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# **Special Article**

### Certification in Molecular Pathology in the United States

### An Update from the Association for Molecular Pathology Training and Education Committee

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The past 25 years have witnessed the field of molecular pathology evolving from an imprecisely defined discipline to a firmly established medical subspecialty that plays an essential role in patient care. During this time, the training, certification, and licensure requirements for directing and performing testing in a molecular pathology or molecular diagnostics laboratory have become better defined. The purpose of this document is to describe the various board certifications available to individuals seeking certification in molecular diagnostics at the level of laboratory director, supervisor, or technologist. Several national organizations offer certification in molecular pathology or molecular diagnostics for doctoral-level clinical scientists to function as the director of a molecular diagnostics laboratory. Furthermore, 12 states and Puerto Rico require licensing of medical technologists, including those working in molecular diagnostic laboratories. The information provided here updates a 2002 document by the Training and Education Committee of the Association for Molecular Pathology and has been expanded to include certification and licensing requirements for laboratory technologists. (J Mol Diagn 2012, 14:541-549; http://dx. doi.org/10.1016/j.jmoldx.2012.05.004)

The present document is an update to "Certification in Molecular Pathology in the United States," by the Training and Education Committee of the Association for Molecular Pathology, published in 2002.<sup>1</sup> This update includes certification and licensing requirements for laboratory technologists.

### Overview of Certification Routes in Molecular Diagnostics

The qualifications of laboratory director for a laboratory that performs high complexity testing are defined in subpart M, section 493.1443 of current regulations under Clinical Laboratory Improvement Amendments (CLIA) of 1988 (*http://www.cdc.gov/clia/regs/subpart\_m.aspx#* 493.1443). Licensed physicians who are certified in anatomic and/or clinical pathology by the American Board of Pathology (ABP) or anatomic pathology and/or laboratory medicine by the American Osteopathic Board of Pathology (AOBP) meet these qualification standards. In addition, licensed physicians with either 1 year of laboratory training during medical residency [eg, physicians certified in hematology or medical oncology by the Amer-

Standard of practice is not being defined, and there may be alternatives. See *Disclaimer* for further details.

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The findings, conclusions, and opinions expressed in this report do not necessarily reflect those of any individual committee member or his or her employer.

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Agency (website)	Certification designation	Examination frequency	Certificate duration	CE requirements
ABP (http://www.abpath.org) or ABMG (http://www.abmg.org)	MGP	Annual	10 years	MOC program required
ABMG (http://www.abmg.org)	CMG	Biennial	10 years	MOC program required
ABB (http://www.aab.org)	HCLD(ABB), BCLD(ABB), TS(ABB)	Semiannual	1 year	24 contact hours (2.4 CEU) of acceptable CE every 2 years
ABCC (http://www.abclinchem.org)	DABCC	Semiannual	2 years	50 contact hours (5.0 CEU) of participation every 2 years in an organized CE experience
ASCP BOC (http://www. ascp.org/Board-of-Certification)	MB(ASCP)	Open*	3 years	MOC program participation required
AAB (http://www.aab.org)	MT(AAB), MLT(AAB)	Five times per year	1 year	CE optional

Table 1.	Boards Offering	Certification in Molecular	Diagnostics or	Molecular Pathology

\*Applicants schedule an examination at a Pearson Professional Center (http://www.pearsonvue.com/ascp).

AAB, American Association of Bioanalysts; ABCC, American Board of Clinical Chemistry; ABMG, American Board of Medical Genetics, ABB, American Board of Bioanalysis; ABP, American Board of Pathology; ASCP, American Society for Clinical Chemistry; BCLD, Bioanalyst Clinical Laboratory Director; CE, continuing education; CEU, continuing education units; CMG, Clinical Molecular Genetics; DABCC, Diplomate of the American Board of Clinical Chemistry; HCLD, High Complexity Laboratory Director; MB, Molecular Biology; MGP, Molecular Genetic Pathology; MLT, Medical Laboratory Technician; MOC, maintenance of certification; MT, Medical Technologist; TS, Technical Supervisor.

ican Board of Internal Medicine (AIBM)] or at least 2 years of experience directing or supervising high complexity testing also meet these qualification standards. Doctoral-level clinical scientists also satisfy the requirements for laboratory director, provided they are certified by a board approved by the U.S. Department of Health and Human Services (HHS) (Tables 1 and 2). Licensure must be by the state in which the laboratory is located.

The subspecialty of molecular diagnostics has grown dramatically in both scope and scale over recent years. Recognizing the need to prepare future directors of molecular diagnostic laboratories, Molecular Genetic Pathology (MGP) fellowship training programs accredited by the Accreditation Council of Graduate Medical Education (ACGME) recently became available for eligible medical doctors. Board certification in MGP is offered jointly by the ABP and the American Board of Medical Genetics (ABMG). Although MGP certification is not a CLIA requirement for laboratory director, it provides the opportunity to gain additional experience and ability in directing a molecular diagnostics laboratory. Recognizing that the distinctions between molecular pathology and molecular diagnostics are imprecise, the two terms are used interchangeably in this document; a distinction is made only when necessary to comply with the wording used by specific certification agencies.

Of the HHS-approved boards that offer certification for doctoral-level clinical scientists, the ABMG, the American Board of Bioanalysis (ABB), and the American Board of Clinical Chemistry (ABCC) provide specific certification in molecular diagnostics for individuals with a Ph.D. degree. For non-director-level laboratory professionals, such as laboratory supervisors and technologists, the ABB, the American Society for Clinical Pathology (ASCP), and the American Association of Bioanalysts (AAB) also offer certification in molecular diagnostics.

Table 2.	Educational	Requirements	for Certificates	in Molecular	Diagnostics
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Degree and laboratory role	Certification designation (certifying board)	Satisfy CLIA requirements for laboratory director?
M.D., D.O.		
Director	MGP (ABP/ABMG)	Not applicable*
M.D., D.O., or Ph.D.		
Director	CMG (ABMG)	Yes
Director	DABCC (ABCC)	Yes
Director	HCLD (ABB)	Yes <sup>†</sup>
Director	BCLD (ABB)	Yes <sup>†</sup>
M.D., D.O., Ph.D., master, or baccalaureate <sup>‡</sup>		
Supervisor	TS (ABB)	No
Supervisor	MB (ASCP)	No
Supervisor	MT (AAB) <sup>‡</sup>	No
Associate degree <sup>‡</sup> or clinical laboratory training program		
Technologist	MLT (AAB)	No

\*MGP certification is not required to function as a Laboratory Director.

<sup>+</sup>HCLD and BCLD requirements for Laboratory Director vary by state. Individuals should consult the particular state's department of health and/or professional regulation.

<sup>‡</sup>MT(AAB) certification is available to individuals with an associate degree.

CLIA, Clinical Laboratory Improvement Amendments (1988); the remaining abbreviations are as for Table 1.

Finally, the American Society for Histocompatibility and Immunogenetics (ASHI; *http://www.ashi-hla.org*) and the ABB offer various types of certification in histocompatibility and immunogenetics. These specialties make extensive use of molecular diagnostic reagents and techniques and are mentioned here for the benefit of individuals interested in learning more about certification options in this area.

### Medical Doctors: Certification in Molecular Diagnostics

### American Board of Pathology and American Board of Medical Genetics

Certification in MGP is available from the ABP and the ABMG to physicians who have primary certification from one of those boards. These professional organizations cooperatively function to determine the standards and content of the MGP subspecialty examination and to certify the qualifications of the applicants. Accreditation of MGP training programs began in 2002. Applicants must complete at least 1 year of MGP training in an ACGME-accredited fellowship program (*http://www.acgme.org/adspublic*).

MGP training programs are a joint function of the departments of pathology and the departments and/or divisions of medical genetics at the participating institutions. MGP training programs are structured to provide applicants with a functional understanding of the molecular principles and technologies used in the diagnosis, management, and treatment of Mendelian genetic disorders, neoplasia, infectious diseases, histocompatibility, and disorders of human development.

### Eligibility

Pathologist applicants seeking certification in MGP from the ABP must be certified in anatomic pathology and/or clinical pathology by the ABP and have completed an ACGME-accredited MGP fellowship program. Certification in MGP via the ABMG is available to physicians with primary certification by the ABMG in clinical genetics who have completed 1 year of training in an ACGMEaccredited MGP fellowship program. Individuals applying for MGP certification must hold a currently valid, full, and unrestricted state medical license to practice medicine or osteopathy in the United States or Canada. Applicants are required to complete all certification requirements within 5 years from completion of their training, or within 5 years from the date of their primary certification, whichever is later. Once an applicant is qualified by the ABP or ABMG, he or she is permitted to take the MGP examination a maximum of five times.

### Examination

The first MGP examination was offered in 2001 and examinations were given every 2 years until 2011. As of 2011, the MGP examination is offered annually. The MGP

subspecialty examination is a 1-day, computer-based examination consisting of 300 questions. The examination is divided into a written section (100 questions) and a practical section (200 questions). All questions are multiple choice, and applicants must pass both the written and practical sections to pass the MGP examination. During the 2007 and 2009 MGP examination cycles, a total of 106 individuals took the MGP examination for the first time. Before 2007, individuals were permitted to take the MGP examination without completing a 1-year ACGME-accredited MGP fellowship by documenting sufficient experience in MGP (the so-called experience pathway). Beginning in 2007, all applicants are required to complete at least 1 year of training in an ACGMEaccredited MGP fellowship. Individuals applying for the MGP subspecialty examination must complete their training by October 1 of the year of application. To demonstrate sufficient competencies for the MGP subspecialty, applicants are required to submit a logbook documenting their role and level of participation in 150 clinical cases (http://www.abpath.org/FormsApps.htm).

### Maintenance of Certification

The ABP began issuing time-limited certificates in 2006, and consequently ABP certification expires on December 31 of the 10th year after issuance of the original certification. In addition, individuals who passed their primary certification examination in 2006 or later are required to participate in the maintenance of certification (MOC) process to maintain their board certification (http:// www.abpath.org/MOCIndex.htm). MOC was instituted as part of a growing focus on quality health care in the United States and provides a mechanism for an individual to demonstrate his or her commitment to quality patient care, quality improvement, and professional development. MOC is a 10-year process beginning immediately after board certification is obtained from the ABP. Requirements for MOC are divided into four general areas: Part 1, evidence of professional standing; Part 2, evidence of commitment for lifelong learning and involvement in periodic self-assessment; Part 3, evidence of cognitive expertise; and Part 4, evidence of successful evaluation of performance in practice. Each of these main areas has specific requirements that must be satisfied and documented at 2-year checkpoints throughout the 10-year MOC cycle. MGP fellowship training in an ACGME-accredited fellowship program satisfies the Part 2 and Part 4 requirements for a 2-year period. During year 8 of the 10-year cycle, an MOC examination must be satisfactorily completed. The ABP recognizes the breadth and scope of pathology practice and consequently plans to offer a 150question MGP MOC examination.

Medical doctors are eligible for certification in molecular diagnostics by the ABMG, ABCC, and ABB, which is also open to doctoral-level clinical scientists, as described below.

# Doctoral-Level Clinical Scientists: Certification in Molecular Diagnostics

### American Board of Medical Genetics

The ABMG is recognized by the American Board of Medical Specialties and certifies individuals who apply genetics to medical care in several specialties: clinical genetics, clinical biochemical genetics, clinical cytogenetics, and clinical molecular genetics (*http://www.abmg.org/ pages/training\_options.shtml*). The ABMG clinical molecular genetics (CMG) specialty focuses on molecular discovery of and laboratory testing for mutations associated with human disease.

### Eligibility

CMG fellowship programs accredited by the ABMG require a minimum of 24 months of training. Trainees must hold either an M.D. or a Ph.D. degree (or the equivalent) in genetics, molecular biology, or a related biological field. Individuals who earned an M.D. or Ph.D. outside the United States or Canada must have the degree reviewed by the ABMG Credentials Committee (*http://www.abmg.org/2011/cert\_forcredential.shtml*) before entering a training program. In addition to the educational requirements, an online logbook documenting the applicant's direct and meaningful involvement with specimen processing, analysis, and interpretation of 150 laboratory specimens must be submitted to the ABMG.

### Examination

The CMG examination is offered annually at an examination center managed by Prometric (Baltimore, MD) and consists of two parts: a 3-hour general examination and a 2.5-hour CMG specialty examination. Both parts consist of multiple choice questions, and both parts of the examination must be passed on the same test date for certification. Applicants who do not pass the examination after three consecutive examination cycles are required to complete an additional 24 months of ABMG-accredited CMG postdoctoral training.

### Maintenance of Certification

Examinees who pass both portions of the certification examination are diplomates of the ABMG for a 10-year period. Diplomates certified in 1993 or later are required to participate in the four-part MOC program (*http://www.abmg.org/pages/maint\_definitions.shtml*).

### American Board of Clinical Chemistry

Founded in 1950, the American Board of Clinical Chemistry (ABCC) was established to certify individuals holding Ph.D. degrees to serve as clinical laboratory directors. The ABCC offers certification in Molecular Diagnostics, as well as a number of other clinical science disciplines. Persons holding a valid Certificate of Qualification issued by the ABCC are entitled to use the designation Diplomate of the American Board of Clinical Chemistry and the initials DABCC. Certification by the ABCC satisfies the CLIA 1988 regulations to serve as the director of a high complexity clinical laboratory and clinical consultant in laboratory medicine.

### Eligibility

Applicants must possess an earned Ph.D. or an equivalent doctoral degree in biochemistry, molecular biology, or another of the natural sciences, or an M.D. degree from an appropriately accredited university or college acceptable to the Board. In addition, applicants must have satisfactorily completed a minimum of 30 semester hours (or equivalent) in undergraduate and/or graduate level courses in biochemistry, molecular biology, or related fields taken at institutions acceptable to the Board. Hands-on laboratory research experience in molecular biology may be substituted for coursework if the applicant's personal experience in the laboratory is documented by a laboratory director, with 1 full year of laboratory work equated to 10 semester hours of coursework. Applicants with education obtained at institutions outside the United States or Canada must, at their expense, have their credentials evaluated by the International Education Research Foundation (http://www.ierf.org) or an acceptable equivalent (http://www.abclinchem.org/ geninfo/Pages/cred\_eval.aspx).

Before admission to examination, the applicant must demonstrate 5 years of full-time (or equivalent part-time) diverse professional experience in clinical molecular diagnostics. The experience must be obtained subsequent to conferral of the doctoral degree and in laboratories or institutions maintaining standards in molecular diagnostics that are acceptable to the Board. Exceptions to these professional requirements may be made if, before admission to examination, the applicant has completed 2 or more years of full-time (or equivalent part-time) diverse professional experience in clinical molecular diagnostics and has successfully completed requirements for diplomate status from one of these boards: the ABCC, ABMG, ABP, American Board of Medical Microbiology (ABMM), American Board of Medical Laboratory Immunology (AB-MLI), or American Board of Histocompatibility and Immunogenetics (ABHI). Applicants from or graduates of postdoctoral training programs accredited by the Commission for Accreditation in Clinical Chemistry (http://www.comacc.org/ Pages/default.aspx) who have passed the ABCC examination in either clinical chemistry or toxicological chemistry may be admitted to the molecular diagnostics examination on documentation of 1 year of focused experience in molecular diagnostics.

### Examination

Applicants must successfully pass the ABCC Molecular Diagnostics examination for DABCC certification. The multiple choice, 3-hour examination is offered twice per year. The examination tests knowledge of inherited disease testing, infectious disease testing, identity testing, oncology, pharmacogenetics, and general laboratory principles.

Table 3.	American Board of Bioanalysis Certification Standards for Bioanalyst Clinical Laboratory Director (BCLD) and High Complexity
	Clinical Laboratory Director (HCLD)

	BCLD	HCLD
Eligibility (Ph.D.)*	Ph.D. in chemical, physical, or biological science from an accredited institution recognized by the U.S. Department of Education and successful completion of 32 semester hours in chemistry or biological sciences acceptable to the board	Either i) meet the eligibility described for BCLD or ii) meet the qualifications as a Laboratory Director of a laboratory performing high complexity testing under the CLIA 1988 regulations, Subpart M, Section 493.1443 (http:// wwwn.cdc.gov/clia/regs/subpart_m.aspx#493.1443)
Eligibility (M.D., D.O., D.P.M., or equivalent)*	Licensed to practice medicine in at least one (1) state in the United States	
Experience	4 years of experience in the 10-year period prior to application date on human specimens in a clinical laboratory at the minimum level of medical technologist, including: 2 years of experience in the 10-year period prior to application date must be at the level of supervisor or director of high complexity testing <sup>†</sup>	
Examination	Pass an ABB examination in general knowledge and in at least three (3) of the clinical laboratory disciplines: chemistry, diagnostic immunology, hematology, microbiology or public health microbiology, and molecular diagnostics	Pass an ABB examination in general knowledge and in at least one (1) the clinical laboratory disciplines described (eg, molecular diagnostics)

\*All degrees received outside the United States must be evaluated for equivalency by an agency acceptable to the ABB; a current list is available at http://www.aab.org/aab/Equivalency\_Evaluations.asp.

<sup>+</sup>Effective January 1, 2012, ABB will accept up to 2 years of alternative experience to meet the 4-year experience requirement; see examples under ABB General Regulations, Rule 17 (*http://www.aab.org/aab/General\_Regulations.asp*).

### Maintenance of Certification

As of January 1, 2004, Diplomates of the ABCC must document 50 contact hours of continuing education credit every 2 years to maintain listing in the directory of active diplomates.

### American Board of Bioanalysis

Certification by the ABB is based on an individual's education, experience, and knowledge of the field in which the certification is granted. Three certifications in Molecular Diagnostics are offered by the ABB: Technical Supervisor (TS), Bioanalyst Clinical Laboratory Director (BCLD), and High Complexity Clinical Laboratory Director (HCLD). Both BCLD and HCLD certifications satisfy CLIA 1988 requirements for laboratory director in most states.

### Eligibility

Eligibility criteria for BCLD and HCLD certification are listed in Table 3.

### Examination

Examination requirements for BCLD and HCLD certification are listed in Table 3.

### Maintenance of Certification

To maintain their ABB certification, BCLD and HCLD laboratory directors are required to participate in the Professional Education Enrichment Renewal program, which consists of 24 contact hours (2.4 CEU) of acceptable continuing education every 2 years.

## Supervisors and Technologists: Certification in Molecular Diagnostics

### American Board of Bioanalysis

The ABB offers TS certification in molecular diagnostics. The TS(ABB) designation is for individuals who are responsible for the technical and scientific oversight of a laboratory performing high complexity testing, but who do not fulfill CLIA 1988 requirements for laboratory director.

### Eligibility

Eligibility criteria for TS(ABB) certification are listed in Table 4.

### Examination

TS applicants must pass an ABB examination in molecular diagnostics, but are not required to take the general knowledge examination that is required for director applicants.

### Maintenance of Certification

Supervisors are required to participate in the Professional Education Enrichment Renewal program to maintain their ABB certification; this program consists of 24 contact hours (2.4 CEU) of acceptable continuing education every 2 years.

### American Society for Clinical Pathology Board of Certification

The American Society for Clinical Pathology Board of Registry (ASCP BOR) established Molecular Pathology certification as MP(ASCP) in 2003. On October 23,

**Table 4.** Eligibility Requirements for Certification in Molecular Diagnostics for Medical Technologists by the American Board of Bioanalysts (ABB), American Society of Clinical Pathology (ASCP), and the American Association of Bioanalysis (AAB)

Option	TS(ABB)	MB(ASCP)	MT(AAB)	MLT(AAB)*	
		Applicants must meet one of	the following requirements		
1	Doctoral degree from an accredited institution in a chemical, physical, biological or clinical laboratory science or medical technology	Both baccalaureate degree and ASCP certification as a technologist	Doctoral, master's, or baccalaureate degree from an accredited institution, or the equivalent, with a major in a chemical, physical, biological, or clinical laboratory science or medical technology	Successful completion of a clinical laboratory training program approved or accredited by an organization approved by the HHS	
2	Doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy	Both baccalaureate degree, including courses in the biological sciences, chemistry, and mathematics, and completion of a NACCLS diagnostic molecular science program within the past five (5) years	Associate degree or associate of applied science degree with a major in a laboratory science or medical technology	Associate degree (or equivalent) in a laboratory science, or medical laboratory technology, from an accredited institution <sup>†</sup>	
3	Master's degree from an accredited institution in a chemical, physical, biological, or clinical laboratory science or medical technology	Baccalaureate degree with a major in biological sciences or chemistry, or with a combination of 30 semester hours (or 45 quarter hours) of biology, chemistry, and/ or medical sciences	At least 60 semester hours, or equivalent, from an accredited institution including either 24 hours of medical laboratory technology courses or 24 semester hours of science courses (6 semester hours of chemistry, 6 semester hours of biology, and 12 semester hours of chemistry, biology or medical laboratory technology)	Successful completion of an official U.S. military medical laboratory procedures course of at least 50 weeks duration, earning the Military Occupational Specialty of Medical Laboratory Specialist (Laboratory Technician)	
4	Bachelor's degree from an accredited institution in a chemical, physical or biological science or medical technology	Graduate degree in chemistry, biology, immunology, microbiology, allied health, clinical laboratory sciences, or an appropriately related field	Qualify as a technologist under the revised Medicare/CLIA '67 regulations <sup>‡</sup>	Five (5) years of full-time clinical laboratory experience (in the applicable disciplines) acceptable to the AAB Board of Registry	
5				A combination of i) certification as a POLT(AAB), ii) four (4) years of acceptable clinical laboratory experience (in the applicable disciplines), and iii) 6 CEUs	
		Additional laboratory t	raining requirements		
	For option 1 or 2: At least one (1) year of relevant experience <sup>§</sup> For option 3: At least two (2) years of relevant experience <sup>§</sup> For option 4: At least four (4) years of relevant experience <sup>§</sup>	For option 3: One (1) year of full-time experience in a molecular biology laboratory in the United States or Canada or in an accredited laboratory <sup>11</sup> For option 4: Six (6) months of clinical laboratory experience in molecular diagnostics in an	Either completion of a clinical laborate approved or accredited by an accr the HHS (eg, ABHES, NAACLS) or documented laboratory training in e individual performs high complexity	n accrediting agency approved by S) or at least three (3) months of ng in each specialty in which the	

\*Requirements differ for applicants seeking certification in California and include the added requirement of at least 60 semester hours from an accredited college or university, of which at least 36 units are in physical and biological sciences with an emphasis on applied clinical science and include 6 semester hours of biology and 6 of chemistry. Full detail is available at (http://www.aab.org/aab/Application\_MLT\_California.asp).

accredited laboratory<sup>¶</sup>

<sup>†</sup>For the AAB, the equivalent of an associate degree is defined as 60 semester hours, of which 24 semester hours are either medical laboratory technology courses or 6 semester hours of chemistry, 6 semester hours of biology, and 12 semester hours of courses in chemistry, biology, or medical laboratory technology in any combination.

<sup>+</sup>42 CFR 493.1433, published on March 14, 1990 (55 FR 9538).

<sup>S</sup>For the ABB, "relevant experience" includes clinical laboratory training or experience within the 10 years immediately prior to the application date on human specimens in high complexity testing within the specialty. <sup>¶</sup>For the ASCP, an "accredited laboratory" is one accredited by a CMS-approved accrediting organization (*http://www.cms.gov/Regulations-and-*

<sup>1</sup>For the ASCP, an "accredited laboratory" is one accredited by a CMS-approved accrediting organization (http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Accreditation\_Organizations\_and\_Exempt\_States.html). ABHES, Accrediting Bureau of Health Education Schools; CMS, U.S. Centers for Medicare and Medicaid Services; HHS, U.S. Department

ABHES, Accrediting Bureau of Health Education Schools; CMS, U.S. Centers for Medicare and Medicaid Services; HHS, U.S. Department of Health and Human Services; NAACLS, National Accrediting Agency for Clinical Laboratory Sciences; POLT, Physician Office Laboratory Technician.

2009, ASCP BOR and the National Credentialing Agency for Laboratory Personnel (NCA) merged and formed a single certification agency for medical laboratory professionals. The resulting agency is called the American Society for Clinical Pathology Board of Certification (ASCP BOC); the NCA dissolved as a corporation at that time. Before this merger, each agency offered certification in molecular pathology or molecular biology. The ASCP BOR offered MP(ASCP) certification, and the NCA offered certification as a Clinical Laboratory Specialist in Molecular Biology [CLSp (MB)]. At the time of the merger, it was decided to use the designation Molecular Biology (MB) for certification. The new designation adopted by the ASCP BOC is  $\mathsf{MB}(\mathsf{ASCP})^{\mathsf{CM}};$  the CM superscript is used to designate those who recertify voluntarily (see below, under Maintenance of Certification).

### Eligibility

Eligibility criteria for MB(ASCP) certification are listed in Table 4.

### Examination

Applicants must successfully pass the MB(ASCP) certification examination. The examination is divided into four subtests: molecular science (25% to 30%), molecular techniques (35% to 40%), laboratory operations (15% to 20%), and applications of molecular testing (15% to 20%). A total score of 400 points is required to pass the examination.

#### Maintenance of Certification

A Certification Maintenance Program (CMP) is required for all individuals newly certified as MB(ASCP) since January 1, 2004, and for all active NCA certificants who were not ASCP-certified before January 1, 2004. Certificants must recertify every 3 years. Regarding the designation of the certification, several scenarios existed after the merger. First, individuals certified by the ASCP BOR before January 1, 2004, have lifetime certification and continue under the previous ASCP BOR designation [MP(ASCP)], unless they elect for voluntary recertification, in which case they are permitted to append the CM superscript to their designation [MP(ASCP)<sup>CM</sup>]. Second, individuals certified after January 1, 2004, are required to recertify every 3 years by documenting continuing education activities in the CMP, leading to the MB(ASCP)<sup>CM</sup> designation. Failure to recertify leads to loss of certification. Third, individuals certified by the NCA at any time are required to recertify, because recertification is one of the founding principles of the NCA. Individuals with NCA certification status were transferred to the ASCP BOC database and received new designations [MB(ASCP)<sup>CM</sup>]. Finally, individuals with NCA certification who did not continue to recertify are not considered to be certified, but have the option at any time to participate in the recertification program, which would then reinstate the original ASCP BOR designation as MB(ASCP), provided they continue to recertify every 3 years.

### American Association of Bioanalysts Board of Registry

The AAB Board of Registry (ABOR; http://www.aab.org/ aab/AAB Board of Registry.asp) is an independent credentialing agency organized in 1962 that functions to identify individuals who satisfy the requirements for certification as Medical Technologist MT(AAB) or Medical Laboratory Technician MLT(AAB). The MT(AAB) and MLT(AAB) certification examinations satisfy licensing requirements for 11 of the 12 states (Table 5) that require laboratory technologists or laboratory technicians to pass certifying or licensure examinations; New York is the exception. MT(AAB) certification is offered in one or more of the following eight disciplines: chemistry, hematology, immunology, immunohematology, microbiology, andrology, embryology, and molecular diagnostics. Generalist certification is also offered for both MT(AAB) and ML-T(AAB), covering chemistry, hematology, immunology, immunohematology, and microbiology. The major differences between the MT(AAB) and MLT(AAB) are responsibility and supervisory roles in the laboratory; those with MT(AAB) certification may perform high complexity procedures with minimal supervision; those with MLT(AAB) certification perform waived and moderately complex clinical laboratory procedures under the supervision of a laboratory director, supervisor, or MT(AAB) technologist.

### Eligibility

Eligibility criteria for ABOR certification are listed in Table 4.

### Examination

The MT(AAB) examinations are offered in two formats: a discipline-specific examination or a Generalist examination. Applicants taking the MT(AAB) certification examination by discipline must successfully pass an examination in basic knowledge and an examination in at least one discipline. Applicants taking either the MT(AAB) or MLT(AAB) Generalist certification examinations must successfully pass an examination in basic knowledge and examinations in all of the following individual disciplines: chemistry, hematology, immunology, immunohematology, and microbiology. Applicants who take the Generalist examination are required to meet a minimum score in each of the disciplines, as well as a minimum overall score. Both examinations were offered five times in 2011.

### Maintenance of Certification

All individuals certified by the AAB Board of Registry are required to revalidate their certification annually. A new certificate is issued each year, documenting the individual's certification status. Certificants who document a minimum of 1.2 CEUs (12 contact hours) in a calendar year will be

State	Contact	CE, examination, and othe requirements
California	http://www.cdph.ca.gov/programs/lfs/Pages/MedicalLaboratory	12 contact hours annually;
	Technician(MLT).aspx	ASCP BOR or AAB BOF
	California State Department of Health Services	examinations
	Laboratory Field Services	
	Attn: Personnel Licensing	
	850 Marina Bay Parkway Bldg P, 1st Floor	
	Richmond, CA 94804–6403	
Florida	Tel.: (510) 620–3800; fax: (510) 620–3692	24 contact hours
Tonua	http://www.doh.state.fl.us/mga Board of Clinical Laboratory Personnel	biannually
	Division of Medical Quality Assurance	Diaimuany
	4052 Bald Cypress Way, Bin C07	
	Tallahassee, FL 32399–3257	
	Tel.: (850) 245–4355; fax: (850) 922–8876	
Georgia	http://dch.georgia.gov/about-hfr	None
0	Georgia Department of Community	
	Health Healthcare Facility Regulation Division	
	2 Peachtree Street, NW	
	Atlanta, GA 30303-3142	
	Tel.: (404) 657–5450; fax: (404) 657–5442	
Hawaii	http://hawaii.gov/health/laboratories/index_html	None
	Hawaii Department of Health	
	State Laboratory Division 2725 Waimano Home Road	
	Pearl City, HI 96782–1496	
	Tel.: (808) 453–6653; fax: (808) 453–6662	
Louisiana	http://www.lsbme.la.gov	12 contact hours annually
	Louisiana State Board of Medical Examiners	
	Licensure Division	
	P. O. Box 30250	
	New Orleans, LA 70190-0250	
	Tel. (504) 568–6820; fax: (504) 599–0503	
Montana	http://bsd.dli.mt.gov/license/bsd_boards/cls_board/board_page.asp	14 contact hours annually
	Montana Board of Clinical Laboratory Science Practitioners	
	301 South Park, 4th Floor	
	P. O. Box 200513	
	Helena, MT 59620-0513	
Nevada	Tel.: (406) 841–2395; fax: (406) 841–2305	10 contact hours appually
Nevaua	http://health.nv.gov/HCQC_Medical.htm Nevada Bureau of Licensure and Certification	10 contact hours annually
	1550 East College Parkway Suite 158	
	Carson City, NV 89716	
	Tel.: (775) 687–4475; fax: (775) 687–6588	
New York	http://www.op.nysed.gov/home.html	None
	New York State Education Department	
	Office of the Professions	
	Division of Professional Licensing Services	
	89 Washington Avenue 2nd Floor	
	Albany, NY 12234–1000	
	Tel.: (518) 474–3817 ext. 150; fax: (518) 474–4846	
North Dakota	http://www.ndhealth.gov	20 contact hours
	North Dakota Department of Health	continuing education
	Division of Laboratory Services	biannually
	P. O. Box 4103 Bismarck, ND 58502–4103 Tel.: (701) 530–1099	
Puerto Rico	http://www.ctmpr.com	36 contact hours
	Puerto Rico Department of Health	continuing education
	Junta Examinadora de Tecnólogos Médicos de	every 3 years;
	Puerto Rico	membership in the
	Box 10200	Puerto Rico College of
	Santurce, PR 00908–0200	Medical Technologists
	Tel: (787) 792–6400; fax: (787) 792–6627	
Rhode Island	http://www.health.state.ri.us	30 contact hours
	Rhode Island Department of Health	biannually
	Board of Clinical Laboratory Sciences	
	3 Capitol Hill, Room 104	
	Providence, RI 02908–5097	
	Tel.: (401) 222–5960; fax: (401) 222–6548	
		(table continue

### Table 5. States Requiring Licensing for Medical Technologists or Technicians (as of 2011)

#### Table 5. Continued

State	Contact	CE, examination, and other requirements
Tennessee	http://www.health.state.tn.us/Boards/MedLab/index.htm Tennessee State Licensure Board Medical Laboratory Board 227 French Landing, Ste 300 Heritage Place, Metro Center Nashville, TN 37243–1608 Tel.: (615) 532–3202	None
West Virginia	http://www.wvdhhr.org West Virginia Department of Health and Human Resources Office of Laboratory Science 167 Eleventh Ave South Charleston, WV 25303–1114 Tel.: (304) 558–3530; fax: (304) 558–2006	10 contact hours annually

Initial and licensing fees vary widely; individuals should consult the relevant state offices.

CE, continuing education; CLS, Clinical Laboratory Scientist; CLT, Clinical Laboratory Technician or Clinical Laboratory Technologist; CT, Cytotechnologist; HT, Histotechnologist; PB, phlebotomist.

certified "With Commendation," and this wording is displayed on the individual's annual certificate.

### Licensure

Laboratory directors must possess a current laboratory director license issued by the State in which the laboratory is located, if such licensing is required. Twelve states and Puerto Rico require medical technologists, including technologists working in molecular diagnostic laboratories, to obtain a license from their respective state's Department of Health (Table 5). The requirements vary from state to state. Licensure for medical technologists typically requires an annual or biannual licensing fee, some form of continuing education, and professional competency requirements, often in the form of certification from the ASCP or the AAB. Many states, with the notable exception of California, give reciprocity for another state's license. In the remaining 38 states that do not license medical technologists, federal CLIA 1988 rules apply: to perform high complexity testing, technologists must have an associate degree or equivalent, with a major in laboratory science.

### Summary

This document provides an update on the routes leading to certification in molecular pathology that are available to medical doctors, doctoral-level clinical scientists, and medical technologists. As the subspecialty of molecular pathology grows with increased test volume and the introduction of new technologies, formal and accredited training programs in laboratory medicine for doctoral and non-doctoral-level clinical scientists will become increasingly important in producing highly trained molecular pathology laboratory professionals. Certification in clinical molecular diagnostics helps to maintain uniform educational requirements and ensures that continuing medical education is sustained. Various routes toward obtaining certification in molecular diagnostics are available. MGP certification is available only to medical doctors and requires completion of an ACGME-accredited MGP training program. Other clinical laboratory scientists can become certified in molecular pathology by satisfying specific educational and training requirements. Finally, several states have licensure requirements for medical technologists that include certification in molecular diagnostics.

### Disclaimer

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### Reference

 Killeen AA, Leung WC, Payne D, Sabath DE, Snow K, Tsongalis GJ, Van Deerlin V, Weck K; Training and Education Committee, the Association for Molecular Pathology: Certification in molecular pathology in the United States (Training and Education Committee, The Association for Molecular Pathology). J Mol Diagn 2002, 4:181–184