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College of American Pathologists (CAP) Laboratory Personnel Evaluation Roster

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

A. The College of American Pathologists (CAP) Personnel Evaluation Roster is used to include all personnel performing any Clinical Laboratory Improvement Amendments (CLIA)-defined duty.
   1. Lab section leadership will update the personnel roster for their assigned areas on the CAP website.
   2. Personnel performing waived testing only are listed by Point-of-Care (POC) and maintained by Point-of-Care.

B. Personnel performing any CLIA-defined duty must be listed on the roster.
   1. Note: Personnel performing waived testing only or whose duties are limited to phlebotomy, clerical work or specimen processing are not required to be listed on the Laboratory Personnel Evaluation Roster. Histology personnel that do not perform high complexity testing are also excluded. All grossing or verifying acceptable performance of special stains and studies using immunologic and/or ISH (in situ hybridization) methodology performed in Anatomic Pathology is considered high complexity .

II. ACRONYMS:

A. Code of Federal Regulations (CFR)

B. Health and Human Services (HHS)

III. POLICY STATEMENT:

CAP GEN.54025 requires as evidence of compliance:

A. Records of completed rosters accurately reflect personnel **AND**

B. Records of **annual audits** are performed by the laboratory director or **designee**

1. The laboratory's audit of the laboratory personnel evaluation roster must include a review of a mixture of the following types of personnel:

    a. All nonwaived testing personnel hired within the last 12 months (laboratory and non-laboratory)

    b. Laboratory and non-laboratory (POC, Radiology, Respiratory, etc.) personnel

    c. Full and part-time nonwaived testing personnel on all shifts and throughout all departments

    d. Personnel fulfilling supervisory roles (eg, laboratory director, technical supervisor, staff pathologist)

Special Note: This roster needs to be maintained as personnel change (new hires, transfers, termed, etc). The Personnel Evaluation Roster should be current at all times – add or delete personnel online as the changes occur.

IV. ROLES AND RESPONSIBILITIES:

A. **Section Director (Technical Supervisor) Qualifications/Responsibilities- High Complexity Testing.** Per GEN.53400, for high complexity testing, one or more individuals qualified as a technical supervisor must be identified on the CAP's Laboratory Personnel Evaluation Roster.

NOTE: Requirements for the section directors of clinical cytogenetics, histocompatibility, molecular pathology, and transfusion medicine services are more stringent and are found in the Cytogenetics, Histocompatibility, Molecular Pathology, and Transfusion Medicine Checklists, respectively.

1. The technical supervisor must meet the following requirements:

    a. MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located with certification in anatomic pathology or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications equivalent to those required for certification.

        i. If responsible for anatomic pathology or cytopathology must be board certified in anatomic pathology or possess equivalent qualifications,

        ii. If responsible for clinical pathology must be board certified in clinical pathology or possess equivalent qualifications,

        iii. If responsible for anatomic pathology and/or cytopathology, and

clinical pathology, must be board certified in both anatomic and clinical pathology or possess equivalent qualifications **OR**

b. For specialties other than Anatomic Pathology and Cytopathology, an individual will meet the qualifications of a technical supervisor providing the following qualifications are met:

    i. MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located with at least one year of training and/or experience in high-complexity testing*; or

    ii. Doctoral degree in chemical, physical, biological or clinical laboratory science from an accredited institution with at least one year of laboratory training and/or experience in high complexity testing*;or

    iii. Master's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution with at least two years of laboratory training and/or experience in high complexity testing*; or

    iv. Bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution with at least four years of laboratory training and/or experience in high complexity testing*.

2. *NOTE: The technical supervisor's training and experience must be in the designated specialty or subspecialty area of service for which the individual is responsible.
3. Alternate qualifications for the following specialty areas can be found in Fed Register. 1992 (Feb 28): 7177-7180 [42CFR493.1449]: bacteriology, mycobacteriology, mycology, parasitology, virology, cytology, ophthalmic pathology, dermatopathology, oral pathology, and radiobioassay.
4. The section director, as designated by the laboratory director, must be accessible to the laboratory as needed for on-site, telephone, or electronic consultation and is responsible for the technical and scientific oversight of the laboratory. The section director is responsible for performing and recording competency assessment for high complexity testing. The duties for performing the competency assessment may be delegated, in writing, to individuals meeting general supervisor qualifications for high complexity testing. Other responsibilities of the technical supervisor include:
    a. Selection of test methodology.
    b. Establishment or verification of laboratory test performance specifications.
    c. Enrollment and participation in proficiency testing.
    d. Establishment of a quality control program to monitor ongoing test performance.
    e. Resolution of technical problems and ensuring that remedial actions are taken.

f. Ensuring that patient/client results are not reported until corrective actions are taken and test systems are functioning properly.

g. Identification of training needs.

5. For functions that are delegated, such as review of quality control data, assessment of competency, or review of proficiency testing performance, delegation must be in writing and the technical supervisor is responsible to ensure that those functions are properly carried out by a qualified individual.

B. **General Supervisor Qualifications/Responsibilities- High Complexity Testing.** Per CAP GEN.53600, for high complexity testing, one or more individuals qualified as a general supervisor must be defined on the CAP's Laboratory Personnel Evaluation Roster.

1. Supervisors who do not qualify as a laboratory director or section director/technical supervisor must qualify as testing personnel and possess the minimum of a:

a. Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least one year of training and/or experience in high complexity testing*; or

b. Associate degree in a laboratory science or medical technology or equivalent education and training as defined in 42CFR493.1489(b)(2)(ii), with at least two years of training and/or experience in high complexity testing*; or

c. Have previously qualified or could have qualified as a general supervisor prior to February 28, 1992.

2. *Note: The general supervisor's training and experience must be in the **designated discipline or area of service for which the individual is responsible.**

3. Requirements for the supervisors/general supervisors of cytopathology, cytogenetics, histocompatibility, and molecular pathology are more stringent and are found in the Cytopathology, Cytogenetics, Histocompatibility, and Molecular Pathology Checklists.

4. The supervisor of high-complexity testing must be accessible to the laboratory as needed for on-site, telephone, or electronic consultation and is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. Individuals meeting the qualifications of a general supervisor for high complexity testing may assess the competency of high complexity testing personnel, if this duty is delegated, in writing, by the section director. Other responsibilities of the general supervisor include:

a. Resolution of technical problems in accordance with policies and procedures established by the laboratory director or technical supervisor.

b. Monitoring of test performance.

c. Ensuring that remedial actions are taken when test systems deviate from the laboratory's established performance specifications.

d. Providing orientation of testing personnel

C. **Technical Consultant Qualifications/Responsibilities-Moderate Complexity Testing**. Per CAP

GEN.53625, for moderate complexity testing, one or more individuals qualified as a technical consultant must be identified on the CAP's Laboratory Personnel Evaluation Roster.

1. The technical consultant (including the laboratory director who serves as a technical consultant) must be qualified by education and experience by one of the following combinations:
    a. MD or DO, licensed to practice medicine in the jurisdiction where the laboratory is located (if required), with certification in anatomic and/or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or possess qualifications equivalent to those required for certification; or
    b. MD, DO, or DPM, licensed to practice in the jurisdiction where the laboratory is located (if required), with at least one year of training and/or experience in nonwaived testing*; or
    c. Doctoral or master's degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution with at least one year of training and/or experience in nonwaived testing*; or
    d. Bachelor's degree in a chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution, with at least two years of training and/or experience in nonwaived testing*.
2. *NOTE: The technical consultant's training and experience must be **in the designated specialty or subspecialty area of service for which the individual is responsible.**
3. The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant must be available to the laboratory as needed for telephone, electronic and on-site consultation. Individuals meeting the qualifications of a technical consultant may assess the competency of personnel performing moderate complexity testing, if this duty is delegated, in writing, by the laboratory director. Other responsibilities of the technical consultant include:
    a. Establishment or verification of laboratory test performance specifications.
    b. Selection of test methodology.
    c. Enrollment and participation in proficiency testing.
    d. Establishment of a quality control program to monitor ongoing test performance.
    e. Resolution of technical problems and ensuring that remedial actions are taken.
    f. Ensuring that patient results are not reported until corrective actions are taken and test systems are functioning properly.
    g. Identification of training needs.

D. **Clinical Consultant Qualifications/Responsibilities-Moderate Complexity and/or High Complexity Testing**. Per GEN.53650, for moderate complexity testing and/or high complexity testing, one or more individuals qualified as a clinical consultant must be identified on the

CAP's Laboratory Personnel Evaluation Roster.

1. Clinical consultants must be an MD, DO, DPM licensed to practice medicine in the jurisdiction where the laboratory is located (if required) or doctoral scientist certified by an HHS-approved board.
2. The clinical consultant must be available to provide and ensure that consultation is available on test ordering, and interpretation of results relating to specific patient conditions, and for matters relating to the quality of test results reported. The clinical consultant must also ensure that patient/client reports include pertinent information required for interpretation.

E. The term "section director" may be considered synonymous to the technical supervisor in the CAP checklist requirements. The term "supervisor" may be considered synonymous to the general supervisor in the checklist requirements. Within the laboratory's organizational structure, the actual position titles may be different. A qualified laboratory director may serve as the section director and general supervisor, and may set position requirements more stringent than defined in the checklist.

V. PROCEDURE:

A. Access for the CAP website organizational profile is managed by the laboratory site administrators identified in the CAP website. If access is needed, contact the site administrator to update the user profile for access.

B. The Laboratory Testing Personnel roster is located on the CAP website under Organizational Profile. Refer to the CAP website for the most recent instructions for adding or removing personnel on the roster.

C. Enter all Clinical Laboratory Improvement Amendments (CLIA) roles in the Organization Profile.

VI. REFERENCES:

A. College of American Pathologists Laboratory General Checklist, Current Version, GEN. 54025 *Laboratory Personnel Evaluation Roster.*

B. College of American Pathologists Laboratory General Checklist, Current Version, GEN.53400 Section Director (Technical Supervisor) Qualifications/Responsibilities.

C. College of American Pathologists Laboratory General Checklist, Current Version, GEN.53600 *General Supervisor Qualifications/Responsibilities.*

D. College of American Pathologists Laboratory General Checklist, Current Version, GEN.53625 *Technical Consultant Qualifications/Responsibilities.*

E. College of American Pathologists Laboratory General Checklist, Current Version, GEN.53650 *Clinical Consultant Qualifications/Responsibilities.*

F. CAP Personnel Requirements by Testing Complexity

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Jeremy Powers: Chief, Pathology	5/13/2024
CLIA Site Licensed Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	5/7/2024
CLIA Site Licensed Medical Directors	Muhammad Arshad: Chief, Pathology	5/7/2024
CLIA Site Licensed Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	5/6/2024
CLIA Site Licensed Medical Directors	Masood Siddiqui: Staff Pathologist	5/2/2024
CLIA Site Licensed Medical Directors	Subhashree Mallika Krishnan: Staff Physician	5/2/2024
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	5/2/2024
CLIA Site Licensed Medical Directors	Kurt Bernacki: System Med Dir, Surgical Path	5/2/2024
CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	5/2/2024
Policy and Forms Steering Committee Approval (if needed)	Michele Sedlak: Lab Quality Coord	5/2/2024
	Sarah Britton: VP, Laboratory Svcs	5/1/2024
Operations Directors	Joan Wehby: Dir, Lab Operations C	5/1/2024
Operations Directors	Brittnie Berger: Dir Sr, Lab Operations	4/30/2024
Operations Directors	Elzbieta Wystepek: Dir, Lab Operations B	4/22/2024
Operations Directors	Christopher Ferguson: Dir, Lab Operations B	4/22/2024
Operations Directors	Amy Knaus: Dir, Lab Operations C	4/22/2024
	Michele Sedlak: Lab Quality Coord	4/22/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne