ABMGG Laboratory Program
Accreditation Requirements for
Clinical Cytogenetics and Genomics,
Clinical Molecular Genetics and Genomics,
Clinical Biochemical Genetics, and
Laboratory Genetics and Genomics

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**Introduction**

Intr.A. The American Board of Medical Genetics and Genomics (ABMGG) accredits medical genetics and genomics laboratory training programs to ensure that they provide the necessary formal education and clinical laboratory-based experience to allow trainees to develop the knowledge, skills, and professional attitudes required for the practice in the specialty fields.

To ensure that state-of-the-art techniques, standards and practices are being met at the institutional level, a stringent process of accreditation has been made available to programs that train medical genetics and genomics professionals in the areas of clinical and laboratory medicine. The ABMGG accredits laboratory training programs; accreditation for Medical Genetics and Genomics residency programs falls under the purview of the American Council for Graduate Medical Education (ACGME).

Intr.B. The ABMGG is solely responsible for the accreditation of clinical laboratory medical genetics and genomics training programs. The three primary specialties for which a program can seek accreditation by the ABMGG are: Clinical Biochemical Genetics, Clinical Cytogenetics and Genomics, and Clinical Molecular Genetics and Genomics.

Intr.C. A minimum of 24 months, full-time training is required for one laboratory specialty. An additional minimum of 12 months, full-time clinical laboratory specialty training is required for adding Clinical Biochemical Genetics as a second laboratory specialty. [Adding Laboratory Genetics and Genomics requires a 24 months of full-time training.]

**Institutions**

I.A. Sponsoring institution

I.A.1 Affiliation with an academic medical institution is strongly preferred. At a minimum, the program must be affiliated with an institution that offers facilities comparable to those of an ACGME-approved medical genetics and genomics training program.

I.A.2 It is recommended that the Program Director (PD) be provided at least four hours per week or 0.1 full time equivalent (FTE) protected time and financial support for educational and administrative responsibilities to the program, with the exception of PDs who have already been guaranteed protected time for their duties as Laboratory Training Directors (TD) or Residency Program Directors.

I.B. Participating Sites

I.B.1 Primary Training Sites: Specialty laboratory in which fellows receive at least 50% of primary specialty laboratory training and cases; must be an on-site laboratory.

I.B.2 Non-Primary Training Sites

I.B.2.a Ancillary Training Laboratory: Specialty laboratory in which fellows receive less than 50% of primary specialty laboratory training and cases.
I.B.2.a.1 Ancillary training laboratories are frequently on-site, but may be offsite.

I.B.2.a.2 Ancillary training laboratories require prior approval from the ABMGG Accreditation Committee for use as training site.

I.B.2.b Non-specialty rotation laboratory: Laboratory in which fellows receive exposure to and experience in an ABMGG-recognized primary laboratory specialty different from the specialty in which they are training.

I.B.2.b.1 Non-specialty rotation laboratories may be on-site or offsite.

I.B.2.b.2 Non-specialty rotation laboratories require prior approval from the ABMGG Accreditation Committee for use as training site.

I.B.3. On-Site Laboratories: On-site Laboratories are housed within the academic/administrative unit of the training program.

I.B.3.a All laboratories affiliated with the training program must be CLIA-certified.

I.B.3.b A program must have an on-site clinical laboratory in each of the primary specialties for which it is seeking accreditation.

I.B.3.c On-site laboratories for at least two of the ABMGG primary specialties (clinical biochemical genetics, laboratory genetics and genomics, clinical cytogenetics and genomics, or clinical molecular genetics and genomics) are required for all programs, even if a program is seeking accreditation in only one primary specialty.

I.B.4. Off-Site Laboratories: Off-site Laboratories are those not housed within the administrative unit of the training program.

I.B.4.a All off-site laboratories must be CLIA-certified.

I.B.4.b Offsite laboratories must be formally affiliated with the ABMGG-accredited training program.

I.B.4.b.1 The relationship must be documented in writing as part of the accreditation application or upon addition of a new affiliate site by providing ABMGG with a signed Laboratory/Clinic Training Arrangement Form for each participating off-site laboratory.

I.B.4.c Travel to offsite training sites should be reasonable and should not interfere with other training requirements.

I.B.4.d An offsite laboratory may function as an ancillary training site for the discipline in which a fellow is training or as a rotation site for a genetics laboratory specialty other than that in which the fellow is training.
I.B.4.e Offsite laboratories may not function as a primary training site.

I.B.4.f Off-site laboratories require prior approval by the ABMGG Accreditation Committee for use as a training site.

Program Personnel and Resources

II.A. Program Director (PD)
The PD has overall responsibility and accountability for the entire training program.

II.A.1 There must be a single PD with authority and accountability for the operation of the program. The ABMGG must approve any change in PD.

II.A.1.a The current PD or Department Chair at the sponsoring institution must submit the request to change PD in writing to the ABMGG and include an updated CV for the proposed PD.

II.A.1.b If a PD becomes incapacitated and unable to complete their duties, an interim PD must be appointed within two weeks of the event.

II.A.1.b.1 The interim PD must be a diplomate of the ABMGG with at least two years of professional practice and must be actively participating in the ABMGG MOC Program in at least one specialty area.

II.A.1.b.2 If the absence of the permanent PD extends beyond 3 months, a permanent replacement must be appointed.

II.A.2 PD Requirements

II.A.2.a The PD must be a diplomate of the ABMGG and actively participating in the ABMGG MOC Program in at least one specialty area.

II.A.2.b The PD must have adequate medical genetics expertise and educational and administrative experience. A minimum of two years of professional practice, preferably with administrative and educational experience, is required.

II.A.2.c The PD may also function in other capacities in the training program, but must have dedicated time and financial support for educational and administrative responsibilities to the program.

II.A.3 PD Responsibilities
The PD administers and maintains an educational environment conducive to educating fellows in each of the ABMGG competencies. Specifically, the PD is required to:

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II.A.3.a Organize and oversee educational components of training;

II.A.3.b Approve training and laboratory directors at participating sites;

II.A.3.c Evaluate training program faculty, designate roles for program faculty, and assure continued participation of key faculty in MOC;

II.A.3.d Secure a sufficient number of qualified faculty to train and supervise fellows;

II.A.3.e Ensure that the trainees evaluate the training program and faculty annually;

II.A.3.f Ensure that trainees are able to satisfy the requirements necessary to participate in the ABMGG certification examination process;

II.A.3.g Examine case logs that trainees are building during the training period at least semi-annually to monitor the progress and assess the experience of the trainee in compliance with logbook certification requirements;

II.A.3.h Communicate all the requirements and rotations, including rotations that are offsite, to trainees at the start of their training;

II.A.3.i Oversee assignment of fellows at all participating sites;

II.A.3.j Ensure that accommodations are available to trainees for offsite training, especially if overnight stays are required;

II.A.3.k Monitor the supervision of fellows at all participating sites;

II.A.3.l Ensure that fellows receive formal evaluations with feedback based on the ABMGG Laboratory Training Milestones at least semi-annually [documented and communicated by the Program Director or Training Director];

II.A.3.m Provide verification to ABMGG of satisfactory completion of all training program requirements for each fellow;

II.A.3.n Develop and ensure compliance with grievance and due process procedures;

II.A.3.o Review and approve trainee logbooks submitted to ABMGG, after Training Director has reviewed and approved;

II.A.3.p Notify the ABMGG within thirty (30) days of any significant change(s) in the organization or operation of the training program, including but not limited to:
II.A.3.m.1 A change in Program Director or Training Director (both require ABMGG approval);

II.A.3.m.2 A change in ACGME- accredited medical genetics and genomics residency status;

II.A.3.m.3 Enrollment of new trainees via submission of a Trainee Information Form;

II.A.3.m.4 Changes to trainees’ length and dates of training via submission of a revised Trainee Information Form;

II.A.3.m.5 Verification of Training in Medical Genetics Form for each trainee at the time of application for the ABMGG certification examinations.

II.B. Specialty Training Director (Training Director)

II.B.1 Training Director (TD) Requirements

II.B.1.a The TD must be certified by the ABMGG in the corresponding primary laboratory specialty and must actively participate in MOC for that specialty. [Note: LGG Training Director/Co-Directors must be certified in MGG and CGG. If one individual is certified in both specialties, a Training co-Director is not required.]

II.B.1.b The TD must have adequate medical genetics expertise and educational and administrative experience. A minimum of two years of professional practice in that specialty is required, preferably with administrative and educational experience.

II.B.1.c The TD must be willing to spend a minimum of 10% of overall time and effort to training fellows in the specialty.

II.B.1.d It is preferable that the TD is based on-site, but the TD may be located off-site with ABMGG approval.

II.B.1.d.1 If a TD is located off-site, the program must have an on-site laboratory director in that specialty who meets the requirements of the primary training site laboratory director.

II.B.1.d.2 To gain approval for an offsite TD, the Program must submit a plan for communication between the TD and all current fellows in that specialty, as well as submit progress reports to the ABMGG at pre-determined intervals.

II.B.2 TD Responsibilities
II.B.2.a  The TD is required to:

II.B.2.a.1  Provide and coordinate instruction in a given laboratory specialty according to the defined training requirements;

II.B.2.a.2  Coordinate all laboratory rotations;

II.B.2.a.3  Evaluate and document trainees’ progress based on the ABMGG Laboratory Training Milestones and performance at least semi-annually;

II.B.2.a.4  Interface with the specialty Laboratory Director(s) [if not one and the same];

II.B.2.a.5  Review and approve trainees’ logbooks submitted to ABMGG.

II.C  Clinical Genetics Rotation Director

II.C.1  Clinical Genetics Rotation Director Requirements

II.C.1.a  The Clinical Genetics Rotation Director must be certified by the ABMGG in Clinical Genetics.

II.C.1.b  Active participation in MOC is strongly encouraged.

II.C.2  Clinical Genetics Rotation Director is required to:

II.C.2.a  Provide and coordinate instruction related to patient care experiences;

II.C.2.b  Coordinate clinical rotations;

II.C.2.c  Evaluate fellows’ progress and performance.

II.D.1  Primary Training Site Laboratory Director: An individual who directs the laboratory in which fellows receive at least 50% of their primary specialty training. NOTE: There may be more than one Laboratory Director at the primary training site; at least one co-director must meet the requirements of the Primary Training Site Laboratory Director.

II.D.1.a  Primary Training Site Laboratory Director Requirements

II.D.1.a.1  The Primary Training Site Laboratory Director must be certified by the ABMGG in the corresponding specialty.

II.D.1.a.2  Active participation in MOC for that specialty.

II.D.1.a.3  Meet local and state requirements for directing a clinical laboratory.
II.D.1.b Primary Training Site Laboratory Director Responsibilities include:

II.D.1.b.1 Supervise the training within his or her laboratory;

II.D.1.b.2 Evaluate fellows’ progress and performance based on the ABMGG Laboratory Training Milestones;

II.D.1.b.3 Provide clinical laboratory data required for the ABMGG Laboratory Case Report Form on an annual basis, including specific tests performed, volume of tests and proficiency/licensure information.

II.D.2 Ancillary Training Site Laboratory Director: An individual who directs a laboratory in which fellows receive less than 50% of their primary specialty training. NOTE: There may be more than one Laboratory Director at an ancillary training site; at least one co-director must meet the requirements of the Primary Training Site Laboratory Director.

II.D.2.a Ancillary Training Site Laboratory Director Requirements/Preferred Qualifications

II.D.2.a.1 The Ancillary Training Site Laboratory Director must meet local and state requirements for directing a clinical laboratory.

II.D.2.a.2 The Ancillary Training Site Laboratory Director should be:

II.D.2.a.3.a certified by the ABMGG in the corresponding specialty or in Molecular Genetic Pathology (MGP) (preferred);

II.D.2.a.3.b certified in Pathology or another specialty (acceptable).

II.D.2.a.3.b.1 If the Director is certified by another agency, prior review and approval by the ABMGG Accreditation Committee is required before the laboratory can be used as a training site.

II.D.2.b Ancillary Training Site Laboratory Director is required to:

II.D.2.b.1 Supervise training within his or her laboratory;

II.D.2.b.2 Evaluate fellows’ progress and performance;

II.D.2.b.3 Provide clinical laboratory data required for the ABMGG Laboratory Case Report Form on an annual basis, including specific tests performed, volume of tests and proficiency/licensure information.

II.D.3 Non-Specialty Rotation Site Laboratory Director: A Laboratory Director of a non-specialty rotation site directs a laboratory in which fellows receive exposure to and experience in a genetics laboratory specialty other than the specific specialty in which they are training.
II.D.3.a Non-Specialty Rotation Site Laboratory Director Requirements/Preferred Qualifications

II.D.3.a.1 The Laboratory Director must be certified by the ABMGG in the corresponding specialty.

II.D.3.a.2 Active participation in MOC is encouraged.

II.D.3.a.3 The Laboratory Director must meet local and state requirements for directing a clinical laboratory.

II.D.3.b Non-Specialty Rotation Site Laboratory Director is required to:

II.D.3.b.1 Provide the fellows with educational experience in the specialty for which they are not training;

II.D.3.b.2 Evaluate the fellows’ progress and performance in the rotation;

II.D.3.b.3 Provide clinical laboratory data required for the ABMGG Laboratory Case Report Form on an annual basis, including specific tests performed, volume of tests and proficiency/licensure information.

II.D.4 Resources: The institution and the program must jointly ensure the availability of adequate resources for the education of fellows. The following resources must be available to trainees at on-site laboratories:

II.D.4.a Laboratory facilities/resources appropriate for the specialty, including:

II.D.4.a.1 Offices, lounges and study space for trainees;

II.D.4.a.2 Conference rooms and space for didactic teaching;

II.D.4.a.3 Technical and clerical/administrative support;

II.D.4.a.4 Library services including electronic medical literature databases with search capabilities and computer-based genetic diagnostic systems;

II.D.4.a.5 Computers and appropriate software;

II.D.4.a.6 Audiovisual equipment.

II.D.4.b Out-patient clinical genetics and genomics facilities

II.D.4.c Inpatient clinical genetics and genomics facilities
Fellow Appointments
For Eligibility Criteria for ABMGG laboratory programs, see ABMGG’s Training Options page at http://abmgg.org/pages/training_options.shtml.

Educational Program Requirements
A training program in a clinical laboratory medical genetics and genomics specialty must provide the necessary formal education and clinical laboratory-based experience to allow trainees to develop the knowledge, skills, and professional attitudes required for the practice in the specialty fields.

IV.A. Didactic Teaching
IV.A.1 Training must include classroom exposure to courses of sufficient rigor in the principles and applications of human genetics.

IV.A.2 Trainees must participate in a comprehensive and organized course in basic human medical genetics.

IV.B. Training in Laboratory Specialties
IV.B.1 Clinical Biochemical Genetics, Clinical Cytogenetics and Genomics, and Clinical Molecular Genetics and Genomics
IV.B.1.a A minimum of 24 months of full-time training is required for one laboratory specialty.
IV.B.1.a.1 The program must include a minimum of 12 months, full-time clinical laboratory work.
IV.B.1.a.2 Within the 24 months of training, up to six months may be used as elective time, which may be used to fortify laboratory training or complete a research project.
IV.B.1.a.3 Within the 24 months of training, the following requirements must be included: Didactic course work, other educational opportunities, non-specialty rotations (4 weeks), and attending clinics to gain clinical exposure (the equivalent of ten half-day clinics [40 hours]).
IV.B.1.b An additional 24 months of full-time clinical laboratory specialty training is required for a second laboratory specialty in LGG; this does not include elective time.
IV.B.2 Laboratory Genetics and Genomics

IV.B.2.a A minimum of 24 months of full-time training is required for one laboratory specialty.

IV.B.2.a.1 The program must include a minimum of 18 months, full-time clinical laboratory work.

IV.B.2.a.2 Within the 24 months of training, the following requirements must be included: Didactic course work, other educational opportunities, non-specialty rotations (2 weeks), and attending clinics to gain clinical exposure (the equivalent of ten half-day clinics [40 hours]).

IV.B.2.a.3 Within the 24 months of training, LGG trainees are required to spend up to six months on an area of concentration.

IV.B.2.a.3.a Intended to provide a period of focused experience, the content of the concentration will be designed by the trainee and Training Director(s) with final approval by the PD.

IV.B.2.a.3.b Content of this concentration must be determined no later than the trainee’s 12-month semi-annual review with the PD and must include a documented, structured, written plan based on the trainee’s career goals.

IV.B.2.b An additional minimum of 12 months of full-time clinical laboratory specialty training is required for a second laboratory specialty in CBG; this does not include elective time.

IV.B.3 Fellows should gain experience in a wide array of techniques within the specialty in which they are training at the primary on-site laboratory.

IV.B.3.a If a breadth of techniques is not available in the primary laboratory, the program should arrange formal rotations with other laboratories to create sufficient breadth of training. Each rotation to another laboratory must be documented with a Lab/Clinic Arrangement Form.

IV.B.4 Specialty laboratory training must provide the breadth and depth of experience to allow trainees to become knowledgeable and proficient in the specialty in which they are training.

IV.B.5 The training experience must assure that trainees can satisfy the requirements necessary to complete the ABMGG credentialing process.

IV.B.6 General knowledge areas for all clinical laboratory specialties include:

IV.B.6.a general pre-analytic, analytic, and post-analytic laboratory skills;
IV.B.6.b   technical competence and troubleshooting capabilities;
IV.B.6.c   result interpretation and reporting;
IV.B.6.d   communication with patients regarding inheritance/risk counseling;

IV.B.6.d.1 Trainees are expected to observe and/or participate in the interaction between physicians or genetic counselors and patients to better understand the application of laboratory principles to clinical practice;

IV.B.6.d.2 Trainees are expected to interact with patients to gain sensitivity and a heightened awareness of the difficulties in communicating certain genetic information to patients, as well as the impact of such information on the lives of the patients;

IV.B.6.e   communication with healthcare providers;
IV.B.6.f   laboratory management, including principles of quality assurance, quality control, and quality improvement;

IV.B.6.f.1 performance and development of genetic tests on a variety of testing platforms;
IV.B.6.f.2 supervision of technical and administrative staff;
IV.B.6.f.3 establishment and management of a CLIA-approved laboratory;
IV.B.6.g   development and validation of a clinical test and understanding the acceptable performance parameters;
IV.B.6.h   knowledge of practice guidelines, regulations and quality indicators;
IV.B.6.i   professionalism.

NOTE: Specific topics relevant to each primary laboratory specialty are described in the ABMGG Learning Guides.

IV.B.7 For each specific specialty, trainees must obtain at least 50% of clinical laboratory and case experience in one on-site primary training laboratory of the program.

IV.B.7.a Additional case experience can occur in ancillary training laboratories.
IV.B.7.b A small percentage of experience may be gained in specialty laboratories for unique circumstances.

IV.C Experience in Non-Specialty Rotation Laboratories

IV.C.1 Trainees must spend sufficient time in each of the non-specialty clinical laboratory specialties, i.e., the medical genetics and genomics laboratory specialties for which the
trainee is not receiving primary training, to gain an appreciation and understanding of the activities and functions of those specialties and how the different laboratory specialties interact and are utilized for provision of care in medical genetics and genomics.

IV.C.2 At minimum, trainees must spend the following amounts of time over a period of 24 months for non-specialty rotations: 160 hours for CBG trainees rotating to LGG laboratories; 80 hours for LGG trainees rotating to CBG laboratories.

IV.C.2.a Attending case conferences in these laboratory specialties is considered part of these rotations.

IV.C.2.b A continuous experience in the non-specialty rotations is strongly encouraged.

IV.D. Direct Patient Experience in Medical Genetics and Genomics

IV.D.1 Trainees must participate in a minimum of ten case conferences and the equivalent of ten half-day clinics (i.e., 40 hours)

IV.D.2 The laboratory trainee should have direct exposure to the clinical evaluation of patients, medical decision-making, and genetic counseling.

IV.D.3 Exposure to pre-conception/prenatal, neonatal, pediatric and adult non-obstetric patients with a variety of clinical indications should be included in the experience.

IV.D.4 Trainees should be exposed to gathering and organization of: relevant elements of personal, family and social history, important features of the physical examination, risk assessment and pedigree analysis, and ordering and interpreting of laboratory tests and procedures.

IV.E. Elective Time/Research [Optional]

IV.E.1 The trainee experience may include elective time that can involve basic, clinical, or health services research. A research experience is encouraged but not required; there are no restrictions on the type of research that can be conducted.

IV.E.2 Development of clinical laboratory methods or tests is encouraged as a component of the training. The development of a method or test would not be considered as research.

IV.E.3 Amount of Allowed Elective Time

IV.E.3.a If a fellow is pursuing Clinical Biochemical Genetics, the elective (research) experience should consist of no more than the equivalent of six months of a 24-month program.

IV.E.3.b 24-month LGG and 12-month CBG fellowships do not include elective/research time. If research/elective time is desired, it must be in addition to the required specialty training time.
V. Other Educational Opportunities
Trainees are expected to participate in a minimum of 20 hours over a period of 24 months in other educational opportunities, such as seminars, journal clubs, rotation in a clinical chemistry laboratory, etc. Topics should broadly relate to medical genetics and genomics training.

Evaluation

VI.A. Trainee Evaluation

VI.A.1 The PD must provide objective assessments of competence in patient care and procedural skills, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice based on the ABMGG Laboratory Training Milestones.

VI.A.2 The PD is responsible for ensuring that fellows receive formal evaluations at least semi-annually of performance with feedback.

VI.A.2.a This feedback must be documented and communicated by the PD or Training Director.

VI.B. Faculty Evaluation

VI.B.1. At least annually, the program must evaluate faculty performance as it relates to the educational program.

VI.B.2. These evaluations should include a review of the faculty’s clinical teaching abilities, commitment to the educational program, medical knowledge, professionalism, and scholarly activities.

VI.B.3. This evaluation must include at least annual written confidential evaluations by the fellows.

VI.C. Program Evaluation

VI.C.1 At least annually, ABMGG will evaluate the program based on the following areas:

VI.C.1.a fellow recruitment;

VI.C.1.b retention and graduation rate;

VI.C.1.c board pass rate;

VI.C.1.d trainee satisfaction with the program;

VI.C.1.e program/rotation evaluations.
END OF REQUIREMENTS