**QA.GEN.2.0 AUTHORIZATION OF RESPONSIBILITIES AND JOB DUTIES**

**STATEMENT OF PURPOSE**

This procedure provides a method for a MACL Medical Director (CLIA laboratory director) to authorize, delegate or reapportion, in writing, the responsibilities and duties of each qualified consultant and supervisor, as well as each person engaged in the performance of preanalytic, analytic, and postanalytic phases of testing. This authorization function cannot be delegated. [493.1407(e)(14) and 493.1445(e)(15)] In addition, Consultants, Supervisors and Testing Personnel must acknowledge responsibility for the delegated duties.

**SCOPE**

This procedure applies to all Mid America Clinical Laboratory associates involved in any phase of the testing process–preanalytical, analytical, and postanalytical—at all complexity levels. This includes staff in the following areas: client services, logistics, specimen processing/referral testing, phlebotomy, and testing departments and information services.

**POLICY OWNERS**

QA and Safety Officer

**RELATED FORMS**

QA.GEN.2.1 Medical Director Responsibilities

QA.GEN.2.2 Clinical Consultant Delegation

QA.GEN.2.3 Technical Supervisor Delegation (High Complexity)

QA.GEN.2.4 Technical Supervisor Responsibilities Acknowledgement (use also for POC technical supervisor responsibilities acknowledgement)

QA.GEN.2.5 Cytology Technical Supervisor (High Complexity)

QA.GEN.2.6 Cytology Technical Supervisor Responsibilities Acknowledgement

QA.GEN.2.7 General Supervisor Delegation (High Complexity)

QA.GEN.2.8 General Supervisor Responsibilities Acknowledgement (High Complexity)

QA.GEN.2.9 Cytology General Supervisor Delegation (High Complexity)

QA.GEN.2.10 Cytology General Supervisor Responsibilities Acknowledgement (High Complexity)

QA.GEN.2.11 Preanalytic/Postanalytic Department Supervisor Delegation

QA.GEN.2.12 Preanalytic/Postanalytic Department Supervisor Delegation

QA.GEN.2.13 Quality Assurance Delegation (Proficiency Testing)

QA.GEN.2.14 Technical Consultant Delegation (Moderate Complexity)

QA.GEN.2.15 Technical Consultant Responsibilities Acknowledgement (Moderate Complexity)

QA.GEN.2.16 POC Technical Supervisor Delegation (Moderate Complexity)

QA.GEN.2.17 Testing Personnel Responsibilities Acknowledgement (High Complexity)

QA.GEN.2.18 Testing Personnel Responsibilities Acknowledgement (Moderate Complexity)

QA.GEN.2.19 Testing Personnel Responsibilities Acknowledgement (Waived)

QA.GEN.2.20 Cytotechnologist Responsibilities Acknowledgement

QA.GEN.2.21 Personnel Evaluation Form

QA.GEN.2.22 Laboratory Assistant (Nontesting) Responsibilities Acknowledgement Form

QA.GEN.2.23 Processing Associate Responsibilities Acknowledgement Form

**RESPONSIBILITIES**

A. Laboratory Medical Director

1. Specifies the qualified consultant and supervisor for each laboratory site or department in writing.

2. Gives written authorization for the specific duties that have been reapportioned or delegated.

B. Clinical Consultants

1. Are responsible to perform the duties delegated to them by the Medical Director.

C. Technical Supervisor

1. Ensures that all delegated assignments are completed by direct reports if designated the responsibility as General Supervisor or Testing Personnel.

2. Keeps Delegation and Responsibility documents current.

D. QA and Safety Officer

1. Provides oversight to ensure delegation/reapportion documents are updated as necessary.

**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]

***Cytology General Supervisor—***Individual(s) qualified to supervise cytology services. [493.1469]

***Cytology Technical Supervisor—***Individual(s) qualified to provide technical consultation and supervision in cytology. [493.1449 and 493.1257(c)]

***General Supervisor—***Individual(s) who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing associate and reporting of test results (high complexity testing). [493.1461]

***Laboratory Medical Director—***An individual qualified to manage and direct laboratory associates and performance of moderate complexity or high complexity tests. [493.1405 and 493.1441]

***Preanalytic Process—***A process, which occurs prior to the testing process, such as patient preparation, and specimen collection, identification, preservation, transportation and processing.

***Postanalytic Process—***A process, which occurs after the testing process, is complete, such as result reporting and interpretation.

***Transfusion Medicine General Supervisor—***Role is generally filled by the Transfusion Medicine Testing Supervisor or Manager

***Technical Supervisor—***Individual(s) qualified to provide technical consultation for each of the specialties and subspecialties of service in which a laboratory performs high complexity tests or procedures. [493.1449]. Requirements for Transfusion Medicine and Cytology are more stringent and typically require a minimum of an MD.

**PROCEDURE**

A. Delegation of CLIA consultant/technical and general supervisor duties

1. Prepare the appropriate delegation documents for the individuals that perform the duties of clinical consultant, technical supervisor, or general supervisor. (Includes the transfusion medicine and cytology subspecialties, if these services are offered).

2. Delegation documents must name the individuals performing these duties. A document that delegates only by job title is unacceptable.

3. The delegation document should also contain:

a. An authorization statement, which assigns consultant or supervisor responsibilities and duties to the individual(s).

b. Laboratory identification (eg, name, location, CLIA number).

c. Specialty(s) or subspecialty(s) for which the individual is responsible,

d. Specific laboratory director or technical supervisor responsibilities which have been delegated

4. The Laboratory Medical Director must sign and date the technical supervisor and clinical consultant delegation documents. For a high complexity laboratory, either the Laboratory Medical Director or the technical supervisor may sign the general supervisor delegation document. The technical supervisor of cytology should also sign the delegation document for a cytology general supervisor.

5. Delegation documents (or copies) must be readily available to the Laboratory Director, each consultant or supervisor, the QA Officer and Human Resources staff.

6. Delegation assignments are reviewed for accurateness by the QA Officer at least annually. Technical Supervisors must revise delegation forms within a reasonable time period for changes or reassignment of delegate designees.

B. Responsibilities that may be delegated

1. Technical Supervisor—The following laboratory director responsibilities may be reapportioned to the technical supervisor (high complexity laboratory):

a. Ensure that:

(1) The test methodologies selected have the capability of providing the quality of results required for patient care.

(2) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

(3) Laboratory associates are performing the test results as required for accurate and reliable test results.

b. Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that:

(1) The proficiency testing samples are tested as required under Subpart H of the CLIA `88 regulations (42 CFR Part 493).

(2) The results are returned within the timeframes established by the proficiency testing program.

(3) 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.

(4) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

c. 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.

d. Ensure that establishment and maintenance of acceptable levels of analytical performance for each test system.

e. 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.

f. Ensure that prior to testing patients’ specimens, all associates 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.

g. 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.

h. Ensure that an approved procedure manual is available to all associates for any aspect of the testing process. MACL policy requires the Laboratory’s Medical Director to sign procedures when initially placed in use, when a major/significant change is made to a procedure, or when there is a change in medical director. Minor, grammatical/clerical changes and annual or biannual review of procedures may be reapportioned to the technical supervisor.

2. Cytology Technical Supervisor—The laboratory director responsibilities listed above in section B may also be reapportioned to the Cytology Technical Supervisor. The technical supervisor of cytology may also perform the duties of the cytology general supervisor.

a. Ensure that all gynecologic smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant or malignant category are confirmed by a technical supervisor in cytology. The report must be signed to reflect the review or, if a computer report is generated, it must reflect an electronic signature authorized by the technical supervisor in cytology.

b. Ensure that all nongynecologic cytologic preparations are reviewed by the technical supervisor in cytology. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor.

c. Ensure that the slide examination performance of each cytotechnologist is evaluated, including performance through the reexamination of normal and negative cases and feedback on the reactive, reparative, atypical, malignant or premalignant cases.

d. Ensure that a maximum number of slides, not to exceed the maximum workload limit, is established by the technical supervisor for each individual examining slide preparations by nonautomated microscopic technique.

(1) The actual workload limit must be documented for each individual and established in accordance with the individual's capability based on the performance evaluation described above.

(2) Records are available to document that each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

e. Ensure that each individual examining gynecologic preparations participates in an approved cytology proficiency program and achieves a passing score.

3. Clinical Consultant—The following laboratory director responsibilities may be reapportioned to the clinical consultant:

a. Ensure that reports of test results include pertinent information required for interpretation.

b. 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.

4. General Supervisor—The laboratory director or technical supervisor may delegate the following responsibilities to the general supervisor:

a. Ensure that all remedial actions are taken and documented whenever test systems deviate from the laboratory’s established performance specifications.

b. Ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly.

c. Provide orientation to all testing associates.

d. Annually evaluate and document the performance of all testing associates.

5. Transfusion Medicine General Supervisor—The technical supervisor of Transfusion Medicine may delegate the following responsibilities to the Transfusion Medicine general supervisor:

a. Take responsibility for the day-to-day supervision or oversight of the Transfusion Medicine department operations and associates performing testing and reporting test results.

b. Be accessible to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of Transfusion Medicine.

6. Cytology General Supervisor—The technical supervisor of cytology may delegate the following responsibilities to the cytology general supervisor:

a. Take responsibility for the day-to-day supervision or oversight of the cytology department operation and associates performing testing and reporting test results.

b. Be accessible to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology.

7. Preanalytic/Postanalytic Department Supervisors—MACL policy allows certain laboratory director responsibilities for preanalytical and postanalytical phases of testing to be reapportioned to department supervisors.

a. Ensure that quality assurance 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.

b. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory’s preanalytic and/or postanalytic processes are identified.

c. Ensure that prior to performing preanalyical and/or postanalytical procedures, all associates have the appropriate training and have demonstrated that they can perform the procedures correctly.

d. 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.

e. Ensure that an approved procedure manual is available to all associates for any aspect of the testing process.

C. Responsibilities That Cannot Be Delegated

1. Laboratory Medical Director—The following laboratory director responsibilities cannot be reapportioned or delegated:

a. 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.

b. Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which associates are protected from physical, chemical, and biologic hazards.

c. Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing associates qualified under Sec. 493.1489(b)(4).

d. Employ a sufficient number of laboratory associates 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 associate responsibilities described in this subpart.

e. Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic 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.

# 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)]. It is MACL policy 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 major/significant revisions are made.

(3) If there is a change in laboratory director, the new director must review and sign all procedures within a reasonable time period.

(4) 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 significantly changed procedures.

(5) Annual review of procedures and responsibility for approving minor, grammatical/clerical changes, change can be reapportioned to the appropriate technical supervisor. (The department supervisor may perform this function in preanalytical and postanalytical departments).

D. Acknowledgement of Responsibilities:

1. Consultants, supervisors and testing personnel must acknowledge acceptance of the delegation of duties in writing (See QA.GEN.2.1-2.23 for both the delegation and the acknowledgement of responsibilities forms)

2. A responsibility form must be signed by the designee and the Medical Director.

3. Each Medical Director Delegation form must have a companion Consultant, Supervisor.

4. All testing personnel must also have a completed Testing Personnel Responsibility form.

5. Documents should be retained in the associate’s training file typically stored in the department and also retained in an easily retrievable for the Quality Assurance Department.

E. Personnel Evaluation Form:

1. Per the Centers for Medicine and Medicaid Services (CMS), this form (QA.GEN.2.21, Personnel Evaluation Form) must be completed by **all** laboratories accredited by (or applying for accreditation) the College of American Pathologists. Laboratory employees fulfilling one or more of the CLIA-88 defined roles listed below need to be included on this form. In addition, all non-laboratory personnel performing **non-waived** point of care testing need to be listed.

2. Instructions for completing laboratory personnel roster form:

a. Section (A): Highest Academic Degree; indicate the highest degree documentation provided to MACL for each associate. This information is provided in ADP for MACL associates. Request information for pathologists from QA.

b. Section (B): Position(s) Held; indicate the position(s)/role(s) for which the associate is responsible. If associate fulfills more than one set of responsibilities, select each one that applies (eg, Manager, serving as the Technical Supervisor, also performs testing—both Technical Supervisor and Testing Personnel should be selected).

c. Section (C): Complexity of testing performed; indicate the highest level of testing performed by an individual. For example, if an employee performs both moderate and high complexity testing, you would enter “H” for high complexity.

W = Waived

M = Moderate complexity

H = High complexity

**REFERENCES**

A. College of American Pathologists Commission of Laboratory Accreditation. *Accreditation Checklists (Laboratory General, Team Leader Assessment)*. Northfield, IL: College of American Pathologists, current versions.

B. Code of Federal Regulations, Title 42, Part 493. [42 CFR Part 493] (Laboratory Requirements)