



STEM CELL LABORATORY (STCL)



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Product Safety - Minimizing Cross-Contamination

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STCL-GEN-014

PRODUCT SAFETY - MINIMIZING CROSS-CONTAMINATION

1 PURPOSE

- 1.1 The purpose of this procedure is to outline the process by which cross-contamination is minimized for all cellular products handled and stored within the Stem Cell Laboratory (STCL) that have not been tested or have known positive infectious disease test results.
- 1.2 It is also the purpose of this procedure to address additional measures taken to ensure there are no mix-ups when common equipment is used at the same time (*ie. centrifuges, coolers, refrigerators, etc*).

2 INTRODUCTION

- 2.1 This procedure describes the systems currently in place to ensure the safe collection and storage of all cellular products in an effort to minimize cross-contamination in the processing laboratory. Cellular products include but are not limited to bone marrow, peripheral blood progenitor cells, cord blood, and granulocytes. Each donor/patient is screened extensively, as outlined in procedure *Donor Selection, Evaluation, and Management*, before any cellular product is collected or processed.
- 2.2 Under rare circumstances, known infectious positive cellular products are cleared for clinical use. In these instances, those cellular products must be isolated from other cellular products (*ie. vapor LN2*) in an effort to minimize cross-contamination.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The Adult and Pediatric Blood and Marrow Transplant Program Medical Directors, STCL Manager, Collection Staff, Processing Staff, and Quality Manager are responsible for ensuring that the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- | | | |
|-----|------|-------------------------------|
| 4.1 | STCL | Stem Cell Laboratory |
| 4.2 | LN2 | Liquid nitrogen |
| 4.3 | N/A | Not Applicable |
| 4.4 | BSC | Biological Safety Cabinet |
| 4.5 | PPE | Personal Protective Equipment |

5 MATERIALS

- 5.1 N/A

6 EQUIPMENT

- 6.1 LN2 freezers used to store cellular products

6.2 Biological Safety Cabinets

6.3 Centrifuges

7 SAFETY

- 7.1 Use appropriate personal protective equipment at all times when handling potentially infectious blood and body fluids to include, by not limited to, gloves, goggles, lab coats, etc. Refer to *STCL-GEN-012 Safety* for additional details regarding safety-related requirements and practices within the STCL.
- 7.2 A technologist will only handle/process **one cellular therapy product** (ie. HPC, Apheresis, HPC, Marrow, HPC, Cord, etc) in the biological safety cabinet at any given time. (**NOTE:** This is specific for the processing section of the laboratory; HPCA and Flow Cytometry testing sections of the laboratory perform batch testing whenever practical).

8 PROCEDURE

- 8.1 All appropriate PPEs must be worn by laboratory staff whenever handling any potentially infectious blood or body fluid.
- 8.2 Employees working with blood and body fluids must complete all required on-line safety-related training modules offered by Duke OESO.
- 8.3 A technologist will only handle/process **one cellular therapy product** (ie. HPC, Apheresis, HPC, Marrow, HPC, Cord, etc) in the biological safety cabinet at any given time. (**NOTE:** This is specific for the processing section of the laboratory; HPCA and Flow Cytometry testing sections of the laboratory perform batch testing whenever practical).
- 8.4 When centrifuging multiple products at the same time, each cellular product will be contained within a sterile zip lock bag in the event of a breach during centrifugation. This practice will minimize cross contamination to other products.
- 8.5 Verification of product labels and associated paperwork will be re-verified upon removal from the centrifuge (or other common equipment used) in an effort to avoid any mix-up of products.
- 8.6 BSCs are cleaned before and after each use. See *STCL-EQUIP-004 Operation of Biological Safety Cabinets* for additional details.
- 8.7 If more than one product is transported in a cooler, each product will be placed in a zip lock bag so there is minimal chance of cross-contamination between products.
- 8.8 If more than one cellular product is stored in the refrigerator at any given time, those products will be segregated within the refrigerator and/or placed in a zip lock bag so there is minimal chance of cross-contamination between products.
- 8.9 Equipment and work surfaces are cleaned with appropriate disinfectants on a regular basis and immediately if a noticeable spill is observed. Refer to *STCL-SOP-035 Cleaning and Decontamination Protocol for STCL* and *STCL-SOP-054 Cleaning and Decontamination of STCL by External Vendors* for more details

- 8.10 All patients/donors whose cellular products are being considered for clinical use must be evaluated in accordance with *Donor Selection, Evaluation, and Management* procedure. Cord blood donors are evaluated using procedure *Obtaining Medical History* and *Medical History Exclusion Criteria*.
- 8.11 As part of the evaluation process, infectious disease test results for all patients/donors must be reviewed by designated nursing personnel to determine whether a patient/donor is cleared for donation.
- 8.12 The vast majority of cellular products have negative infectious disease test results and are therefore cleared for clinical use.
- 8.13 On rare occasion, a known infectious positive cellular product may be cleared by the medical director or designee for clinical use. In those cases, the directed cellular products must be approved in the *Emergency and Exceptional Release* section of the *Summary of Donor Eligibility and Infectious Disease Testing* form by the medical director and quality manager.
 - 8.13.1 In an effort to minimize cross-contamination, known infectious disease positive products that require short-term or long-term term storage can be stored in designated LN2 vapor freezer locations with the appropriate labeling.
 - 8.13.2 Cellular products with known positive infectious disease test results can also be stored in MedSep bags (*with overwrap*) in a liquid phase freezer with the appropriate labeling.
 - 8.13.3 Cellular products with known positive infectious disease test results could also be stored in a designated mechanical freezer (*if instructed by the medical staff*) with the appropriate labeling.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-GEN-012 Safety
- 9.2 STCL-SOP-035 Cleaning and Decontamination Protocol for STCL
- 9.3 STCL-SOP-054 Cleaning and Decontamination of STCL by External Vendors
- 9.4 STCL-EQUIP-004 Operation of Biological Safety Cabinets

10 REFERENCES

- 10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition.
- 10.2 American Association of Blood Banks. Standards For Blood Banks And Transfusion Services. Current edition.
- 10.3 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT). Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation. Current edition

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
05	B. Waters-Pick	<ul style="list-style-type: none"> Added section 1.2 <i>"It is also the purpose of this procedure to address additional measures taken to ensure there are no mix-ups when common equipment is used at the same time (ie. centrifuges, coolers, refrigerators, etc)."</i> Section 4 added 4.4 and 4.5 Section 6 added 6.2 and 6.3 Section 7.1 added reference to <i>STCL-GEN-012 Safety</i> Section 7 added 7.2 <i>"A technologist will only handle/process one cellular therapy product (ie. HPC, Apheresis, HPC, Marrow, HPC, Cord, etc) in the biological safety cabinet at any given time. (NOTE: This is specific for the processing section of the laboratory; HPCA and Flow Cytometry testing sections of the laboratory perform batch testing whenever practical)"</i> Section 8 added sections 8.1 – 8.9 to address the FACT citation issued for standard D5.1 in May 2019. Section 9 added related documents to this section

Signature Manifest**Document Number:** STCL-GEN-014**Revision:** 05**Title:** Product Safety - Minimizing Cross-Contamination

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