American College of Medical Genetics and Genomics (ACMG)

TECHNICAL STANDARDS FOR CLINICAL GENETICS LABORATORIES
(2021 Revision)

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B: PERSONNEL POLICIES

(For a general overview of these standards, including purpose and disclaimer, see Section A.)

B1 Personnel Qualifications

The personnel qualifications described in this section are based on federal regulations as well as College of American Pathologists (CAP) checklist requirements. Note, the terminology used to describe personnel is not consistent between the various regulatory agencies and the text below is an attempt to match these titles to the day-to-day operational responsibilities of clinical genetics laboratories. The Clinical Laboratories Improvement Amendment (CLIA) of 1988 was last updated December of 2019 (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA) and defines legal requirements expected by the Centers for Medicare and Medicaid Services (CMS; previously the Health Care Financing Administration or HCFA). The relevant legal code is found within Title 42 - Public Health Chapter IV - CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES, Part 493 - LABORATORY REQUIREMENTS. Specific subpart requirements are cited below with each laboratory position.

B2 Staff Size

Sufficient appropriately qualified staff, able to perform high complexity testing, must be available to ensure the accuracy of results with prompt and proficient performance of tests and reporting of results.

B3 Clinical Consultant, Section Director/Technical Supervisor

The term used to describe the individual(s) who is responsible for the day-to-day administrative, technical and/or reporting functions of a clinical laboratory varies. While we use the term "**Clinical Consultant**" to refer to this individual within this document, it should be noted that this individual may also fulfill many, if not all, of the responsibilities attributed to the Section

Director or Technical Supervisor and vice versa. A Clinical Consultant is required by CLIA regulations for all clinical genetics laboratories and provides consultation to health care providers and/or patients. According to the CAP Checklist, the term "**Laboratory Director**" currently refers to an appropriately qualified individual who oversees all laboratory sections within an organization and whose name appears on accreditation documentation (CAP Laboratory General Checklist - Definition of Terms).

A **Clinical Consultant** may be an MD/DO or equivalent medical geneticist, a PhD medical geneticist, or an MD/DO or PhD clinical laboratory geneticist board certified in Clinical Molecular Genetics and Genomics, Clinical Cytogenetics and Genomics, Clinical Biochemical Genetics, and/or Laboratory Genetics and Genomics. Certification or eligibility is expected in the relevant specialty through the American Board of Medical Genetics and Genomics (ABMGG), the American Board of Pathology (ABP), the Canadian College of Medical Geneticists (CCMG), the Royal College of Physicians and Surgeons (RCPS), or another comparable accreditation organization with similarly rigorous training requirements. These requirements include certification exams and maintenance of certification/continuing certification requirements. If more stringent state or local requirements exist, these requirements must also be met. If the terminal degrees are obtained outside the United States and its territories, the degrees must be evaluated by an independent organization and deemed equivalent to a degree obtained in the United States.
[CLIA, Subpart M, Section 493.1455, 2019; CAP GEN.53650, 2020]

A **Section Director/Technical Supervisor** may have an appropriate doctoral degree (MD, DO, and/or PhD) and at least two years of postdoctoral training and/or experience in their clinical laboratory specialty. If more stringent state or local requirements exist, these requirements must also be met. If the terminal degrees are obtained outside the United States and its territories the degrees must be evaluated by an independent organization and deemed equivalent to a degree obtained in the United States.
[CLIA, Subpart M, Section 493.1443, 2019; CLIA, Subpart M, Section 493.1449, 2019; CAP GEN.53400, 2020]

B3.1 To function as a Clinical Consultant (Section Director/Technical Supervisor) **within a clinical cytogenetics laboratory**, CAP indicates this individual must have either completed an accredited fellowship with an emphasis on clinical cytogenetics, or have at least "four years of training in human medical genetics or pathology, two of which have been in clinical cytogenetics."
[CAP CYG.50000, 2020]

B3.2 To function as a Clinical Consultant (Section Director/Technical Supervisor) **within a clinical molecular genetics laboratory**, CAP indicates this individual is a pathologist, board-certified physician in a specialty other than pathology, or a doctoral scientist in a chemical, physical, or biologic science, with specialized training and/or appropriate experience in molecular pathology.
[CAP MOL.49650, 2020]

B3.3 To function as a Clinical Consultant (Section Director/Technical Supervisor) **within a**

clinical biochemical genetics laboratory, this individual must have completed an accredited fellowship with an emphasis on biochemical genetics such as that overseen by the ABMGG, and more recently the ACGME, or have equivalent advanced training and experience.
[CAP GEN.53400, 2020]

B3.4 The expectations of the individual(s) responsible for the day-to-day administrative, technical and/or reporting functions of a clinical laboratory, and to ensure regular laboratory operations, are listed below. As indicated above, **this individual(s) may be designated as the Clinical Consultant**, **the Section Director/Technical Supervisor or both**.

B3.4.1 The laboratory Clinical Consultant (Section Director/Technical Supervisor) must be on site regularly (at least weekly). When not on site, this individual must be accessible by telephone or electronically to provide consultation to the laboratory and to referring professionals.

B3.4.2 The laboratory Clinical Consultant (Section Director/Technical Supervisor) must perform all functions listed below for each laboratory they oversee.

- Delegate responsibilities as appropriate.
- Ensure all laboratory faculty and staff have appropriate education, experience and training to perform laboratory testing accurately, promptly and proficiently.
- Implement and maintain a safe laboratory environment in compliance with good practice and applicable regulations.
- Establish and maintain a quality assurance/quality improvement program that encompasses all aspects of the laboratory.
- Participate in proficiency testing consistent with the laboratory's test menu.
- Be responsible for the technical and scientific oversight of the laboratory including, but not limited to the following:
    - Selection of test methodology.
    - Establishment and verification of laboratory test performance specifications.
    - Monitoring of ongoing test performance.
    - Resolution of all technical problems and appropriate remediation of staff and/or protocols.
- Review, approve, interpret and report laboratory results in an accurate, prompt, and proficient way.

B4 Laboratory or General Supervisor

A laboratory or general supervisor must have prior experience in a clinical genetics laboratory. CAP recommends at least two years for general supervisors of high complexity testing and at least four years for molecular pathology general supervisors. Additionally, certification by a national testing agency is recommended.
[CLIA, Subpart M, Section 493.1461, 2019; CAP CYG.50180, 2020; CAP GEN.53600, 2020; CAP MOL.49655, 2020]

B4.1 To function as a General Supervisor **within a clinical cytogenetics laboratory**, CAP indicates this individual must have at least a bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology. Additionally they must have at least two years of experience in clinical cytogenetics under the direction of a qualified section

director/technical supervisor. Alternatively, a section director/technical supervisor may qualify as the general supervisor.
[CAP CYG.50000, CYG.50180, 2020]

B4.2 To function as a General Supervisor **within a molecular genetics laboratory**, CAP indicates this individual must have at least a bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology. Additionally they must have at least four years of experience in molecular pathology under the direction of a qualified section director/technical supervisor, with at least one year focusing on molecular pathology methods. Alternatively, a section director/technical supervisor may qualify as the general supervisor.
[CAP MOL.49650, MOL.49655, 2020]

B4.3 CAP does not specifically outline the requirements for an individual to function as a General Supervisor **within a biochemical genetics laboratory** in their Clinical Biochemical Genetics Checklist. However according to requirements cited in the CAP Laboratory General Checklist, this individual should have 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 with biochemical genetic testing. Alternatively this individual may have an associate's degree in an appropriate laboratory or clinical science, as well as at least two years of training and/or experience in biochemical genetic testing. A section director/technical supervisor may also qualify as the general supervisor.
[CAP GEN.53400, GEN.53600, 2020]

B5 Clinical Laboratory Technologist/Technician
A clinical laboratory technologist/technician must hold an undergraduate degree in a relevant scientific field or have documentation of relevant laboratory training to perform high complexity testing. If more stringent state or local requirements exist, these requirements must also be met.
[CLIA, Subpart M, Section 493.1489, 2019; CAP GEN.54750, 2020]

B5.1 For clinical cytogenetics, it is recommended there be at least one full-time technologist in the laboratory who is certified in cytogenetics by a recognized national certification body. Certification should be pursued by all technologists/technicians and current certification should be maintained by re-examination or by acquiring continuing education units (CEUs).

B5.2 For laboratories subject to US regulations, the credentials of all personnel trained outside the US must be reviewed for equivalency by a nationally recognized outside organization.
[CLIA, Subpart M, Section 493.1489; CAP GEN.53400, GEN.54400, GEN.53600, GEN.53625, GEN.53650, 2020].

References
College of American Pathologists (CAP), Cytogenetics Checklist, CYG.50000 Section Director/Technical Supervisor Qualifications, June 4, 2020 edition.

College of American Pathologists (CAP), Cytogenetics Checklist, CYG.50180 Cytogenetics General Supervisor Qualifications, June 4, 2020 edition.

College of American Pathologists (CAP), Laboratory General Checklist, GEN.53400 Section Director (Technical Supervisor) Qualifications/Responsibilities, June 4, 2020 edition.

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College of American Pathologists (CAP), Laboratory General Checklist, GEN.53650 Clinical Consultant Qualifications/Responsibilities, June 4, 2020 edition.

College of American Pathologists (CAP), Cytogenetics Checklist, GEN.54400 Personnel Records, June 4, 2020 edition

College of American Pathologists (CAP), Laboratory General Checklist, GEN.54750 Nonwaived Testing Personnel Qualifications, June 4, 2020 edition.

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Title 42 - Public Health Chapter IV - CLIA, Subpart M - Personnel for Nonwaived Testing, Section 493.1443 – Standard; Laboratory director qualifications. https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_11443/. Updated December 20, 2019. Accessed December 26, 2019.

Title 42 - Public Health Chapter IV - CLIA, Subpart M - Personnel for Nonwaived Testing, Section 493.1449 – Standard; Technical supervisor qualifications. https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_11449/. Updated December 20, 2019. Accessed December 26, 2019.

Title 42 - Public Health Chapter IV - CLIA, Subpart M - Personnel for Nonwaived Testing, Section 493.1455 – Standard; Clinical consultant qualifications. https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m/. Updated December 20, 2019. Accessed December 26, 2019.

Title 42 - Public Health Chapter IV - CLIA, Subpart M - Personnel for Nonwaived Testing, Section 493.1461 – Standard; General supervisor qualifications. https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_11461/. Updated December 20, 2019. Accessed December 26, 2019.

Title 42 - Public Health Chapter IV - CLIA, Subpart M - Personnel for Nonwaived Testing, Section 493.1489 – Standard; Testing personnel qualifications. https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_11489/. Updated December 20, 2019. Accessed December 26, 2019.