



STEM CELL LABORATORY (STCL)



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Receipt of Products in the STCL

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STCL-SOP-043

RECEIPT OF PRODUCTS IN THE STEM CELL LABORATORY

1 PURPOSE

- 1.1 Products or specimens received in the Stem Cell Laboratory must be scrutinized carefully to ensure they are considered acceptable before they can be processed or distributed elsewhere.

2 INTRODUCTION

- 2.1 This procedure describes the steps involved in receiving cellular products or blood specimens in the Stem Cell Laboratory. Each cellular product or specimen must be maintained at the appropriate transport temperature whether it be room temperature, 2-8° C or -150 degrees Celsius or colder. Each product or specimen should be inspected to ensure it is labeled properly, to ensure the container is intact, to ensure the appropriate temperature has been maintained during transit, and/or to ensure that the appropriate paperwork has been included with each cellular product or specimen.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The Medical Directors, Laboratory Manager, Quality System Unit, and laboratory staff are responsible for ensuring that the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- | | | |
|-----|------|---|
| 4.1 | ISBT | International Society Blood Transfusion |
| 4.2 | PBPC | Peripheral Blood Progenitor Cells |
| 4.3 | BM | Bone Marrow |
| 4.4 | LN2 | Liquid Nitrogen |
| 4.5 | HPC | Hematopoietic Progenitor Cell |
| 4.6 | DOB | Date of Birth |
| 4.7 | SOP | Standard Operation Procedure |
| 4.8 | NMDP | National Marrow Donor Program |

5 MATERIALS

- 5.1 N/A

6 EQUIPMENT

- 6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 CELLULAR PRODUCTS HAND DELIVERED BY A DESIGNATED COURIER (such as fresh NMDP products)

- 8.1.1 Request that the courier complete and sign the appropriate chain of custody form.
- 8.1.2 Determine if the specimen is properly labeled.
- 8.1.3 Verify that all necessary paperwork accompanies the specimen.
- 8.1.4 Verify that the paperwork and the product labels match one another and assign an internal (Stem Cell Laboratory) ISBT 128 barcode to the product.
- 8.1.5 Verify that the appropriate temperature has been maintained during transport.
- 8.1.6 Inspect the product to ensure there are no visible problems such as leaks, tears, clumps, or flaws in the bag (container) housing the cellular product.
- 8.1.7 Determine how the product is to be handled if required processing is not to be initiated.
- 8.1.8 If the cellular product is bone marrow obtained from a bone marrow harvest procedure, maintain the product at room temperature until processing, testing, and /or distribution is initiated.
- 8.1.9 If the cellular product is a peripheral stem cell product, collected by apheresis, store the product in a temperature controlled and monitored (by continuous chart recorder and/or continuous temperature monitoring) refrigerator to ensure that the temperature is maintained between 1-8 degrees Celsius.
- 8.1.10 If any discrepancies or problems are identified, notify the laboratory manager or designee immediately so that corrective action can be determined. If deemed appropriate, the laboratory manager or designee will initiate an event report form.
- 8.1.11 All paperwork accompanying the cellular product will be maintained by the laboratory for a minimum of 10 years or indefinitely.

8.2 PRODUCTS ARRIVING IN A DRY SHIPPER such as cryopreserved cord blood units, PBPCs, BM, etc.

- 8.2.1 Carefully open the dry shipper and review the paperwork enclosed to ensure that it is all been included, accurate, and complete.
- 8.2.2 Inspect the data logger on the dry shipper to ensure that the appropriate temperature has been maintained throughout the shipment (i.e. digital

temperature display or normal/warning read out). Print the temperature tracing, if appropriate.

- 8.2.3 With another technologist present, remove the product from the dry shipper.
- 8.2.4 Working together, in vapor phase of a liquid nitrogen (LN2) freezer, verify that the specimen is labeled accurately and the paperwork matches the identification of the specimen. Assign an internal ISBT 128 barcode to the product.
- 8.2.5 Inspect the product carefully to ensure that there are no visible flaws in the container (freezer bag) such as leaks or cracks.
- 8.2.6 Store the frozen sample inside a canister and place in the appropriate designated LN2 freezer until it is to be used for transplant, etc.
- 8.2.7 If any discrepancies or problems are identified, notify the laboratory manager or designee immediately so the integrity of the unit can be determined as quickly as possible. If deemed appropriate, the laboratory manager or designee will initiate an event report form.
- 8.2.8 All paperwork accompanying the cellular product will be maintained by the laboratory for a minimum of 10 years or indefinitely.

8.3 PRODUCTS ARRIVING BY STANDARD MAIL, FEDERAL EXPRESS, UPS, ETC (i.e. directed donor UCB units or blood specimens for flow cytometry, HPC assays, or samples to be redirected to other performing laboratories, etc.)

- 8.3.1 Inspect the packaging to ensure that there is no evidence of leakage on the outside of the container.
- 8.3.2 Carefully open the box and review the paperwork enclosed to ensure that it is accurate and complete.
- 8.3.3 Remove the specimen(s) from the package and inspect to ensure the sample is not compromised and it is labeled correctly. If appropriate, assign the product an internal ISBT 128 barcode label.
 - 8.3.3.1 Blood specimens must contain (at minimum) as noted in the Specimen Labeling Requirements SOP for Clinical Laboratories.

8.3.3.1.1 First Name

8.3.3.1.2 Last Name

8.3.3.1.3 Duke History # or DOB (date of birth)

NOTE: The below information can be found in EPIC until such time that the phlebotomy staff have hand-held scanners to capture date, time, and initials in real time.

8.3.3.1.4 Date of Collection

8.3.3.1.5 Time of Collection

- 8.3.3.1.6 Initials of person collecting specimen
 - 8.3.3.1.7 Other cellular products should be labeled according to the *COMM-PASS-003 Labeling Cellular Therapy Products*.
- 8.3.4 Verify that the temperature of the product, if appropriate, was maintained appropriately during shipment.
- 8.3.5 Store the sample appropriately until it is tested, processed and/or cryopreserved.
- 8.3.6 If any discrepancies or problems are identified, notify the laboratory manager or designee immediately.
 - 8.3.6.1 If deemed appropriate, the manager may initiate an event report form.
 - 8.3.6.2 For blood specimens that are not deemed appropriate for analysis, complete an *STCL-SOP-037 Unacceptable Specimen Log* and/or *STCL-SOP-038 FRM2 Confirmation of Specimen Identification Form*.
- 8.3.7 All paperwork accompanying the specimen will be maintained by the laboratory according to Record Retention Schedule.
- 8.4 PRODUCTS OR SPECIMENS DELIVERED FROM DUKE SITES
 - 8.4.1 The clinician, technologist or designated courier will deliver the product or specimen to the laboratory.
 - 8.4.2 Check all labels for accuracy and complete a chain of custody, if required.
 - 8.4.3 Inspect the product to ensure that there are no flaws in the sample container such as leaks or tears.
 - 8.4.4 Verify that the sample was transported correctly and store appropriately until it is tested, processed, and/or cryopreserved.
 - 8.4.5 If any discrepancies or problems are identified, notify the laboratory manager or designee immediately.
 - 8.4.6 If deemed appropriate, the manager may initiate an event report form.
 - 8.4.7 For blood specimens deemed unacceptable for analysis, complete an *STCL-SOP-037 Unacceptable Specimen Log* and/or *STCL-SOP-038 FRM2 Confirmation of Specimen Identification Form*.
- 8.5 PRODUCTS RETURNED FROM ISSUE (i.e. patient not available for infusion, blood returned from a bone marrow harvest case that was not used, clotted product returned for rework, etc).
 - 8.5.1 The clinician or designated courier may return a product to the laboratory.

- 8.5.2 Inspect the product and verify that it was stored and transported appropriately.
- 8.5.3 Complete a *STCL-DIST-001 FRM1 HPC Return from Issue Form* and/or *STCL-SOP-045 FRM1 Record of Discard Form*.
- 8.5.4 Store the product appropriately until it is needed for re-issue.
- 8.5.5 If the product is deemed unacceptable upon return to the laboratory, it may be discarded as per the Disposition of Cellular Products SOP.
- 8.5.6 If any discrepancies or problems are identified, notify the laboratory manager or designee immediately. If deemed appropriate, the manger may initiate an event report form, *STCL-SOP-045 FRM1 Record of Discard Form*, *STCL-DIST-001 FRM1 HPC Return from Issue Form*, etc.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form
- 9.2 STCL-DIST-001 FRM1 HPC Return from Issue Form
- 9.3 STCL-SOP-037 Unacceptable Specimen Log
- 9.4 STCL-SOP-038 FRM2 Confirmation of Specimen Identification Form
- 9.5 STCL-SOP-045 FRM1 Record of Discard Form
- 9.6 STCL-DIST-001 Blood Component Storage and Distribution

10 REFERENCES

- 10.1 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT) and Netcord. International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release. Current edition.
- 10.2 American Association of Blood Banks. Standards for Cellular Therapy Products Services. Current edition.
- 10.3 Specimen Labeling Requirements (LTR21294) SOP for Clinical Laboratories.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
06	Barbara Waters-Pick	<p>Add procedure numbers to the documents.</p> <p>Added note to section 8.3.3.1 “NOTE: The below information can be found in EPIC until such time that the phlebotomy staff have hand-held scanners to capture date, time, and initials in real time” and and deleted reference to LTR21294.</p> <p>Added STCL-DIST-001 Blood Component Storage and Distribution to section 9.</p>

STCL-SOP-043 Receipt of Products in the Stem Cell Laboratory
 Stem Cell Laboratory, DUMC
 Durham, NC

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