BIOSEND

Emory LBD Study

PDBP Study ID 283

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

Site Equipment

Sites will need to supply the following items:

Phlebotomy

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



Site Equipment

Sites will need to supply the following items:

Processing

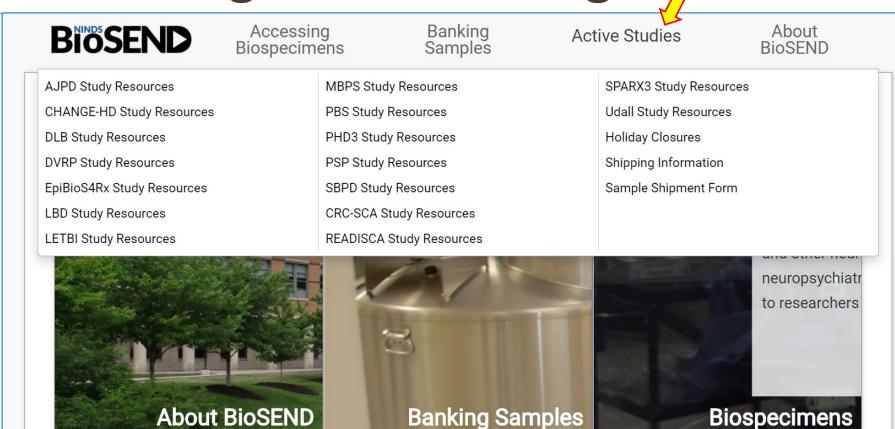
- Crushed ice
- Microcentrifuge tube rack
- Calibrated pipettes and pipette tips
- Centrifuge capable of maintaining 4°C
- -80°C Freezer
- Dry ice



Collection Schedule – PDBP Study 283

	BL	12M	24M	36M	48M
Buffy coat (2 aliquots)	X	X	X	X	X
Plasma (6 x 1ml)	X	X	X	X	X
Serum (6 x 1ml)	X	X	X	X	X
RNA (2 x 2.5ml)	X	X	X	X	X
Whole Blood (1 x 3ml)	X	X	X	X	X
CSF (10 x 1ml)	X		X		X

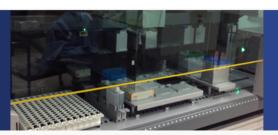
Kit Ordering – Biosend.org



Kit Ordering – LBD Emory Resource Page

Study Resource page includes MOP, training slides, and links to the online sample form and kit request module

Lewy Body Dementia Active Study Page



Welcome LBD Study staff, coordinators, and PIs. This section encompasses study specific tools and resources for **PDBP Study IDs 229, 231, 232, and 233**. If you have any questions, comments, or new ideas please contact biosend@iu.edu or by phone directlyat (317)278-0594.

Specimen Table

Cohort	Population	Genomic DNA	RNA	Plasma	Serum	CSF
LBD	Lewy Body Dementia (LBD) or high likelihood LBD subtype of mild cognitive impairment (MCI)	✓	✓	✓	✓	✓

Study Resources

Kit Request Module

Study Specific Sample Notification Forms

LBD Manual of Procedures

Downloads

Sample Shipment Form (pdf)
DLBC (PDBP Study ID 233) Manual of Procedures
DLBC (PDBP Study ID 233) Training Slides
LBD Studies 231, 232, and 229 Manual of Procedures
LBD Studies 231, 232, and 229 Training Slides

Additional Resources

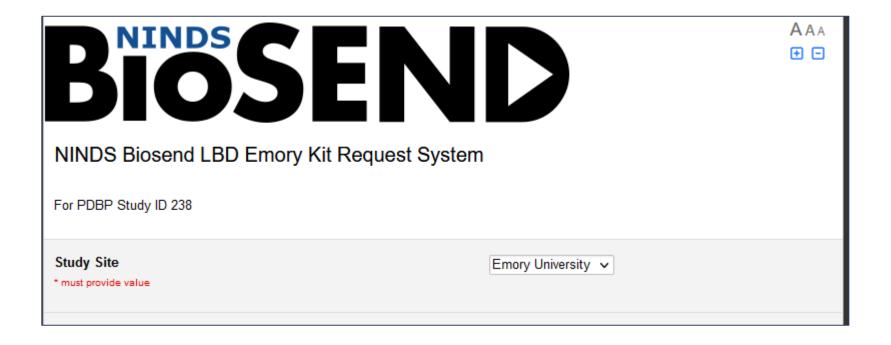
Online Sample Form

Contact Us

biosend@iu.edu 317-278-0594

BioSEND Kit Request Module

http://kits.iu.edu/biosend/EmoryLBD



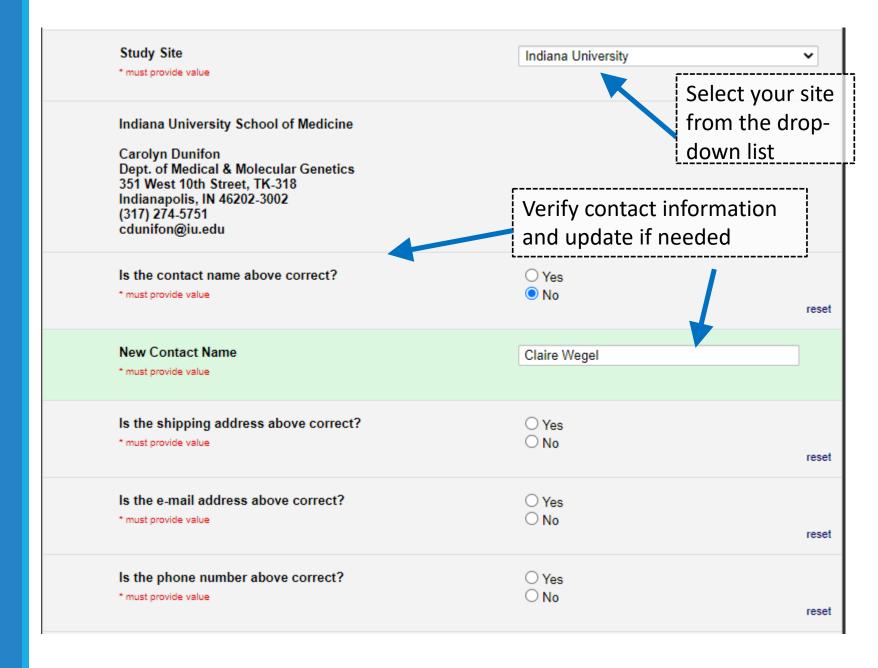
Confirm Shipping Info

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

Kit Contents and Ordering



Kit Type

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

Multiple kit types available

Baseline or Annual Kits

- Contains all specimen labels, blood collection, and shipping supplies
- Kits will have a unique "Kit Number" on labels, rather than a subject ID and time point. This allows kits to be used for any subject or time point.

Kit Type **Please allow two weeks for shipment** *must provide value	■ Baseline/Annual Visit Kit ■ CSF Collection Kit ■ Extra Supplies Please specify in comments if you need kits before the standard two week shipment time.
Baseline/Annual Visit Kit Quantity * must provide value	3
Comments	Expand
Baseline/Annual Visit Collection Kit 15 - Siliconized cryogenic vial, 2ml 2 - Serum (glass) tube, 10ml 2 - EDTA (glass) tube, 10ml 1 - EDTA (plastic) tube, 3ml 2 - PAXGene® tube, 2.5ml 7 - Bubble-tube sleeve 2 - Disposable pipet, 3ml 1 - Cryobox, 25 cell 2 - Biohazard bag w/ absorbent sheet 1 - Fragile label 1 - UN3373 label 1 - Dry ice label 1 - Airway bill envelope 1 - Frozen shipper 1 - Label set (kit & specimen labels)	

Important Note: Kit Numbers

- Kit number system allows you to use a visit kit for any study visit
- Kit numbers are unique to a specific kit and will not be used again. That is, a single subject will have a different kit number for each time point
- When sites ship samples to BioSEND, they indicate the subject ID, visit, and kit number on the sample shipping form. BioSEND will keep this link in our database
- Sites are encouraged to maintain their own log of which kit numbers were assigned to which visit

Automatic Kit Shipments

After subject completes baseline visit and <u>BioSEND receives BL</u> <u>samples</u>, BioSEND sets up automated kit sending schedule for subject's subsequent visits

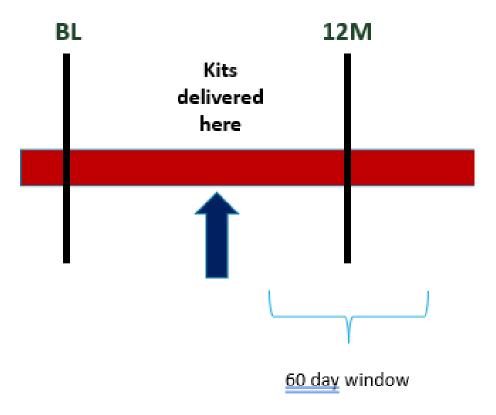
Schedule gives 2 month window around the longitudinal study visit target (1 month on either side)

BioSEND will send kits prior to start of study window

- Reduces effort for study coordinators
- Sites only need to order kits if visit will occur AHEAD of the study visit window

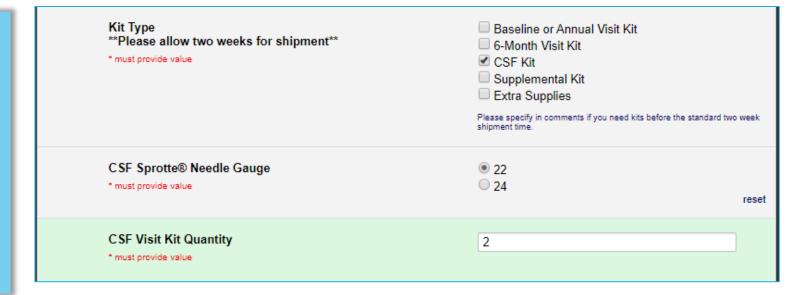
All study visit target dates are determined from Baseline Visit (not from last study visit date)

Automatic Kit Shipments



CSF Kits

- CSF collection kits are ordered independently of BL/Annual kits
- CSF labels will be included with all BL/Annual kits, so that CSF kits may be paired with any visit/ID



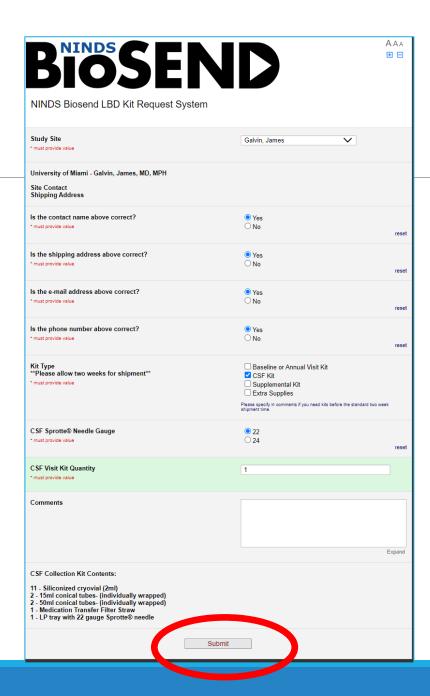
Extra Supplies

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 □ CSF Kit □ Supplemental Kit ☑ Extra Supplies Please specify in comments if you need kits before the standard two week shipment time.
Individual Tube Bubble Pouch	○ 2 ○ 4 reset
25-Slot Cryobox	○ 2 ○ 4 reset
Siliconized Cryoial (2 ml)	● 10 ○ 20 reset
Lumbar Puncture Trays with Lidocaine, 22g	○ 2 ○ 4 reset
Airway bill envelope	$\begin{tabular}{c} \begin{tabular}{c} tabu$
Lumbar Puncture Trays with Lidocaine, 24g	○ 2 ○ 4 reset
Medication Transfer Filter Straws (for LP)	© 2
15ml Conical Tube, individually wrapped	○ 2 ○ 4 reset

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 Labeling

Labels are provided by Indiana University

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



Kit Labels



Specimen Labels

Kit Labels

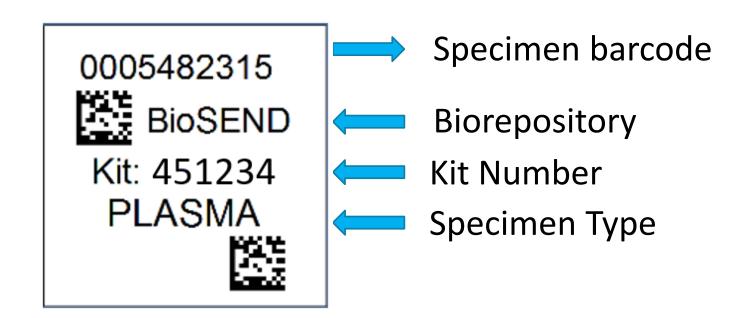
Kit labels are placed:

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



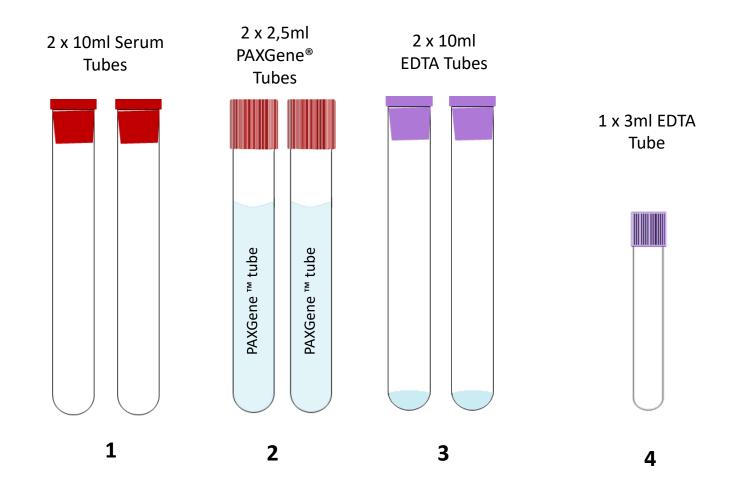


Specimen Label

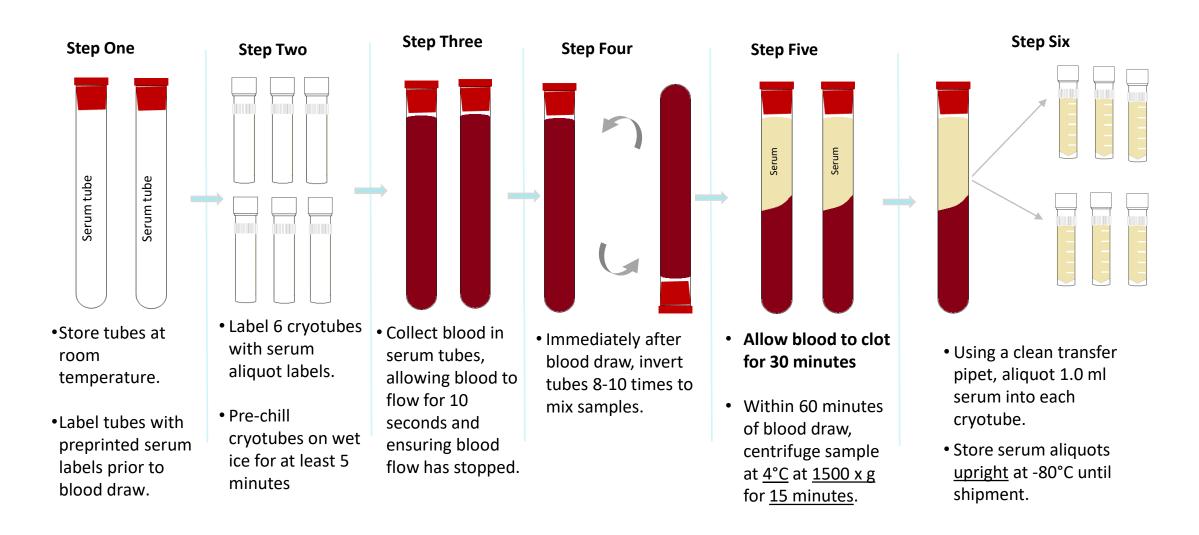


Sample Collection and Processing

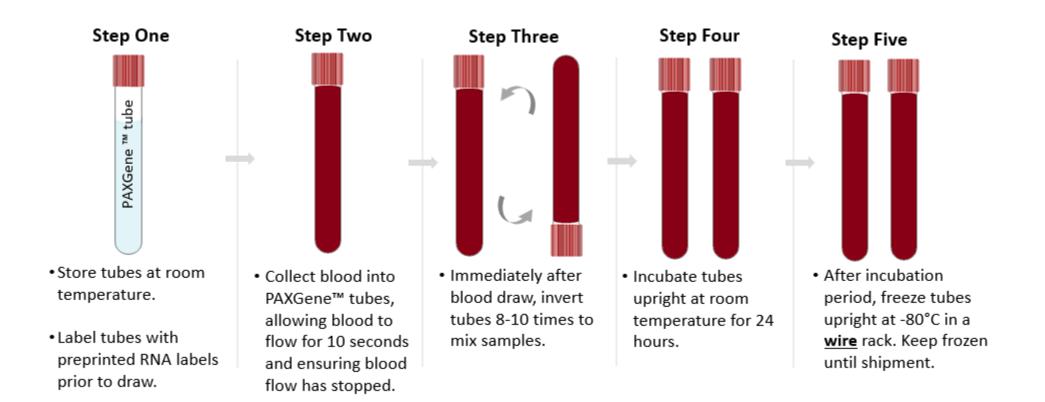
Blood Tube Draw Order



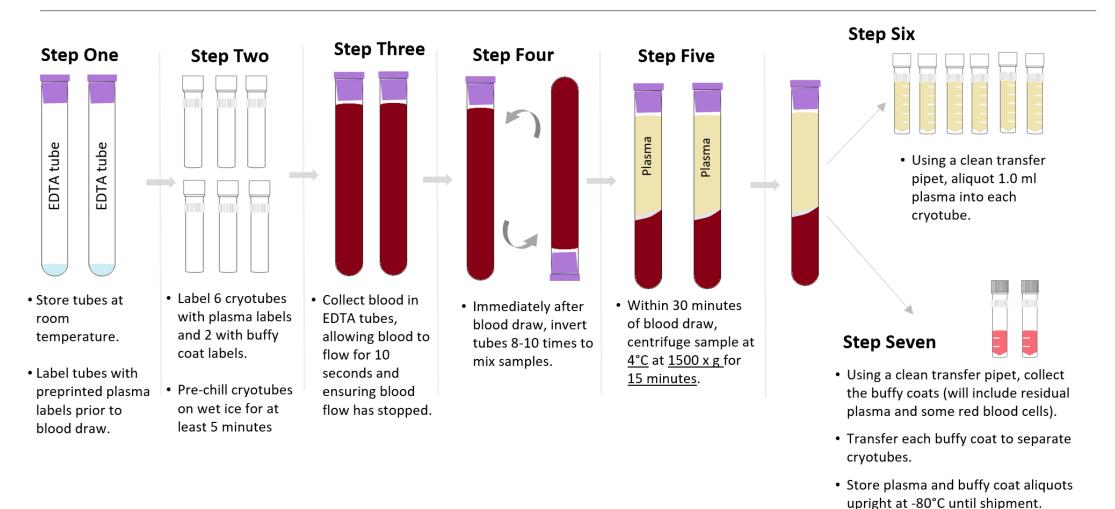
Sample Collection and Processing: Serum



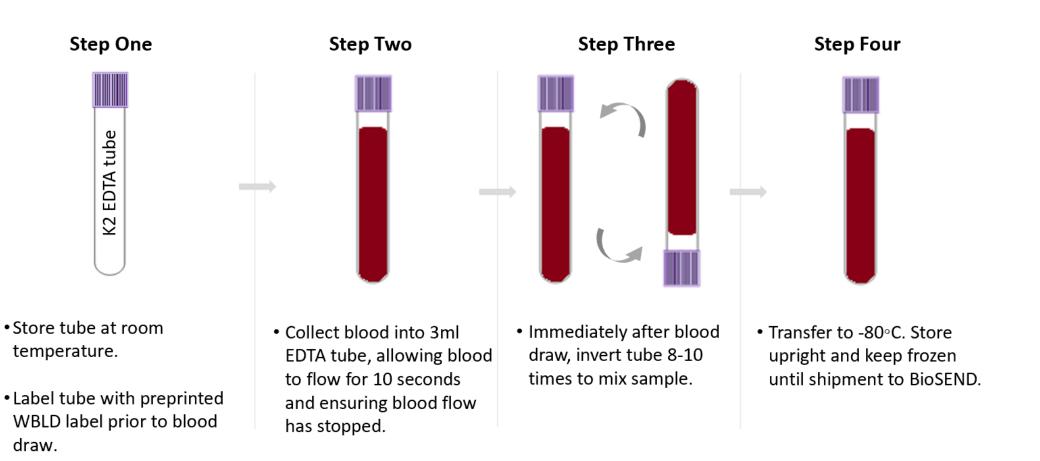
Sample Collection and Processing: RNA



Sample Collection and Processing: Plasma & Buffy Coat



Sample Collection and Processing: Whole Blood

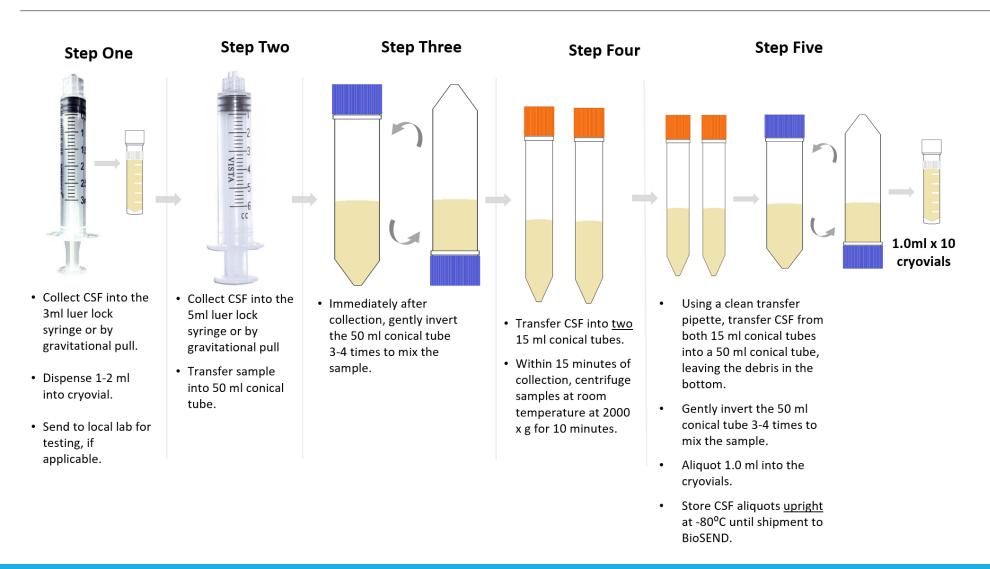


Blood Collection Troubleshooting

Most common issues with draw:

- Store collection tubes at room temperature
- Check expiration dates and keep extra tubes on hand
- Avoid vigorous mixing of collected sample
- Do not leave tubes uncentrifuged for longer than indicated time

Sample Collection and Processing: CSF



Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- All other 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 Frozen Samples

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

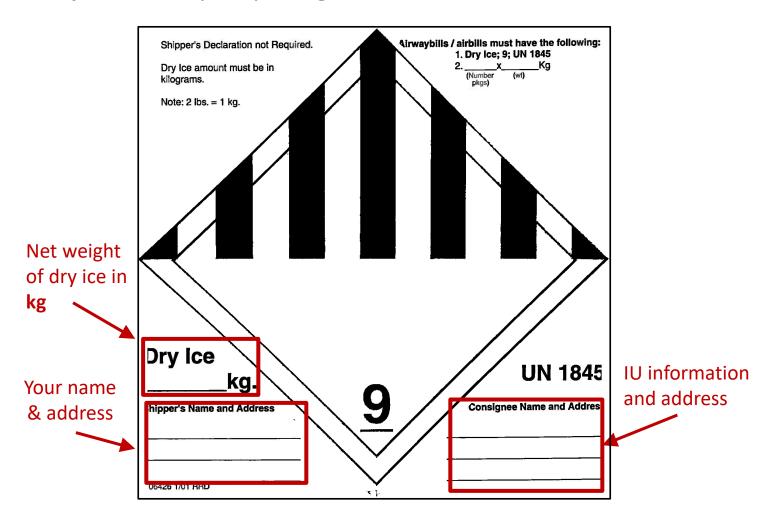
Samples should be received at BioSEND within 2 weeks of collection.



Shipping Samples

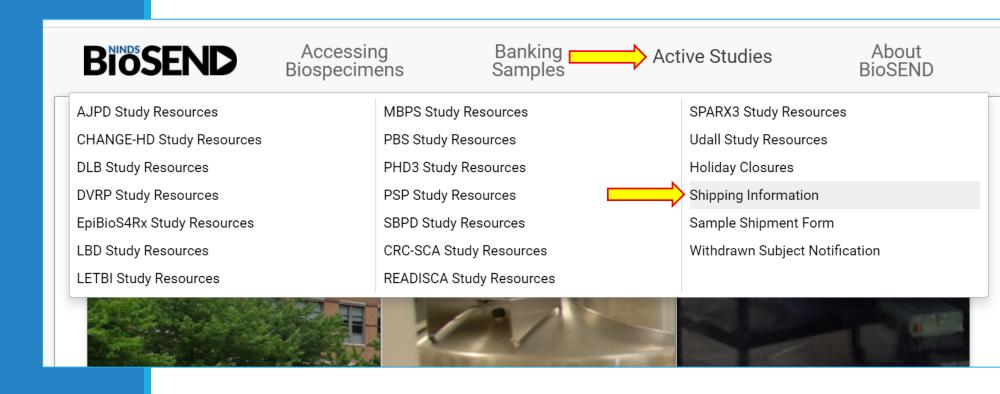
Packing and Shipping Frozen Samples

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



Shipping Information Page

Links on this page to:

- Generate airwaybills & schedule pickups
- 2. View printed guide on how to use ShipExec™
- 3. Request user account and update site address in system
- View video tutorial for using UPS ShipExec™

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.

Navigating UPS ShipExec™











Shipping Samples – UPS ShipExec™

If you will be assisting in shipping samples, please request a user account and familiarize yourself with the system well in advance of your first sample shipment

Shipping Samples: Frozen

Please notify BioSEND ahead of shipment

- Please complete the Sample Collection and Processing Form in REDCap ahead of shipment (can be competed day of shipment).
 - > A completed copy of this form should be included in the sample shipper
- If you are having trouble with REDCap, please notify BioSEND directly of shipment at biosend@iu.edu

Sample Collection and Processing Form

Direct link:

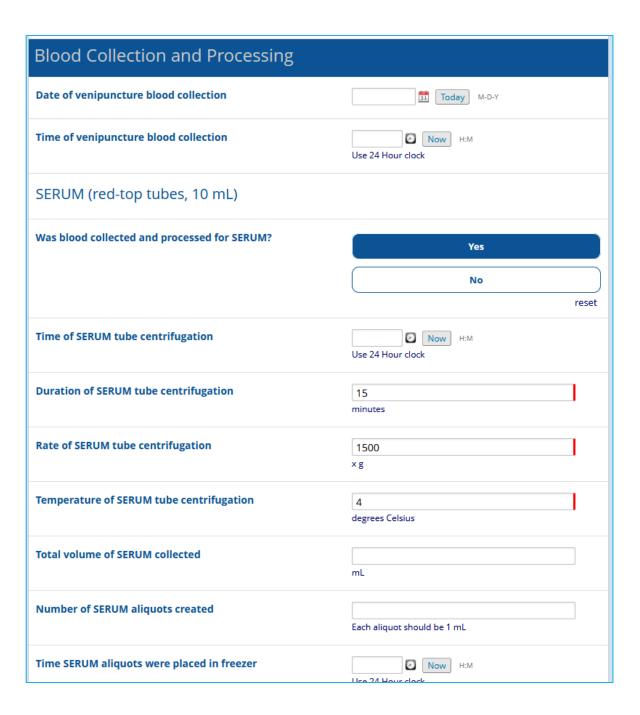
http://kits.iu.edu/biosend/EmoryLBDSampleForm

First page captures basic subject and visit information



Sample Collection and Processing Form

Second page captures processing information



Sample Collection and Processing Form

PDF form of responses will be emailed to you. Print a copy of the Frozen
Shipping Manifest and include with shipment.

LBD Emory Frozen Shipping Manifest			
Please verify/update the information below. When you Shipping Manifest will be emailed to you for Subject [s	click the "Submit" button below, a PDF copy of the Frozen ubj_id].		
Please print a copy of that document and include it in	the shipping container.		
Study Site:	Emory University		
GUID:			
Visit:	○ BL ○ 12M ○ 24M ○ 36M ○ 48M		
ST Number:			
Date of blood collection:			
Date of CSF collection:			
SERUM			
Number of SERUM aliquots shipped:			
RNA			
Number of PAXGene™ tubes shipped:			
PLASMA EDTA			
Number of PLASMA EDTA aliquots shipped:			
Number of BUFFY COAT aliquots shipped:			

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
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.

Contact Info

Indiana University

biosend@iu.edu

317-278-0594

https://biosend.org