

# American College of Medical Genetics and Genomics STANDARDS AND GUIDELINES FOR CLINICAL GENETICS LABORATORIES

2008 Edition, Revised 02/2007

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

B	<b>PERSONNEL POLICIES</b>
B1	<p><b>Additional Requirements Specified Elsewhere</b>            In addition to the personnel requirements specified by the Health Care Financing Administration (HCFA; now known as the Centers for Medicare and Medicaid Services, or CMS) and published in the Federal Register on February 28, 1992 (Vol. 57/No. 40: 7001-7288) sections §493.1443, §493.1449 (encompassed by §493.1443 for genetics laboratories), §493.1455 and §493.1489, the following requirements must be met:</p>
B2	<p><b>Staff Size</b>            Sufficient <b>staff</b> must be available to ensure accuracy of results with prompt and proficient performance of tests and reporting of results.</p>
B3	<b>Laboratory Director and/or Laboratory Technical Supervisor</b>
B3.1	<p>A laboratory director and/or technical supervisor must have an appropriate <b>doctoral degree</b> and at least 2 years of postdoctoral training and/or experience in his/her clinical laboratory subspecialty, and</p>
	<p><b>a) American Board of Medical Genetics and Genomics (ABMGG)</b> certification or eligibility in the specific specialty or for molecular genetic testing only, the conjoint <b>American Board of Medical Genetics</b> and <b>American Board of Pathology</b> subspecialty certification in molecular genetic pathology            OR  <b>b) Canadian College of Medical Geneticists (CCMG)</b> certification or eligibility in the specific specialty.</p>
	<p>Note: The question exists as to whether certification by the American Board of Pathology (ABP) or the American Board of Clinical Chemistry (ABCC) may substitute for certification by the ABMG. A mechanism should be available whereby individuals who have training and experience in genetics and are diplomates of ABP or ABCC can serve as laboratory directors, whether by joint pathology/genetics training programs, eligibility of ABP diplomates with genetics and human genetics training to stand for ABMG exams, or other processes. Until such mechanisms are developed, ABP or ABCC diplomates</p>

	with appropriate training and/or experience in genetics should be able to serve as laboratory directors and/or laboratory technical supervisors.
B3.2	A laboratory <b>director must be on site regularly</b> (at least weekly) and must perform or oversee the following duties:
B3.2.1	When not on site, <b>be accessible</b> to the laboratory and to referring professionals to provide consultation.
B3.2.2	Ensure that the laboratory maintains an ongoing <b>quality assurance/improvement program</b> .
B3.2.3	Ensure <b>compliance with all applicable laboratory regulations</b> .
B3.2.4	Ensure that laboratory <b>staff</b> have <b>appropriate education, experience and training</b> to perform laboratory testing accurately, promptly and proficiently.
B3.2.5	As with other medical specialties, establish and maintain <b>appropriate procedures</b> to ensure the privacy and security of patient identity and all patient information, as required by applicable laws and professional standards.
B3.2.6	<b>Consult regularly with laboratory supervisor(s) and other staff members</b> .
B3.2.7	<b>Determine</b> the appropriate laboratory tests to be performed, the techniques to be followed and the equipment and reagents to be used.
B3.2.8	Review, approve, interpret and report all <b>laboratory results</b> in an accurate, prompt and proficient way.
B3.3	A laboratory director or technical supervisor must <b>delegate responsibilities</b> as appropriate <b>during absences</b> from the laboratory.
B3.4	A laboratory director or technical supervisor may <b>direct no more than 3 laboratories, each of which must meet all of the above</b> responsibilities for each of the laboratories.
B3.5	Implement a safe laboratory environment in compliance with good practice and applicable regulations.
B4	<b>Laboratory or General Supervisor</b>
B4.1	A <b>laboratory or general supervisor (clinical cytogenetics)</b> must have at least 3 years of experience in a clinical cytogenetics laboratory. Additionally, certification by a national testing agency is recommended.

B4.2	A <b>laboratory or general supervisor (biochemical genetics)</b> must have at least 3 years of experience in a clinical biochemical genetics laboratory.
B4.3	A <b>laboratory or general supervisor (molecular genetics)</b> must have at least 3 years of experience in a clinical molecular genetics laboratory. Additionally, certification by a national testing agency is recommended.
B5	<p><b>Clinical Laboratory Technologist/Technician</b></p> <p>A clinical laboratory technologist/technician must hold an undergraduate degree in a relevant scientific field or have at least 5 years of relevant laboratory experience.</p>
B5.1	For <b>clinical cytogenetics</b> it is recommended that 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).
B6	<p><b>Clinical Consultant</b></p> <p>A clinical consultant is required by the Clinical Laboratories Improvement Amendment of 1988 (CLIA '88) regulations for all laboratories. The clinical consultant must be an American Board of Medical Genetics certified clinical geneticist, PhD medical geneticist, or clinical laboratory geneticist. The laboratory director can fulfill this role. The clinical consultant is required to provide consultation but not counseling to the patient.</p>