National Institute of Neurological Disorders and Stroke Biorepository:

**BioS**pecimen **E**xchange for **N**eurological **D**isorders, **BioSEND**

# Biospecimen Collection, Processing, and Shipment Manual for

SPARX3

NINDS BioSEND

# Table of Contents

## 1.0 PURPOSE

The purpose of this manual is to provide collection site staff (PIs, study coordinators, and the sample collection and processing teams) at various study sites with instructions for collection and submission of biological samples. It includes instructions for biospecimen submission to the BioSpecimen Exchange for Neurological Disorders (BioSEND) located at Indiana University.

This manual includes instructions for the collection, processing, aliquoting and shipping of the following samples:

- Plasma
- Buffy Coat (for DNA extraction)
- Whole Blood (for banking)

These procedures are relevant to all study personnel responsible for processing blood specimens to be submitted to BioSEND.

## 2.0 ABBREVIATIONS

| | |
|---|---|
| BioSEND | BioSpecimen Exchange for Neurological Disorders |
| EDTA | Ethylene Diamine Tetra-acetic Acid |
| IATA | International Air Transport Association |
| RBC | Red Blood Cells |
| RCF | Relative Centrifugal Force |
| RPM | Revolutions Per Minute |

# 3.0 BioSEND Information

## 3.1 BioSEND Contacts

**Tatiana Foroud, PhD, Principal Investigator**
Phone: 317-274-2218
Email: tforoud@iu.edu

**Carolyn Dunifon, Clinical Research Coordinator**
Phone: 317-274-5751
Email: cdunifon@iu.edu

**General BioSEND Contact Information**
Fax: 317-278-1100
Email: biosend@iu.edu
Website: www.BioSEND.org

**Sample Shipment Mailing Address**
BioSEND
Indiana University School of Medicine
351 W. 10th Street. TK-217
Indianapolis, IN 46202-5188

## 3.2 Hours of Operation

Indiana University business hours are from 8 AM to 5 PM Eastern Time, Monday through Friday.

**Frozen samples must be shipped Monday- Wednesday only.**

For packaging and shipment details, please refer to Appendix K (Frozen Shipping Instructions).

Check the weather reports and the FedEx.com website to make sure impending weather events (blizzards, hurricanes, etc.) will not impact the shipping or delivery of the samples. FedEx® often reports anticipated weather delays on their website.

### 3.3 Holiday Schedules

- Please note that courier services may observe a different set of holidays. Please be sure to verify shipping dates with your courier prior to any holiday.
- **Weekend/holiday deliveries will not be accepted.**

### 3.4 Holiday Observations

| Date | Holiday |
|---|---|
| January 1 | New Year's Day |
| 3rd Monday in January | Martin Luther King, Jr Day |
| 4th Monday in May | Memorial Day |
| July 4 | Independence Day (observed) |
| 1st Monday in September | Labor Day |
| 4th Thursday in November | Thanksgiving |
| 4th Friday in November | Friday after Thanksgiving |
| December 25 | Christmas Day |

Please note that between December 24th and January 2nd (or the first business day after New Year's Day) Indiana University will be open Monday through Friday for essential operations **ONLY** and will re-open for normal operations on January 2nd. If at all possible, biological specimens for submission to Indiana University should **NOT** be collected and shipped to Indiana University between December 24th and January 2nd. Frozen specimens collected during this period should be held at your site to ship after the first business day in January.

**Please see https://www.biosend.org/holiday_closures.html for additional information.**

## 4.0 BioSEND Sample Requirements

NINDS approves each study for a specific biospecimen collection protocol. Studies and study sites should make every effort to meet their approved biospecimen collection requirements. The expected number of samples from each site that should be returned to BioSEND are listed in sections 4.1-4.2.

If a sample is not obtained at a particular visit, this should be recorded in the notes section of the **Sample Record and Shipment Notification Form (see Appendix I).** These forms are submitted with your sample shipment to BioSEND.

### 4.1 Protocol Schedule for Biospecimen Submission to BioSEND-SPARX3

| Visit | BL | 6M | 12M | 18M | 24M |
|---|---|---|---|---|---|
| Plasma aliquots, 1.5ml | 6 | 6 | 6 | 6 | 6 |
| Buffy Coat | 2 | 2 | 2 | 2 | 2 |
| Whole blood, 6ml | 1 | 1 | 1 | 1 | 1 |

## 5.0 SPECIMEN COLLECTION KITS, SHIPPING KITS AND SUPPLIES

Research specimen collection kits as well as clinical lab supplies (except dry ice and equipment listed in Section 5.7) will be provided by BioSEND. These materials include blood tubes, boxes for buffy coats and plasma aliquots, as well as partially completed shipping labels to send materials to BioSEND. Barcoded kit labels, collection tube labels, and aliquot tube labels will all be provided by BioSEND. Collection tube labels and aliquot tube labels will be pre-printed with study information specific to the type of sample being drawn. BioSEND will provide a sufficient number of labels only for those specimens that are to be shipped back to the BioSEND repository (See the Protocol Schedule for Biospecimen Submission to BioSEND for your site in Sections 4.1-4.2); any tubes that will remain at the collection site should be labeled accordingly. Ensure that all tubes are properly labeled during processing and at the time of shipment according to Section 6.2.

### 5.1 Kit Supply to Study Sites

Each individual site will be responsible for ordering kits from BioSEND. We advise sites to proactively confirm kits are on hand ahead of study visits.

Within the kit request module, there is a drop down menu to request kits based on site institution. Kits and individual items can be ordered as required through the kit request module.

The link to the kit request module is shown below:

- SPARX3: http://kits.iu.edu/biosend/sparx3

Please allow **TWO weeks** for kit orders to be processed and delivered.

## 5.2 Specimen Collection Kit General Contents

Collection kits contain the following (for each subject) as designated per your protocol and/or NINDS resource development agreement. Kits provide the necessary supplies to collect samples from a given subject. Do not replace or supplement any of the tubes or kit components provided with your own supplies unless you have received approval from the NINDS/BioSEND Study team to do so. *Please store all kits at room temperature until use.* Note that "supplemental" kits can be provided should you require additional supplies from those contained in the visit specific kits. Replacement supplemental kits can be requested on the kit request website. In addition, individual supplies can be requested as well.

**BioSEND Supplies**

Available upon request from the online kit request module (Section 5.1)

| **General Items** |
|---|
| 25 cell cryobox |
| Cryogenic Vials |
| FedEx® return airbill |
| Shipping container for dry ice shipment (shipping and Styrofoam® box) |
| Sterile pipettes (3ml) |
| Plastic biohazard bag with absorbent sheet |
| Shipping label packet (dry ice, fragile, and UN3373 label) |
| **Blood Collection Items** |
| Purple-top EDTA blood collection tube (glass, 10 ml) |
| Purple-top EDTA blood collection tube (plastic, 6 ml) |

### 5.3 Specimen Collection Kit Contents – SPARX3

| SPARX3 BL/Annual Collection Kit | |
|---|---|
| **Supply** | **Amount** |
| Purple cryogenic vial, 2ml | 6 |
| Grey cryogenic vial, 2ml | 2 |
| EDTA (glass) tube, 10ml | 2 |
| EDTA (plastic) tube, 6ml | 1 |
| Bubble-tube sleeve | 3 |
| Disposable pipet, 3ml | 2 |
| Cryobox, 25 cell | 1 |
| Biohazard bag w/ absorbent sheet | 2 |
| Fragile label | 1 |
| UN3373 label | 1 |
| Dry ice label | 1 |
| Waybill | 1 |
| Frozen shipper | 1 |
| Label set (case and collection tube labels) | 1 |

| SPARX3 Supplemental Kit | |
|---|---|
| **Supply** | **Amount** |
| Purple cryogenic vial, 2ml | 10 |
| Grey cryogenic vial, 2ml | 10 |
| EDTA (glass) tube, 10ml | 5 |
| EDTA (plastic) tube, 6ml | 5 |
| Bubble-tube sleeve | 10 |
| Disposable pipet, 3ml | 10 |
| Cryobox, 25 cell | 2 |
| Biohazard bag w/ absorbent sheet | 5 |
| Fragile label | 5 |
| UN3373 label | 5 |
| Dry ice label | 5 |

### 5.4 Site Required Equipment

The following materials and equipment are necessary for the processing of specimens at the collection site and are to be **supplied by the local site**:

- Personal Protective Equipment: lab coat, nitrile/latex gloves, safety glasses
- Tourniquets
- Alcohol Prep Pads
- Gauze Pads
- Bandages
- Butterfly needles and hubs
- Microcentrifuge tube rack
- Test tube rack
- Sharps bin and lid

In order to process samples consistently across all projects and ensure the highest quality samples possible, project sites must have access to the following equipment:

- Centrifuge capable of ≥ 1500 rcf (1500 x g)
- -80°C Freezer

In order to ship specimens, you must provide:

- Dry ice (approximately 10 pounds per shipment)

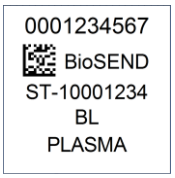
## 6.0 SPECIMEN LABELS

Labels must be affixed on all collection and aliquot tubes to ensure unique specimen identity. BioSEND provides labels for all samples being collected and returned to BioSEND. The site is responsible for providing labels for biospecimens that will be retained at the site.

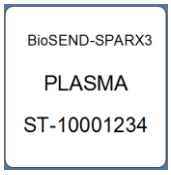
### 6.1 Types of Labels

Each kit contains all labels required for the return of biospecimens to BioSEND.


The **Case Labels** do not indicate a specimen type, but are affixed on BioSEND forms and on specific packing materials. See Appendix K for further instructions.




The **Collection Tube Labels for Blood** are placed on all blood collection tubes. See Appendices B-C for further instructions.

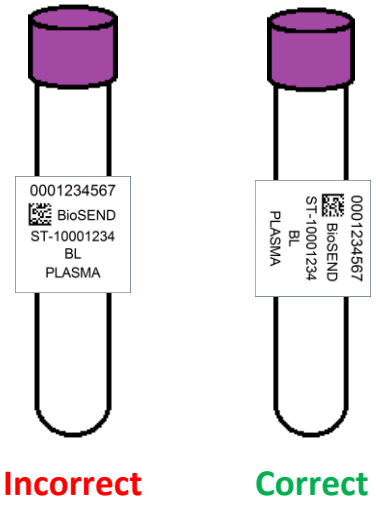



**Plasma and Buffy Coat Aliquot Tubes** will come pre-labeled with the study abbreviation, specimen type, and ST number. The tube itself with have a unique barcode printed in both 2D format (on bottom of tube) and human readable formats (alongside of tube).

### 6.2 Affixing Labels

In order to ensure the label adheres properly and remains on the tube, follow these instructions:

- Place blood collection labels on **ALL** collection tubes **BEFORE** sample collection, sample processing, or freezing. This will help to ensure the label properly adheres to the tube before exposure to moisture or different temperatures.
- The blood collection tube labels contain a 2D barcode on the left hand side of the label. When turned horizontally, the barcode should be closer to the top (cap end) of the tube.
- Place label **horizontally** on the tube (wrapped around sideways if the tube is upright); see below.




- Take a moment to ensure the label is **completely affixed** to each tube. It may be helpful to roll the tube between your fingers after applying the label.

## 7.0 SPECIMEN COLLECTION AND PROCESSING PROCEDURES

Consistency in sample collection and processing is essential for biomarker studies. All samples are drawn in the same order and then processed in a uniform fashion. **Please read the instructions before collecting any specimens. Have all your supplies and equipment out and prepared prior to drawing blood.**

### 7.1 Collection Tubes for BioSEND

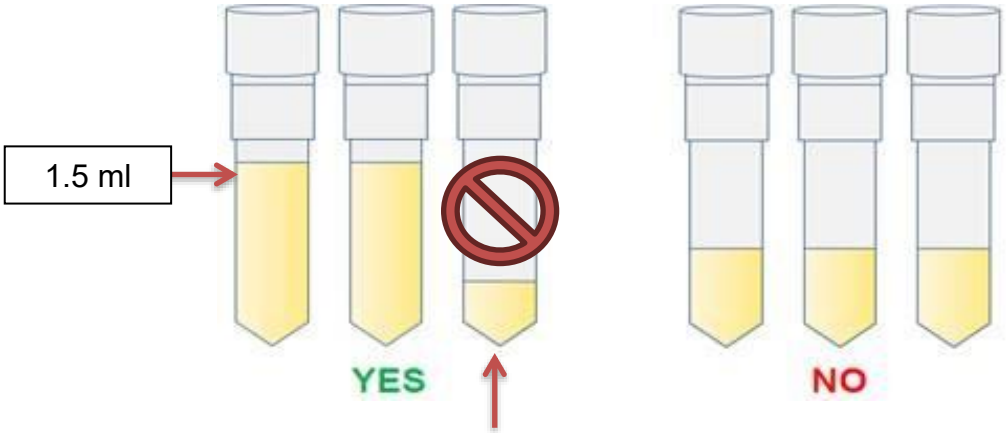
1. EDTA (purple top, 10ml) x 2 for plasma and buffy coat
2. EDTA (purple top, 6ml) x 1 for whole blood

### 7.2 Blood Collection Protocols

1. EDTA (purple top) blood collection for plasma **(Appendix B)**
2. EDTA (purple top) blood collection for Buffy Coat **(Appendix C)**
3. EDTA (purple top) blood collection for whole blood **(Appendix D)**

## 7.4 Filling Aliquot Tubes (Plasma and Buffy Coat)

In order to ensure that BioSEND receives a sufficient amount of sample for processing and storage, and to avoid cracking of the tubes prior to shipment, each aliquot tube should be filled to the assigned volume (refer to detailed processing instructions for average yield per sample). Over-filled tubes may burst once placed in the freezer, resulting in a loss of that sample. Each site is supplied with sufficient collection tubes to provide the specimen volume described in the Protocol Schedules for Biospecimen Submission (see Section 4). Specimens collected in addition to those described in Section 4 are collected at the site's discretion and are not returned to BioSEND.




**Please note:** It is critical for the integrity of future studies using these samples that study staff **not submit** residual aliquot tubes (anything under 1.5 ml) to BioSEND.

Each aliquot cryovial will be have a color-coded cap as follows:

| Cap Color | Specimen Type |
|---|---|
| Purple | Plasma |
| Grey | Buffy Coat |

**Please be sure to use the appropriate colored top for the appropriate sample type.**

## 8.0 Packaging and Shipping Instructions

**ALL** study personnel responsible for shipping should be certified in biospecimen shipping. If not available at your University, training and certification is available through the CITI training site (Course titled "Shipping and Transport of Regulated Biological Materials" at https://www.citiprogram.org/).

### 8.1 Sample Record and Shipment Notification Form

All sample shipments to BioSEND must include the BioSEND Sample Record and Shipment Notification Form. The completed forms are:

- Emailed to BioSEND@iu.edu at the time the samples are being shipped
- And the original document should be Included in the shipment with the samples

### 8.2 Shipping Instructions

Frozen Shipment (baseline and follow-up). Reference Appendix K for frozen shipping instructions.

- Frozen 1.5 ml aliquots of plasma
- Frozen Buffy Coat
- Frozen 6 ml EDTA for whole blood

*****Important Note*****
**Please do not include more than 1-2 subjects worth of samples in a single shipper.**

**This ensures room for a sufficient amount of dry ice to keep samples frozen up to 24 hours.**

### 8.3 Shipping Address

All samples are shipped to the BioSEND laboratory:

BioSEND
Indiana University School of Medicine
351 W. 10th Street. TK-217
Indianapolis, IN 46202-5188

## 9.0 Data Queries and Reconciliation

Appendix I must be completed the day that samples are collected to capture information related to sample collection and processing. This form includes information that will be used to reconcile sample collection and receipt, as well as information essential to future analyses.

The SPARX3 Study team will be collaborating with BioSEND to reconcile information captured in the database compared to samples received and logged at BioSEND. Information that appears incorrect in the clinical database will be queried through the standard system. Additional discrepancies that may be unrelated to data entry will be resolved with the Principal Investigator in a separate follow up communication. If applicable, a non-conformance report will be provided to sites.

Data discrepancies with samples shipped and received at BioSEND may result from:

- Missing samples
- Incorrect samples collected and shipped
- Damaged or incorrectly prepared samples
- Unlabeled or mislabeled samples
- Discrepant information reported in the clinical database compared to information on Appendix I
- Samples frozen and stored longer than three months at the site

## 10.0 APPENDICES

Appendix B: Whole Blood Collection for Isolation of Plasma

Appendix C: Whole Blood Collection for Isolation of Buffy Coat

Appendix D: Whole Blood Collection for Banking

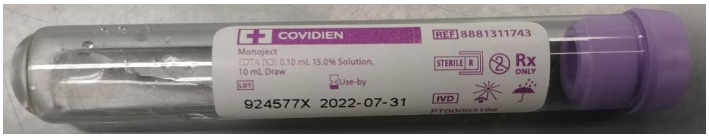
Appendix I: Sample Record and Shipment Notification Form

Appendix K: Frozen Shipping Instructions

Appendix O: Low Fat Diet Menu Suggestions

# Appendix B – Whole Blood Collection for Isolation of Plasma

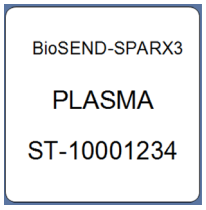
Whole Blood Collection for Isolation of Plasma: 10 ml Purple-Top EDTA tubes and cryovials are provided by BioSEND for the collection of plasma.




1. **CRITICAL STEP: Store empty purple-top EDTA tubes at room temperature 64°F – 77°F (18°C to 25°C) prior to use.**

2. Place provided "**PLASMA**" labels on 10 ml purple-top EDTA tube(s); the six 2 ml purple cryovial tubes will already be labeled. These six cryovials will be shipped to BioSEND. Any remaining cryovials can be retained by the site and labeled per site standards. Labels for aliquots kept by the site are not provided by BioSEND.


Collection Tube Label




Label on cryovials

3. Pre-chill the cryovials on wet ice for at least 5 minutes.

4. Set centrifuge to 4°C to pre-chill before use. Time needed to pre-chill the centrifuge will depend on your centrifuge model.

5. Using a blood collection set and a holder, collect blood into the **purple top 10 ml EDTA tube(s)** using your institution's recommended procedure for standard venipuncture technique.

   **The following techniques shall be used to prevent possible backflow:**
   a. Place donor's arm in a downward position.
   b. Hold tube in a vertical position, below the donor's arm during blood collection.
   c. Release tourniquet as soon as blood starts to flow into the tube.
   d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

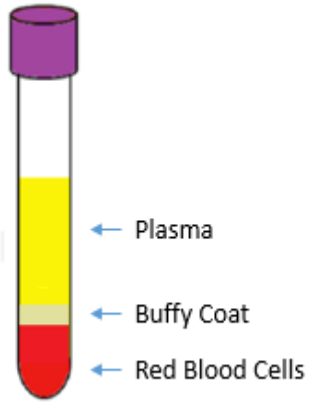
6. Allow at least 10 seconds for a complete blood draw to take place in each tube. **Ensure that the blood has stopped flowing into the tube before removing the tube from the holder.** The tube vacuum is designed to draw 10 ml of blood into the tube.

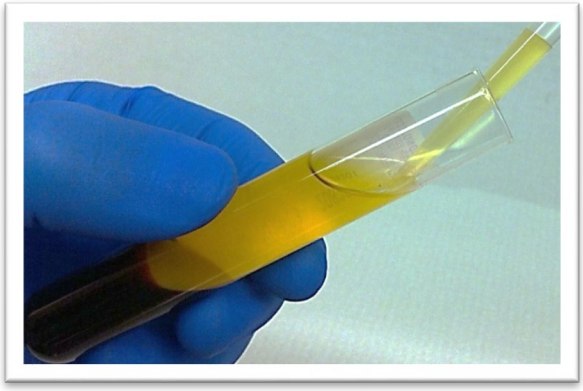
7. **CRITICAL STEP: Immediately after blood collection, gently invert/mix (180 degree turns) the purple-top EDTA tube(s) 8 – 10 times. Do not shake the tubes!**

8. Within 30 minutes of blood collection, centrifuge balanced tubes for 15 minutes at 1500 RCF (x g). **It is critical that the tubes be centrifuged at the appropriate speed to ensure proper plasma separation.**

9. Remove the plasma by tilting the tube and placing the pipette tip along the lower side of the wall. **Use caution not to touch the buffy coat or packed red blood cells at the bottom of the collection tube so that the plasma is not contaminated** (see below).

10. Using a disposable pipette, aliquot 1.5 ml into each cryovial. Send 6 x 1.5 ml aliquots to BioSEND. If you cannot obtain the requested number of aliquots, please note "low volume draw" on the Sample Record and Shipment Notification form (Appendix I) under "Notification of Problems". Each 10 ml EDTA tube should yield, on average, 4-5 ml of plasma.



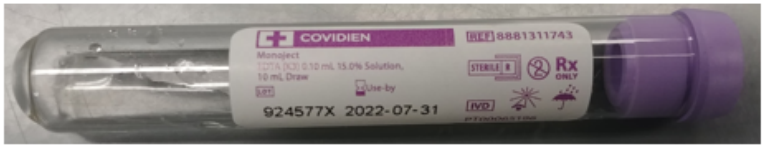



11. Complete the **Sample Record and Shipment Notification form (Appendix I).**

12. Place the labeled cryovials in the 25 slot cryobox. Place the cryobox UPRIGHT on dry ice. Transfer to **-80°C freezer as soon as possible, within 2 hours of blood draw**. Store all samples at **-80°C until shipped** to BioSEND on dry ice.

13. Ship the frozen plasma aliquots to BioSEND according to **Appendix K – Frozen Shipping Instructions.**

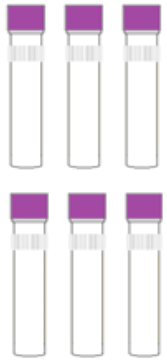
# Plasma Preparation –10 ml EDTA (Purple Top) Tube




## Step One


- Store tubes at room temperature.
- Label tubes with preprinted plasma labels prior to blood draw.

## Step Two

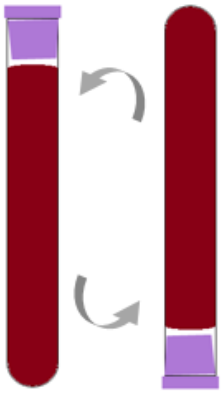


- Pre-chill cryotubes on wet ice for at least 5 minutes.

## Step Three

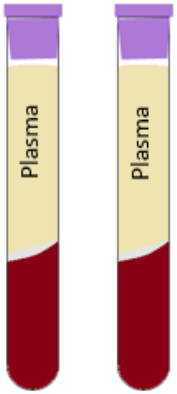
- Collect blood in EDTA tubes, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

## Step Four



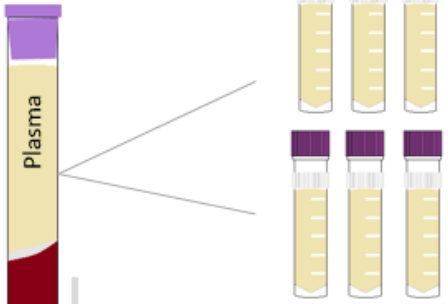
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

## Step Five




- Within 30 minutes of blood draw, centrifuge sample at <u>1500 x g at 4°C</u> for <u>15 minutes</u>.

## Step Six



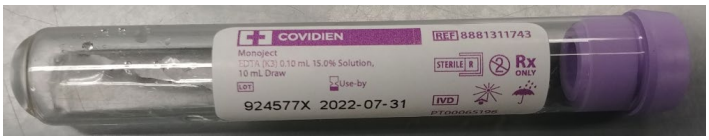



- Using a clean transfer pipet, aliquot 1.5 ml plasma into each purple cryotube.
- Store plasma aliquots <u>upright</u> at -80°C until shipment.

- See Appendix C for instructions on buffy coat collection.

# Appendix C –Whole Blood Collection for Isolation of Buffy Coat

Whole Blood Collection for Isolation of Buffy Coat: 10 ml Purple-Top EDTA tubes and cryovials are provided by BioSEND for the collection of the buffy coat.

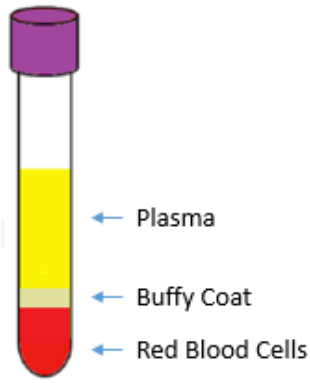


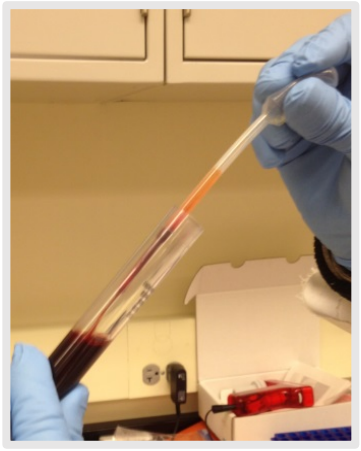

1. **CRITICAL STEP: Store Purple-Top EDTA tubes at room temperature 64$^0$F - 77$^0$F (18°C to 25°C) before use.**

2. Place grey cryovials pre-labeled with "**Buffy Coat**" to chill on wet ice for at least 5 minutes.

3. Set centrifuge to 4°C to pre-chill before use. Time needed to pre-chill the centrifuge will depend on your centrifuge model.

4. After plasma has been removed from the EDTA purple-top tube (see Appendix B), aliquot buffy coat layer (see figure below) into labeled cryovial with grey cap using a disposable graduated micropipette. All of the buffy coat from a single 10 ml purple-top EDTA tube will be placed into one cryovial. The buffy coat aliquot is expected to have a reddish color from the red blood cells.



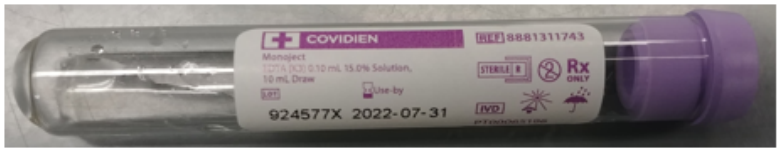



5. Complete the **Sample Record and Shipment Notification form (Appendix I).**

6. Freeze cryovial(s) in upright position on dry ice. Transfer to a **-80°C Freezer when possible**. Store all samples UPRIGHT at **-80°C until shipped** to BioSEND on dry ice.

7. Ship the frozen buffy coat aliquots to BioSEND according to **Appendix K – Frozen Shipping Instructions.**

# Buffy Coat Preparation –10 ml EDTA (Purple Top) Tube



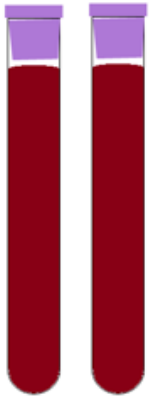

## Step One


- Store tubes at room temperature.
- Label tubes with preprinted plasma labels prior to blood draw.

## Step Two

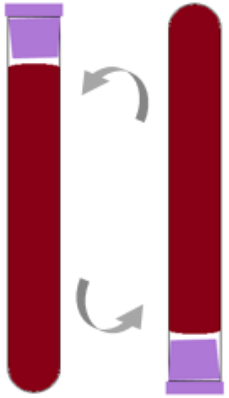
- Pre-chill cryotubes on wet ice for at least 5 minutes.

## Step Three



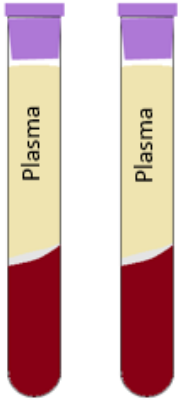
- Collect blood in EDTA tubes, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

## Step Four



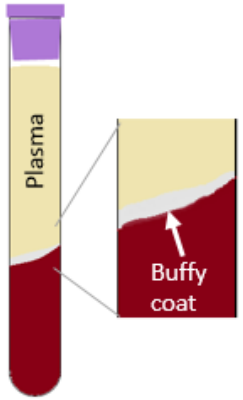
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

## Step Five




- Within 30 minutes of blood draw, centrifuge sample at <u>1500 x g at 4°C</u> for <u>15 minutes</u>.

## Step Six




- Using a clean transfer pipet, collect the buffy coat (will have residual plasma and some RBCs included).
- Transfer the buffy coat from each EDTA tube into a grey cryotube.
- Store plasma aliquots <u>upright</u> at -80°C until shipment.

# Appendix D – Whole Blood Collection (No Processing)

One 6 ml Purple-Top EDTA Tube is provided by BioSEND for Whole Blood collection (to be shipped to BioSEND FROZEN; no processing required).

0001234567
BioSEND
ST-10001234
BL
WBLD

1. **CRITICAL STEP: Store empty Whole Blood EDTA tubes at room temperature, 64°F - 77°F (18°C to 25°C) before use.**
2. Place pre-printed specimen label (WBLD) on the **6 ml purple top EDTA tube** prior to blood draw.
3. Using a blood collection set and a holder, collect whole blood into the 6 ml purple-top whole blood tube using your institution's recommended procedure for standard venipuncture technique.

   **The following techniques shall be used to prevent possible backflow:**

   a. Place donor's arm in a downward position.
   b. Hold tube in a vertical position, below the donor's arm during blood collection.
   c. Release tourniquet as soon as blood starts to flow into tube.
   d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

4. **CRITICAL STEP: Immediately after blood collection, gently invert/mix (180 degree turns) the EDTA tube 8-10 times. Do not shake the tube!**
5. Complete the **Sample Record and Shipment Notification form (Appendix I).**
6. Place the Purple-Top EDTA in a **WIRE** or **PLASTIC** rack. Do **NOT** use a Styrofoam rack. This will cause the Purple-Top EDTA tube to crack when frozen. Place the Purple-Top EDTA tube immediately to a **-80°C Freezer.**
7. Ship the whole blood tube to BioSEND according to **Appendix K - Frozen Shipping Instructions.**

# Frozen Whole Blood Preparation (6ml Purple Top Tube)

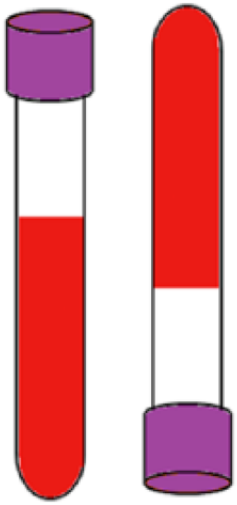
## Step One

- Store tube at room temperature.
- Label tube with pre-printed labels prior to blood draw.

## Step Two

- Collect blood in tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

## Step Three



- Immediately after blood draw, invert tubes 8-10 times to mix samples.

## Step Four

- Transfer to -80°C freezer. Store upright and keep frozen until shipment to BioSEND.

# Sample Record and Shipment Notification

Study:

Site Name: Principal Investigator:

Coordinator: Telephone: Email:

**Please list only ONE subject per Sample Record Summary and Shipment Notification Form**

GUID: Subject ID (ST# from pre-printed labels):

Gender: Visit Type:

Age in Years: Plus Months:

**Instructions: Ship Frozen Shipments Monday- Wednesday ONLY! Ambient Shipments (purple-top EDTA tube) may be shipped Monday- Thursday (preferably Monday- Wednesday) provided they are received at Indiana University within five days of collection.** This form must be completed for shipment of all research samples. Notify Indiana University (email preferred) and the DMR in advance of shipment using contact information below. Place a copy in the shipment box and file a copy of the completed form in the study binder. **Ensure all frozen shipments are completely filled with dry ice.**

Date Sample(s) Shipped: FedEx Tracking Number:

**In the table below, please indicate the date of specimen collection and number of tubes/aliquots submitted.**

| **Completed by Submitter/Site** | | | |
|---|---|---|---|
| Dates of Draw | Specimen Type | Number of Tubes/ Aliquots sent to BioSEND | Notation of Problems |
| | DNA | | |
| | RNA | | |
| | Buffy Coat | | |
| | Plasma | | |
| | Serum | | |
| | CSF | | |
| | Whole Blood | | |
| | | | |

**Contact Information: Indiana University; Email:** biosend@iu.edu **Ph:** 317-278-0594
**Data Management Resource (DMR); Email:** PDBP-OPS@mail.nih.gov

# Appendix K – Frozen Shipping Instructions

**IMPORTANT!**

**FROZEN SAMPLES MUST BE SHIPPED MONDAY THROUGH WEDNESDAY ONLY USING PRIORITY OVERNIGHT DELIVERY**

**Please be aware of holidays and inclement weather, and plan your shipments accordingly.**

Specimens being shipped to BioSEND are Category B UN3373 specimens and as such must be triple packaged and compliant with IATA Packing Instructions. *See the latest eEdition of the IATA regulations for complete documentation.*

Triple packaging consists of a primary receptacle(s), a secondary packaging, and a rigid outer packaging. The primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging. Secondary packaging must be secured in outer packaging with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

## IATA Packing and Labeling Guidelines

- The primary receptacle (cryovials or blood collection tubes) must be leak proof and must not contain more than 1 L total.
- The secondary packaging (plastic canister or biohazard bag) must be leak proof and if multiple blood tubes are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent direct contact with adjacent blood tubes.
- Absorbent material must be placed between the primary receptacle (cryovials or blood collection tubes) and the secondary packaging. The absorbent material must be of sufficient quantity to absorb the entire contents of the specimens being shipped. Examples of absorbent material are paper towels, absorbent pads, cotton balls, or cellulose wadding.
- A shipping manifest listing the specimens being shipped must be included between the secondary and outer packaging.
- The outer shipping container must display the following labels:
  - ✓ Sender's name and address
  - ✓ Recipient's name and address
  - ✓ Responsible persons (shipper and recipient)
  - ✓ The words "Biological Substance, Category B"
  - ✓ UN3373
  - ✓ Class 9 label including UN 1845, and net weight of dry ice contained

## BioSEND Packaging and Shipment Instructions – Frozen Shipments

1. Contact FedEx® to confirm service is available and schedule package to be picked up.

2. **Record the FedEx® tracking number (found at the top of the FedEx® airbill) onto the Sample Record and Shipment Notification form (Appendix I).**

3. Make a copy of the Sample Record and Shipment Notification form.

4. Place all frozen labeled 1.5 ml aliquots of plasma and buffy coats in the cryobox. Only include specimens from one subject in each cryobox.

5. Place the cryobox in the clear plastic biohazard bag. Leave the absorbent sheet in the biohazard bag and seal according to the instructions on the biohazard bag. Affix a Case Label to the outside of the biohazard bag.


6. Insert 6ml EDTA whole blood tube into the bubble wrap tube shuttle, and place the tube shuttle in the 2nd clear plastic biohazard bag. Seal the biohazard bag according to the instructions on the bag. Affix a Case Label to the outside of the biohazard bag.

7. Place approximately 2-3 inches of dry ice in the bottom of the Styrofoam® shipping container.

8. Place the biohazard bag containing the cryobox into the provided Styrofoam® shipping container on top of the dry ice. Please ensure that the cryobox is placed so that the cryovials are upright in the shipping container (as pictured).

9. Fully cover the cryobox with approximately 2 inches of dry ice. Please do not include more than two subjects' cases in a single box.

10. The inner Styrofoam® shipping container must contain approximately 10 lbs (or 4.5 kg) of dry ice. The dry ice should entirely fill the inner box and be placed on top of the cryoboxes to ensure the frozen state of the specimens.

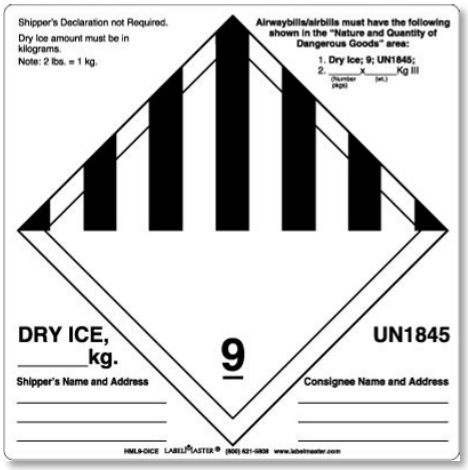
11. Replace the lid on the Styrofoam® container. Place the completed Sample Record and Shipment Notification form in the package on top of the Styrofoam lid for each patient specimen, and close and seal the outer cardboard shipping carton with packing tape.

12. Complete the FedEx® return airbill with the following information:
    - Section 1, "From": fill in your name, address, phone number.
    - Section 6, "Special Handling and Delivery Signature Options": under "Does this shipment contain dangerous goods?" check the boxes for "Yes, Shipper's Declaration not required" and "Dry Ice". Enter the number of packages (1) x the net weight of dry ice in kg.

13. Complete the Class 9 UN 1845 Dry Ice Label (black and white diamond) with the following information:
    - Your name and return address
    - Net weight of dry ice in kg (this amount must match the amount recorded on the airbill)
    - Consignee name and address:

      BioSEND
      IU School of Medicine
      351 W. 10th Street
      TK-217
      Indianapolis, IN 46202

    - Do not cover any part of this label with other stickers, including pre-printed address labels.




| IMPORTANT! |
| --- |
| **Complete the required fields on the FedEx® return airbill and Class 9 Dry Ice labels, or FedEx® may reject or return your package.** |

14. Apply all provided warning labels (UN3373, Dry Ice Label and Fragile Label) as well as the completed FedEx® return airbill to the outside of package, taking care not to overlap labels.

15. Hold packaged samples in -80°C freezer until time of FedEx® pick-up/drop-off.

16. Specimens should be sent to the address below via ***FedEx® Priority Overnight***. Frozen shipments should be sent Monday through Wednesday only to avoid shipping delays on Thursday or Friday. FedEx does not replenish dry ice if shipments are delayed or held over during the weekend.

BioSEND
IU School of Medicine
351 W. 10th Street
TK-217
Indianapolis, IN 46202

17. **Notify BioSEND by email (biosend@iu.edu) that a shipment has been sent and attach the Sample Record and Shipment Notification form to your email. Alternatively, you can submit an online form through on the BioSEND website at** https://biosend.org/sample_form.html**. Do not ship until you've contacted and notified BioSEND staff about the shipment in advance.**

18. Use FedEx® tracking to ensure the delivery occurs as scheduled and is received by BioSEND.

In addition to tracking and reconciliation of samples, the condition and amount of samples received are tracked by BioSEND for each sample type. Investigators and clinical coordinators for each project are responsible for ensuring that the requested amounts of each fluid are collected to the best of their ability and that samples are packed with sufficient amounts of dry ice to avoid thawing in the shipment process.

# Appendix O – Low Fat Diet Menu Suggestions

**Foods to avoid prior to blood collection:**

**Avoid:** *All fats and nuts such as:*

- Butter
- Cream
- Bacon fat
- Lard
- All oils
- All margarine
- All nuts
- Peanut butter
- Coconut
- Whole seeds such as pumpkin and sunflower

**Avoid:** *All milk and dairy products such as:*

- All whole milk products
- All cheese
- All products containing cheese
- Sour cream
- All ice cream
- Milk chocolate

**Avoid:** *High fat prepared foods and foods naturally high in fat:*

All red meats or meats containing fat such as pork and:

- Fatty meats such as:
  - Luncheon meats
  - Organ meats
  - Bacon
- Fatty fish such as:
  - Salmon
  - Mackerel

---

- Salad dressing and mayonnaise
- Buttered, au gratin, creamed, or fried vegetables

---

- Fried foods
- Gravies and sauces

---

- Fried snacks such as:
  - Chips
  - Crackers
  - French Fries
- Baked goods and frosting