



STEM CELL LABORATORY (STCL)



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Stem Cell Laboratory Overview

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STEM CELL LABORATORY OVERVIEW

1 PURPOSE

- 1.1 The Stem Cell Laboratory (STCL) is an integral part of the Adult and Pediatric Blood and Marrow Transplant Program at Duke University Medical Center. It is located in the North Pavilion Building, 2400 Pratt Street, Suite 1300, Durham, NC adjacent to the Adult BMT Clinic and Parking Garage III.

2 INTRODUCTION

- 2.1 The Stem Cell Laboratory occupies approximately 3,000 square feet of bench and administrative space. The lab is divided into work areas that allow for performance of individual tasks and operations and to eliminate the potential for labeling or other types of errors leading to product contamination.
- 2.2 The work areas are:
 - 2.2.1 Receiving Area
 - 2.2.2 Cellular Therapy Product Processing Area (processing, testing, cryopreservation, thawing, distribution, etc.)
 - 2.2.3 Freezer Room
 - 2.2.4 Flow Cytometry Area (staining, acquisition, and analysis)
 - 2.2.5 Colony Forming Units (CFU) Area (plating and microscopy)
 - 2.2.6 Filing Area
 - 2.2.7 Administrative Office Space

3 SCOPE AND RESPONSIBILITIES

- 3.1 The STCL provides laboratory support for the recipients/donors being evaluated and treated by the Adult Blood & Marrow Transplant Program and the Pediatric Blood & Marrow Transplant Program. Laboratory support includes testing, processing, cryopreservation, storage, thawing/washing, and preparation for administration of all hematopoietic cellular products used to support our recipients to include, but not limited to, bone marrow, peripheral blood progenitor cells, cord blood, donor lymphocytes, etc. The facility follows hospital-wide policies and procedures for infection control, biological safety, chemical safety, radiological safety, waste disposal, emergency response to disasters, etc.
- 3.2 The STCL also participates in studies sponsored by other departments within the Duke system (*ie. cardiology studies, neonatology, nephrology, etc.*) as deemed appropriate based on the scope of services offered in the laboratory.
- 3.3 The STCL is contracted by the Carolinas Cord Blood Bank (CCBB) Laboratory to perform flow cytometry, human progenitor colony assays, and manual differentials on cord blood units processed for the public cord blood bank. The STCL also performs processing, thawing, and testing of cord blood units, as deemed necessary for validations, stability studies, etc., as required by the CCBB Program's Biologics License Application (BLA) requirements.

4 DEFINITIONS/ACRONYMS

- 4.1 BMT Bone Marrow Transplant
- 4.2 NMDP National Marrow and Donor Transplant Program
- 4.3 CALGB Cancer and Leukemia Group B
- 4.4 COG Children's Oncology Group
- 4.5 HEPA Hepa filtration system
- 4.6 CLIA Clinical Laboratory Improvement Act
- 4.7 CAP College of American Pathologists
- 4.8 ASHI American Society
- 4.9 HLA Human Leukocyte Antigen
- 4.10 COBLT Cord Blood Transplantation Study
- 4.11 CTN Clinical Transplant Network
- 4.12 CIBMTR Center for International Blood and Marrow Transplant Research
- 4.13 ASBMT American Society for Blood and Marrow Transplantation
- 4.14 ISCT International Society for Computed Tomography
- 4.15 STCL Stem Cell Laboratory
- 4.16 CCBB Carolinas Cord Blood Bank
- 4.17 BLA Biologics License Application
- 4.18 APBMTP Adult and Pediatric Blood and Marrow Transplant Programs

5 MATERIALS

- 5.1 Contamination Control Mats (VWR# 87004-022) or equivalent

6 EQUIPMENT

- 6.1 The laboratory is equipped with the necessary equipment needed to test, process, cryopreserve, and thaw cellular products. This includes, but is not limited to, biological safety cabinets, refrigerated centrifuges, pipets, flow cytometers, hematology analyzer, mechanical refrigerators and freezers, liquid nitrogen freezers (vapor and liquid), robotic high density liquid nitrogen freezer, automated slide stainer, Miltenyi CliniMACS instruments, microscopes, inverted microscope, etc. All of the equipment in the STCL is validated and/or maintained on a regular schedule, as deemed appropriate.

7 SAFETY

- 7.1 Personal Protective Equipment (PPE) should be worn at all times when handling potentially infectious blood and body fluids to include, but not limited to, gloves, lab coats, etc.

NOTE: All PPEs MUST be removed before leaving the laboratory.

- 7.2 Laboratory staff is required to complete on-line safety-related training at those time intervals required by the institution.

- 7.3 Eating, drinking, smoking, application of cosmetics, removal of contact lenses, and other personal hygiene activities is PROHIBITED in the work area.

8 PROCEDURE

- 8.1 The North Pavilion building is monitored by a guard station just inside the main entrance of the building and is manned by a security guard 24 hours per day, 7 days/week. Key card entry is required to access the North Pavilion after hours and on weekends.
- 8.2 The Stem Cell Laboratory is staffed approximately 13.5 hours per day Monday-Friday and 8 hours on Saturday to cover CCBB Program contract work (*or on-call work*). The programming schedule for the main entrance of the laboratory was changed effective 05/14/2018 to lock the door at all times. Personnel who have been granted access to enter the Stem Cell Laboratory, can use their ID badge on the swipe station located on the wall outside the main entrance. For those individuals who do not have unescorted access to the STCL, a door bell and camera were installed so access can be monitored. The back door to the laboratory is always locked and can only be accessed using a swipe station on the wall. These enhanced measures were implemented in the STCL in an effort to maximize the security of the laboratory.
- 8.3 Emergency power is available for all equipment and alarms within the STCL.
- 8.4 The freezer room is equipped with an O2 monitor located which detects low levels of oxygen in the freezer room and alerts staff if there is a problem.
- 8.5 Temperature and humidity are continuously monitored in the Stem Cell Laboratory using the REES Environmental Monitoring System as part of the processing facility's qualification of environmental control systems. See *STCL-GEN-017 JAI Assessment of STCL Facility Parameters*.
- 8.6 Cleaning and sanitation procedures are evaluated to make sure they are appropriate for the degree of processing and manipulation of cellular therapy products that is occurring in the STCL. See *STCL-GEN-017 JAI Assessment of STCL Facility Parameters*. The use of contamination control mats at both STCL entrances was implemented 03/28/2018 in an effort to minimize the contaminants tracked into the laboratory on people's shoes.
- 8.7 Fire alarm pull stations and ceiling sprinklers are located throughout the building. A fire extinguisher and fire blanket are located in the laboratory. An eyewash station is located at the main sink in the laboratory.
- 8.8 The Stem Cell Laboratory is an integral part of the Adult and Pediatric Blood and Marrow Transplant Programs (APBMTP) which are comprised of integrated medical and nursing teams located at Duke University Medical Center in Durham, NC. The programs utilize common staff training programs, protocols, document-control systems, and quality management systems. Hematopoietic cell collection and processing facilities are an integral part of the program. The Clinical and Laboratory Programs abide by all applicable governmental laws and regulations. The Stem Cell Laboratory is CLIA, FACT, and CAP certified. The program is supported by an ASHI-certified HLA laboratory and AABB Accredited Transfusion Service at Duke Hospital.

- 8.9 The program is supported by a full complement of board certified, licensed medical and pediatric sub-specialists at Duke Medical Center including, but not limited to, experts in radiation therapy, infectious diseases, surgery, intensive care, anesthesiology, gastroenterology, pulmonology, cardiology, dermatology, neurology, oncology, hematology, transfusion medicine, immunology, hepatology, interventional radiology, diagnostic radiology, otolaryngology, orthopedics, urology, psychiatry, emergency medicine, psychology, rehabilitation services (PT/OT/ST), nutrition and pharmacy medicine.
- 8.10 The program has been a member of the National Marrow Donor Program since 1992 and serves as an NMDP donor collection center. The program reports consecutive transplants to the CIBMTR and all other regulatory and reporting agencies as required.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-GEN-017 JA1 Assessment of STCL Facility Parameters

10 REFERENCES

- 10.1 N/A

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
03	B. Waters-Pick	<ul style="list-style-type: none"> Section 5.1 – Added Contamination Control Mats Section 8.2- Added the fact that the STCL main entrance is now locked at all times effective 05/14/2018 instead of being open Monday-Friday from 8:30 to 7 pm. Implementation included addition of a door bell and camera to monitor access to this secure location. Section 8.6 - Added the fact that the STCL started using contamination control mats at both entrances on 03/28/2018 in an effort to minimize the contaminants tracked into the lab on people's shoes.

Signature Manifest**Document Number:** STCL-GEN-017**Revision:** 03**Title:** Stem Cell Laboratory Overview

All dates and times are in Eastern Time.

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