

Clinical Laboratory Technologist Restricted License Form 4

Attestation of Training Program Content in Molecular Testing or Molecular Testing (Enhanced) Restricted to Molecular Diagnosis Included in Genetic Testing-Molecular and Molecular Oncology

Applicant Instructions

Complete Section I. Review and complete Section II with the Director of the Molecular Testing training program in which you wish to participate. Be sure to sign and date the applicant attestation and ask the Director to return all pages of the form to the Office of the Professions at the address at the end of the form. **This form will not be accepted if returned by the applicant.**

Indicate the type of training program to be offered (check one): Molecular Testing Molecular Testing (Enhanced)

Section I: Applicant Information

1. Social Security Number _____ 2. Birth Date Month _____ Day _____ Year _____
(Leave this blank if you do not have a U.S. Social Security Number)

3. Print Name Last _____
First _____
Middle _____

5. Telephone/Email Address
Daytime Phone _____
 Home or Business

Licensee business address, phone and email address are public information. Failure to indicate business or home on this form for each item will deem it public information.

4. Mailing Address Home or Business
(You must notify the Department within 30 days of any address or name changes)

Area Code _____ Phone _____
Email Address (please print clearly)
 Home or Business

Line 1

Line 2

Line 3

City _____

State _____ ZIP Code _____

Country/
Province _____

6. New York State DMV ID Number
(Driver or Non-Driver ID)

(Leave this blank if you do not have a New York State DMV ID Number)

Section II: Training Program Information

1. Name of Clinical Laboratory offering the Training Program _____

Address of Clinical Laboratory _____

New York State Department of Health (DOH) Clinical Laboratory Permit Number _____

Indicate whether the following testing categories are authorized by the DOH issued Clinical Laboratory Permit (check all that apply)

Oncology - Molecular & Cellular Tumor Markers Genetic Testing - Molecular

2. Name of Molecular Testing Training Program Director _____

Job Title _____

Contact Email Address _____

Contact Telephone Number _____

Check Each that apply

I hold a DOH issued Laboratory Director Certificate of Qualification in Oncology - Molecular Tumor Markers.

I hold a DOH issued Laboratory Director Certificate of Qualification in Genetic Testing - Molecular.

I am the Clinical Laboratory Director of the Clinical Laboratory described above.

I am a sole Assistant Clinical Laboratory Director at the Clinical Laboratory described above.

Section II: Training Program Information (Continued)

3. The applicant and the training program director must initial below indicating that all the following training program requirements will be met.

The Training Program will cover Molecular Testing in the fields of genetics, genomics, oncology, infectious diseases, pharmacogenomics, and transfusion medicine and will have a planned sequence of supervised employment or engagement in this subject matter. The Training Program will provide education (i.e., lectures, reading, and/or practice) in: (1) nucleic acids and proteins, human molecular biology, molecular pathology, molecular diagnosis, molecular oncology (including the role of genetics in molecular diagnosis and molecularly targeted therapies), human and microbial molecular genetics, and molecular test result calculation, interpretation, and reporting; (2) laboratory operations relevant to molecular testing, including, but not limited to, quality control, quality assurance, safety, instrument operation and maintenance; (3) molecular techniques, including nucleic acid isolation, separation, detection, amplification, and sequencing. The training program will offer the applicant hands-on training in molecular techniques, including but not limited to nucleic acid isolation; manipulation of RNA/DNA; separation and detection; nucleic acid amplification; sequencing; and techniques to prevent specimen contamination. The Training Program may include hands-on molecular testing training in additional scientific fields if the Clinical Laboratory is authorized by DOH to provide molecular testing services in the additional fields. The Training Program may address other concepts and topics in Molecular Testing.

Applicant Initials _____ Training Program Director Initials _____

The Training Program will be at least 1750 hours (1 year) and will not involve any testing or procedures on specimens which are outside the restricted license category of Molecular Testing. The Training Program Director shall verify that the applicant successfully completes a summative competency assessment in molecular testing in the field of Human Genetics and/or Oncology.

Applicant Initials _____ Training Program Director Initials _____

The Training Program will provide continuous on-site personal supervision and training by qualified staff whenever the applicant performs any clinical laboratory services. The staff shall meet the following qualifications: (1) hold a DOH issued Laboratory Director Certificate of Qualification in *Oncology-Molecular and Cellular Tumor Markers* or in *Genetic Testing-Molecular* or (2) be a New York State licensed clinical laboratory technologist or physician who qualifies as a "laboratory supervisor" under DOH regulations (10 NYCRR section 58-1.4) and who is authorized by the Clinical Laboratory to perform molecular testing and authorized by the Training Program Director to train or supervise the applicant or (3) be a laboratory director or sole assistant laboratory director who holds a DOH issued Laboratory Director Certificate of Qualification in the testing area in which the trainee is performing molecular tests. For example, a laboratory director with a CQ in virology may supervise or train an applicant who is performing molecular tests to detect SARS-CoV-2.

Applicant Initials _____ Training Program Director Initials _____

4. The applicant and the Training Program Director must initial below **ONLY** if the Training Program will qualify the applicant for a Restricted License in Molecular Testing (Enhanced).

The Training Program will cover clinical laboratory molecular testing research including: (1) the development of new or improved methodologies and procedures for molecular testing and (2) molecular test validation. The Clinical Laboratory offering the Training Program is either: (1) part of a National Cancer Institute Designated Cancer Center or (2) located in a teaching hospital offering ACGME accredited medical residency programs and is eligible for New York State funding pursuant to Public Health Law section 2807.

Applicant Initials _____ Training Program Director Initials _____

Applicant Attestation

I hereby attest that the information I provided on this form is accurate and complete, and that I understand the above-described training program requirements must be met to successfully complete the training program.

Applicant Signature _____ Date _____

Print Name _____

Training Program Director Attestation

I hereby attest that the information I provided on this form is accurate and complete, and that I understand the above-described training program requirements must be met for the applicant to successfully complete the training program.

Training Program Director Signature _____ Date _____

Print Name _____

Return Directly to: New York State Education Department, Office of the Professions, Division of Professional Licensing Services, Clinical Laboratory Technology Unit, 89 Washington Avenue, Albany, NY 12234-1000.