TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	3/12/2014
Department:	Mgmt and QA	**Due Date:**	3/31/2014
		Implementation:	**4/1/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Authorization of Responsibilities and Job Duties
GEC / SGAH / WAH.QA24 v4

Description of change(s):

Section 4:	Added Periodic Review
Section 5&6:	Replaced annual SOP review with periodic
Section 8:	Added staff authorization for multiple locations, quarterly update and electronic filing of grids
Section 12:	Forms updated to reflect periodic SOP review

Content changes are shown in yellow highlight on the attached SOP.

This revised SOP will be implemented on April 1, 2014

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

Non-Technical SOP

Title	**Authorization of Responsibilities and Job Duties**	
Prepared by	Leslie Barrett	Date: 10/13/2009
Owner	Cynthia Bowman-Gholston	Date: 10/13/2009

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

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1. PURPOSE

This procedure provides a standard process and templates for CLIA Laboratory Director to:

1) Document to whom he/she has reapportioned certain responsibilities and duties, and

2) Document which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether supervisory, consultant, or director review is required prior to reporting patient test results.

2. SCOPE

This procedure applies to all personnel involved in any phase of the testing process – preanalytical, analytical, and postanalytical. This includes staff in the following areas: client services, specimen processing, phlebotomy, and clinical testing departments. This procedure applies to information technology (IT) only in regard to the specific IT delegation document included as Appendix H.

3. RESPONSIBILITY

Laboratory Director
Specifies the responsibilities of each qualified consultant and supervisor in writing and indicates which laboratory director duties have been reapportioned or delegated.

Gives written authorization identifying which examinations or 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.

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Technical Consultant or **Technical Supervisor**
Assures that each individual involved in the testing process has received appropriate training and has maintained competency to perform procedures.

Quality Assurance Manager
Provides oversight to ensure delegation/reapportion documents are updated as necessary.

4. DEFINITIONS

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. [493.1417 and 493.1455]
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 (high complexity testing). [493.1461]
Job Assignment- A specific process, workstation or analyzer that describes a typical job function within the laboratory. Multiple procedures are typically included in a single job assignment.
Job Authorization Grid- A summary form or spreadsheet that divides laboratory operations into job assignments. The Laboratory Director uses the grid to authorize employees to perform tasks for which they have been trained, and to specify the performance levels for each employee and job assignment.
Laboratory Director- An individual qualified to manage and direct laboratory personnel and performance of moderate complexity or high complexity test performance. [493.1403 and 493.1441]
Periodic Review- Process for review and re-approval of all procedures on a periodic basis not to exceed 24 months from the previous reviewed date.
Preanalytical/Postanalytical Department Manager- An individual who, under the direction of the Laboratory Director, is primarily responsible for a preanalytic or postanalytic area or department. (The Quest Diagnostics job title may vary and does not have to include the word "manager.")
Preanalytical/Postanalytical Department Supervisor- An individual who, under the direction of the Laboratory Director or Preanalytical/Postanalytical Department Manager, provides day-to-day supervision of personnel performing preanalytic and postanalytic 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. [493.1411]
Technical Supervisor- Individual(s) qualified to provide technical consultation for each of the specialties and subspecialties of service in which a laboratories performing **high** complexity tests or procedures. [493.1449]

5. LABORATORY DIRECTOR RESPONSIBILITIES THAT MAY BE DELEGATED:

5.1 Technical Consultant or Technical Supervisor

Certain Laboratory Director responsibilities may be reapportioned to the Technical Consultant (moderate complexity testing) or 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 be clear, unambiguous, and not overlap (i.e. it must be clear who is responsible for each duty in a particular area).
- Delegation 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.
- The following Laboratory Director responsibilities may be delegated to a Technical Supervisor or Technical Consultant:

1. Ensure that.....
   a) The test methodologies selected have the capability of providing the quality of results required for patient care;
   b) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and
   c) Laboratory personnel are performing tests as required for accurate and reliable test results;

Examples include but are not limited to:
- Timely and accurate implementation of Best Practice Team (BPT) initiatives,
- Submission of complete method validation studies to the Laboratory Director for approval prior to patient testing,
- 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,
- Documented training prior to performing the test for all testing personnel for any new or changed test methods.

2. Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-----
   a) The proficiency testing samples are tested as required under Subpart H of the CLIA `88 regulations (42 CFR Part 493);
   b) The results are returned within the timeframes established by the proficiency testing program;
   c) All proficiency testing results received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;
   d) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

Examples include but are not limited to:
- Documentation that all tests are covered by proficiency testing (PT) or alternative performance assessment (APA),
- Timely and accurate submission of PT results,

- Documented review of PT results and performance, including documented approval of corrective actions taken in response to PT failures and/or near miss evaluations,
- Documented steps taken to prevent inappropriate referral of PT samples or inappropriate communication of PT results.

3. 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:
- Establishment of department-specific Quality Control and Quality Management programs,
- Documented monthly review of Quality Control data, Quality Assurance monitors, and Quality Improvement activities,
- Timely and effective responses to quality failures identified through the laboratory's Problem Tracking process.

4. Ensure the establishment and maintenance of acceptable levels of analytic performance for each test system;
Examples include but are not limited to:
- Ensuring appropriate QC frequency is defined in each SOP,
- Establishing appropriate QC ranges prior to using each test system,
- Documented monthly review of QC data to monitor analytic bias and/or imprecision.

5. 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;
Examples include but are not limited to:
- Review and approval of corrective actions taken in response to QC failures, revised reports, and Reportable Quality Issues (RQIs),
- Review and approval of corrective actions taken in response to quality issues identified through the laboratory's Problem Tracking Program and department Quality Management activities,
- Review of corrective actions taken in response to major instrument or test system failures.

6. Ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;
Examples include but are not limited to:
- Ensure a complete and documented training program is established for all staff,
- Signing the Job Authorization Grid(s) attesting that department employees are trained and competent to perform the applicable job assignments.

7. 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 their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

Examples include but are not limited to:
- Establishing a complete and documented competency assessment program for all staff,
- Signing the Job Authorization Grid(s) attesting that department employees are competent to perform the applicable job assignments,
- Documenting that remedial training and/or continuing education is provided (as appropriate).

8. Ensure that an approved procedure manual is available to all personnel for any aspect of the testing process. [Quest Diagnostics policy requires the Laboratory Director to sign procedures when 1) initially placed in use, 2) a change is made to a procedure, or 3) there is a change in Laboratory Director. The periodic review of procedures may be reapportioned to the Technical Supervisor or Technical Consultant.]
Examples include but are not limited to:
- Periodic review of approved Standard Operating Procedures to ensure SOPs are current, complete, readily available, and reflect current practice.

5.2 Clinical Consultant

The following Laboratory Director responsibilities may be reapportioned 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.

1. Ensure that reports of test results include pertinent information required for interpretation;
For example:
- Explanatory medical interpretations added to laboratory reports.

2. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.
For example:
- Conversations with clients to discuss test results and possible clinical implications for specific patients or types of patients.

5.3 General Supervisor

The Laboratory Director or Technical Supervisor may delegate the following responsibilities to one or more General Supervisors:
- The Laboratory Director or Technical Supervisor must ensure that these responsibilities are delegated to qualified individuals.
- The Laboratory Director or Technical Supervisor may delegate all of the responsibilities, a single duty, or combination of duties.
- If a Technical Supervisor delegates responsibilities to one or more General Supervisors, the Delegation Document(s) must be maintained under

document control and maintained in the QA Manual with other Delegation Documents.

- Overlap in the assignment of General Supervisor duties is acceptable in order to provide adequate supervisory coverage.
- Delegation may be restricted by department, shift, or discipline.
- The Laboratory Director or Technical Supervisor may elect to retain (personally perform) any of these responsibilities.

1. Assure that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; Examples include but are not limited to: o Advise testing personnel on appropriate remedial 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 Documented review of quality control, instrument function, preventative maintenance and other laboratory records (monitor QC weekly, other records at least monthly - more often if necessary).
2. Ensure 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.
3. Provide orientation to all testing personnel; Examples include but are not limited to: o Ensure that orientation of all testing personnel is completed and documented (as applicable), o Ensure that employees receive documented training from another trained individual (does not have to be a supervisor) prior to performing patient testing, o Signing Training Verification forms attesting that employee training is complete and the trainee has demonstrated the ability to successfully perform the job assignment. (Note: Trainers are not listed on the General Supervisor delegation form unless they have been delegated complete responsibility for employee training and sign the Training Verification form as the approving supervisor, not just as the trainer. If a Trainer is listed on the delegation form, it is expected that training is a major part of his/her job function and not just an occasional expectation.)
4. Annually evaluate and document the performance of all testing 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: direct observation,

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record review, test performance, and problem-solving quizzes, o Review and grade competency assessment documentation, address deviations that are identified, and approve/sign the documents. (See note regarding Trainers under responsibility #3 above.)

5.4 Pre-analytic/Post-analytic Department Manager

Quest Diagnostics policy allows certain Laboratory Director responsibilities for pre-analytic and post-analytic phases of testing to be delegated to 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 be clear, unambiguous, and not overlap (i.e. it must be clear who is responsible for each duty in a particular area).
- Delegation may be restricted by shift or department.

1. Ensure 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 Establishment of department-specific Quality Management programs, 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.
2. Ensure 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 program and Quality Management activities.
3. Ensure that prior to performing pre-analytic and/or post-analytic procedures, all personnel have the appropriate training and have demonstrated that they can perform job assignments correctly; Examples include but are not limited to: o Establishing a complete and documented training program for all staff, o Signing the Job Authorization Grid(s) attesting that department employees are trained.
4. Ensure 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 their competency to perform these tasks promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

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Examples include but are not limited to:
- Establishing a complete and documented competency assessment program for all staff,
- Signing the Job Authorization Grid(s) attesting that department employees are competent,
- Documentation that remedial training and/or continuing education is provided (as appropriate).

5. Ensure that an approved procedure manual is available to all personnel for any aspect of the testing process. [Quest Diagnostics policy requires the Laboratory Director to sign pre-analytic/post-analytic procedures when 1) initially placed in use, 2) a change is made to a procedure, or 3) there is a change in Laboratory Director. The periodic review of procedures may be delegated to the department manager.]
Examples include but are not limited to:
- Periodic review of approved pre-analytic and/or post-analytic Standard Operating Procedures to ensure SOPs are current, complete, readily available, and reflect current practice.

5.5 Preanalytical/Postanalytical Department Supervisor

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

1. Assure that all remedial 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:
- Advise personnel on appropriate remedial actions when problems occur,
- Ensure that corrective action documentation is complete,
- Consult with and obtain approval of the department manager for major or frequently recurring problems,
- Review instrument function, preventative maintenance and other department records (at least monthly, more often if necessary).

2. Ensure that preanalytical/postanalytical corrective actions are taken in accordance with policies and procedures established by the Laboratory Director;
Examples include but are not limited to:
- Supervisory review of workflow, work practices, and department records (such as route sheets, accuracy of data entry from patient requisitions, documentation of client calls, etc.)
- Initial review and approval of corrective action documentation,
- Advise preanalytical/postanalytical personnel on daily problem-solving actions.

3. Provide orientation to all preanalytical/postanalytical personnel;
Examples include but are not limited to:
- Ensure that orientation of all preanalytical/postanalytical personnel is completed and documented (as applicable),
- Ensuring employees receive documented training from another trained individual (does not have to be a supervisor) prior to performing job assignments,
- Signing Training Verification forms attesting that employee training is complete and the trainee has demonstrated the ability to successfully perform the job assignment. (Note: Trainers are not listed on the Preanalytical/Postanalytical Department Supervisor delegation form unless they have been delegated complete responsibility for employee training and sign the Training Verification form as the approving supervisor, not just as the trainer. If a Trainer is listed on the delegation form, it is expected that training is a major part of his/her job function and not just an occasional expectation.)

4. Annually evaluate and document the performance of all preanalytical/ postanalytical personnel.
Examples include but are not limited to:
- Manage and administer the department competency program,
- Ensure that all employees are assessed by a trained individual (does not have to be a supervisor) using all applicable tools (direct observation, record review, and problem-solving quizzes),
- Review and grade competency assessment documentation, address deviations that are identified, and approve/sign the documents. (See note regarding Trainers under responsibility #3 above.)

5.6 Information Technology (IT) Department Manager

Quest Diagnostics policy allows certain College of American Pathologists (CAP) Laboratory Director responsibilities for laboratory computer services to be delegated to an IT department manager. (This individual is not required to hold a job title of manager, but must be a supervisory level staff member who is primarily responsible for oversight of the IT department.)
- The Laboratory Director may delegate all of the responsibilities, a single duty, or a combination of duties.
- The Laboratory Director is personally responsible for policies and procedures that deal with medical content of patient reports and procedures or protocols that deal with autoverification of patient results prior to release.

1. Ensure that an approved procedure manual is available to all personnel for any aspect of the testing process. [Quest Diagnostics policy requires the Laboratory Director to sign procedures when 1) initially placed in use, 2) a change is made to a procedure, or 3) there is a change in Laboratory Director. The periodic review of

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IT procedures may be reapportioned to the IT Department Manager.]
2. Maintains the Laboratory Information System (LIS) hardware and software in a manner that ensures the functionality and reliability of the system in meeting the needs of patient care, maintains system security, and complies with regulatory and accreditation requirements.

6. LABORATORY DIRECTOR RESPONSIBILITIES THAT MAY NOT BE DELEGATED:

6.1 Laboratory Director

The following Laboratory Director responsibilities **may not** be reapportioned or delegated:

1. 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; 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 Monthly 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 o Interacting with government and other agencies as appropriate o Documented review and approval of the content and format of patient reports at least annually * 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.
2. 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 the safety manual 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.

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3. Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under Sec. 493.1489(b)(4); (now 493.1489(b)(5)) o If grandfathered individuals (see 493.1489(b)(5)) perform high complexity testing in the laboratory, the Laboratory Director must ensure that General Supervision is provided as described in 493.1463(a)(4) and 493.1495(b)(7) or as described in 493.1463(c) and 495,1495(c), whichever is applicable.
4. Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; Examples include but are not limited to: o Establishing systems to ensure consultants, supervisors, managers, and testing personnel are qualified to perform their assigned duties o Ensuring staffing levels are sufficient for the workload. o Ensure that all applicable credentials and certifications are documented in PeopleSoft.
5. 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 reapportioned to qualified Clinical Consultants, Technical Supervisors, and Preanalytical/Postanalytical Department Managers using this standard operating procedure. (Either the Laboratory Director or Technical Supervisor or Preanalytical/Postanalytical Department Manager may delegate to General Supervisors or Preanalytical/Postanalytical Department Supervisors, as appropriate.) o Signing the Job Authorization Grid (as authorizer) for all pre-analytical, analytical, and post-analytical employees, in accordance with this standard operating procedure.

6.2 Approval of Standard Operating Procedures

It is the laboratory director's responsibility to 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 preanalytic, analytic and postanalytic phases of testing [493.1407(e)(1) and 493.1445(e)(1)]. Therefore, it is the policy of Quest Diagnostics that:

1) The Laboratory Director must sign and approve 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 [refer to 493.1251(d)].

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2) The Laboratory Director must sign and approve procedures whenever revisions are made.
3) If there is a change in Laboratory Director, the new director must review and sign all procedures within a reasonable period of time.
4) Approval of procedures and changes to procedures must be personally performed by the director named on the laboratory's CLIA certificate.
5) 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 or changed procedures.
6) Periodic review of procedures may be reapportioned to the appropriate Technical Supervisor. (The department manager may perform this function in pre-analytic and post-analytic departments.)

7. DELEGATING SUPERVISOR/CONSULTANT DUTIES

Appendices A through J are provided as tools for developing specific supervisory delegation documents.
Note: Each document must list the specific Laboratory Director responsibilities being delegated.

Step	Action
1	Choose the appropriate forms (Appendices A-J) for the responsibilities to be delegated.
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 duties (listed on the form) are being 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 specialty(s) or subspecialty(s) for each person. (This applies only to analytical areas. Use the CLIA specialty(s) and NOT the department name. Standardized abbreviations in Appendix L may be used.) **NOTE**: The individual must be qualified under CLIA, state, and local regulations to perform the duties being delegated.
6	List the department(s) or area(s) for which this person has responsibility. (Standardized abbreviations in Appendix L may be used. Additional standardized department abbreviations may be added to this list if needed.)
7	List the shift(s) during which the person has responsibility. (Standardized abbreviations may be used.)
8	List the actual duties (by number) that are being 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 doesn't have to include the word "supervisor."
9	List any specific limitations under "Other Qualifier". EXAMPLE: An employee may be responsible for reviewing QC and SOPs for HPLC tests only. This could be noted by her/his name as "HPLC Only."
10	Each form must be restricted to a single page signed by the individual who is reapportioning the duties (usually the Laboratory Director but may be the Technical Supervisor or Preanalytical/Postanalytical Department Manager in some cases). 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, such as TS-1, TS-2, TS-3.
11	• The Laboratory Director must sign and date the Technical Supervisor (or Technical Consultant), Clinical Consultant, Preanalytical/Postanalytical Department Manager, and IT Department Manager delegation documents. • For a high complexity laboratory, either the Laboratory Director or the Technical Supervisor may sign a General Supervisor delegation document. • Either the Laboratory Director or Preanalytical/Postanalytical Department Manager may sign a Preanalytical/Postanalytical Department Supervisor delegation document.
12	Original delegation documents must be filed in the Master QA Manual. Controlled copies specific to the applicable department must be available in each department QA manual.
13	**Delegation documents must be updated:** **a) Whenever the individuals listed on the form, CLIA designations, or reapportioned duties change from what is on the current form.** **b) Whenever there is a change in directorship.**
14	Retired delegation documents (original) must be kept with Quality Assurance records and follow standard document control processes. Record retention is categorized as Delegation/Authorization Forms, LAB200.

8. AUTHORIZATION OF PERSONNEL DUTIES

Use the appropriate **Job Authorization Grid (Appendix K)** or equivalent to document Laboratory Director authorization for each employee involved in pre-analytic, analytic or post-analytic processes.
Note: The Job Authorization Grid is not a supervisor delegation document and is not intended to be used in place of Appendices A-J.

Step	Action
1	List department employee names across the top of the grid. All employees performing analytical, pre-analytical, and/or post-analytical tasks must be listed. If multiple pages are needed, the pages must be numbered as "x of y". Each page must reflect Technical Supervisor (or Technical Consultant or Preanalytical/Postanalytical Department Manager, as applicable) and Laboratory Director approval. **NOTE**: Procedures, equipment and training are system-wide. Employees are

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	authorized to work at multiple locations with the exception of Germantown Emergency Center.
2	List job assignments along the left side of the grid. **NOTE**: Job assignment descriptions must correspond with those in the Training Plan. It is generally not appropriate to list individual SOPs on the grid.
3	Define the levels at which each job assignment may be performed, as appropriate for the department. Suggested performance levels are included in the templates, but the laboratory may modify them to better convey actual performance levels. NOTE: If licensure laws or state regulations have unique requirements, define performance levels as appropriate to describe those requirements.
4	Add department managers and supervisors to the Job Authorization Grid (Appendix K) only if they actually perform one or more of the job assignments listed. If managers/supervisors perform any of the listed job assignments, they must appear on the grid and have appropriate training and competency assessment documentation for those job assignments. If a manager or supervisor is listed on the Job Authorization Grid for some or all job assignments, he/she must also have a delegation document that lists specific reapportioned supervisory duties (Appendices A – J, as appropriate). The Job Authorization Grid is not a supervisor delegation document.
5	Assign a numeric key to each level of performance and place the key on the grid. (Level of performance keys must accurately reflect the way work is performed in the department and may be modified if necessary to reflect actual practice.)
6	If direct supervision or work review is required in testing areas, assign an alphabetic key to define the level of supervision required for each employee and each job assignment. (Do not use an alphabetic key if direct supervision or work review is not required.) Alphabetic keys must be defined on the grid. EXAMPLES: Direct supervision is required while performing a job assignment or supervisory review is required prior to reporting test results. NOTE: If licensure or state regulations have unique supervision requirements, define those requirements as appropriate.
7	Fill in the grid with the appropriate performance level and supervision requirement (if applicable) for each employee and job assignment [number or number and letter(s)]**.** Leave blank if the employee has not been trained to perform a job assignment or if employee training for the job assignment is not current.
8	The Technical Supervisor or Technical Consultant reviews, signs, and dates the document attesting that employees are trained and competent to perform job assignments at the stated level of performance, based on existing training documentation. For pre-analytic and post-analytic departments, the designated department manager signs and dates in this space. Annual or semi-annual competency assessment documentation must also be up-to-date.
9	The Laboratory Director signs and dates the document authorizing each employee to perform job assignments at the stated level. For employees located at remote sites such as phlebotomy/specimen collection personnel, the Laboratory Director of the main laboratory may sign the Job Authorization Grids or that duty may be assigned to another Laboratory Director (such as the director of a Rapid Response Laboratory) within the business unit. Allocation of Laboratory Director Job Authorization responsibilities for remote sites must be clearly defined.

10	Job Authorization Grids are updated quarterly but may be done more frequently ~~Update the Job Authorization Grid as needed~~ (i.e. when new employees are trained, new job assignments are added, employees are trained to perform additional job assignments, or employees no longer work in the department). Employees may begin performing a job assignment as soon as training is successfully completed and documented, but must be added to the approved Job Authorization Grid as soon as possible (within one month of training completion).
11	Signed and dated Job Authorization Grids must be available in each department or Rapid Response Laboratory, as applicable**.** Copies are acceptable. For remote Patient Service Center (PSC) sites, faxed copies are acceptable. Copies of signed grids from remote PSC sites must be available at the site where the responsible Laboratory Director is located and at the site where the Preanalytical/Postanalytical Department Manager is located.
12	Retired Job Authorization Grids must be kept in the department for at least 6 months and then retained according to standard record retention policy.
13	Signed and dated Job Authorization Grids are scanned and retained electronically on a shared drive.

9. RELATED DOCUMENTS

Training Verification, QA procedure
Competency Assessment, QA procedure
Authorization of Responsibilities and Job Duties, QDNQA602 v2.0, corporate issue date 2/7/2011

10. REFERENCES

- College of American Pathologists Commission of Laboratory Accreditation. *Accreditation Checklist 1 (Laboratory General)*. Northfield, IL: College of American Pathologists, current edition.
- Code of Federal Regulations, Title 42, Part 493 [42 CFR Part 493] (Laboratory Requirements)

11. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP SGAH L004.005		
000	3/24/2010	Section 11: Appendices moved to Attachment Tab of Infocard Appendices updated	L. Barrett	C. Bowman
001	1/31/2011	Update cover page Section 11: update A-F	C.Bowman	C. Bowman
002	4/1/2011	Section 1: Reworded and clarified Section 2: Add IT specifications Section 4: Definitions added Section 5: Examples of specific supervisor/ consultant responsibilities added. Use of delegation forms/Job Authorization Grid clarified Section 9: Add NQA sop Section 12: Forms updated to allow specific descriptions of duties Pre/Post-analytical Supervisor and IT Manager forms added Authorization grid templates added for non-testing areas Abbreviations appendix added	L. Barrett	C. Bowman
003	3/1/2014	Section 4: Added Periodic Review Section 5&6: Replaced annual SOP review with periodic Section 8: Added staff authorization for multiple locations, quarterly update and electronic filing of grids Section 12: Forms updated to reflect periodic SOP review Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	C. Bowman

Form revised 3/31/00

12. ADDENDA AND APPENDICES

Appendices are provided as tools to assist in the development of delegation and authorization systems within the laboratory. (see Attachment Tab of Infocard)

- Appendices A through H – Delegation documents for Clinical Consultant, Technical Supervisor, General Supervisors, and Preanalytical/Postanalytical Department Manager, Pre-analytic/Post-analytic Department Supervisor, and IT Department Manager.
  These appendices provide a framework to develop delegation documents for consulting and supervisory personnel within the laboratory. The responsibilities listed are those which may be reapportioned or delegated. The delegating individual may elect not to reapportion or delegate some or all of the listed responsibilities. **Responsibilities that are retained must be removed from the delegation document prior to signing**. **Alternatively, the Laboratory Director (or other appropriate delegator) may indicate "Retained" for any responsibility he/she does not wish to delegate.** Equivalent documents must include:
  - The name of the individual to whom the responsibilities are being delegated
  - The specific CLIA supervisor or consultant title assigned to the individual (or similar area of responsibility for preanalytical and postanalytical areas)
  - The CLIA specialty or subspecialty for which the individual is responsible (analytical areas only)
  - The department and/or shift (when relevant)
  - The specific CLIA responsibilities that are reapportioned or delegated
  - Other qualifiers to describe how the responsibilities are allocated (if needed)
  - The signature and date of the individual delegating the responsibilities (secure electronic signature processes are acceptable).

- Appendix I – Delegation of Laboratory Director responsibilities during absences
- Appendix J – Delegation of Proficiency Testing

- Appendix K – Training Grid/Authorization Form
  This document is provided as a spreadsheet that can be easily updated and printed. If necessary, a blank spreadsheet may be printed and filled out manually. The grid is used to summarize successful completion of training by department individuals involved in pre-analytic, analytic, and post-analytic parts of the testing process. After successful completion of training has been documented, the Laboratory Director authorizes the individuals listed on the Job Authorization Grid to perform the described job assignments at the specified level of performance. Equivalent systems must include:
  - Names of all department individuals involved in pre-analytic, analytic, or post-analytic processes
  - Description of job assignments, corresponding to the Training Plan
  - Brief description of the performance level authorized for each individual
  - Technical Supervisor or Technical Consultant signature (or department manager for non-testing areas). Secure electronic approval processes are also acceptable.
  - Laboratory Director signature (or secure electronic approval)

Form revised 3/31/00

Appendix L

Standard Abbreviations

CLIA Specialties and Subspecialties	
All - All specialties performed in lab	**IH** – Immunohematology
All ex – All performed in lab except	**ABO** – ABO and Rh
CH - Chemistry	**ADT** – Antibody Detection Transfusion
HEM – Hematology	**ADN** – Antibody Detection Nontransfusion
IMM – Diagnostic Immunology	**ABID** – Antibody Identification
MIC – Microbiology	**COMP** – Compatibility Testing

Department Names	
Blood Bank: **BB**	Client Services: **CS**
Core (Chem,Hem,Coag,UA,Imm): **CORE**	Specimen Processing: **SP**
Microbiology: **MIC**	Phlebotomy: **PH**
Quality Assurance: **QA**	
Information Technology: **IT**	All laboratory departments: **All**
Point of Care: **POCT**	All departments except: **All ex**

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 revised 3/31/00

Appendix A – Clinical Consultant

Authorization of Responsibilities and Job Duties - Delegation Document

CLINICAL CONSULTANT DELEGATION

I authorize the qualified individual(s) listed below to perform the duties of Clinical Consultant as described in 42 CFR 493.1419 (moderate complexity) or 42 CFR 493.1457 (high complexity). I also reapportion the following laboratory director responsibilities to the Clinical Consultant:

1) Interpretation of Test Results: *Ensure that test reports include all pertinent information required for specific patient interpretation. These include explanatory medical interpretations added to the patient report.*
Ensure that reports of test results include pertinent information required for interpretation;

2) Client Consultation: *Be available to assist clients in ordering appropriate tests to meet clinical expectations, communicate with clients regarding the quality of test results reported and their interpretation concerning specific patient conditions.*
Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.

Laboratory Name and Location:

Moderate or High Complexity Testing: **High Complexity Testing**

Name of CLIA Clinical Consultant	Specialty or Subspecialty	Department	Shift	Duties Delegated	Other Qualifier

This document reapportions or assigns specific responsibilities described in the CLIA regulations. It is not intended to be a job description. Quest Diagnostics job titles and other job duties not included on this form may be different for the individuals listed.

Appendix B – Technical Supervisor

Authorization of Responsibilities and Job Duties - Delegation Document

TECHNICAL SUPERVISOR DELEGATION (High Complexity)

I authorize the qualified individual(s) listed below to perform the duties of Technical Supervisor as described in 42 CFR 493.1451. I also reapportion the following laboratory director responsibilities to the Technical Supervisor:

1) Method Validation Studies: *Ensure that method validation studies are completed and submitted to Laboratory Director for approval and laboratory personnel are appropriately trained prior to method implementation.*
Ensure that.....
a) The test methodologies selected have the capability of providing the quality of results required for patient care;
b) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and
c) Laboratory personnel are performing the test results as required for accurate and reliable test results;

2) Proficiency Testing: *Ensure that 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.*
Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-----
a) The proficiency testing samples are tested as required under Subpart H of the CLIA `88 regulations (42 CFR Part 493);
b) The results are returned within the timeframes established by the proficiency testing program;
c) All proficiency testing results received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;
d) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

3) Quality Control and Quality Management: *Establish department Quality Control (QC) and Quality Management (QM) programs and ensure that they are maintained.*
Ensure that the quality control and quality assurance programs are established and maintained to assure that quality of laboratory services provided and to identify failures in quality as they occur;

4) Monthly QC/QM Review: *Perform high level* ***review*** *of quality control performance and QM programs (at least monthly).*
Ensure that establishment and maintenance of acceptable levels of analytical performance for each test system;

5) Remedial/Corrective Action: ***Review and approve*** *documentation of corrective actions for QC failures, failures to meet 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;

6) Training: *Establish department training program and ensure that it is maintained.* ***Sign*** *the Job Authorization Grid attesting that department employees are trained.*
Ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

7) Competency Assessment: *Establish department training program and ensure that it is maintained.* ***Sign*** *the Job Authorization Grid attesting that department employees are competent.*
Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

8) Periodic 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~~ within 24 months of previous review.*
Ensure that an approved procedure manual is available to all personnel for any aspect of the testing process. [Quest Diagnostics policy requires the Laboratory Director to sign procedures when 1) initially placed in use, 2) a change is made to a procedure, or 3) there is a change in Laboratory Director. The review of procedures may be reapportioned to the Technical Supervisor.]

Laboratory Name and Location:

Name of CLIA Technical Supervisor	Specialty or Subspecialty	Department	Shift	Duties Delegated	Other Qualifier

This document reapportions or assigns specific responsibilities described in the CLIA regulations. It is not intended to be a job description. Quest Diagnostics job titles and other job duties not included on this form may be different for the individuals listed.

Appendix C – General Supervisor

Authorization of Responsibilities and Job Duties - Delegation Document
GENERAL SUPERVISOR DELEGATION (High Complexity)

I authorize the qualified individual(s) listed below to perform the duties of General Supervisor as described in 42 CFR 493.1463. I also delegate the following responsibilities to the General Supervisor:

1) Record Review: *Advise personnel on appropriate remedial actions when problems occur, ensure that corrective action documentation is complete, consult with Technical Supervisor and obtain approval for major or frequently recurring corrective actions.* ***Review*** *quality control, instrument function, preventive maintenance, and other laboratory records (monitor QC weekly, other records at least monthly - more often if necessary).* Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;
2) Corrective Actions: *Ensure that employees adhere to department policies regarding release of patient results and appropriate corrective actions. Initially* ***review and approve*** *corrective action documentation to ensure it is complete and in accordance with laboratory and department policies.* Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;
3) Training: *Administer the department 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.* Providing orientation to all testing personnel;
4) 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 problem-solving quizzes.* ***Approve and sign*** *competency assessment documentation.* Annually evaluating and documenting the performance of all testing personnel.

Laboratory Name and Location:

Name of CLIA General Supervisor	Specialty or Subspecialty	Department	Shift	Duties Delegated	Other Qualifier

Laboratory Director Signature or Technical Supervisor Signature **Date** **Page**

This document reapportions or assigns specific responsibilities described in the CLIA regulations. It is not intended to be a job description. Quest Diagnostics job titles and other job duties not included on this form may be different for the individuals listed.

Appendix D – Preanalytical/Postanalytical Department Manager

Authorization of Responsibilities and Job Duties - Delegation Document
PREANALYTIC/POSTANALYTIC DEPARTMENT MANAGER*

I authorize the individual(s) listed below to perform department manager duties for the preanalytic and/or postanalytic areas listed below. I also delegate the following laboratory director responsibilities for these preanalytic/postanalytic areas to the department manager*.

* The department manager is the individual with primary responsibility for managing the preanalytical or postanalytical area. "Department manager" is not intended to be a formal job title.

1) Quality Management: *Establish department Quality Management (QM) programs and ensure that they are maintained. Perform review of quality management programs (at least monthly).* Ensure that quality management programs are established and maintained to assure that quality preanalytic and/or postanalytic laboratory services are provided and to identify failures in quality as they occur;
2) Remedial/Corrective Action: ***Review and approve*** *documentation of corrective actions for failures to meet QM goals, Reportable Quality Issues (RQIs), and other major department problems.* Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's preanalytic and/or postanalytic processes are identified;
3) Training: *Establish department training program and ensure that it is maintained.* ***Sign*** *the Job Authorization Grid attesting that department employees are trained.* Ensure that prior to performing preanalytic and/or postanalytic procedures, all personnel have the appropriate training and have demonstrated that they can perform job assignments correctly;
4) Competency Assessment: *Establish department training program and ensure that it is maintained.* ***Sign*** *the Job Authorization Grid attesting that department employees are competent.* Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical and postanalytical phases of testing to assure that they are competent and maintain their competency to perform these tasks promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;
5) Periodic Procedure Review: *Ensure that approved procedures are available, complete, and reflect current practice. Submit SOPs to the Laboratory Director for approval.* ***Review*** *SOPs ~~at least annually~~ within 24 months of previous review.* Ensure that an approved procedure manual is available to all personnel for preanalytical and/or postanalytical processes. [Quest Diagnostics policy requires the Laboratory Director to sign preanalytic/postanalytic procedures when 1) initially placed in use, 2) a change is made to a procedure, or 3) there is a change in Laboratory Director. The review of procedures may be reapportioned to the department manager.]

Laboratory Name and Location:

Name of Department Manager	Preanalytic or Postanalytic Area	Shift	Duties Delegated	Other Qualifier

Laboratory Director Signature **Date** **Page**

This document reapportions or assigns specific responsibilities described in the CLIA regulations. It is not intended to be a job description. Quest Diagnostics job titles and other job duties not included on this form may be different for the individuals listed.

Appendix E – Preanalytical/Postanalytical Department Supervisor

Authorization of Responsibilities and Job Duties - Delegation Document
PREANALYTIC/POSTANALYTIC DEPARTMENT SUPERVISOR*

I authorize the individual(s) listed below to perform department supervisor duties for the preanalytic and/or postanalytic areas listed below. I also delegate the following responsibilities for these preanalytic/postanalytic areas to the department supervisor*.

* A department supervisor is an individual with responsibility for supervising personnel in preanalytical or postanalytical areas. "Department supervisor" is not intended to be a formal job title.

1) Record Review: *Advise personnel on appropriate remedial actions when problems occur, ensure that corrective action documentation is complete, consult with department manager and obtain approval for major or frequently recurring corrective actions.* ***Review*** *instrument function, preventive maintenance, error and complaint logs, and other department records (at least monthly, more often if necessary).* Assuring that all remedial actions are taken whenever preanalytical/postanalytical systems deviate from the laboratory's established performance specifications;
2) Corrective Actions: *Ensure that employees adhere to department policies regarding appropriate corrective actions. Initially* ***review and approve*** *corrective action documentation to ensure it is complete and in accordance with laboratory and department policies.* Ensuring that preanalytical/postanalytical corrective actions have been taken and specimens are handled and results are reported according to policies established by the Laboratory Director;
3) Training: *Administer the department 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.* Providing orientation to all preanalytical/postanalytical personnel;
4) Competency Assessment: *Administer the department competency program and ensure that all employees are assessed by another trained individual using direct observation, record review, and problem-solving quizzes.* ***Approve and sign*** *competency assessment documentation.* Annually evaluating and documenting the performance of all preanalytical/postanalytical personnel.

Laboratory Name and Location:

Name of Department Supervisor	Preanalytic or Postanalytic Area	Shift	Duties Delegated	Other Qualifier

PS-

Laboratory Director signature or department manager signature **Date** **Page**

Appendix F – General Supervisor, Safety

Authorization of Responsibilities and Job Duties - Delegation Document

GENERAL SUPERVISOR DELEGATION (High Complexity)

I authorize the qualified individual(s) listed below to perform the duties of General Supervisor as described in 42 CFR 493.1463. I also delegate the following responsibilities to the General Supervisor:

Periodic review of Safety Policies and Procedures.
Review and approve all changes to Safety Policies before implementation.
Providing training as necessary to all personnel

Laboratory Name and Location:

Name of General Supervisor	Department

Laboratory Director Signature **Date**

Appendix G – Technical Supervisor

Authorization of Responsibilities and Job Duties - Delegation Document

TECHNICAL SUPERVISOR DELEGATION (High Complexity)

I authorize the qualified individual(s) listed below to perform the duties of Technical Supervisor as described in 42 CFR 493.1451. I also reapportion the following laboratory director responsibilities to the Technical Supervisor:

1) Method Validation Studies: *Ensure that method validation studies are completed and submitted to Laboratory Director for approval and laboratory personnel are appropriately trained prior to method implementation.*
Ensure that.....
a) The test methodologies selected have the capability of providing the quality of results required for patient care;
b) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and
c) Laboratory personnel are performing the test results as required for accurate and reliable test results;

2) Proficiency Testing: *Ensure that 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.*
Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-----
a) The proficiency testing samples are tested as required under Subpart H of the CLIA `88 regulations (42 CFR Part 493);
b) The results are returned within the timeframes established by the proficiency testing program;
c) All proficiency testing results received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;
d) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

3) Quality Control and Quality Management: *Establish department Quality Control (QC) and Quality Management (QM) programs and ensure that they are maintained.*
Ensure that the quality control and quality assurance programs are established and maintained to assure that quality of laboratory services provided and to identify failures in quality as they occur;

4) Monthly QC/QM Review: *Perform high level* ***review*** *of quality control performance and QM programs (at least monthly).*
Ensure that establishment and maintenance of acceptable levels of analytical performance for each test system;

5) Remedial/Corrective Action: ***Review and approve*** *documentation of corrective actions for QC failures, failures to meet 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;

6) Training: *Establish department training program and ensure that it is maintained.* ***Sign*** *the Job Authorization Grid attesting that department employees are trained.*
Ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

7) Competency Assessment: *Establish department training program and ensure that it is maintained.* ***Sign*** *the Job Authorization Grid attesting that department employees are competent.*
Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

8) Periodic 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~~ within 24 months of previous review.*
Ensure that an approved procedure manual is available to all personnel for any aspect of the testing process. [Quest Diagnostics policy requires the Laboratory Director to sign procedures when 1) initially placed in use, 2) a change is made to a procedure, or 3) there is a change in Laboratory Director. The review of procedures may be reapportioned to the Technical Supervisor.]

Laboratory Name and Location: _____

Name of CLIA Technical Supervisor	Specialty or Subspecialty	Department	Shift	Duties Delegated	Other Qualifier

Laboratory Director Signature **Date**

This document reapportions or assigns specific responsibilities described in the CLIA regulations. It is not intended to be a job description. Quest Diagnostics job titles and other job duties not included on this form may be different for the individuals listed.

Appendix H – Information Technology Department Manager

Authorization of Responsibilities and Job Duties - Delegation Document

INFORMATION TECHNOLOGY DEPARTMENT MANAGER*

I authorize the individual(s) listed below to perform department manager duties for the Information Technology area. I also delegate the following laboratory director responsibilities for this area to the department manager*.

* The department manager is the individual with primary responsibility for managing the Information Technology area. "Department manager" is not intended to be a formal job title.

1) Periodic Procedure Review: *Ensure that approved procedures are available, complete, and reflect current practice. Submit SOPs to the Laboratory Director for approval.* ***Review*** *SOPs ~~at least annually~~ within 24 months of previous review.*
Ensure that an approved procedure manual is available to all IT personnel. [Quest Diagnostics policy requires the Laboratory Director to sign locally applicable IT procedures when 1) initially placed in use, 2) there a change is made to a procedure, or 3) there is a change in Laboratory Director. The review of procedures may be reapportioned to the IT Department Manager.]

2) Maintenance of Laboratory Information System (LIS) Hardware and Software: *The LIS must be maintained in a manner that ensures the functionality and reliability of the system in meeting the needs of patient care, maintains system security, and complies with regulatory and accreditation requirements.*

Laboratory Name and Location:

Name of Information Technology Manager	IT Area of Responsibility	Shift	Duties Delegated	Other Qualifier

IT-

Laboratory Director Signature **Date** **Page**

This document reapportions or assigns specific responsibilities described in the CLIA regulations. It is not intended to be a job description. Quest Diagnostics job titles and other job duties not included on this form may be different for the individuals listed.

Appendix I – Laboratory Director

Authorization of Responsibilities and Job Duties - Delegation Document

I authorize the qualified individual(s) listed below to perform the duties of Laboratory Director as described in 42 CFR 493.1415 (moderate complexity) or 42 CFR 493.1441 (high complexity) in my absence. I also reapportion the following laboratory director responsibilities:

It is the laboratory director's responsibility to 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 preanalytic, analytic and postanalytic phases of testing [493.1407(e)(1) and 493.1445(e)(1)]. Therefore, it is the policy of Quest Diagnostics that:

1) The laboratory director must sign and approve all testing procedures when initially placed in use. This includes all analytic procedures, as well as procedures that contain preanalytic and postanalytic processes, such as specimen collection, specimen transport, specimen processing, and reporting of patient results;
2) The laboratory director must sign and approve procedures when significant revisions are made;

Laboratory Name and Location:

Moderate or High Complexity Testing: **High Complexity Testing**

Name of Clinical Consultant	Specialty or Subspecialty *

Laboratory Director Signature **Date**

This document reapportions or assigns specific responsibilities described in the CLIA regulations. It is not intended to be a job description. Quest Diagnostics job titles and other job duties not included on this form may be different for the individuals listed.

Authorization of Responsibilities and Job Duties

Appendix J

QUALITY ASSURANCE MANAGER
Proficiency Testing Delegation

I authorize the qualified individual(s) listed below to manage proficiency testing activities within this laboratory. I also reapportion the laboratory director responsibilities listed under 493.1445(e)(4) to this (these) individual(s). Specific duties include:

Activity	Description
1.	Coordinate proficiency testing (PT) activities within the laboratory.
2.	Ensure that the laboratory is enrolled in an HHS approved PT program for all testing performed and is reviewed on an annual basis.
3.	Ensure that alternative assessment is performed for tests that do not have an external PT program.
4.	Ensure that PT samples are tested as required under Subpart H of 42 CFR Part 493.
5.	Ensure that PT results are reviewed and returned within the timeframes established by the proficiency testing program.
6.	Provide oversight of Rapid Response Laboratory (RRL) proficiency testing programs.
7.	Administer the CAP e-LAB program within the laboratory.
8.	Ensure that 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.
9.	Ensure that an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory.
10.	Ensure that the laboratory director is aware of the laboratory's PT performance statistics, PT failures, and corrective actions.
11.	Ensure that monthly summary statistics regarding PT performance and non-conformances are furnished to National Quality Assurance staff according to NQA established guidelines.
12.	Assist the Laboratory Director with his/her formal response to Proficiency Test Exception Summaries (PTES) or other notifications of unsuccessful PT performance. (Note: the actual written response must come from the Laboratory Director.)
13.	Ensure that the Laboratory Director notifies NQA, Medical Regulatory Affairs and Legal Operations whenever 2 of 3 consecutive proficiency testing events are unsuccessful or to report identification of any PT violation.
14.	Ensures annual PT compliance training is conducted and documented in all appropriate departments as required.

Laboratory Name and Location:

Name of Individual	Activity

Laboratory Director Signature **Date**

This document reapportions or assigns specific responsibilities described in the CLIA regulations. It is not intended to be a job description. Quest Diagnostics job titles and other job duties not included on this form may be different for the individuals listed.