New York State Clinical Laboratory Technology Board Guidance for Molecular Testing Training Programs

New York State law establishes a restricted license in Molecular Testing and a restricted licensed in Molecular Testing (Enhanced). To qualify for either of these licenses, an applicant must complete: (1) an acceptable bachelor's or higher degree in science and (2) a New York State Education Department (NYSED) approved Molecular Testing Training Program. This Guidance describes key requirements for Molecular Testing Training Programs.

I. Molecular Testing Training Program Approval Process

1. To obtain NYSED approval to participate in the Molecular Testing Training Program, an applicant for a restricted license in Molecular Testing or Molecular Testing (Enhanced) must submit to NYSED: *Form 1-Application for a Restricted License.* Additionally, the applicant must ensure that NYSED receives *Form 4-Attestation of Training Program Content in Molecular Testing,* and a written Molecular Testing Training Program Plan. NYSED may require the applicant to submit additional documentation (i.e., a training program syllabus, curriculum).
2. If acceptable, NYSED will issue a Molecular Testing Training Program Certificate to the applicant.
3. The applicant begins the NYSED approved Molecular Testing Training Program.
4. To verify to NYSED that the applicant has successfully completed the NYSED approved Molecular Testing Training Program, the applicant ensures that NYSED receives *Form 4A-Certification of Completion of Training Program in Molecular Testing.*

II. General Requirements for Molecular Testing Training Programs

A Clinical Laboratory located in New York must operate the Molecular Testing Training Program. The Clinical Laboratory must hold a New York State Department of Health (DOH) issued clinical laboratory permit in ONCOLOGY- MOLECULAR & CELLULAR TUMOR MARKERS and/or GENETIC TESTING – MOLECULAR.

The Training Program must have a planned sequence of supervised employment or engagement in activities appropriate for a Restricted License in Molecular Testing or Molecular Testing (Enhanced). Trainees are only allowed to perform any molecular testing and services that are within the scope of practice of a Restricted License in Molecular Testing or Molecular Testing (Enhanced). The Training Program must be at least 1750 clock hours (I year).

The Clinical Laboratory must employ a Laboratory Director or Sole Assistant Laboratory Director holding a DOH issued Certificate of Qualification (CQ) in *Oncology- Molecular and Cellular Tumor Markers and/or Genetic Testing -Molecular* to oversee the Training Program. This person (hereinafter the "Training Program Director") must sign NYSED's *FORMs 4 and 4A* (described above).

The Clinical Laboratory and Training Program Director must ensure that at least one of the following qualified staff provide continuous onsite training and supervision of the Molecular Testing Training Program trainee while they perform clinical laboratory services:

- A laboratory director or sole assistant laboratory director with a DOH issued CQ in *Oncology-Molecular and Cellular Tumor Markers and/*or *Genetic Testing-Molecular*; or
- A clinical laboratory technologist or physician who qualifies as a "laboratory supervisor" under DOH regulations (10 NYCRR section 58-1.4) and authorized by the Clinical Laboratory to perform molecular testing and authorized by the Training Program Director to train or supervise Training Program trainees or,

- A laboratory director or sole assistant laboratory director may supervise or train a trainee who is performing molecular testing in the same testing area in which the director holds a DOH issued CQ. For example, a laboratory director with a CQ in virology may supervise or train a trainee who performs molecular tests to detect COVID-19.

III. Molecular Testing Training Program Content Requirements

The Molecular Testing Training Program must 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, laboratory procedures, quality control, quality assurance, safety, and instrument operation and maintenance.

(3) molecular techniques, including nucleic acid isolation, separation, detection, amplification, sequencing; and molecular testing trouble shooting.

(4) molecular testing in each of the following scientific fields: infectious disease, oncology, genetics, genomics, transfusion medicine, pharmacogenomics (as described in more detail in the chart below).

Scientific Field	Examples of Applications for Molecular Testing *Note: Training Program must cover some examples described below in each scientific field.*
Genetics	o Hemoglobinopathies (e.g., Thalassemias, Sickle Cell Anemias) o Coagulopathies (e.g., Factor V Leiden, Prothrombin) o Trinucleotide repeat disorders (e.g., Fragile X, Huntington, Muscular Dystrophy) o Single gene disorders (e.g., Cystic Fibrosis, Gaucher, Hereditary Hemochromatosis) o Epigenetic disorders (e.g., Prader-Willi, Angelman) o Disease-associated HLA
Genomics	o Identify molecular biomarkers for certain diseases. o Predict progression and recurrence of a disease. o Identify treatment options and efficacy of those treatments.
Oncology	o Leukemias/lymphomas (e.g., CML, ALL, chromosomal translocations, clonal rearrangements) o Solid tumors o Hereditary cancer syndromes (e.g., breast, colon, ovarian)
Infectious Diseases	o Qualitative analysis (e.g., MRSA, Clostridioides Difficile, respiratory pathogens, STI) o Quantitative analysis (e.g., viral load) o Genotypic characterization (e.g., molecular epidemiology, viral typing, resistance testing)
Pharmacogenomics	o Efficacy of pharmacotherapy (e.g., Trastuzumab, Warfarin, Clopidogrel, Carbamazepine, Amitriptyline, Statins, or Ivacaftor)
Transfusion Medicine o Hemolytic disease of the fetus and newborn (HDFN)	o Human Erythrocyte Antigen (HEA) Genotyping Panel o RhD Genotyping for D variants. o RhCE Genotyping for C, c, E, and e variants including hrB and hrS status. o Rh Characterization o RhD Zygosity

o Anemias o Hemostasis and coagulation o Transfusion incompatibilities	o ABO Common Allele Determination o ABO Variants o Non-Rh/Non-ABO Variants o Human Platelet Antigen 1a/1b (HPA-1a/1b) Genotyping o Human Platelet Antigen (HPA) Genotyping Panel

The Training Program may cover additional subjects in the field of clinical laboratory molecular testing, as determined by the Training Program Director.

IV. Hands-on Training/Practicum Requirements

Each trainee must engage in hands-on training in molecular techniques, including nucleic acid isolation; manipulation of RNA/DNA; separation and detection; nucleic acid amplification; sequencing; and techniques to prevent specimen contamination.

The Training Program Director must verify that the trainee has successfully completed a summative competency assessment in molecular testing in the field of Human Genetics and/or Oncology. The Training Program may include hands-on molecular testing training in additional scientific fields if the Clinical Laboratory is authorized to provide molecular testing services in the additional fields.

V. Additional Requirements for Molecular Testing (Enhanced) Training Programs

To offer a Molecular Testing (Enhanced) Training Program the following additional criteria must be met:

- The Clinical Laboratory must be part of a National Cancer Institute Designated Cancer Center or located within a teaching hospital offering ACGME accredited medical residency programs and is eligible for New York State funding pursuant to Public Health Law section 2807.

- The Training Program must 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.