BIOSEND

EpiBioS4Rx Training Webinar

BIOSPECIMEN COLLECTION & PROCESSING

Overview

- 1. Specimen uniformity and quality
- 2. Site Equipment
- 3. Procedures
 - Kit Ordering
 - Sample Labels
 - Sample Collection and Processing
 - Shipping Closures
- 4. Contact Information

Specimen Uniformity and Quality

GENERAL REMINDERS

Specimen Uniformity and Quality

Most biomarkers are sensitive to *time* and *temperature*

- Standardization of processing across sites is key
- Reference the BioSEND Specimen Collection, Processing, and Shipment Manual as needed
- Do not replace or supplement any kit components without first receiving approval from BioSEND/NINDS

Questions? Email biosend@iu.edu

Site Equipment

Sites will need to supply the following items:

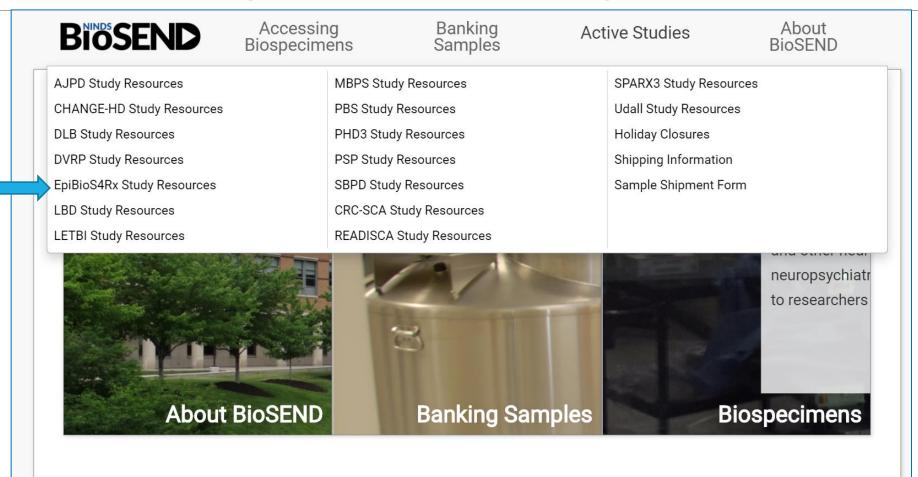
- Gloves
- Alcohol wipes
- Butterfly needles
- Tourniquet
- Gauze pads
- Bandages
- Microcentrifuge tube rack
- Sharps bin and lid

- Crushed ice
- Pipettes and pipette tips
- Centrifuge capable of maintaining 4°C
- -80°C Freezer
- Dry ice

Biospecimen Collection Protocol

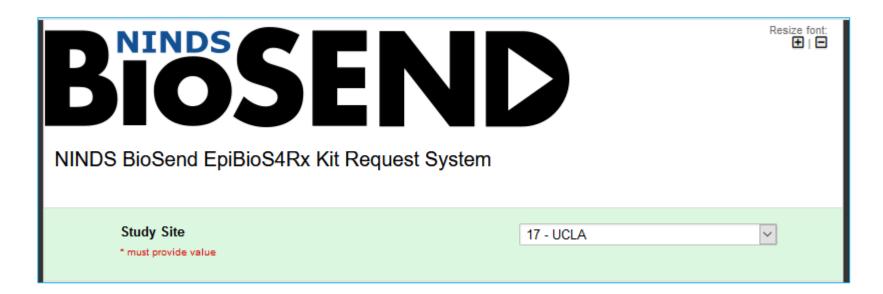
	D1	D3	D5	D15	D30	D90	D180
Buffy Coat (2 aliquots)	X	X	X	X	X	X	X
Plasma (6 x 1ml)	X	X	X	X	X	X	X
RNA (2 x 2.5ml)			X	X			

Kit Ordering – Biosend.org



BioSEND Kit Request Module

- http://kits.iu.edu/biosend/EPIBIOS4RX
- Choose your site from the drop-down list.



Confirm Shipping Info

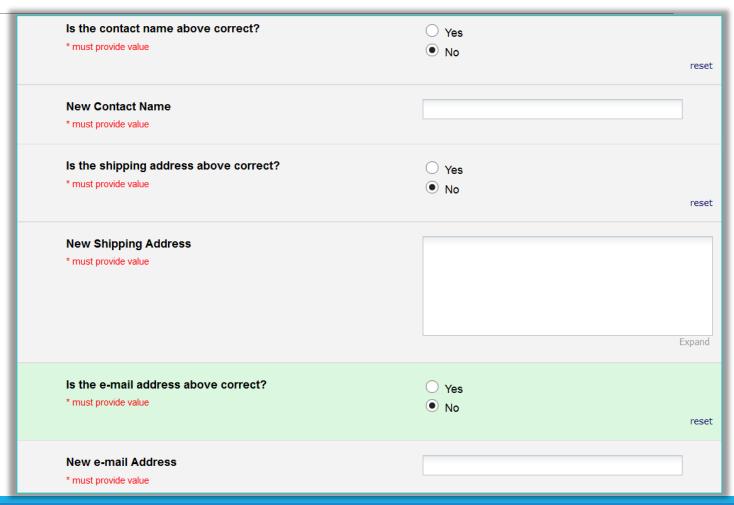
Confirm site information:

- Study site
- Shipping address
- Contact name
- Email
- Phone Number

Car Ind 351 TK Ind (31	iana University rolyn Dunifon iana University School of Medicine West 10th Street -217 ianapolis, IN 46202 7) 274-5751 send@iu.edu		
	he contact name above correct? ust provide value	○ Yes ○ No	reset
	he shipping address above correct?	○ Yes ○ No	reset
	he e-mail address above correct? ust provide value	○ Yes ○ No	reset

Update Information

Provide corrected/updated information, as needed



Kit Type

Kit Type **Please allow two weeks for shipment** * must provide value	✓ Standard Kit ☐ Supplemental Kit ☐ Extra Supplies Please specify in comments if you need kits before the standard two week shipment time.
Standard Kit Quantity * must provide value	If you need more than 10 kits or labels, please use the file upload option or submit multiple requests.

Multiple kit types available

Standard Kits

 Contains supplies and labels for all visits for a subject

Kit Type **Please allow two weeks for shipment** * must provide value	✓ Standard Kit Supplemental Kit Extra Supplies Please specify in comments if you need kits before the standard two week shipment time.
Standard Kit Quantity * must provide value	If you need more than 10 kits or labels, please use the file upload option or submit multiple requests.
Comments	Expand
Each Standard Collection Kit Contains: Blood Collection Kit Contents: 7 - Lavender-top K2 EDTA tube (10 ml) 4 - PAXGene® tubes (2.5 ml) 50 - Siliconized cryovials, sterile (0.5ml) 10 - Siliconized Sterile Cryogenic Vial (2.0 ml) 7 - Disposable transfer pipette (1ml) 2 - Cryobox 1 - Warning label packet (incl. dry ice label) 1 - FedEx® return Airbills 1 - Shipping container for dry ice shipments 2 - Biohazard bag 2 - 100 ml absorbent sheet	

Standard Kits



 Only need to request specific ST-Number if requesting replacement labels

Important Note: ST-Numbers

Please note: the ST-Number provided in a BL kit can be used for any subject's BL visit. This ST number is a subject identifier and will need to stay linked to the patient through the entirety of the study.

Supplemental Kit

Contains a variety of extra kit components

Kit Type **Please allow two weeks for shipment** * must provide value	☐ Standard Kit ☐ Supplemental Kit ☐ Extra Supplies Please specify in comments if you need kits before the standard two week shipment time.
Comments	Expand
Each Supplemental Kit Contains: 5 100 ml absorbent sheets 5 6-tube bubble pouches 5 Cryoboxes 50 Siliconized sterile cryogenic vials (0.5 ml) 5 Siliconized Sterile Cryogenic Vial (2.0 ml) 5 Biohazard bags 5 PAXGene® tubes (2.5 ml) 10 Lavender-top K2EDTA tubes (10 ml) 10 Disposable transfer pipettes (1ml) 2 Warning label packets	

Extra Supplies

Allows you to choose specific supplies and particular quantities

Kit Type **Please allow two weeks for shipment** * must provide value	■ Baseline or Annual Visit Kit ■ 6-Month Visit Kit ■ Supplemental Kit ■ Extra Supplies Please specify in comments if you need kits before the standard two week shipment time.
6-Tube Bubble Pouch	○ 2 ○ 4 reset
Cryobox	○ 2 ○ 4 reset
Siliconized Sterile Cryogenic Vial (2 ml)	○ 10 ○ 20 reset
FedEx® return Airbill	○ 2 ○ 4 reset
Lumbar Puncture Trays with Lidocaine	○ 2 ○ 4 reset
Needles - Introducer	○ 5 reset

Multiple Orders

Kit Type
Please allow two weeks for shipment

* must provide value

✓ Standard Kit

☑ Supplemental Kit

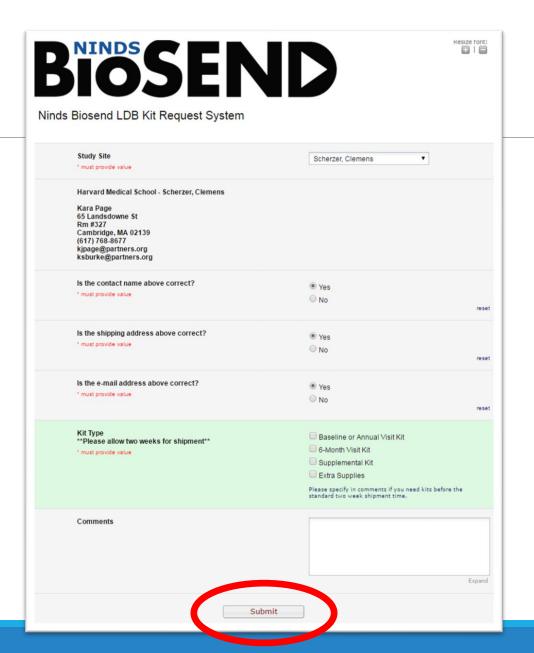
☑ Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

You can order more than one type of kit in a single kit request

Submit Request

- Click "Submit" to send order to BioSEND; staff will confirm receipt of your order
- Please allow two week turnaround time for kit shipments
- If urgent request needed, please note date needed by in comments and email BioSEND



Sample Labelling

Labels are provided by Indiana University

Please check that all samples are properly labelled with correct specimen type and visit

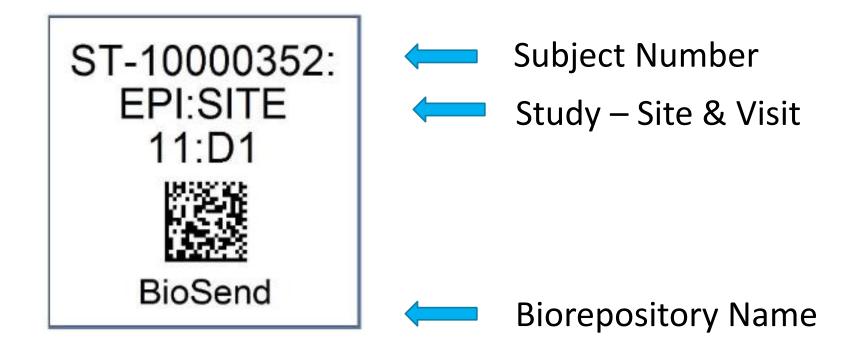


Case Labels



Specimen Labels

Case Label



Case Labels

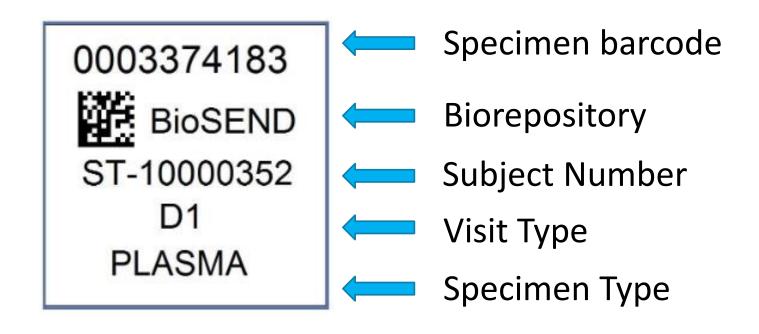
Case labels are placed:

- On the plastic biohazard bags
- On the lid of frozen shippers



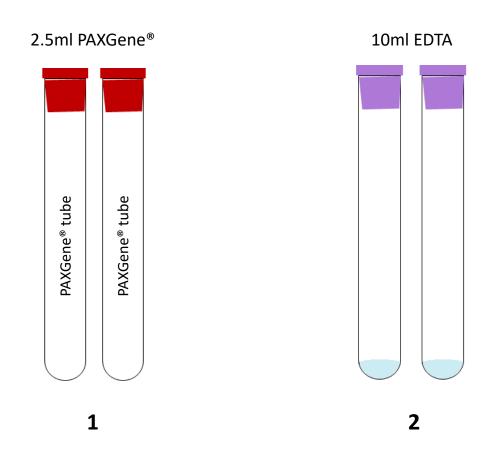


Specimen Label

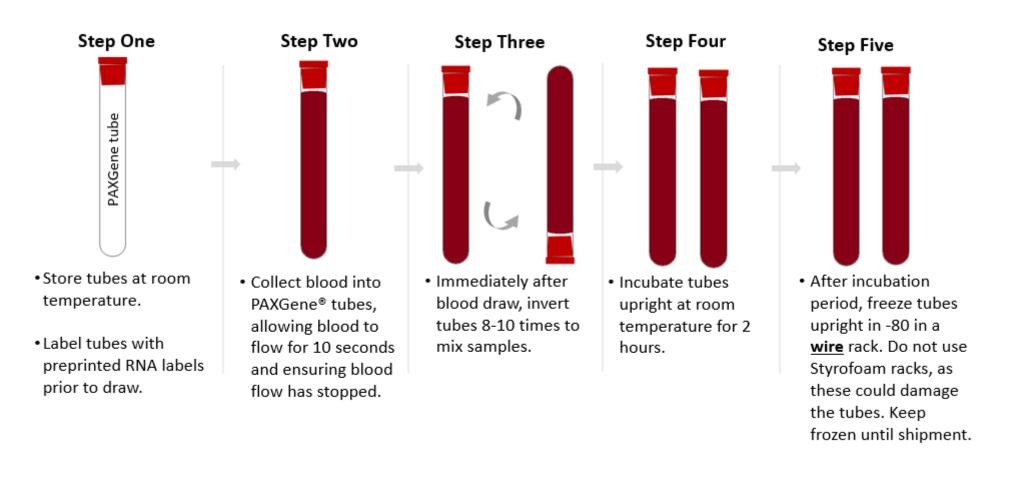


Sample Collection and Processing

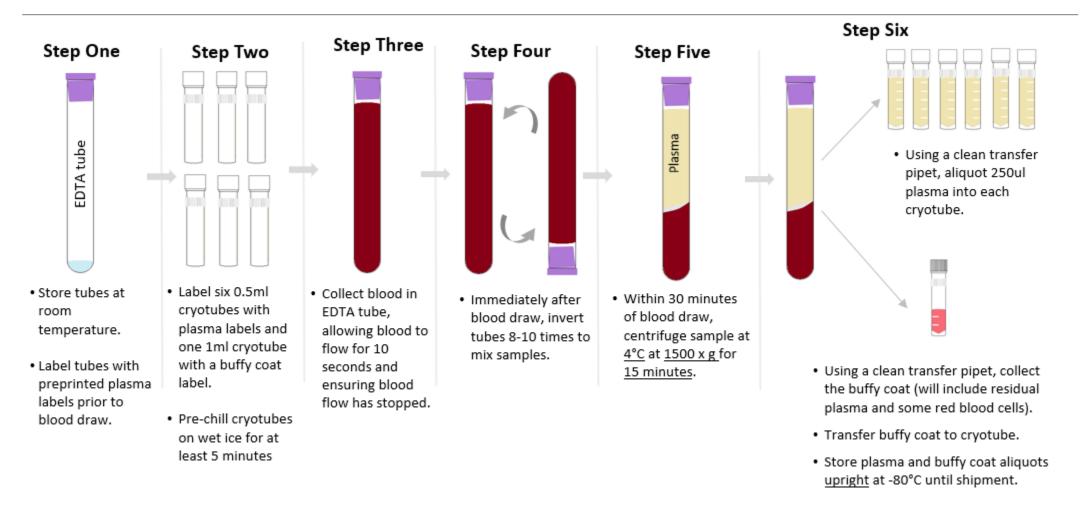
Blood Tube Draw Order



Sample Collection and Processing: RNA



Sample Collection and Processing: Plasma & Buffy Coat



Blood Collection: Troubleshooting

Issue #1: Collection tube with little/no vacuum

Always check expiration dates before beginning blood draw and discard expired tubes

- Tubes expire on last day of month printed on tube

Store tubes at ambient temperature

- Extreme temperatures can affect vacuum

Keep extra collection tubes from supplemental kit nearby during blood draw to replace "bad" tubes. These can also be requested through the Kit Request Module.

If frequent occurrence, report tube type and lot numbers to Indiana University

Blood Collection: Troubleshooting

Issue #2: Hemolyzed (pink/red) plasma

Cause: Blood Collection Methods	Corrective Action
Improper venipuncture site	Draw from median cubital, basalic, and cephalic veins from antecubital region of arm
Prolonged tourniquet use	Tourniquet should be released after no more than 1 min, excessive fist clenching should be avoided
Not allowing alcohol to dry on skin before venipuncture	Without touching, allow the venipuncture site to air dry
Lumen of needle too close to inner wall of vein (indicated by slow blood flow)	
Use of too large/small bore needle resulting in excess force applied to blood	Avoid using too small/large needle. Needle size dependent on the subject's physical characteristics & amount of blood to be drawn. Most commonly used sizes are 19 – 23.
Pulling/pushing plunger too fast while drawing/transferring blood	Avoid drawing the syringe plunger too forcefully when collecting blood
	Ensure all blood collection assemblies are fitted securely, to avoid frothing

Reference: BD's "Tech Talk" newsletter, Vol. 2, No. 2, October 2003 (http://www.bd.com/vacutainer/pdfs/techtalk/TechTalk_Jan2004_VS7167.pdf)

Blood Collection: Troubleshooting

Issue #2: Hemolyzed (pink/red) plasma

Cause: Sample Processing Methods	Corrective Actions
Vigorous mixing/shaking	Gently invert blood collection tube when mixing additive with specimen, follow guidelines in Biologics Manual regarding number of times to invert each type of tube
Not allowing serum to clot for recommended time	Serum tubes without clot activator should be allowed to clot for 60 min in a vertical position
Exposure to excessive heat or cold	Keep samples at ambient temp
Prolonged contact of serum/plasma with cells	Do not store uncentrifuged samples beyond recommended time

Reference: BD's "Tech Talk" newsletter, Vol. 2, No. 2, October 2003 (http://www.bd.com/vacutainer/pdfs/techtalk/TechTalk Jan2004 VS7167.pdf)

Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- All samples ship frozen
- Ship frozen samples on dry ice
- Frozen samples should be shipped only Monday through Wednesday
- International shipments should be shipped only Monday
- Always fill carton to top with dry ice
- Do not pack shipment until the day of pickup



Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- Shippers use approx. 10lbs of dry ice
- Place layer of dry ice in between cryoboxes

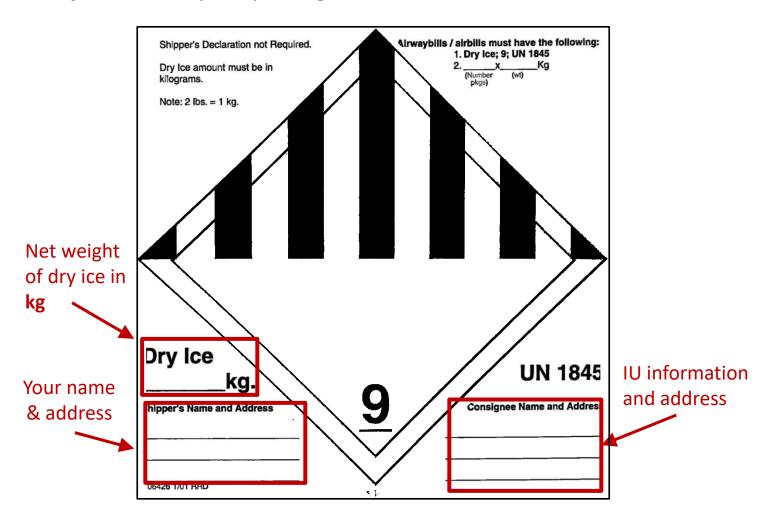




Shipping Samples

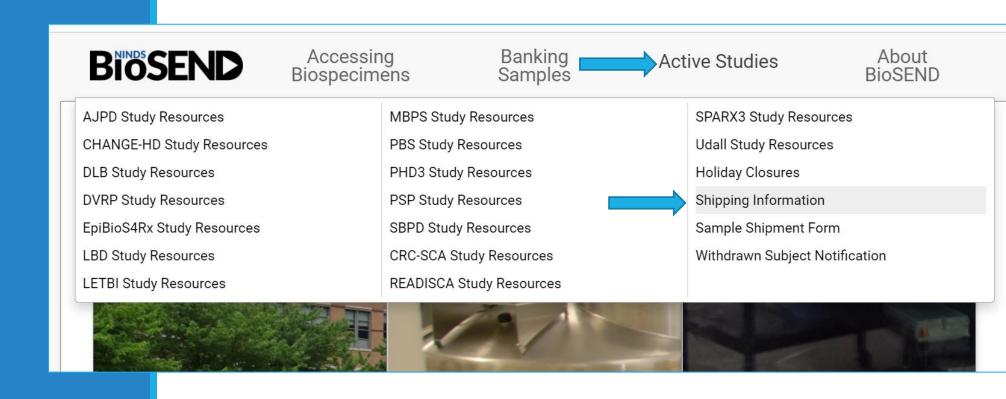
Packing and Shipping Frozen Samples

Class 9 Dry Ice Label should not be covered with other stickers and must be completed, or courier will reject/return your package!



Shipping Samples

UPS resources available on BioSEND website





Links on this page to generate airwaybills, schedule pickups, request account, and view a guide for using the UPS ShipExec Thin Client system.



Accessing Biospecimens Banking Samples

Active Studies

About BioSEND





Shipping Address

BioSEND

Indiana University School of Medicine

351 West 10th Street

TK-217

Indianapolis, IN 46202

UPS Shipping Resources

To generate air waybills and schedule UPS pickups for shipments to BioSEND, please visit the UPS $ShipExec^{T}$ Thin Client website.

For instructions on how to use the UPS ShipExec™ Thin Client website, please refer to the BioSEND UPS ShipExec™ Thin Client Guide

To request a new user account for UPS ShipExec[™] Thin Client or to request an update to your site's address in the system, please use this form to submit your request.

Additional Resources

Sample Submission Form UPS ShipExec™ Guide

Contact Us

biosend@iu.edu 317-278-0594

Shipping Samples: Frozen

Please notify BioSEND ahead of shipment

- Email <u>biosend@iu.edu</u> with copy of Sample Form and tracking number
- Include physical copy of sample form in shipment

Shipping Samples: Sample Form

STUDY: EPIBIOS4RX		
SHIP FROZEN SHIPMENTS MONDAY - WEDNESDAY of Ensure all frozen shipments are completely filled w		
This form must be completed for shipment of all research samples.		
Prior to shipping, email a PDF copy of this complet Also place a hard copy of this form in the shipment		
Site Name:		
Site #	(The site # is the 2 digit number in your patient's study ID. Ex. 17 for UCLA, study ID = 3_17_0000)	
Principal Investigator:		
Coordinator Name:		
Coordinator Telephone:		
Coordinator Email:		
PATIENT INFORMATION		
Patient's Study ID:	(ex. 3_17_0000)	
ST Number	(FOR ONE PATIENT, ALL VIAL LABELS FROM ALL 6 DRAW TIME POINTS MUST HAVE THE SAME ST NUMBER.)	
Patient's Gender	○ Male ○ Female ○ Unknown ○ Not reported	
Patient's Age	(years)	

Please complete:

- One form for each subject shipped
- Coordinator contact information
- Patient Information

Shipping Samples: Sample Form

SHIPPING INFORMATION:	
Date samples were shipped?	
Time samples were shipped?	
FedEx Tracking #:	
Which visit days for this patient are included in the shipment?	Day 1 Day 3 Day 5 Day 15 Day 15 Day 30 Day 90 Day 90
Notation of storage or shipping problems	
DAY 1	
Blood draw date	
# of plasma vials	
# of buffy coat vials	
DAY 3	
Blood draw date	
# of plasma vials	
# of buffy coat vials	
DAY 5	
Blood draw date	
● of plasma vials	
# of buffy coat vials	
# of PAX tubes	

Please complete:

- Date of sample shipment
- Tracking Number
- Quantity of each sample type shipped
- Collection Date
- Any issues

Shipping Schedule

Hold packaged samples in a -80°C freezer until pickup.

Samples should be shipping to BioSEND on a quarterly basis.



Packaging & Shipping Troubleshooting

Issue: Broken/Damaged Tubes

Cause	Preventative Action
Over filling tubes	Fill tubes to suggested volume. If any sample still remains, place in an additional tube
Improper packaging	Ensure any tubes are securely placed into the bubble wrap pouch and are placed in a separate bag from the cryobox
Rough shipping conditions	Extra bubble wrap may be needed to pad blood tubes
Extreme changes in temperature (ambient→freezer; freezer→dry ice)	Wrapping the tubes in bubble wrap before freezing may help slow the cooling process

Shipping Samples: Closures

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

^{*}Please also consider weather when shipping. UPS will post service updates on their webpage. Please reach out to BioSEND if you an unsure if it is safe to ship.

Non-Conformance Reporting

Most common non-conformance issues:

- Samples shipped for weekend/holiday delivery
- Sample form incomplete/inaccurate
- Unlabeled or mislabeled tube(s)
- Sample hemolysis



Contacts

Indiana University

General Questions/Shipment Notifications:

biosend@iu.edu

Biorepository Project Manager:

Claire Wegel

cwegel@iu.edu

Tel: 317.278.6158

Biorepository Clinical Research Coordinator:

Carolyn Dunifon

cdunifon@iu.edu

Tel: 317.274.5751