

## **BMT CTN Protocol 0402 (GVHD Prophylaxis) Lab Sample Information**

**HLA Typing and Pathology/Cytogenetic** samples are processed at the transplant center according to institutional practice. It is the responsibility of the transplant center to obtain collection and processing containers and perform the required test per institutional guidelines.

**This guide includes the collection, processing, and shipping information for the following samples that are tested outside of the transplant center:**

- **Flow Cytometry/Immune Reconstitution** – Esoterix Clinical Trials Services
- **Investigational Future Testing** – NHLBI Repository
- **Donor Genetic Studies** – NHLBI Repository

### **A. Flow Cytometry/Immune Reconstitution Samples– Esoterix Clinical Trials Services**

- **Labels for Flow Cytometry/Immune Reconstitution Samples**

The EMMES Corporation will provide labels for the vacutainers that are being shipped to Esoterix Clinical Trials Services. A label set will consist of the following labels: Patient File, Manifest and Sample (see Appendix I). One set should be used for each sample collected. Centers should contact Linda Johnson (ljohnson@emmes.com) should they need more labels.

- **Collection Containers for Flow Cytometry/Immune Reconstitution Samples**

The Transplant Center will need to supply the following collection containers:

- a. 8.5 mL blood vacutainer Yellow Top, ACD-A anticoagulant
- b. 3 mL blood vacutainer, Lavender Top, EDTA anticoagulant

- **Processing for Flow Cytometry/Immune Reconstitution Samples**

- a. Label an 8.5 mL Yellow Top (ACD-A Anticoagulation) vacutainer and collect 8.5 mL peripheral blood.
- b. Label a 3 mL Lavender Top (EDTA anticoagulant) vacutainer and collect 3 mL peripheral blood.
- c. No additional processing – Do Not Centrifuge.
- d. Add samples in GlobalTrace<sup>SM</sup> immediately after collection.
- e. Ship on ice to Esoterix Clinical Trial Services immediately (Monday through Friday).

- **Shipping Containers for Flow Cytometry/Immune Reconstitution Samples**

Esoterix Clinical Trials Services will provide each site with shipping supplies for only those laboratory samples being shipped priority overnight to their facility. Each site must order the kits (study number 100513) from Esoterix Clinical Trials Services using the Supply Request Form for Patient Blood Sample Shipping Kit found on the BMT CTN secure website ([www.bmtctnsp.net](http://www.bmtctnsp.net)) by selecting the 0402 Subweb and the Transplant

Center Materials link (see Appendix II). More than one patient's samples can be shipped in the same box (with a maximum of 6 tubes per box).

- **Shipping of Flow Cytometry/Immune Reconstitution Samples to Esoterix Clinical Trials Services**

When you are ready to ship to Esoterix Clinical Trials Services, follow the steps detailed below:

- a. Add samples to a shipment in GlobalTrace and print a shipping manifest in preparation for shipping samples to Esoterix Clinical Trails Services.
- b. The Styrofoam shipper will be in the rigid cardboard box. Place one refrigerated cold pack into the bottom of the Styrofoam.
- c. Place each of the tubes in a bubble wrap sleeve.
- d. Place the bubble wrapped tubes on top of the refrigerated cold pack.
- e. **Include a hard copy the shipping manifest created by GlobalTrace in the Styrofoam with the samples.**
- f. Send shipment in GlobalTrace.
- g. Place the top on the Styrofoam and close the kit box.
- h. Place the kit box into the FedEx Diagnostic Pack envelope.
- i. Seal the envelope, fold twice and staple to ensure that it will not open during transit.
- j. Complete one of the pre-printed FedEx Airbills provided.
- k. Affix the Airbill to the outside of the FedEx Diagnostic Pack envelope.
- l. Call FedEx for pickup of the package.

**Esoterix Clinical Trial Services Shipping Address:**

Specimen Management  
Esoterix Clinical Trials Services  
750 Walnut Avenue  
Cranford, NJ 07016  
Phone: 877-788-8861 x 3112

Project Monitor:  
Michelle Whitfield  
Ph: 919-474-4366  
Fax: 919-474-4385  
[Norrid2@labcorp.com](mailto:Norrid2@labcorp.com)

Project Manager  
Marsha Ferguson  
Ph: 919-474-4327  
Fax: 919-474-4383  
[Fergusm@labcorp.com](mailto:Fergusm@labcorp.com)

More than one patient's samples can be shipped in the same box, however, a maximum of 6 tubes is allowed per box.

Sample collections and shipments should be scheduled Monday – Friday so that Esoterix Clinical Trials Services will receive the samples Tuesday through Saturday.

## **B. Investigational Future Testing & Donor Genetic Studies – NHLBI Repository**

- **Labels for Investigational Future Testing and Donor Genetic Studies**

The EMMES Corporation will provide labels for both the vacutainers and the cryovials for all of the laboratory samples that are being shipped to the NHLBI Repository. A label set will consist of the following labels: Patient File, Manifest and Sample (see Appendix II). One set may be used on the vacutainer and another set on the cryovial. One set should be used for each sample collected. Centers should contact Linda Johnson (ljohnson@emmes.com) should they need more labels.

- **Collection Containers for Investigational Future Testing & Donor Genetic Samples**

The Transplant Center will need to supply the following collection containers:

- a. 10 mL serum vacutainer (or 6mL serum vacutainer for children), Red Top, no anticoagulant for investigational future testing
- b. 7 mL plasma vacutainer (or 4 mL plasma vacutainer for children), Lavender Top, EDTA anticoagulant for investigational future testing
- c. 10 mL plasma vacutainer (or 6 mL serum vacutainer for children), Lavender Top, EDTA anticoagulant for donor genetic testing

- **Processing for Investigational Future Testing and Donor Genetic Studies**

Be sure to pre-stock with cryovials (see Appendix III for NHLBI Repository Order Form).

**Investigational Future Testing (serum and plasma)** collected at Baseline, Days 28, 100, 180, 365 and 730.

- a. Label a 10 mL Red Top (No Anticoagulant) vacutainer and collect 10 mL of peripheral blood.
- b. Place sample upright in sample rack and allow sample to clot for ~30 minutes at room temperature.
- c. Centrifuge at 900 x g/2100 rpm for 10 minutes.
- d. Remove serum, being careful not to disturb the clot.
- e. Transfer the serum into ten labeled cryovials.
- f. Label a 7 mL Lavender Top (EDTA Anticoagulant) vacutainer and collect 6 mL of peripheral blood.
- g. Centrifuge at 900 x g/2100 rpm for 10 minutes, within 30 minutes of collection.
- h. Remove plasma, being careful not to disturb the clot.
- i. Transfer the plasma into six labeled cryovials.
- j. Freeze both samples at -70°C.
- k. Add samples in GlobalTrace immediately after collection.
- l. Batch and ship frozen on dry ice to Precision BioServices **every six months or when a shipping container is full.**

**Donor Genetic Studies** collected prior to G-CSF administration

- a. Label a 10 mL Lavender Top (EDTA Anticoagulant) vacutainer and collect 10 mL peripheral blood.
  - b. Centrifuge at 900 x g/2100 rpm for 10 minutes.
  - c. Remove plasma, being careful not to disturb the clot.
  - d. Prior to G-CSF administration, transfer plasma into ten labeled cryovials.
  - e. Freeze at -70°C.
  - f. Re-suspend cellular component in RBC lysis buffer.
  - g. Divide and transfer into 6 labeled cryovials.
  - h. Centrifuge at 900 x g/2100 rpm for 10 minutes.
  - i. Discard buffer and freeze pellet at -70°C immediately.
  - j. Add samples in GlobalTrace immediately after collection.
  - k. Batch and ship frozen on dry ice to Precision BioServices **every six months or when a shipping container is full.**
- **Shipping Containers & Supplies for Investigational Future Testing & Donor Genetic Studies**

Precision Bioservices (formerly known as BBI Biotech and/or SeraCare BioServices), the NHLBI Repository, will provide each Transplant Center with shipping supplies for **only those laboratory samples being batch-shipped quarterly to the repository.** Each site must order the kits from the NHLBI Repository using the BMT CTN 0402 Repository Order Form found on the BMT CTN secure website ([www.bmtctnsp.net](http://www.bmtctnsp.net)) by selecting the 0402 Subweb and the Transplant Center Materials link, see Appendix III.

**Cryovials**

- a. 1.0 mL Cryovials

**Shipping Supplies**

- a. Shipping Container A for dry ice
  - b. FedEx airbill
  - c. 2" or 3" Freezer boxes
  - d. Absorbents
  - e. Clear Biohazard shipping bags for 2" or 3" freezer boxes
  - f. White Biohazard shipping bag for 2" or 3" freezer boxes
- **Shipping of Investigational Future Testing and Donor Genetic Samples to NHLBI Repository**

When you are ready to ship to Precision Bioservices **every six months or when a shipper container is full** follow the steps detailed below:

## Repository Contact Information:

NHLBI Repository  
ATTN: Anthony Perera  
Precision Bioservices Inc.  
8425 Progress Drive, Suite M

Frederick, MD 21701

Phone: 240-306-4100; Fax: 301-668-3416

### Use Shipping Container Saf-T-Pak STP310 (Dry Ice)

A cardboard flap with the words "empty packaging" has been taped to the front of the box to cover the shipping labels when Precision Bioservices ships the supplies to you. This flap can easily be cut from the box and removed. Once removed all shipping labels should be present.

- a. Add samples to a shipment in GlobalTrace and print a shipping manifest in preparation for shipping samples to Precision Bioservices
- b. Once the Empty Packaging Flap is removed, the box should contain the following labels. If any of the labels are missing please contact us for replacements
  - i. To Label (To Anthony Perera)
  - ii. From Label (From your site)
  - iii. 24 Hour Emergency Contact Label
  - iv. Responsible Person Label
  - v. Class 9 Diamond Label
  - vi. UN3373 Diamond Diagnostic Specimens Label
  - vii. Dry Ice Un 1845 Label with space to add weight
- c. Place Dry Ice around the small inner brown box (between brown box and Styrofoam container).
- d. Place rubber band (at least ¼" thick) around freezer box.
- e. Place white absorbent strip around box.
- f. Place box in clear biohazard bag and seal according to instructions on the bag.
- g. Place bag in white biohazard bag and seal according to the instructions on the bag.
- h. Place bag in the inner brown box (the shipping container can hold 3 - 2" freezer boxes or 2- 3" freezer boxes) and tape the inner brown box shut.
- i. Add additional dry ice to bring total amount to the same level as the top of the brown inner box. Note that the total amount of dry ice will be ~16 lbs or 9 kgs.
- j. Place the styrofoam lid onto the container (do not tape the styrofoam lid), place the "empty" packaging flap on top of the styrofoam, and then seal the cardboard box.
- k. Complete FedEx Airbill with your shipping address and the amount of dry ice placed in box:
  - i. Section 2 - The Internal Billing Reference Section must have the following information "**Sir-Tac 0402**"
  - ii. Section 4a - Check the "FedEx Priority Overnight" box
  - iii. Section 5 - Check the "other" box
  - iv. Section 6 - Check the box that says, "Yes Shipper's Declaration not required". Check the "Dry Ice box" and write "1" in the first blank line and the "kg" of dry ice used on the second line; i.e., 1 x 9 kg
  - v. Section 7 - Check Third Party. The account number is **2687-8144-7**
- l. Fill in the Dry Ice Label on box with the amount of dry ice used.

- m. Please fax a copy of the airbill to Precision Bioservices at 301-668-3416 to the Attention of Anthony Perera.
- n. Send an e-mail to Chem-Tel (their 24-hour contact) prior to shipment at [bbibiotech@chemtelinc.com](mailto:bbibiotech@chemtelinc.com) and cc Precision Bioservices at [nhlbi@seracare.com](mailto:nhlbi@seracare.com).

Include the following information in the e-mail

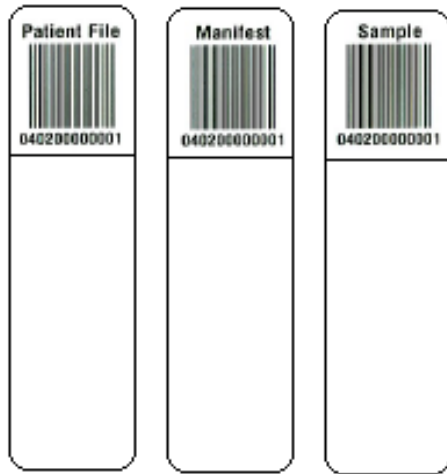
- i. Subject line of e-mail should read: Project # 138, FedEx, “insert tracking number”, “insert date of shipment”:
- ii. Shipper’s Name:
- iii. Shipper’s Address:
- iv. Shipper’s Phone:
- v. Shipment Date:
- vi. Courier: FedEx
- vii. Tracking Number: (no spaces)
- viii. Package Weight and Unit of Measure: (i.e., 20 kg)
- ix. Total Volume: (approximate volume is allowed)
- x. Sample Identifier/Number of vials (Approximate number for Frozen vials is allowed)
- xi. Shipment Temperature: Dry Ice, UN1845, \_\_ kg (insert weight of Dry Ice)
- xii. Dangerous Goods Classification: Diagnostic Specimens UN3373, Dry Ice
- xiii. Shipping Manifest Information: A hard copy of the GlobalTrace manifest must be included in the shipment.**
- xiv. Send shipment in GlobalTrace.
- xv. Recipient: Anthony Perera
- xvi. Recipient Address: 8425 Progress Drive, Suite M, Frederick, MD 21701
- xvii. Recipient Phone: 240-306-4100

Faxes may only be sent to Chem-Tel in an emergency situation when the e-mail system is not functioning at (813) 248-0582.

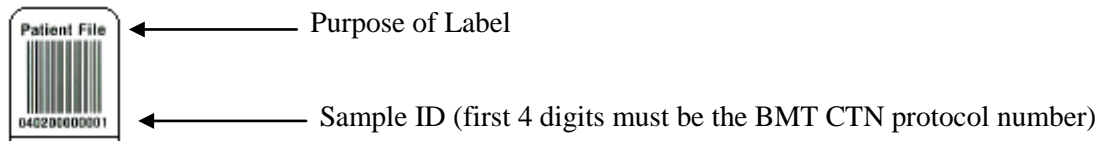
If you should have any questions regarding these instructions please contact Precision Bioservices using the contact information above.

## APPENDIX I. LABELS FOR ALL SAMPLES

### Detailed View of Each Label Set:



### Components of Each Label:

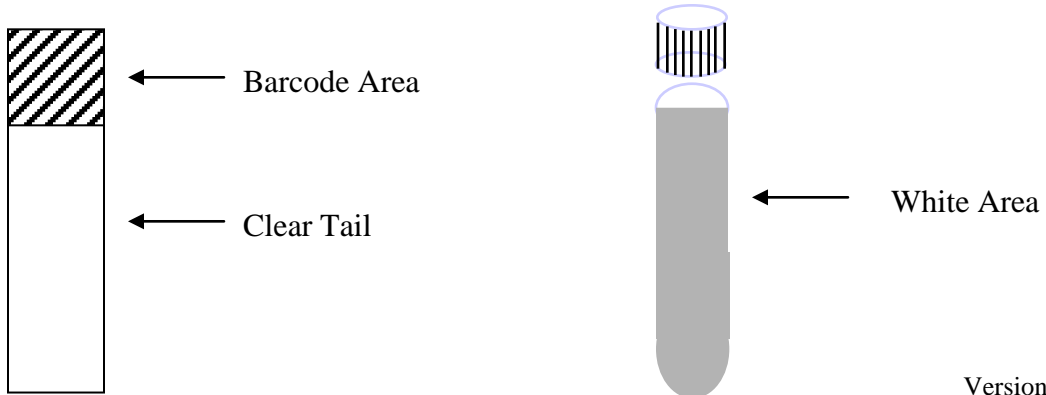


The **Purpose of Label** is where each label should be used:

- a. **Patient File** – keep this label in you patient’s files for record.
- b. **Manifest** – this label is not needed for 0402 as GlobalTrace generates a shipping manifest. Please discard the Manifest labels.
- c. **Sample** – use this label on the specimen vial.

### Labeling Vials

- a. Apply the barcode portion of the label on the vial horizontally starting at the white area on the vial.
- b. Wrap the clear tail around the vial; making sure the tail overlaps the barcode area.
- c. Do NOT write on the labels. There should be no patient identifying information on the labels or vials.



**APPENDIX II. SUPPLY REQUEST FORM FOR FLOW CYTOMETRY/IMMUNE  
RECONSTITUTION SAMPLES**



**SUPPLY REQUEST FORM  
BMTCTN – PROTOCOL 0402  
PATIENT BLOOD SAMPLE SHIPPING KITS  
ESOTERIX STUDY NUMBER 100513**

Date: \_\_\_\_\_ TC Number: \_\_\_\_\_

Ordered By: \_\_\_\_\_ TC Name: \_\_\_\_\_

Phone #: \_\_\_\_\_ P.O. #: **15274**

Part No.	QTY	Description
<b>0402 Central Lab Kit</b>		Patient Sample Kit, Cold, for up to 6 vials (Assembled) For Use With BMT CTN Protocol 0402 Only Each sample kit includes: Kit box with Styrofoam shipper, 1 cold pack, bubble wrap sleeves (for tubes), Fed Ex Diagnostic Pak (Envelope) and preprinted Fed Ex airbills

**Bill To:**  
National Marrow Donor Program  
"NMDP P.O.# 15274"

**Ship To:**

**Special/Shipping Instructions:** \_\_\_\_\_

**ALLOW 5 WORKING DAYS FROM TIME OF REQUEST TO DELIVERY OF SUPPLIES AT YOUR SITE.**

Fax completed order form to Michelle Whitfield at 919-474-4385 or e-mail to [Norrid2@labcorp.com](mailto:Norrid2@labcorp.com).  
(Phone 919-474-4366)



**APPENDIX III. BMT CTN 0402 REPOSITORY ORDER FORM**



<b>Doc #:</b> FORM25309-01	<b>Doc. Name:</b> BMT CTN All Protocol Supply Order Form	<b>Rev.:</b> E	<b>Effective Date:</b> 3/27/13	<b>CR #:</b> 4022	<b>Page</b> 1 of 1
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**BMT CTN Protocol\_\_\_\_\_**

**Precision Bioservices SUPPLY ORDER FORM**  
 Please fax to Precision Bioservices at (301) 668-3416  
 Or email to nhlbi@precisionformedicine.com  
**ATTN: NHLBI Repository Project Manager**  
**Phone (240) 306-4143**

Site NMDP Number: \_\_\_\_\_ Site Name: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Contact Address: \_\_\_\_\_

Phone #: \_\_\_\_\_ Fax# \_\_\_\_\_ E-Mail: \_\_\_\_\_

Date of Request: \_\_\_\_\_ Date Supplies are Needed: \_\_\_\_\_

Item Description	Quantity of Each Item Requested
Shipping Container A – Dry Ice	
Fed Ex Airbills	
2” Freezer Boxes	
3” Freezer Boxes	
Absorbent Strips (one is needed per freezer box)	
Clear Biohazard Bags (one is needed per freezer box)	
White Biohazard Bags (one is needed per freezer box)	