

Genetic Testing Certificate of Qualification (CQ) Guidance Document

Certificates of qualification are granted based on post-doctoral experience of the applicant either through employment or voluntary participation in a clinical laboratory. This experience must include both laboratory management as well as involvement in testing and reporting relevant to the category of Genetic Testing.

Please submit:

- A complete CQ application
- A current CV
- Letters from past and current supervisors documenting your training and experience. *Do not have your previous and current supervisor(s) submit a copy of the same letter.* Each letter should provide specific details about the dates of employment, type of training and experience acquired, methods, diseases, techniques of test procedures used, and volume of testing personally performed, supervised, and/or directed. Letters from responsible administrators at institutions where training or experience was acquired will be accepted only where it is established that other references are not available. Self-attestations and letters from junior staff of experience and training are not acceptable. See the **Qualifying Experience** section below for additional information.
- Your letters of support must clearly indicate your laboratory management experience as it satisfies the following in Subdivision 19.3(c) of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York:

19.3 Director of a clinical laboratory or blood bank; certificate of qualification issuance, duties and responsibilities.

(c) To qualify for, and maintain, a certificate of qualification, a laboratory director and any assistant director shall demonstrate that he or she possesses knowledge of basic clinical laboratory sciences and operations, and shall have the training and/or experience and physical capability to discharge the following responsibilities:

- (1) provide advice to referring health care providers regarding the significance of laboratory findings and ensure that reports of test results include pertinent information required for the interpretation of laboratory data;
- (2) maintain an effective working relationship with applicable accrediting and regulatory agencies, administrative officials, and the medical community,
- (3) define, implement and monitor standards of performance for the laboratory and for other ancillary laboratory testing programs in conformance with the department's clinical laboratory standards of practice;
- (4) monitor all work performed in the laboratory to ensure that medically reliable data are generated;
- (5) assure that the laboratory participates in monitoring and evaluating the quality and appropriateness of services rendered, within the context of a quality management system, regardless of where the testing is performed;
- (6) ensure that sufficient qualified personnel are employed with documented training and/or experience to supervise and perform the work of the laboratory;
- (7) ensure that policies and procedures are established for monitoring staff to assess competency and, whenever necessary, to provide remedial training to improve skills;
- (8) specify in writing the responsibilities and duties of all laboratory personnel;
- (9) provide continuing education to laboratory staff;

- (10) ensure that a current and complete procedure manual is available to all personnel; and
- (11) set goals, develop and allocate resources within the laboratory;
- (12) provide effective administrative direction of the laboratory, in conjunction with the individual(s) responsible for financial management of the laboratory, to ensure adequate resources are available to operate the laboratory in a manner consistent with all state and federal requirements;
- (13) select all reference laboratories for services not offered by the laboratory;
- (14) promote a safe laboratory environment for personnel and the public; and
- (15) ensure that the laboratory, when applicable, is enrolled in a proficiency testing program acceptable to the department for the testing performed and that the laboratory adheres to the proficiency testing program's administrative and technical requirements.

Qualifying Experience:

You must have at least four years of experience after your doctoral degree to qualify for a CQ. Some significant portion of this experience must be within the past six years for initial CQs.

Qualifying experience includes both two years of general clinical laboratory management experience and two years category-specific experience. You must have four full years of post-doctoral experience, you cannot count a two year post-doc position (either research or clinical) as both category and general clinical management experience. Letters of support must clearly define two full years of experience in the category.

If you participated in a fellowship, the letters of support must stipulate the years/months/weeks experience in the category (e.g., assays for detection of somatic/acquired mutations are not relevant), the tests you had experience with, and the volume of tests and any other laboratory responsibilities as described above. Include *month-to-month*, not yearly, experience. If the fellowship is your only experience, then this must equal 24 months.

Research experience: Only research experience on human specimens is relevant to the application for a CQ. If you had experience in a research post-doctoral position, and worked with human specimens, some of this experience may count towards the category-specific experience. A determination will be made based on what was done, and in what setting. Only a maximum of one year of category-specific experience may be applied to the two-year requirement. Research experience does not apply to the laboratory management experience requirement.

CQ Limitations:

A CQ in Genetic Testing is not granted solely on experience in a specific technique (e.g., NGS, SNP). Therefore, experience in a given technique for another purpose (e.g., oncology) may not translate to experience in Genetic Testing.

When applying, please specify whether you are applying for Molecular, Biochemistry, other limitations or Unlimited. CQs can be limited based on experience such as SNP arrays, pharmacogenetics, non-invasive prenatal testing, etc.

Limitation examples:

- If you are responsible for tests such as Factor V Leiden, prothrombin, MTHFR, hemochromatosis – the resulting limitation would be “limited to molecular / hemostasis factors”.
- If you are responsible for tests such as above and cystic fibrosis, pharmacogenetics, pain management – the resulting limitation would be “limited to Molecular Pathology”.