



The Late Effects of TBI (LETBI)

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

	V0	V1	V2
Plasma (6 x 1.5ml)	X	X	X
Buffy Coat (2 aliquots)	X	X	X

Kit Ordering – Biosend.org

NINDS
BioSEND

Accessing
Biospecimens

Banking
Samples

Active Studies

About
BioSEND

AJPD Study Resources

CHANGE-HD Study Resources

DLB Study Resources

DVRP Study Resources

EpiBioS4Rx Study Resources

LBD Study Resources

LETBI Study Resources

MBPS Study Resources

PBS Study Resources

PHD3 Study Resources

PSP Study Resources

SBPD Study Resources

CRC-SCA Study Resources

READISCA Study Resources


SPARX3 Study Resources


Udall Study Resources

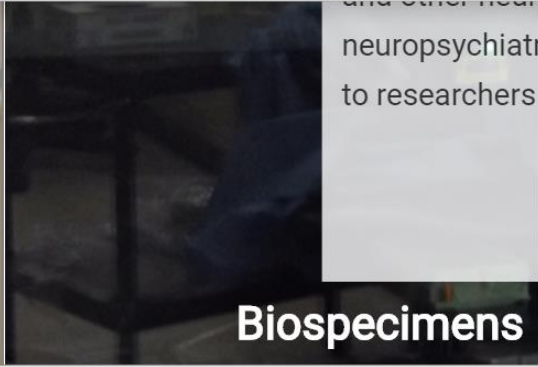
Holiday Closures

Shipping Information

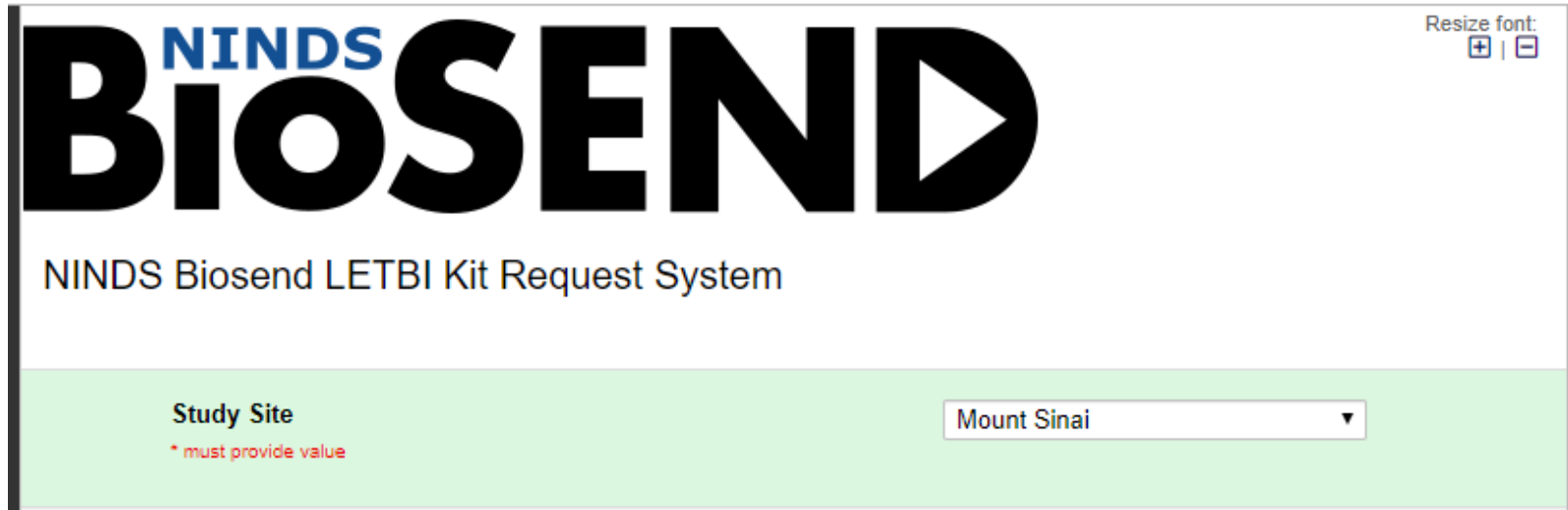
Sample Shipment Form

**About BioSEND**

**Banking Samples**

**Biospecimens**

Select Site



The screenshot shows the NINDS BioSEND logo at the top left, with 'NINDS' in blue and 'BioSEND' in large black letters. Below the logo is the text 'NINDS Biosend LETBI Kit Request System'. In the top right corner, there is a 'Resize font:' link with plus and minus icons. The main content area has a light green background. On the left, it says 'Study Site' with a red asterisk and the text '* must provide value' below it. To the right is a dropdown menu with 'Mount Sinai' selected and a downward arrow icon.

NINDS
BioSEND

NINDS Biosend LETBI Kit Request System

Study Site
* must provide value

Mount Sinai ▼

Resize font:
⊕ | ⊖

- <http://kits.iu.edu/biosend/letbi>
- **Choose your site from the drop-down list.**

Confirm Shipping Info

Confirm site information:

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

Indiana University

Carolyn Dunifon
Indiana University School of Medicine
351 West 10th Street
TK-217
Indianapolis, IN 46202
(317) 274-5751
biosend@iu.edu

Is the contact name above correct?

* must provide value

☐ Yes

☐ No

[reset](#)

Is the shipping address above correct?

* must provide value

☐ Yes

☐ No

[reset](#)

Is the e-mail address above correct?

* must provide value

☐ Yes

☐ No

[reset](#)

Update Information

Provide corrected/updated information, as needed

Is the contact name above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
New Contact Name <small>* must provide value</small>	<input type="text"/>	
Is the shipping address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
New Shipping Address <small>* must provide value</small>	<div><input type="text"/></div> <div>Expand</div>	
Is the e-mail address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
New e-mail Address <small>* must provide value</small>	<input type="text"/>	

Kit Type

Kit Type

****Please allow two weeks for shipment****

** must provide value*

- ☐ Baseline Visit Kit (V0)
- ☐ Longitudinal Visit Kit (V1, V2)
- ☐ Supplemental Kit
- ☐ Extra Supplies

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

Multiple kit types available

Baseline Kits

- BioSEND creates ST numbers for baseline kits
- ST#s serve as the biorepository subject identifier
- Enter kit quantity

Kit Type

****Please allow two weeks for shipment****

* must provide value

- ☒ Baseline Visit Kit (V0)
- ☐ Longitudinal Visit Kit (V1, V2)
- ☐ Supplemental Kit
- ☐ Extra Supplies

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

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.

Annual Visits

Please provide ST-Number and time point. We are unable to complete your request without this information

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input type="checkbox"/> Baseline Visit Kit (V0) <input checked="" type="checkbox"/> Longitudinal Visit Kit (V1, V2) <input type="checkbox"/> Supplemental Kit <input type="checkbox"/> Extra Supplies <small>Please specify in comments if you need kits before the standard two week shipment time.</small>
Annual Visit Kit Quantity <small>* must provide value</small>	<input type="text" value="1"/> <small>If requesting annual kits, please provide the ST-number and visit type of all kits needed. Not doing so will cause delay in shipment, as we are unable to complete your request without this information.</small>
If you going to request more than 10 kits/labels or prefer to upload a file with the Biorepository ID and Visit, you may download this template file and fill in the relevant information. <small>Attachment:</small> BioSEND_Kit_IDs_Template.xlsx (0.01 MB)	
If you are using the provided template to upload Biorepository IDs and Visits, please upload your template file here. Upload file	
1st Kit Visit ID (only if not using file upload option)	<input type="text" value="ST-10001234"/> <small>e.g. ST-00012345</small>
1st Kit Visit Type	<input type="text" value="V1"/>
Comments	<div><div></div><div>Expand</div></div>
Each Annual Collection Kit contains: 2 - Purple-top EDTA tubes (Plastic, 10 ml) 6 - Purple cryogenic vials (2 ml) 2 - Grey cryogenic vials (2 ml) 2 - Disposable transfer pipettes (3ml) 1 - Cryobox, 25-slot 1 - Biohazard bag with absorbent sheet 1 - Shipping label packet (incl. waybill) 1 - Dry Ice Shipper	

Supplemental Kit

Contains a variety of
extra kit components

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input type="checkbox"/> Baseline Visit Kit (V0) <input type="checkbox"/> Longitudinal Visit Kit (V1, V2) <input checked="" type="checkbox"/> Supplemental Kit <input type="checkbox"/> Extra Supplies <small>Please specify in comments if you need kits before the standard two week shipment time.</small>
Supplemental Kit Quantity <small>* must provide value</small>	<input type="text"/>
Comments	<div><input type="text"/></div> <div>Expand</div>
Each Supplemental Kit Contains: 10 - Purple-top EDTA tubes (Plastic, 10 ml) 10 - Purple cryogenic vials (2 ml) 10 - Grey cryogenic vials (2 ml) 10 - Disposable transfer pipettes (3ml) 2 - Cryobox, 25-slot 5 - Biohazard bag with absorbent sheet 5 - Shipping label packet (incl. waybill)	
<div>Submit</div>	

Extra Supplies

Allows you to choose specific supplies and particular quantities

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>		<input type="checkbox"/> Baseline Visit Kit (V0) <input type="checkbox"/> Longitudinal Visit Kit (V1, V2) <input type="checkbox"/> Supplemental Kit <input checked="" type="checkbox"/> Extra Supplies
		<small>Please specify in comments if you need kits before the standard two week shipment time.</small>
Resealable Tube Pouches	<input type="radio"/> 2 <input type="radio"/> 4	reset
Cryobox	<input type="radio"/> 2 <input type="radio"/> 4	reset
Cryogenic Vial (2 ml) - Grey	<input type="radio"/> 10 <input type="radio"/> 20	reset
Cryogenic Vial (2 ml) - Purple	<input type="radio"/> 10 <input type="radio"/> 20	reset
FedEx® return Airbill	<input type="radio"/> 2 <input type="radio"/> 4	reset
Shipping Container for Dry Ice Shipments (includes shipping labels & airbill)	<input type="radio"/> 2 <input type="radio"/> 4	reset

Multiple Orders

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input checked="" type="checkbox"/> Baseline Visit Kit <input checked="" type="checkbox"/> Annual Visit Kit <input checked="" type="checkbox"/> Supplemental Kit <input checked="" type="checkbox"/> Extra Supplies <small>Please specify in comments if you need kits before the standard two week shipment time.</small>
--	--

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 turn-around time for kit shipments
- If urgent request needed, please note date needed by in comments and email BioSEND

NINDS BioSEND Resize font: [icon] [icon]

NINDS Biosend SPARX3 Kit Request System

Study Site * must provide value Northwestern University ▼

Northwestern University
Contact Name
Shipment Address
Email
Phone

Is the contact name above correct? * must provide value ☐ Yes ☐ No [reset](#)

Is the shipping address above correct? * must provide value ☐ Yes ☐ No [reset](#)

Is the e-mail address above correct? * must provide value ☐ Yes ☐ No [reset](#)

Kit Type
****Please allow two weeks for shipment**** * must provide value
☐ Baseline Visit Kit
☐ Annual Visit Kit
☐ Supplemental Kit
☐ Extra Supplies
Please specify in comments if you need kits before the standard two week shipment time.

Comments Expand

Submit

Sample Labelling

Labels are provided by Indiana University

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

ST-10001234:
LETBI:V0



BioSend

Case Labels

0001234567



BioSEND
ST-10001234
V0
PLASMA

Collection Tube
Labels

BioSEND-LETBI
PLASMA
ST-00012345

Cryotube labels

Case Labels

ST-10001234:
LETBI:V0



BioSend



Subject Number



Study & Visit

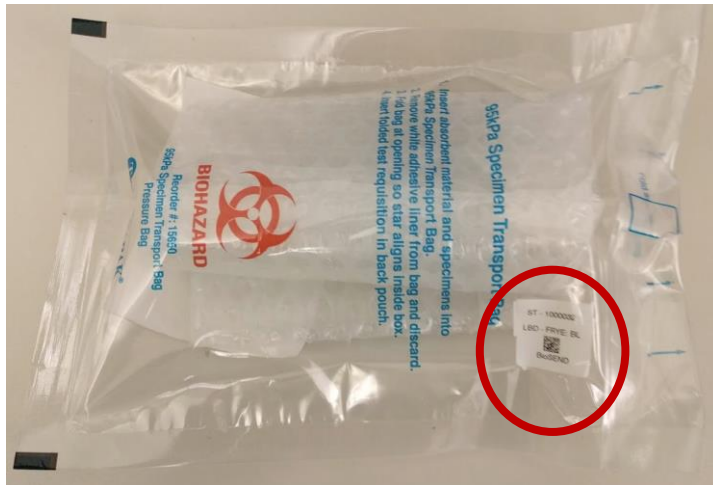


Biorepository Name

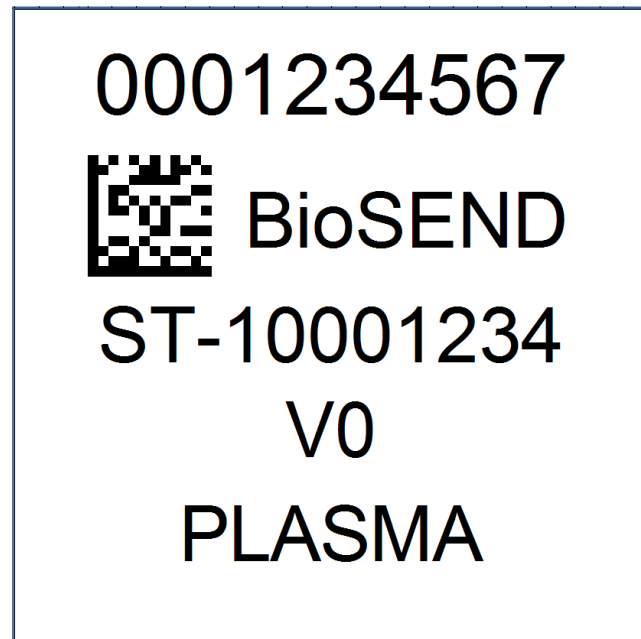
Case Labels

Case labels are placed:

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

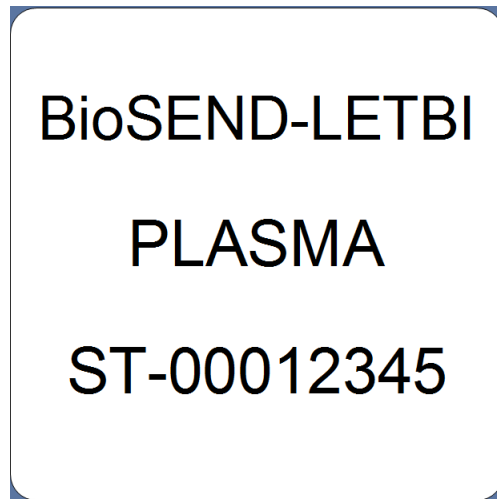


Collection Tube Labels



- ← Specimen barcode
- ← Biorepository
- ← Subject Number
- ← Visit Type
- ← Specimen Type

Cryotube Labels



← Study Abbreviation

← Specimen Type

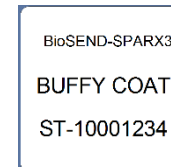
← Subject Number

*Note: The tube itself will have a unique barcode printed in both 2D format (on bottom of tube) and human readable format (alongside of tube).

Cryotube Labels

Note: cryotube barcodes are printed on tube, not on the label. Barcodes are tied to the specific kit they arrive in (ie, a specific subject and visit). **Please do not mix the labels from one kit with the cryotubes from another.**

- Barcode is in human readable format on side of tube, 2D format on bottom of tube



Cryotube Labels

Please verify that you are using the correct cryovial for the correct specimen type

Grey cryovials are used for
Buffy Coat aliquots



BioSEND-SPARX3
BUFFY COAT
ST-10001234

Purple cryovials are used for
plasma aliquots

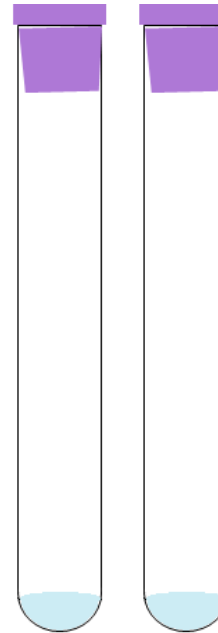


BioSEND-SPARX3
PLASMA
ST-10001234

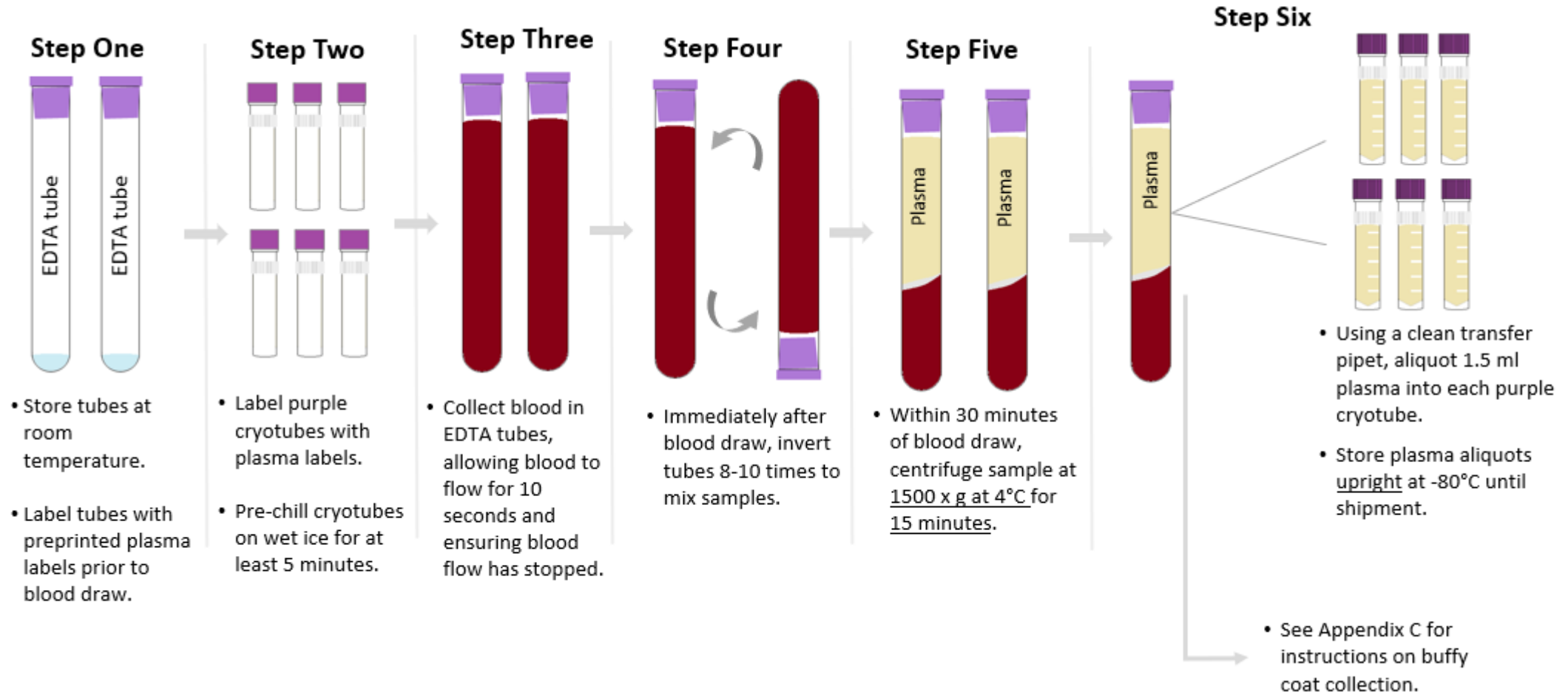
Sample Collection and Processing

Plasma & Buffy Coat

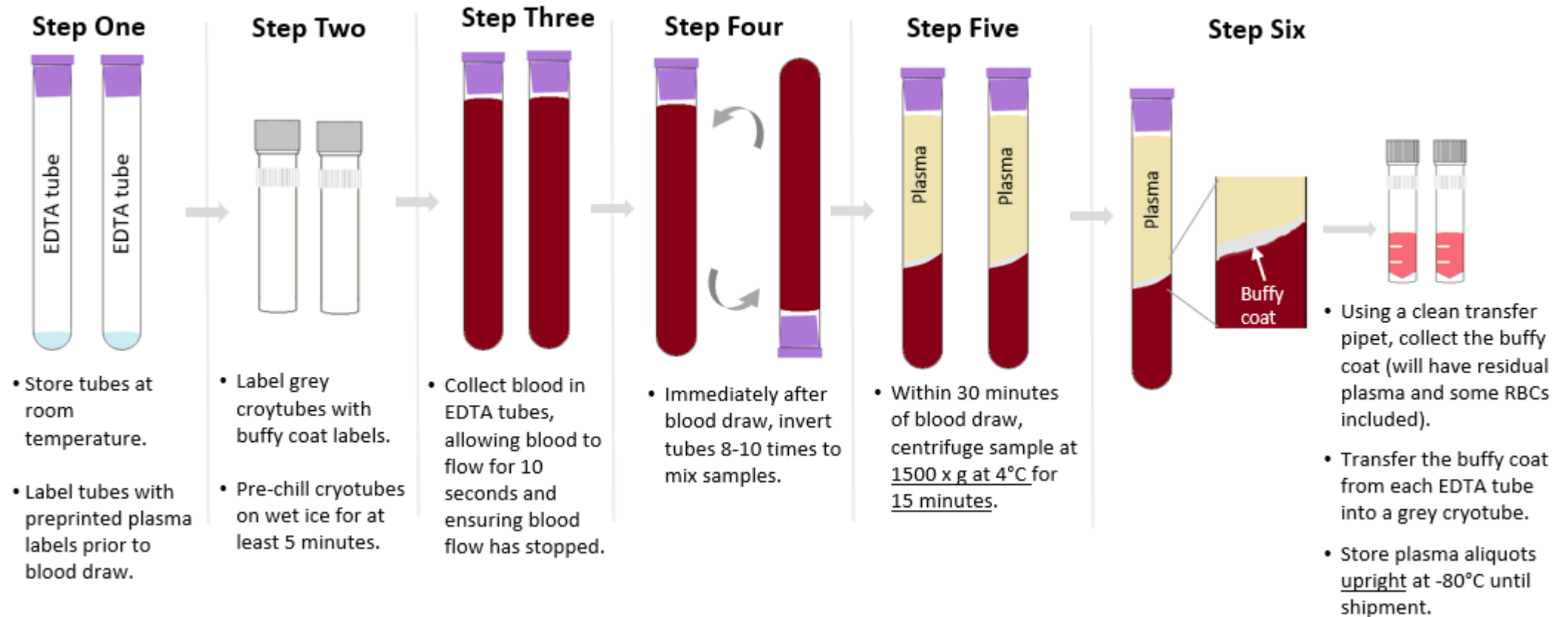
10ml EDTA



Sample Collection and Processing: Plasma & Buffy Coat



Sample Collection and Processing: Plasma & Buffy Coat



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
- Always fill carton to **top** with dry ice
- Do not pack shipment until the day of pickup



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

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

- 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!

Shipper's Declaration not Required.

Dry Ice amount must be in kilograms.

Note: 2 lbs. = 1 kg.

Airwaybills / airbills must have the following:

1. Dry Ice; 9; UN 1845
2. $\frac{\text{Number}}{\text{(Number pks)}} \times \frac{\text{wt}}{\text{(wt)}} \text{ Kg}$

Net weight of dry ice in kg

Dry Ice kg.

Your name & address

Shipper's Name and Address

UN 1845

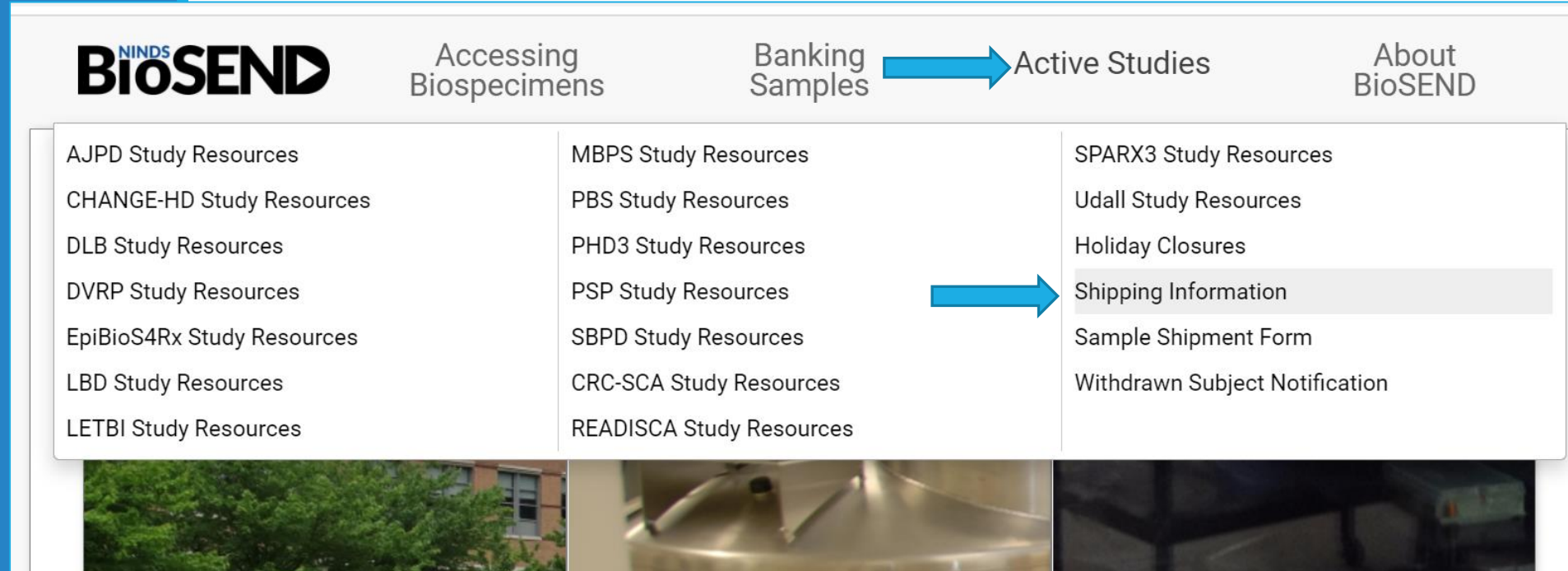
Consignee Name and Address

IU information and address

06426 1/01 RRD

Shipping Samples

UPS resources available on BioSEND website

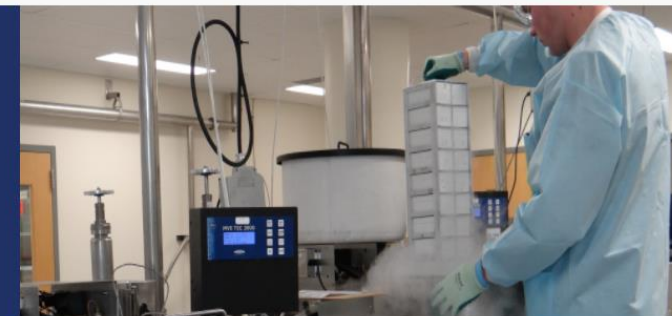


The screenshot shows the NINDS BioSEND website navigation bar and a dropdown menu. The navigation bar includes the BioSEND logo, 'Accessing Biospecimens', 'Banking Samples', 'Active Studies' (highlighted with a blue arrow), and 'About BioSEND'. The dropdown menu lists various study resources and shipping-related links. 'Shipping Information' is highlighted with a blue arrow.

Accessing Biospecimens	Banking Samples	Active Studies	About BioSEND
<ul style="list-style-type: none">AJPD Study ResourcesCHANGE-HD Study ResourcesDLB Study ResourcesDVRP Study ResourcesEpiBioS4Rx Study ResourcesLBD Study ResourcesLETBI Study Resources	<ul style="list-style-type: none">MBPS Study ResourcesPBS Study ResourcesPHD3 Study ResourcesPSP Study ResourcesSBPD Study ResourcesCRC-SCA Study ResourcesREADISCA Study Resources	<ul style="list-style-type: none">SPARX3 Study ResourcesUdall Study ResourcesHoliday ClosuresShipping InformationSample Shipment FormWithdrawn Subject Notification	

Below the navigation bar, there are three small images: a green tree, a close-up of a metal container, and a dark, indistinct image.

Shipping Information



Shipping Samples

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

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™ 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 biosend@iu.edu with copy of Sample Form and tracking number
- OR use Online Sample form on biosend.org

Shipping Samples: Sample Form

Sample Record and Shipment Notification



Please fill out and submit this form when shipping samples to BioSEND. After submission, please print a copy of the form to include with your submission. If you prefer to not use the online system, you may download a pdf version of this form from the sidebar to the right.

Contact Information

Site Name/Number

Coordinator

Telephone

Email

Subject Information

Study

Clinical ID

GUID

Subject ID (ST# from labels)

Gender

Visit Type

Sample Information

Date Sample(s) Shipped

FedEx Tracking Number

Draw Date	Specimen Type	# of Tubes Sent	Notation of Problems
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Shipping Frozen Samples

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

Samples should be received at BioSEND within 2 weeks of collection.



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 are 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