BIOSEND

PREDICT-HD 3.0

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:

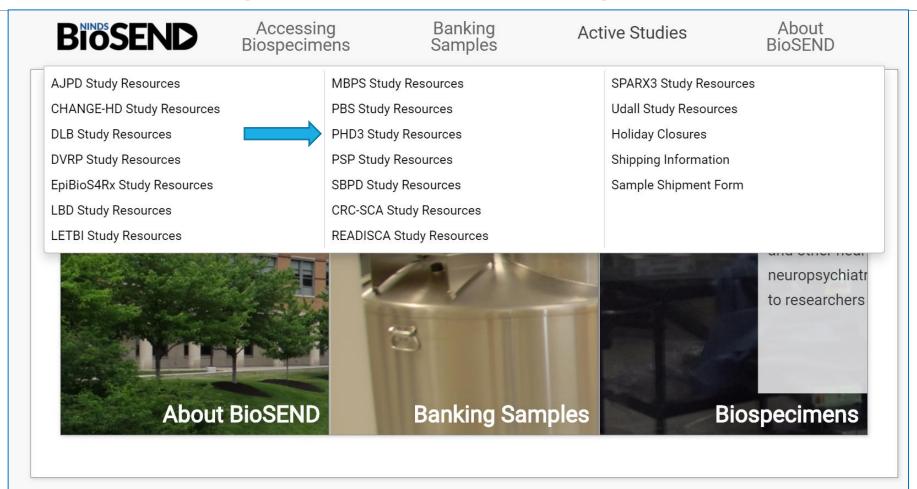
- Gloves
- Alcohol wipes
- Butterfly needles
- Tourniquet
- Gauze pads
- Bandages
- Microcentrifuge tube rack
- Sharps bin and lid

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

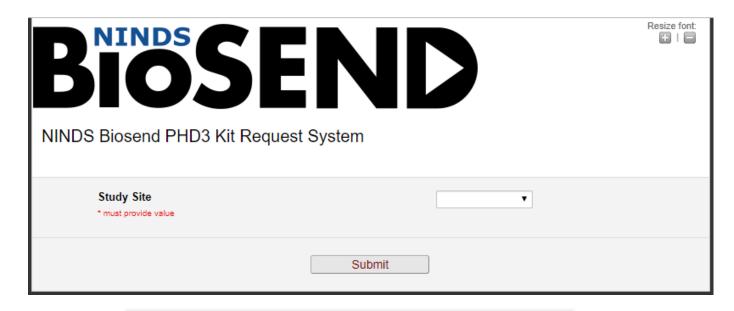
Biospecimen Collection Protocol

	301 (BL)	303 (18-24M)
Whole Blood (1 x 6ml)	X	X
Buffy coat (4 aliquots)	X	X
Plasma (12 x 1.5ml)	X	X
RNA (2 x 2.5ml)	X	X
CSF (13 x 1.5ml)	X	X

Kit Ordering – Biosend.org



Select Site



- http://kits.iu.edu/biosend/phd3
- Choose your site from the drop-down list.

Confirm Shipping Info

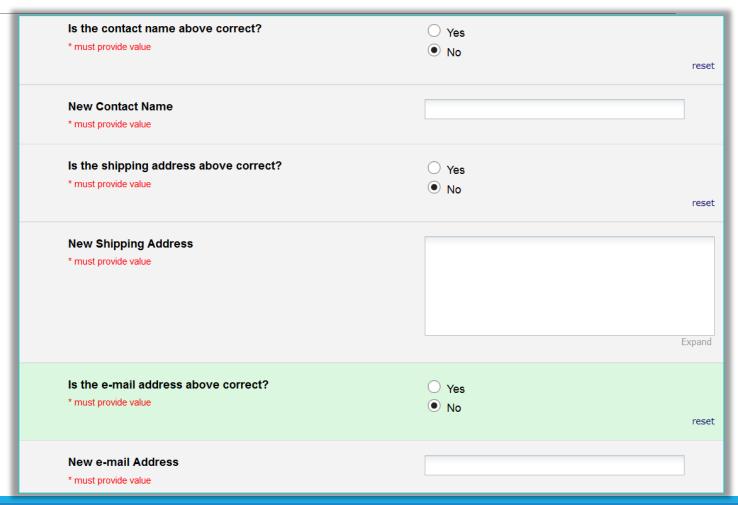
Confirm site information:

- 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



Kit Type



Multiple kit types available

Baseline Kits

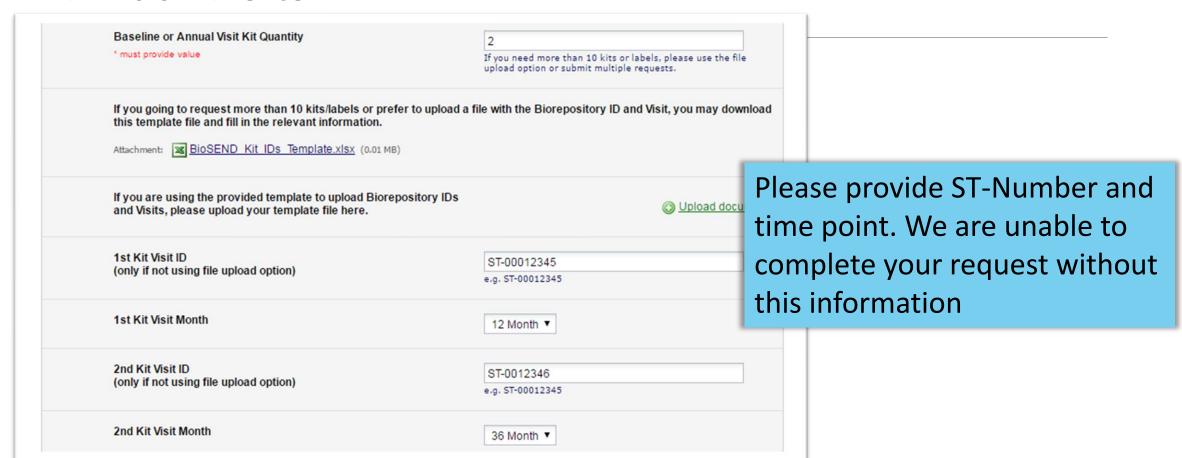
- BioSEND creates ST numbers for baseline kits
- ST#s serve as the biorepository subject identifier
- Enter kit quantity



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



Supplemental Kit

Contains a variety of extra kit components

Kit Type **Please allow two weeks fo * must provide value	r shipment**	■ 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.
Supplemental Kit Quantity * must provide value		1
Comments		Expand
Each Supplemental Kit Cont 10 - Purple-top EDTA tubes (10 - Purple cryogenic vials (2 10 - Grey cryogenic vials (2 10 - Disposable transfer pipe 2 - Cryobox, 25-slot 5 - Biohazard bag with abso 5 - Shipping label packet (in	(Plastic, 10 ml) 2 ml) ml) ettes (3ml) rbent sheet	

Extra Supplies

tra Supplies		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.
		Resealable Tube Pouches	② 2 ③ 4 reset
		Cryobox	○ 2 ○ 4
Allows you to choose specific supplies ar		Cryogenic Vial (2 ml) - Grey	○ 10 ○ 20 reset
particular quantitie	es	Cryogenic Vial (2 ml) - Purple	○ 10 ○ 20 reset
		FedEx® return Airbill	○ 2 ○ 4 reset
		Shipping Container for Dry Ice Shipments (includes shipping labels & airbill)	○ 2 ○ 4

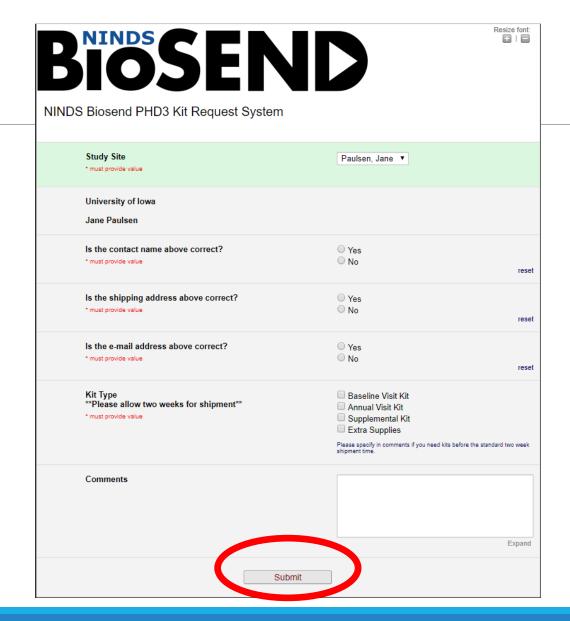
Multiple Orders



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

ST-10012345: PHD3:301

BioSend

Case Labels

0001234567



ST-10001234 BL

PLASMA

Collection Tube Labels BioSEND-PHD3

PLASMA

ST-10001234

Cryotube labels

Case Labels

ST-10012345: PHD3:301



BioSend



Subject Number



Study & Visit



Biorepository Name

Case Labels

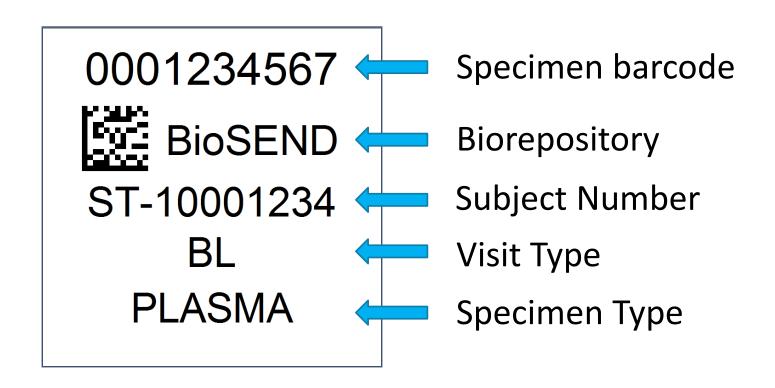
Case labels are placed:

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





Collection Tube Labels



Cryotube Labels

BIOSEND-PHD3 Study Abbreviation

PLASMA Specimen Type

ST-10001234 Subject Number

*Note: The tube itself with 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 crytubes from another.

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



BIOSEND-SPARX3
BUFFY COAT
ST-10001234

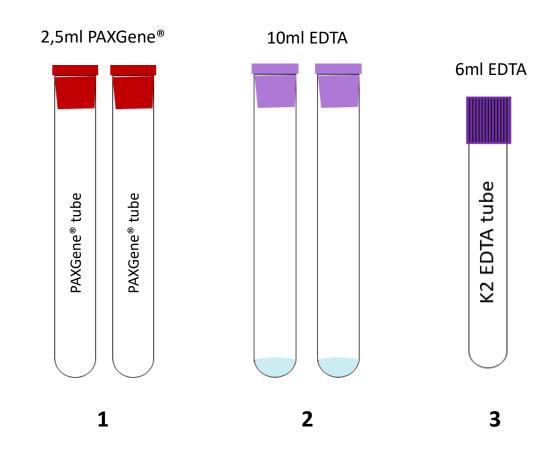
Cryotube Labels

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

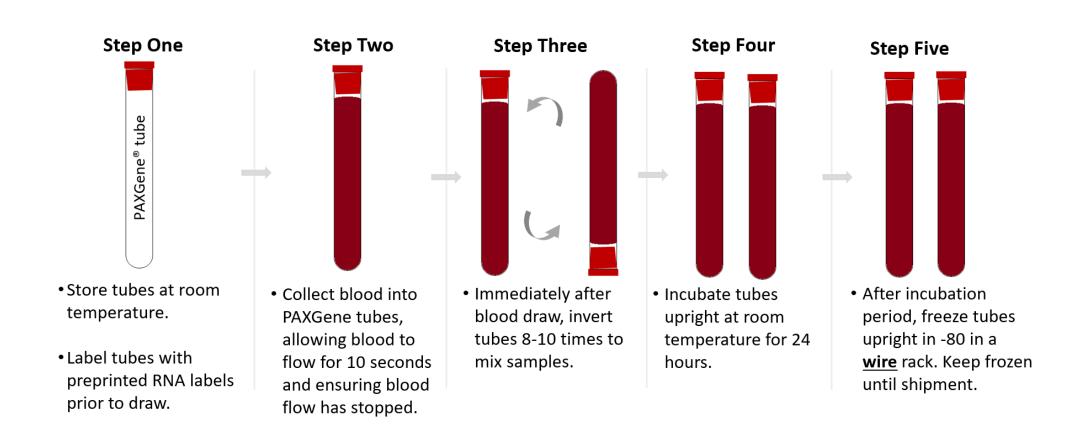
Specimen Type	Cryotube Color
Plasma	Purple
Cerebrospinal Fluid	Orange
Buffy Coat	Grey

Sample Collection and Processing

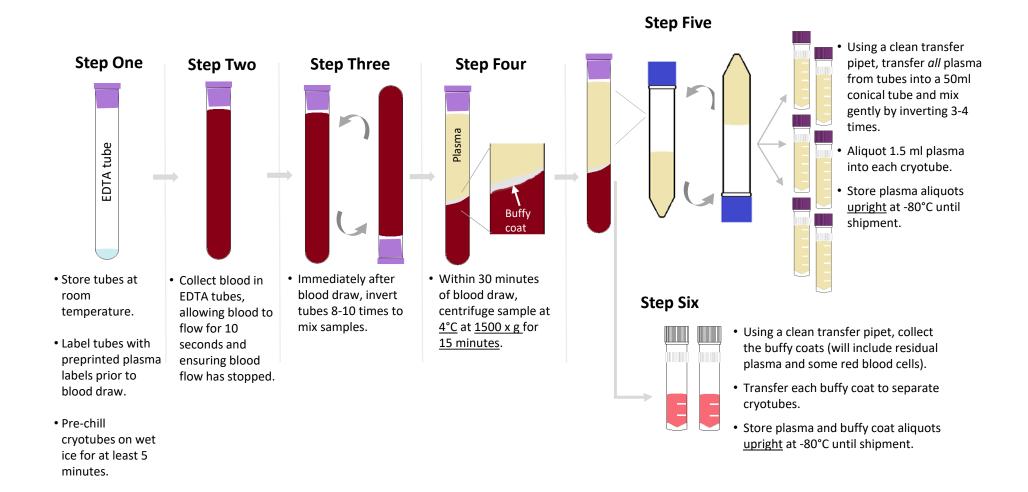
Blood Tube Draw Order



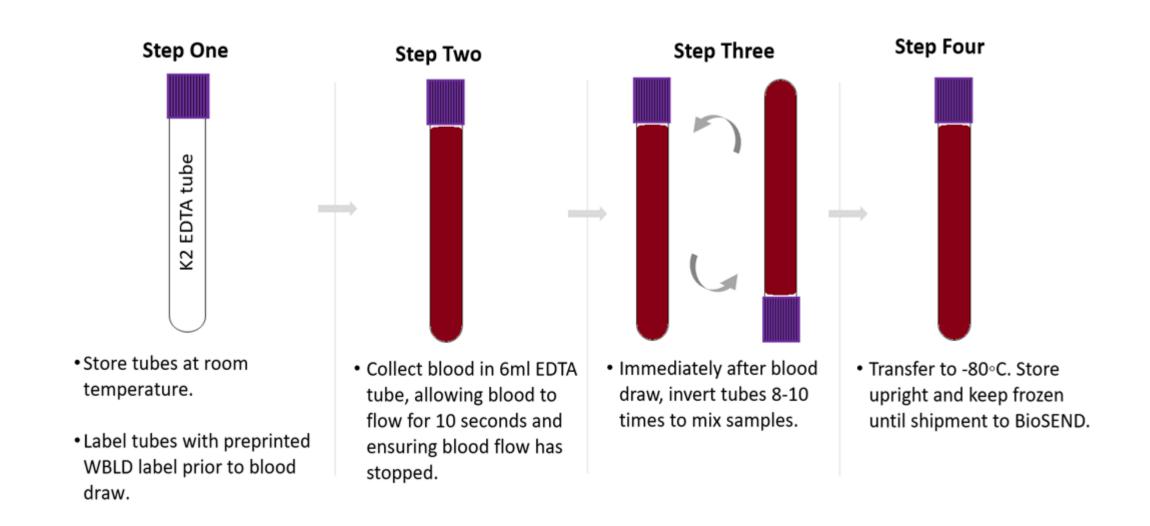
Sample Collection and Processing: RNA



Sample Collection and Processing: Plasma & Buffy Coat



Sample Collection and Processing: Whole Blood



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)

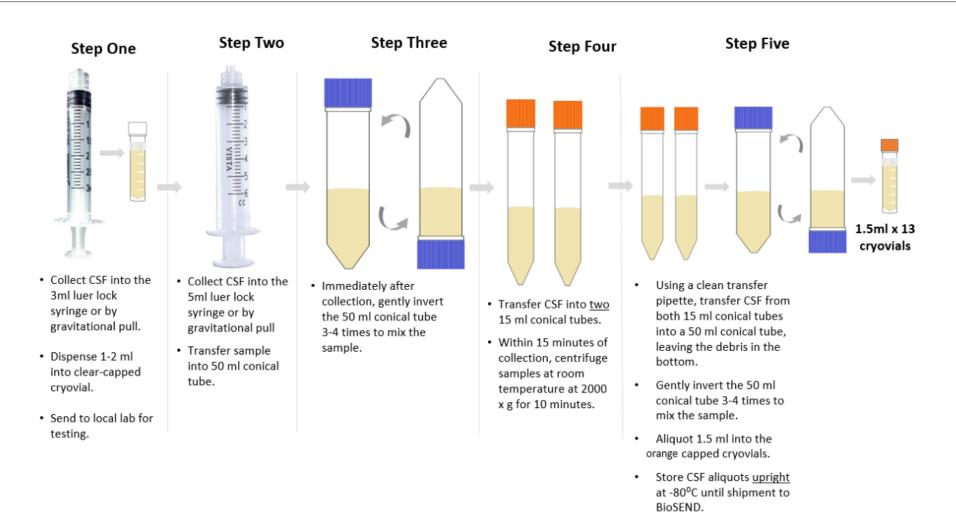
Blood Collection: Troubleshooting

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)

Sample Collection and Processing: CSF



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



Shipping Samples: Frozen

Packing and Shipping Frozen Samples

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

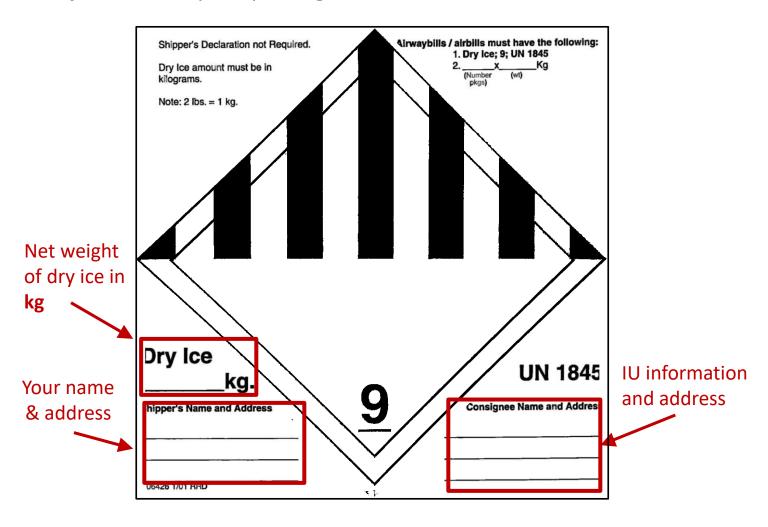




Shipping Samples

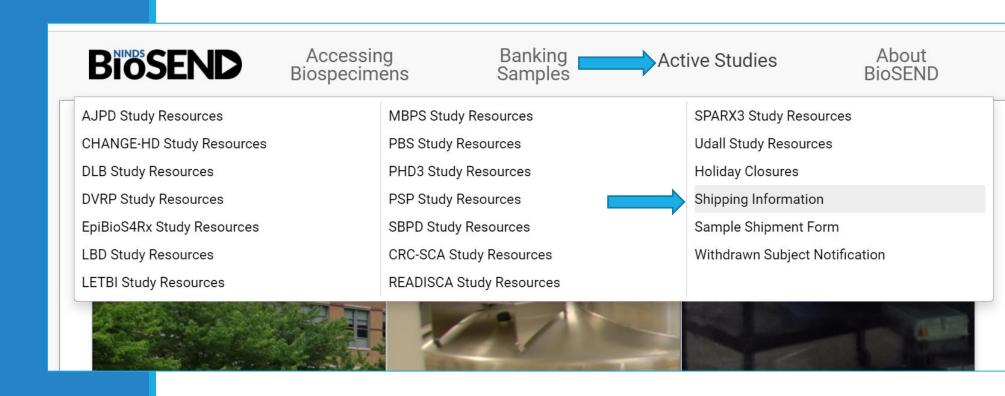
Packing and Shipping Frozen Samples

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 Frozen Samples

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

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

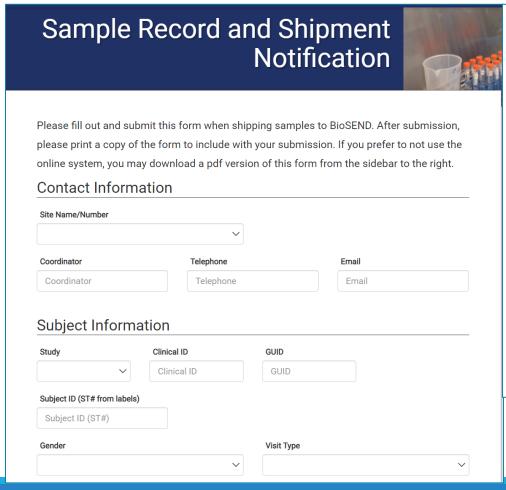


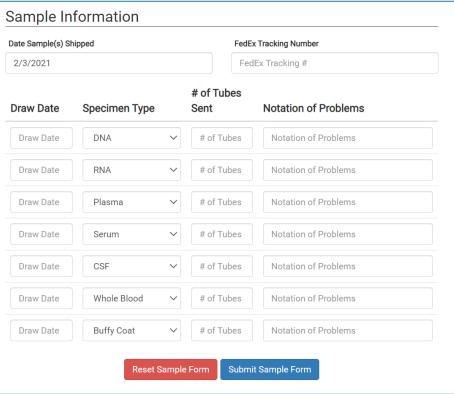
Shipping Samples: Frozen

Please notify BioSEND ahead of shipment

- Email <u>biosend@iu.edu</u> with copy of Sample Form and tracking number
- OR use Online Sample form on biosend.org

Shipping Samples: Sample Form





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 Mondayin May	Memorial Day
June 19	Juneteenth (observed)
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