



STEM CELL LABORATORY (STCL)



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Blue Box Insulated Shipper Inspection and Cleaning

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Blue Box Insulated Shipper Inspection and Cleaning

1 PURPOSE

- 1.1 The purpose of this procedure is to describe the process for inspection and cleaning of the insulated shipping container used in the Stem Cell Laboratory at Duke University Medical Center.

2 INTRODUCTION

- 2.1 Insulated blue box shipping containers are used to transport supplies to and from donors at non-fixed collection sites to the Stem Cell Laboratory at Duke University Medical Center.
- 2.2 The blue box and its components should be stored at an acceptable temperature range. Each shipper is validated to maintain a temperature range between 4°-30°C for 36 hours. The optimal temperature of the cord blood unit during transit should be between 14°-28°C.
- 2.3 An electronic data logger is included to record the temperature during transit to the STCL.
- 2.4 All components of the blue box insulated shipper must be in good working condition and inspected on a regular basis.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The STCL Medical Director, Lab Manager, and designated STCL staff are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- 4.1 STCL Stem Cell Laboratory
- 4.2 QC Quality Control
- 4.3 °C degrees Celsius
- 4.4 UN3373 United Nations Biological Hazard Number for shipping biological specimens

5 MATERIALS

- 5.1 Germicidal wipes (e.g. Clorox Germicidal Wipes)
- 5.2 Insulated shipping container
 - 5.2.1 (1) Silver foil Styrofoam lid
 - 5.2.2 (1) Flexible grey urethane plug
 - 5.2.3 (2) Exogel panels (white temperature stabilizing panels)
 - 5.2.4 (1) Cryopak pouch (clear gel filled pouch) in ziplock bag

6 EQUIPMENT

- 6.1 Insulated shipping container, numbered and validated
 - 6.1.1 Outer corrugated container (blue shell)
 - 6.1.2 Silver Styrofoam liner and lid

7 SAFETY

- 7.1 Wear all appropriate personnel protective equipment when handling potentially infectious blood and body fluids, to include, but not limited to, gloves, lab coat, etc.

8 PROCEDURE

- 8.1 Placing NEW Blue Box Shipping containers into service
 - 8.1.1 Insulated shippers will come pre-assembled from manufacturer with the following components:
 - 8.1.1.1 Insulated shipping container
 - 8.1.1.1.1 (1) Silver foil Styrofoam lid
 - 8.1.1.1.2 (1) Flexible grey urethane plug
 - 8.1.1.1.3 (2) Exogel panels (white temperature stabilizing panels)
 - 8.1.1.1.4 (1) Cryopak pouch (clear gel filled pouch) in ziplock bag
 - 8.1.2 Each new shipper will be labeled with the following:
 - 8.1.2.1 UN3373 Label
 - 8.1.2.2 STCL Label including address and contact information
 - 8.1.2.3 Do NOT X-Ray
 - 8.1.2.4 Private Cord Blood Bank Label
 - 8.1.2.5 Box # assigned
 - 8.1.3 New, properly labeled insulated shippers are numbered in sequential order and documented on a *STCL-COLL-007 FRM7 Blue Box Insulated Shipper Inspection and Cleaning Log*.
- 8.2 Inspection and Cleaning
 - 8.2.1 Visual inspection of shippers will take place after each shipper has been received and unpacked.
 - 8.2.2 Visual inspection will include checking for damage or excessive soiling of any of the following that would interfere with proper use of the shipping container.
 - 8.2.2.1 Outer corrugated container
 - 8.2.2.2 Silver Styrofoam liner and lid

- 8.2.2.3 Exogel panel(s)
- 8.2.2.4 Flexible grey urethane plug
- 8.2.2.5 Cryopak pouch
- 8.2.2.6 Ziplock bag
- 8.2.2.7 If damage or excessive soiling is noted on any items, proceed to section 8.2.3 and record on *STCL-COLL-007 FRM7 Blue Box Insulated Shipper Inspection and Cleaning Log*.
- 8.2.3 Cleaning of shipping containers will take place after each shipping container has been received and unpacked.
 - 8.2.3.1 Remove Silver Styrofoam lid, flexible grey urethane plug, Exogel panels, and Cryopak pouch in ziplock bag from shipping container.
 - 8.2.3.2 Discard any soiled absorbent pads.
 - 8.2.3.3 Wipe down the inside of the Silver Styrofoam liner and outside of the outer corrugated container with germicidal wipes and set aside to dry.
 - 8.2.3.4 Wipe down the exterior and interior of the flexible grey urethane plug, Exogel panels, Cryopak pouch, and ziplock bag with germicidal wipes and allow to air dry.
 - 8.2.3.5 Once shipping container is completely dry, it can be repacked for use.
 - 8.2.3.6 Record inspection and cleaning results as appropriate on *STCL-COLL-007 FRM7 Blue Box Insulated Shipper Inspection and Cleaning Log*.
- 8.2.4 Removing shipping container from service
 - 8.2.4.1 Any shipping container that is damaged beyond repair must be removed from service and discarded. Complete *STCL-COLL-007 FRM7 Blue Box Insulated Shipper Inspection and Cleaning Log* to reflect the date the shipping container was taken out of service.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-COLL-007 Autologous and Directed CBU Donations
- 9.2 STCL-COLL-007 FRM7 Blue Box Insulated Shipper Inspection and Cleaning Log

10 REFERENCES

- 10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition.

- 10.2 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT) and Netcord-FACT International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release Current edition.
- 10.3 21 Code of Federal Regulations part 1270, Human Tissue Intended for Transplant.
- 10.4 21 Code of Federal Regulations part 1271, Human Cells, Tissue and Cellular and Tissue-based Products.
- 10.5 21 Code of Federal Regulations part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	B. Waters-Pick	New Document

Signature Manifest**Document Number:** STCL-COLL-007 JA11**Revision:** 01**Title:** Blue Box Insulated Shipper Inspection and Cleaning

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