

Special Article

Certification in Molecular Pathology in the United States (Training and Education Committee, the Association for Molecular Pathology)

Anthony A. Killeen,* Wai-Choi Leung,[†]
Deborah Payne,[‡] Daniel E. Sabath,[§]
Karen Snow,[¶] Gregory J. Tsongalis,^{||}
Vivianna Van Deerlin,** and Karen Weck^{††}

From the Department of Laboratory Medicine and Pathology, University of Minnesota, Minneapolis, Minnesota; the Department of Pathology and Laboratory Medicine,[‡] Tulane University School of Medicine, New Orleans, Louisiana; the Department of Pathology,[‡] University of Texas Medical Branch, Galveston, Texas; the Department of Laboratory Medicine,[§] University of Washington, Seattle, Washington; the Molecular Genetics Lab/H1970,[¶] Mayo Clinic, Rochester, Minnesota; the Department of Pathology and Laboratory Medicine,^{||} Hartford Hospital, Hartford, Connecticut; the Department of Pathology and Laboratory Medicine,** Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania; and the Division of Molecular Diagnosis,^{††} University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania*

Training in molecular pathology in the United States is undergoing development toward a more structured format involving accreditation of training programs and the availability of recognized professional credentials. The traditional apprenticeship for molecular pathology, composed of experience in a molecular biology laboratory with a strong research focus is being replaced by formal training in residency, fellowship, and other postdoctoral training programs that have a clinical focus. This is a reflection of increasing importance of this field to clinical practice, and to a growing desire of persons interested in molecular pathology to undertake formal training programs. These developments are bringing molecular pathology in line with other clinical laboratory specialties for which structured training and certification have long been the norm.

An important measure of educational achievement is success in professional examinations leading to recognized credentials. These credentials should attest to the holder's professional competence as a practitioner in the field and are frequently used for this purpose by licensing and other regulatory agencies. In the past decade, and especially in the last 5 years, a number of routes for

certification in molecular pathology by examination have been offered by nationally recognized credentialing agencies. This paper provides an update on these certification routes reflective of the growing interest in molecular pathology education.

The principal Boards that offer certification in the United States are the American Board of Pathology, the American Board of Medical Genetics, the American Board for Clinical Chemistry, the National Credentialing Agency for Laboratory Personnel, and the American Board of Bioanalysis. The American Board of Medical Genetics offered a combined examination in Clinical Molecular Genetics and Clinical Biochemical Genetics in 1990 and has offered an examination in Clinical Molecular Genetics alone since 1993. Because of the overlap between molecular genetics and molecular pathology, we have included this examination in this listing.

The information provided here is intended to summarize the requirements for these exams. Complete requirements are available from the boards listed here.

American Board of Pathology and American Board of Medical Genetics

Examination Name: Molecular Genetic Pathology

Examination frequency: Biannually.

Eligibility: Applicants for examination in molecular genetic pathology must hold an M.D. or equivalent medical degree, and be a licensed physician in the United States or Canada. In addition, applicants must hold a primary certificate from the American Board of Pathology or the American Board of Medical Genetics.

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Address reprint requests to Dr. A. A. Killeen, Department of Laboratory Medicine and Pathology, University of Minnesota, Mayo Mail Code 609, 420 Delaware Street, S.E., Minneapolis, MN 55455. E-mail: kill001@umn.edu.

Accreditation of training programs in molecular genetic pathology by the Accreditation Council on Graduate Medical Education (ACGME) began in 2002. Until April 6, 2007, candidates may be eligible to take the examination on the basis of experience. This experience can consist of at least 5 years of experience at 25% effort or 2 years of full-time experience in molecular genetic pathology. After this initial "grandfathering" period, applicants will be required to have completed a 1-year fellowship in molecular genetic pathology in an ACGME-approved program. All candidates must provide a case logbook demonstrating experience with at least 150 cases in molecular pathology acquired during the period of experience or training. The cases should demonstrate broad experience in the field.

Scope of examination: Principles, theory, and technologies of molecular biology and molecular genetics as they are used to make or confirm clinical diagnoses of Mendelian genetic disorders, disorders of human development, infectious diseases and malignancies, to assess the natural history of those disorders, and to guide management of those disorders.

Examination format: The examination is a 1-day test consisting of 300 multiple-choice questions. The American Board of Pathology's test center in Tampa, FL is the examination site.

Certificate duration: The certificate will be valid for 10 years. Details on re-certification are unavailable at the present time.

Contact information: American Board of Pathology, P.O. Box 25915, Tampa, FL 33622-5915, Phone: (813) 286-2444, Fax: (813) 289-5279, Web: www.abpath.org; or American Board of Medical Genetics, 9650 Rockville Pike, Bethesda, MD 20814-3998, Phone: (301) 571-1825, Fax: (301) 571-1895, Web: www.abmg.org.

American Board of Medical Genetics

Examination Name: Clinical Molecular Genetics

Examination frequency: Every 3 years. In 2002, testing was offered at Prometrics test centers.

Eligibility: Candidates must hold a Ph.D. (in genetics or a related field), M.D., D.O., or foreign equivalent acceptable to the Board. In addition, candidates must have completed 24 months of training in an American Board of Medical Genetics (ABMG)-accredited clinical molecular genetics fellowship program or clinical genetics residency and submit a logbook of 150 cases. Longer training may be required for fellowships that involve an extensive research involvement.

Eligibility period: A candidate is considered "active" until the examination results are released. An applicant who fails to pass the examination must re-apply during a future examination cycle. The examination must be passed within 2 examination cycles or 6 years (whichever is shorter) of achieving active candidate status.

Scope of examination: The general examination covers all areas of medical genetics, including clinical

genetics, genetic counseling, cytogenetics, biochemical genetics, and molecular genetics. The clinical molecular genetics specialty examination tests basic principles and concepts of molecular biology, molecular genetic principles relevant to disease, quality assurance and lab operation, and application of techniques for diagnosis of inherited disorders.

Examination format: The examination consists of both a general examination in genetics and a clinical molecular genetics specialty examination. Both of these are multiple-choice examinations.

Certificate duration: The ABMG certificate is valid for 10 years. Renewal of a certificate is possible by either of two options. The first option involves taking a proctored multiple-choice examination on an assigned list of readings. Successful completion of this option will renew a certificate for 2 years. The second option involves a comprehensive examination similar or identical in format to the initial certifying examination. Successful completion of this option will renew a certificate for 10 years.

Contact information: American Board of Medical Genetics, 9650 Rockville Pike, Bethesda, MD 20814-3998, Phone: (301) 571-1825, Fax: (301) 571-1895, Web: www.abmg.org.

American Board of Clinical Chemistry

Examination Name: Molecular Diagnostics

Successful candidates may use the title, Diplomate of the American Board of Clinical Chemistry (DABCC).

Examination frequency: The examination is scheduled yearly, usually just before the American Association for Clinical Chemistry (AACC) annual meeting that is usually held in July or August.

Eligibility requirements: In addition to being of good moral, ethical, and professional standing, candidates must hold an earned doctoral degree in the natural sciences or medicine and hold a certificate from one of the following Boards: American Board of Clinical Chemistry, American Board of Medical Microbiology, American Board of Medical Laboratory Immunology, American Board of Pathology, American Board of Bioanalysis, or the American Board of Histocompatibility and Immunogenetics. Candidates whose eligibility to sit for one of these examinations has been accepted by a board may take the American Board of Clinical Chemistry (ABCC) examination, but the ABCC will not issue a certificate until the candidate has passed both the ABCC examination and the other board's examination.

Eligibility period: Eligibility for the ABCC examination in molecular diagnostics is for a period of 2 years from the date of the first examination after the accepted application. If the examination is not passed within the 2-year eligibility period, a second application for 2-year eligibility may be made.

Scope of examination: Molecular biology principles, concepts, and techniques as applied to the clinical laboratory. Areas of emphasis include inherited disorders, infectious diseases, identity testing, hematopathology, and cancer.

Examination format: A 3-hour multiple-choice examination.

Duration of certificate: Diplomates of the ABCC must document at least 25 hours of continuing education annually to be listed as active in the directory of Diplomates. A biannual report on continuing education activities and payment of a fee are required to retain active status.

Contact information: ABCC, 2101 L Street, N.W., Suite 202, Washington, D.C. 20037-1526, Phone: (202) 835-8727, Fax: (202) 887-5093, Web: www.aacc.org/abcc.

American Board of Bioanalysis

American Board of Bioanalysis (ABB) offers certification for professionals in a variety of roles in the clinical laboratory. The Clinical Laboratory Improvement Act of 1988 (CLIA) recognizes ABB certification for laboratory directors and consultants. Director certification by ABB has three levels: Bioanalyst Clinical Laboratory Director, High-Complexity Clinical Laboratory Director, and Moderate-Complexity Clinical Laboratory Director. The second and third of these are designed to meet the legal definitions of these roles as stipulated by CLIA. ABB offers two levels of certifications for consultants: Technical Consultant (as defined by CLIA) and Clinical Consultant. Finally, certification as Technical Supervisor or General Supervisor (as defined by CLIA) is available. The details of the High-Complexity Laboratory Director (HCLD) certification are presented below.

Examination frequency: Semiannually (spring and fall).

Eligibility: For the HCLD certificate, applicants must meet the requirements stipulated by CLIA '88 Subpart M, Section 493.1443, or hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science and have completed at least 32 hours in chemistry or a biological science acceptable to the Board. Physician applicants must be licensed in at least one state. In addition, applicants must have at least 4 years of laboratory training or experience, or both, including at least 2 years of experience directing or supervising high-complexity laboratories.

Examination format: The examination consists of two components, general knowledge and clinical molecular biology. Both of these 2-hour exams must be passed.

Certificate duration: An active certificate is maintained by documenting participation in 24 contact hours of a Professional Educational Enrichment Renewal every 2 years. A longer period is allowed for new diplomats. Payment of a fee is also required.

Contact information: American Board of Bioanalysis, 917 Locust St. Ste 1100, St. Louis, MO 63101-1419, Phone: (314) 241-1445, Fax: (314) 241-1449, Web: www.abccert.org or www.aab.org.

National Credentialing Agency for Laboratory Personnel (NCA)

Examination Name: Certified Laboratory Specialist in Molecular Biology (CLSp(MB))

Examination frequency: The examination can be taken at any time with the exception of certain public holidays.

Eligibility: Eligibility to take the examination is by one of seven routes as follows.

Route 1. Successfully complete a National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) accredited baccalaureate or post-baccalaureate molecular diagnostic or molecular biotechnology education program.

Route 2. Successfully complete a baccalaureate degree or a post-baccalaureate certificate molecular biology education program sponsored by an accredited college or university that includes the equivalent of 6 months of full-time experience in a full-service molecular biology laboratory. (A full-service molecular biology laboratory is defined as one capable of providing individuals with knowledge and practical experience in all aspects of molecular analysis including, but not limited to, recombinant DNA technologies, polymerase chain reaction, and hybridization technique.)

Route 3. Successfully complete an NAACLS-accredited or NACCLS-approved baccalaureate-level education program in a clinical laboratory science (clinical laboratory sciences, medical technology, or cytogenetics), **and** complete the equivalent of 6 months of full-time experience gained within the last year in a full-service molecular biology laboratory.

Route 4. Be certified as a Clinical Laboratory Scientist (CLS) or equivalent, a Clinical Laboratory Specialist in Cytogenetics [CLSp(CG)], or as an Advanced Registered Technologist (ART, Canadian Society for Medical Laboratory Science), **and** complete the equivalent of 6 months of full-time work experience gained within the last year in a full-service molecular biology laboratory.

Route 5. Have a baccalaureate degree in the biological, chemical, and/or medical sciences from an accredited college or university, **and** complete the equivalent of 1 year of full-time work experience within the last 2 years in a full-service molecular biology laboratory.

Route 6. Have a baccalaureate degree from an accredited college or university **and** complete 36 semester hours in the biological, chemical, and/or medical sciences (in addition to or part of the baccalaureate degree), **and** complete the equivalent of 1 year of full-time work experience gained within the last 2 years in a full-service molecular biology laboratory.

Route 7. Be certified as a Registered Technologist (RT) by the Canadian Society for Medical Laboratory Science, **and** complete the equivalent of 2 years of full-time work experience within the last 4 years in a full-service molecular biology laboratory.

Examination format: Computerized assessment by Applied Measurement Professionals (AMP). The examination can be taken at approximately 100 centers in the U.S.

Certificate duration: The CLSp(MB) certificate is maintained by either demonstrating continuing education experience or by repeating the examination.

Contact information: National Credentialing Agency, P.O. Box 15945-289, Lenexa, KS 66285, Phone: (913) 438-5110 ext 647, Fax: (913) 541-0156, Web: www.nca-info.org.

General Comments on Certification

Both the American Board of Pathology and the American Board of Medical Genetics are members of the American Board of Medical Specialties. Examinations offered by these Boards (molecular genetic pathology and clinical molecular genetics) may confer official recognition from licensing and other regulatory agencies for medical practitioners as specialists in these fields, and accredited programs in these areas may be eligible for graduate medical education funding. Training programs in clinical molecular genetics and in molecular genetic pathology are accredited by the Accreditation Committee on Graduate Medical Education (ACGME). This involves filing a program application and an on-site formal inspection by representatives of ACGME.

Molecular pathology laboratories are high-complexity laboratories, per CLIA '88. Federal regulations (CLIA '88; Section 493.1443) stipulate that directors of such laboratories be a doctor of medicine or a doctor of osteopathy licensed to practice medicine and a) be certified in anatomical or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology, or b) have at least 1 year of laboratory training during medical residency, or c) have at least 2 years of experience directing or supervising high-complexity testing.

Non-physicians who work as laboratory directors must hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science discipline and be certified by either the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology, or another board deemed comparable by the Department of Health and Human Services. Not all of these boards offer specific certification in molecular pathology.

Certification options for Ph.D. holders are essentially the same as those for physicians with the notable exception of the molecular genetic pathology certification offered conjointly by the American Board of Pathology (ABP) and ABMG, which is currently available only to physicians.

Non-doctoral degree holders have options for certification through either the NCA or the ABB. These options are commonly used by medical technologists used in molecular diagnostics laboratories.

Convenience of Examination Center

The ABCC examination is held about the same time, and in the same location, as the annual meeting of the American Association for Clinical Chemistry. This makes it easy for persons attending the meeting to also take this examination. Similarly, the ABMG re-certification examination based on reading assignments is held at the American Society for Human Genetics meeting and at the American College of Medical Genetics meeting. Both the ABMG and the National Credentialing Agency offer exams that can be taken at commercially operated testing centers in the U.S. This seems like a model for other boards to consider implementing for the convenience of the examinees. With the availability of computerized testing, there seems to be little reason to require attendance at single sites that may be remote for many candidates.

Summary

Several routes to certification in molecular pathology presently exist. Examining boards that currently offer molecular pathology (or related) certification include the American Board of Pathology, American Board of Medical Genetics, American Board for Clinical Chemistry, American Board of Bioanalysis, and the National Credentialing Agency for Laboratory Personnel. Some of the examinations offered by these boards have been recently initiated. These examinations can lead to important professional qualifications for candidates with medical degrees, Ph.D.s, and non-doctoral degrees. These certification options should be of interest to specialists in molecular pathology.