Clarification regarding the Scope of Clinical Laboratory Services authorized by a Restricted License in Stem Cell Processes

Background

In 2008, New York law established a Restricted License in Stem Cell Processes. At that time, persons with a Restricted License in Stem Cell Processes worked in clinical laboratories/tissue banks that processed hematopoietic stem cells for homologous therapeutic use (i.e., bone marrow transplants). Since that time, scientific advances have led to the development of new stem cell therapies using additional types of cells. The manufacturing newer stem cell therapy products have expanded the types of stem cell processing services provided by clinical laboratories.

The CLT Board Office requests assistance from CLT Board Members to describe the scope of services authorized by a Restricted License in Stem Cell Processes to reflect current clinical laboratory standards and practices. Key questions/issues are summarized below.

Scope of Clinical Laboratory Services authorized by a Stem Cell Processes Restricted License

1. Which types of stem cells/cell therapy products are processed under a Stem Cell Processes Restricted License?

- Hematopoietic stem cells & hematopoietic progenitor cells (HPCs) obtained from bone marrow, umbilical cord tissue, and/or whole blood for homologous and processed therapeutic use (i.e., bone marrow transplant)
- Mononuclear cells or nucleated cells from a hematopoietic tissue source (bone marrow, umbilical cord, whole blood, blood) and processed for non-homologous therapeutic uses (i.e., CART-T cell or other immune effector cell therapies)
- Tumor infiltrating lymphocytes (TIL) therapy products - lymphocytes obtained from a patient's tumor tissue which are processed for autologous therapeutic uses (i.e., kill cancer cells).
- Mesenchymal stem cells (MSCs) obtained from bone marrow, umbilical cord tissue, and other tissues and processed for therapeutic use (i.e., to treat graft versus host disease (GVHD))
- Induced Pluripotent Stem cells (iPSC) - Adult stem cells that have been engineered in a laboratory to be pluripotent for therapeutic use. (Are IPSCs administered to patients in investigational new drug (IND) trials?)
- Are there additional stem cell types/cell therapy products that should be considered? (Cell (i.e., cell therapies for viral infections, including SARS-CoV2, cytomegalovirus (CMV), adenovirus, and HIV)
- Are there specific cell types that ARE NOT covered? (i.e., erythrocytes, mature granulocytes, mature plasma cells)

2. Which types of processing services are performed on stem cells/cell therapy products under a Stem Cell Processes Restricted License?

Note: Processing means any activity necessary to prepare, preserve for storage, remove from storage and/or conduct laboratory testing to assure the potency, quality and/or sterility of…. tissue for transplantation, transfer, … or implantation. (see, 10 NYCRR sec. 52-1.1)

- Harvested stem cell tissue accessioning?
- Selective removal of cell populations or isolation of specific cell populations?
- Cell culturing?
- Procedures that functionally alters cell populations (i.e., genetic modifications using viral vectors or CISPR)
- Cell population activation and/or expansion of cell populations?
- Cell cryopreservation, thawing and storage under appropriate environmental conditions?
- Any other specific types of services?

2a. Which types of assays are performed on stem cells/cell therapy products under a Stem Cell Processes Restricted License?

- ABO blood group and Rh type
  - *DOH Permit Category(ies): Immunohematology*
- Cell Sterility assays – (i.e., testing for microbes, antigens, antibodies, contaminants)?
  - *DOH Permit Category(ies):* Bacteriology, Diagnostic Immunology, Virology*, Mycology*
- Cell phenotyping analysis?

  - *DOH Permit Category(ies) Cellular Immunology*
- Targeted cell counts, viability tests and/or cell product potency testing during processing.
- HLA Testing (i.e., cross matching, antibody testing)?
  - *DOH Permit Category(ies) Histocompatibility Testing)*
- Tests that demonstrate that final cell therapy product includes adequate viable targeted cell yields, microbial sterility, etc.)
- Are there additional clinical laboratory testing methods/procedures that need to be considered?

3. Does a Stem Cell Processes Restricted License cover testing of specimens OTHER THAN stem cells/cell therapy products?

- Donor Testing: (i.e., ABO group and RH type, HLA Typing Tests, Tests for unexpected antibodies to red cell antigens, pregnancy tests, infectious disease tests).
- For cord blood donations, testing of a sample of donor's birth mother.
- Stem Cell Transplant Recipients (Chimerism tests and other transplant monitoring tests)

Updating Requirements for Training Programs in Stem Cell Processes

After updating and clarifying scope of services authorized by a Restricted License in Stem Cell Processes, the CLT Board Office will update requirements for Training Programs in Stem Cell Processes. Current Training Program requirements are described below:

- A NY clinical laboratory with a DOH issued permit in immunohematology must operate the Training Program.
- A laboratory director or sole assistant laboratory director holding a DOH issued CQ in immunohematology must oversee the Training Program. Qualified staff must provide onsite supervision and hands-on training.
- The Training Program must have a planned sequence of supervised employment or engagement in activities appropriate for a Restricted License in Stem Cell Processes.
- The Training Program must be at least 1750 clock hours (I year).
- The Training Program must cover stem cell biology; general laboratory principles and skills; infection control and aseptic techniques; instrumentation and equipment; quality control and quality assurance; laboratory math; handling stem cell specimens in the laboratory; enumeration and characterization of stem cells; ABO/Rh confirmatory typing; and reagent preparation.

Please Note: If a Restricted License in Stem Cell Processes scope of practice includes new/additional clinical laboratory services, then requirements for Stem Cell Processes TRAINING PROGRAMS will increase to cover the additional services.