are not limited to: o Review and approval of corrective actions taken in response to revised reports or Reportable Quality Issues (RQIs) o Review and approval of corrective actions taken in response to quality issues identified through the laboratory's problem tracking process and Quality Management activities.
Training	Ensures that, prior to performing pre-analytic and/or post-analytic procedures, all personnel have the appropriate training and have demonstrated that they can perform a specific process, workstation or job assignment correctly. Examples include but are not limited to: o Establishing a complete and documented training program for all staff o Signing/attesting that the department employees are trained.
Competency	Ensures that policies and procedures are established for monitoring individuals who conduct pre-analytic and post-analytic phases of testing, to assure that they are competent and maintain competency to perform these tasks proficiently and, whenever necessary, identify needs for remedial training. Examples include but are not limited to: o Establishing a complete and documented competency assessment program for all staff

Responsibility	Duties That May Be Delegated To Pre-Analytic/Post-Analytic Department Managers
	o Signing/attesting that department employees are competent o Documentation that remedial training and/or continuing education is provided (as appropriate).
SOPs	Ensures that approved procedures are available to all personnel for all aspects of the testing process. Examples include but are not limited to: o Recurring review of approved pre-analytic and/or post-analytic SOP's to ensure they are complete, readily available and reflect current practice.

5.3.5. The Laboratory Director or Pre-analytical/Post-analytical Department Manager may delegate the following responsibilities to one or more **Pre-analytical/Post-analytical Department Supervisors.**

- The Laboratory Director or department manager may delegate all of the responsibilities, a single duty, or a combination of duties.
- If a Pre-analytical/Post-analytical Department Manager delegates responsibilities to one or more Department Supervisors, the Delegation Document(s) must be maintained under document control and maintained with other Delegation Documents.
- Overlap in the assignment of Pre-analytical/Post-analytical Department Supervisor duties is acceptable in order to provide adequate supervision.
- Delegation may be restricted by shift or department.

Responsibility	Duties That May Be Delegated To Pre-analytic/Post-analytic Department Supervisor
Corrective Action Instrumentation	Ensure that all corrective actions are taken whenever pre-analytical or post-analytical systems deviate from the laboratory's established performance specifications. Examples include but are not limited to: o Advise personnel on appropriate corrective actions when problems occur o Ensure that corrective action documentation is complete o Consult with and obtain approval of the department manager for major or frequently recurring problems o Review instrument function, preventative maintenance and other department records (at least monthly).
Corrective Action Procedures / Processes	Ensure that pre-analytic/post-analytic corrective actions are taken in accordance with policies and procedures established by the Laboratory Director. Examples include but are not limited to: o Supervisory review of workflow, work practices, and

Responsibility	Duties That May Be Delegated To Pre-analytic/Post-analytic Department Supervisor
	department records (such as route sheets, accuracy of data entry from patient requisitions, documentation of client calls, etc.) o Initial review and approval of corrective action documentation o Advise pre-analytic/post-analytic personnel on daily problem-solving actions.
Orientation/ Training	Provide orientation to all pre-analytic/post-analytic personnel; Examples include but are not limited to: o Ensure that orientation of all pre-analytic/post-analytic personnel is completed and documented (as applicable) o Ensure employees receive documented training from another trained individual (does not have to be a supervisor) prior to performing job assignments
Competency	Annually evaluate and document the performance of all pre-analytical/ post-analytical personnel. Examples include but are not limited to: o Manage and administer the department competency program o Ensure that all employees are assessed by a trained individual (does not have to be a supervisor) using all applicable tools o Review and approve competency assessment activities. o Address identified performance issues and provide documented follow-up on corrective action.

5.3.6. The Laboratory Director or Technical Supervisor may delegate competency assessment responsibilities to an **Assessor**.

- For **Moderate Complexity** testing, Assessor duties may only be delegated by the Laboratory Director
  - The Assessor must meet the qualifications of a Technical Consultant
- For **High Complexity** testing, Assessor duties may be delegated by either the Laboratory Director or Technical Supervisor.
  - The Assessor must meet the qualifications of a General Supervisor.

Responsibility	Duties That May Be Delegated To an Assessor

Competency Assessment Observes employees as they perform all steps of procedure(s) and/or Test Systems	• Observe employees as they perform all steps of procedure(s) and/or Test Systems using the following methods:
	  • Review of all records associated with procedure(s) and/or Test Systems
	  • Evaluate Test Performance
	  • Evaluate Problem Solving Skills
	• Review must include documentation of evidence used to evaluate the employee's performance

5.3.7. The Laboratory Director may delegate responsibilities for Proficiency Testing to the **Quality Assurance Director/Manager.**

Responsibility	Duties That May be Delegated to the Quality Assurance Director/Manager
PT activities	Manage proficiency testing activities within the laboratory Examples include but are not limited to: o Annual review of laboratory enrollment in an HHS approved PT program for all testing performed. o Sign the PT attestation as applicable o Review of PT performance by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. o Review approved corrective action plan when PT results are found to be unacceptable or unsatisfactory.

6. PROCESS FOR DELEGATING DUTIES

Step	Action
1	Choose the appropriate Delegation Form for the responsibilities to be delegated. Refer to Section 8 "Related Documents" for a list of Delegation Forms.
2	Each form must be maintained under the laboratory's document control process.
3	Complete the "Laboratory Name and Location" section of the form.
4	For each form, list the name(s) of all individuals to whom the specified duties (listed on the form) are delegated. **NOTE**: Personnel listed must be the qualified individuals who actually perform these duties. Do not list personnel who are qualified to perform these duties but do not actually perform them as part of their regular job functions.
5	List the appropriate CLIA specialty(s) or subspecialty(s) for each person responsible for an analytical area. (Refer to Appendix A) **NOTE**: The individual must be qualified under CLIA, state, and local regulations to perform the delegated duties.
6	List the local department name(s) or area(s) for which this person has responsibility.
7	List the shift(s) during which the person has responsibility. (Refer to Addendum B "**Standard Abbreviations for Shifts")**
8	List the actual duties (by number on each form) that are delegated. If all, use the word ALL. NOTE: The person to whom duties have been delegated must qualify for the position but does not need to hold that specific job title. For example, a Lead Tech who qualifies as a General Supervisor may be delegated the responsibilities of reviewing corrective action, ensuring staff is trained and managing competency assessment on the night shift as part of her/his duties. The person's actual job title or job description must convey some degree of responsibility and/or supervisory authority over others, but does not have to include the word "supervisor."

Form ID: QDNQA305 v1 issued 8/05/13

Step	Action
9	Each form must be restricted to a single page signed by the individual who is delegating the duties (usually the Laboratory Director but may be the Technical Supervisor or Pre-analytic/Post-analytic Department Manager). Multiple delegated individuals may appear on one form. • If one person on a form changes, the entire form must be updated and signed. Retire the old form and file it according to Quest Diagnostics record retention requirements. • If all individuals will not fit on a single form, multiple forms must be used. For example, a laboratory with 16 Technical Supervisors would require at least 3 Technical Supervisor forms. These forms should be numbered in a sequential manner (e.g., TS-1, TS-2, TS-3).
10	Forms must be signed as follows: • The Laboratory Director must sign and date the Technical Supervisor. Technical Consultant, General Supervisor, Cytology General Supervisor, Clinical Consultant, Pre-analytic/Post-analytic Department Manager delegation documents. • Either the Laboratory Director or Pre-analytic/Post-analytic Department Manager may sign a Pre-analytic/Post-analytic Department Supervisor delegation document. • The Laboratory Director must sign and date the Assessor delegation documents for Moderate Complexity testing. • The Laboratory Director or Technical Supervisor must sign and date the Assessor delegation documents for High Complexity Testing.
11	Place the original delegation documents under document control according to local practice. Controlled copies specific to the applicable department must be available to each department.
12	Update delegation documents: • Whenever the individuals listed on the form, CLIA designations, or delegated duties change from what is on the current form. • Whenever there is a change in directorship.
13	Archive retired (original) delegation documents according to standard record retention guidelines.

7. RECORDS MAINTENANCE

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

8. RELATED DOCUMENTS

- Clinical Consultant Delegation Form (QDNQA341)
- Technical Supervisor Delegation Form (QDNQA342)
- Technical Consultant Delegation Form (QDNQA343)

- General Supervisor Delegation Form (QDNQA346)
- Pre-analytic/Post-Analytic Manager Delegation Form (QDNQA348)
- Pre-analytic/Post-Analytic Supervisor Delegation Form (QDNQA349)
- Assessor Delegation Form, High Complexity (QDNQA351)
- Assessor Delegation Form, Moderate Complexity (QDNQA352)
- QA Director/Manager Delegation Form (QDNQA358)

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	Revision (Immediate retired and prior two versions)	Revised By
2	4/2017	Updated entire document to include MediaLab for electronic documentation of training and changes to regulatory requirements. Added delegations for Assessor, High Complexity and Moderate Complexity, QA Director/Manager Deleted IT Manager delegation	K. Grimes G. Troutman
3	6/21/17	Updated Section 5.3.3 with requirement for local delegation form for Cytology Technical Supervisor Designee. Added corrective action for PT failures in Quality Management Responsibility	K. Grimes
4	8/13/2017	Clarified Assessor qualifications Revised sections for Laboratory Director delegation to General Supervisors and Cytology General Supervisors	D. Zorka
4	9/27/17	Adopting new corporate revisions 2, 3 & 4 Page 1: Add Local Effective Date message 2: Add note for local departments 4, 5, 8, 11: Delete Cytology 11: Add attachments 1- 4	L Barrett

11. ADDENDA

Addendum	Title
A	Standard Abbreviations for CLIA Specialties and Subspecialties
B	Standard Abbreviations for Shifts
Attachment 1	Delegation Form, Safety and Administration
Attachment 2	Delegation Form, Laboratory Director
Attachment 3	Delegation Form, Quality Assurance Specialist
Attachment 4	Delegation Form, Information Technology Manager

ADDENDUM A

Standard Abbreviations for CLIA Specialties and Subspecialties

CLIA Specialties and Subspecialties	
All - All specialties performed in lab	**IH** – Immunohematology
All ex – All performed in lab except	**ABO** – ABO and Rh
	ADT – Antibody Detection Transfusion
CH - Chemistry	**ADN** – Antibody Detection Nontransfusion
CHR – Routine Chemistry	**ABID** – Antibody Identification
UR – Urinalysis	**COMP** – Compatibility Testing
ENDO - Endocrinology	**MIC** – Microbiology
TOX – Toxicology	**BAC** - Bacteriology
HEM – Hematology	**MBAC** – Mycobacteriology
IMM – Diagnostic Immunology	**MYCO** – Mycology
SYPH – Syphilis Serology	**PARA** - Parasitology
IMMG – General Immunology	**VIR** - Virology

ADDENDUM B

Standard Abbreviations for Shifts

Shift Abbreviations	
ALL – All shifts	**SU** - Sundays
D – Day shift	**MO** - Mondays
E – Evening shift	**TU** - Tuesdays
N – Night shift	**WD** - Wednesdays
DE – Day and evening shifts	**TH** - Thursdays
NE – Night and evening shifts	**FR** - Fridays
DN – Day and night shifts	**SA** - Saturdays
M-F – Monday through Friday only	
WE – Weekends only	
H – Holidays only	

Form ID: QDNQA305 v1 issued 8/05/13