BIOSEND

The Dementia With Lewy Bodies Consortium (DLBC) Study PDBP Study ID 233

BIOSPECIMEN COLLECTION & PROCESSING

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

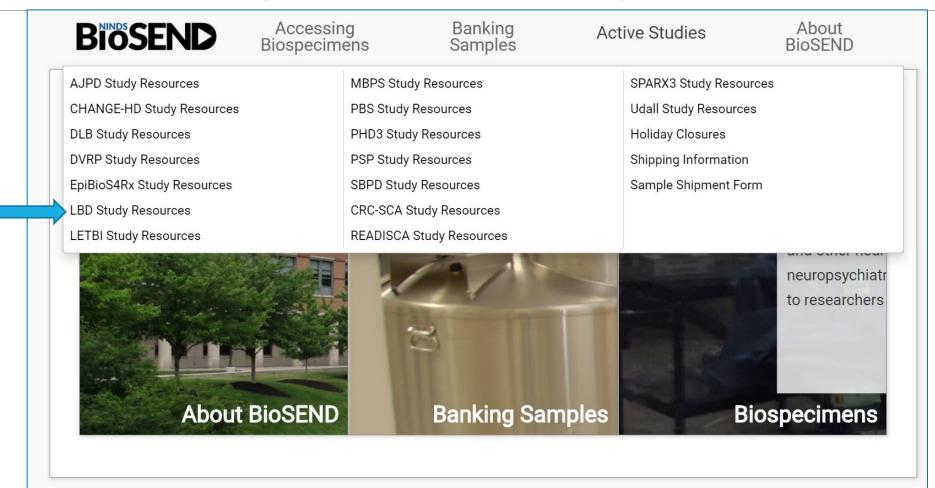
- Crushed ice
- Microcentrifuge tube rack
- Calibrated pipettes and pipette tips
- Centrifuge capable of maintaining 4°C
- -80°C Freezer
- Dry ice



Collection Schedule – PDBP Study 233

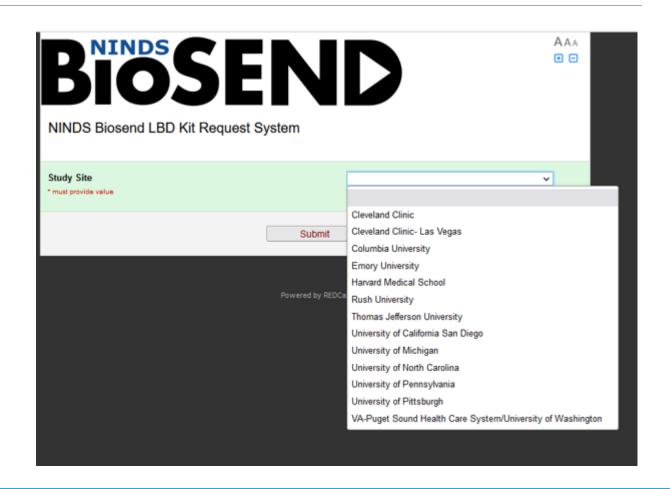
| | BL | 12M | 24M | 36M | 48M | 60M | 72M |
|-------------------------------|----|-----|-----|-----|-----|-----|------------|
| Buffy coat (2 aliquots) | X | X | X | X | X | X | X |
| Plasma (6 x 1ml) | X | X | X | X | X | X | X |
| Serum (6 x 1ml) | X | X | X | X | X | X | X |
| RNA (2 x 2.5ml) | X | X | X | X | X | X | Χ |
| Whole Blood (1x3ml) | X | X | X | X | X | X | X |
| CSF (10 x 1ml) | X | X | X | X | X | X | Χ |

Kit Ordering – Biosend.org



BioSEND Kit Request Module

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



Confirm Shipping Info

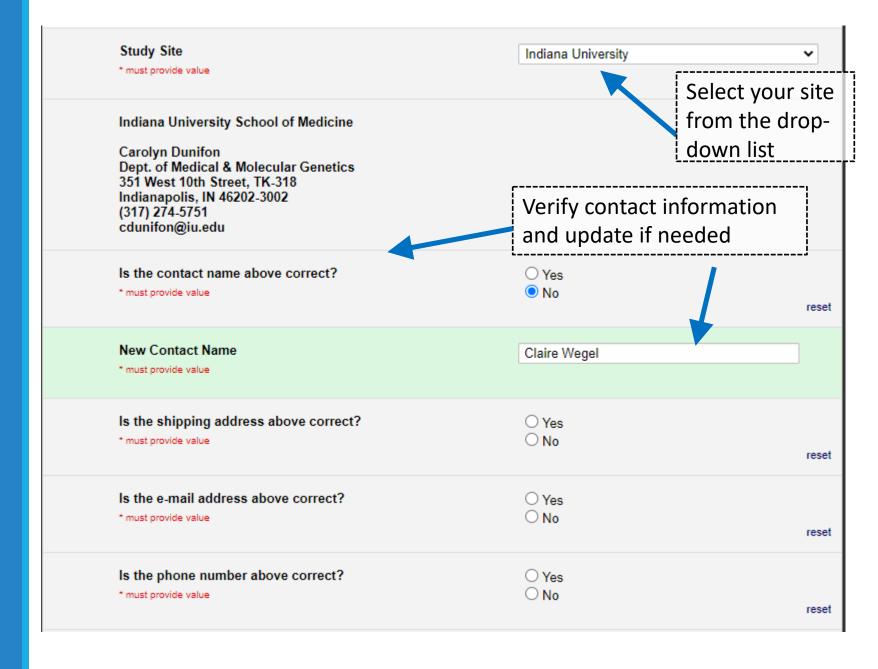
Confirm site information:

- 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 |

Kit Contents and Ordering

Kit Request Module



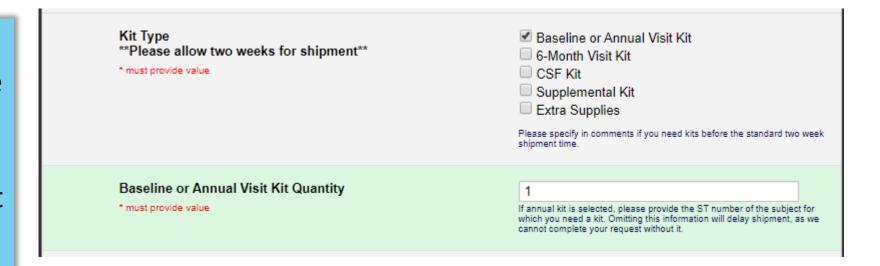
Kit Type

| 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. | | |

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.

Automatic Kit Shipments

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

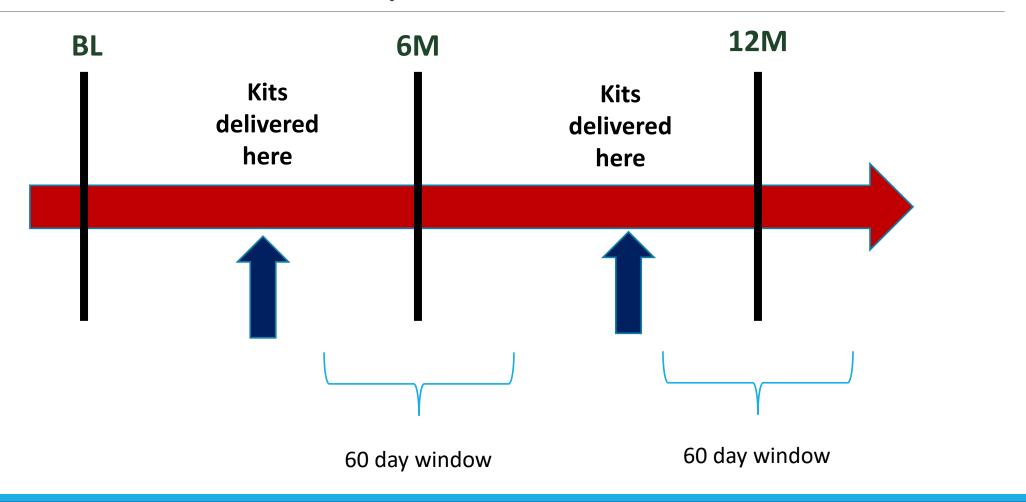
Schedule gives 2 month window around the longitudinal study visit target (1 month on either side)

BioSEND will send kits prior to start of study window

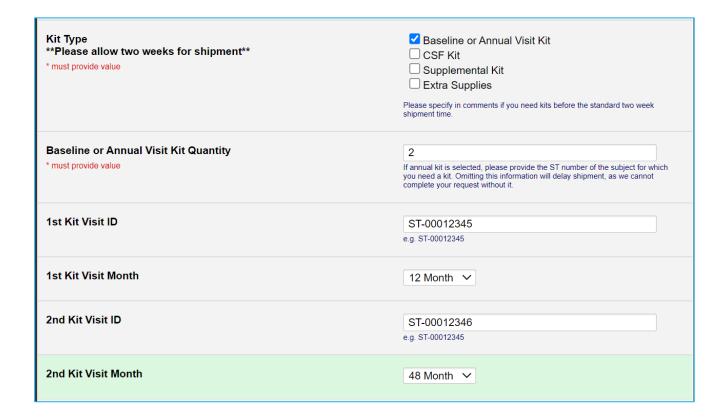
- Reduces effort for study coordinators
- Sites only need to order kits if visit will occur AHEAD of the study visit window

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

Automatic Kit Shipments



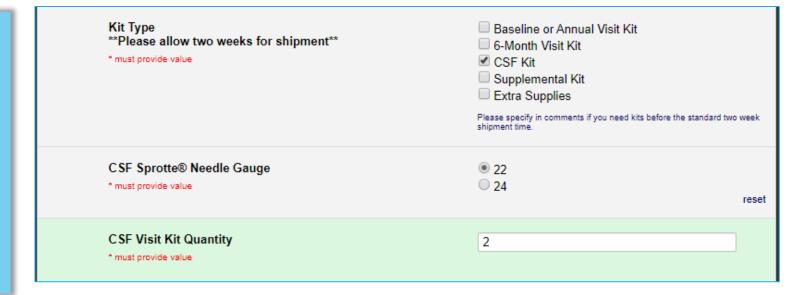
Annual Visits



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

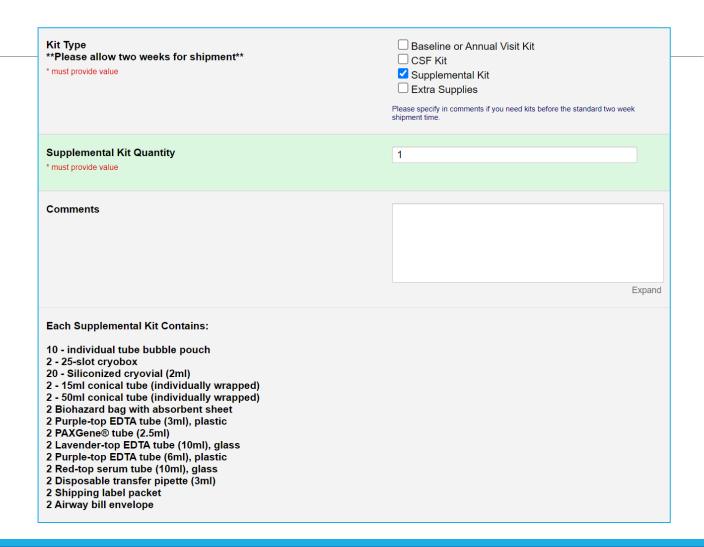
CSF Kits

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



Supplemental Kit

Contains a variety of extra kit components



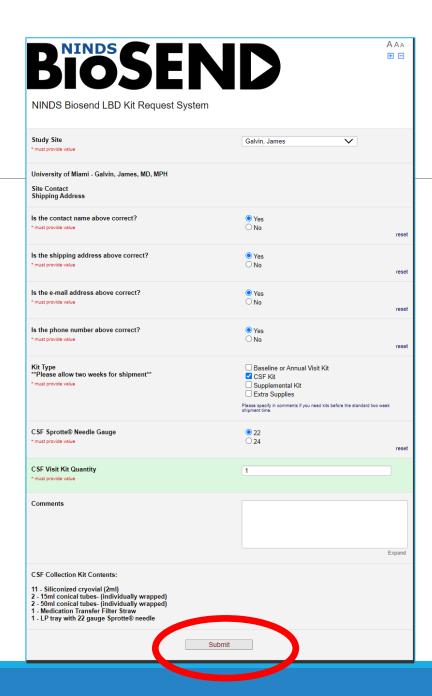
Extra Supplies

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

ST-10001234: LBD-FREY:BL



BioSend

Case Labels

0001234567
BioSEND
ST-10001234
BL

Specimen Labels

PLASMA

Case Label





Subject Number

Study – PI & Visit



BioSend



Biorepository Name

Case Labels

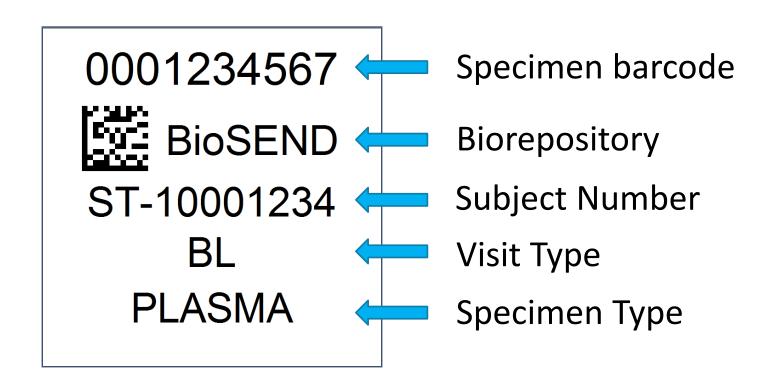
Case labels are placed:

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



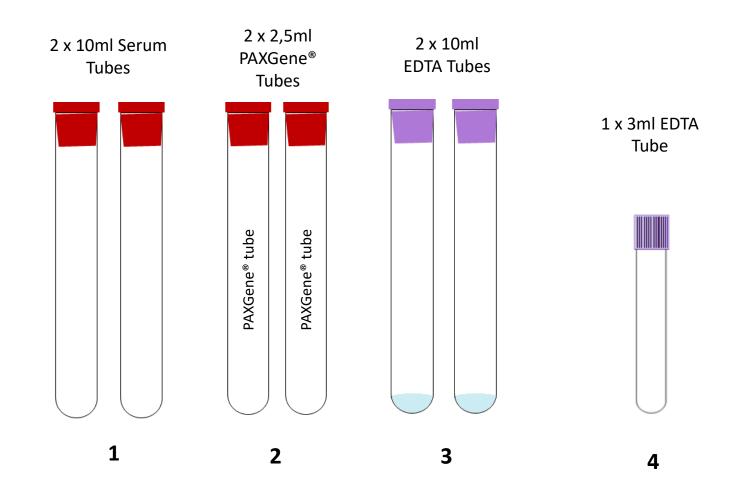


Specimen Label

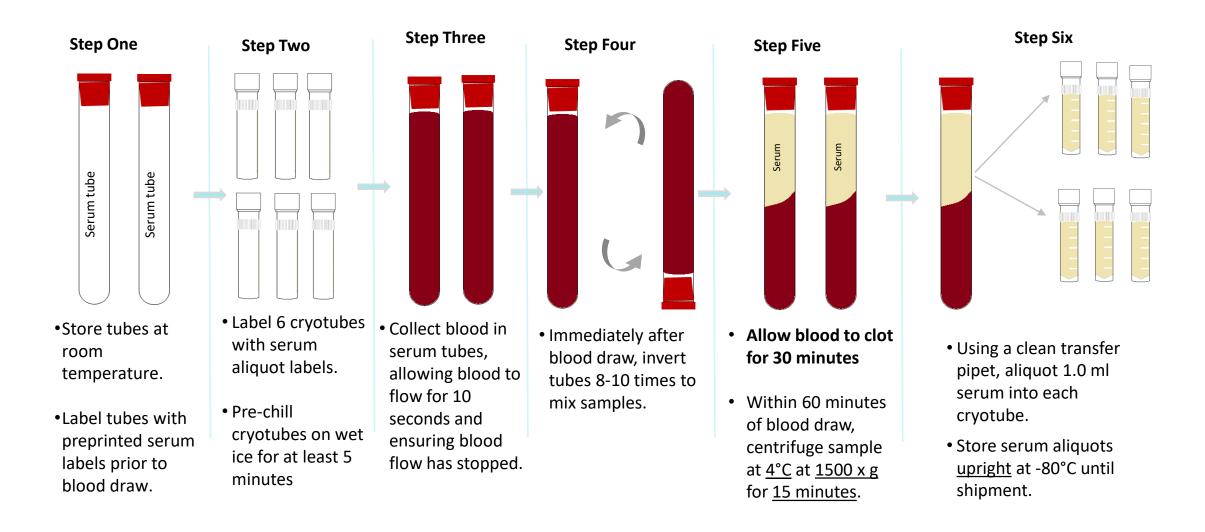


Sample Collection and Processing

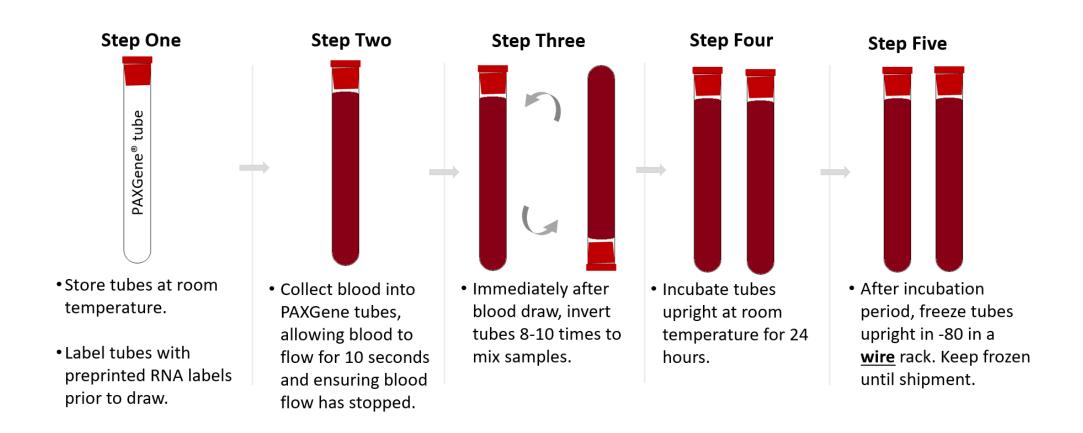
Blood Tube Draw Order for PDBP
Study 233



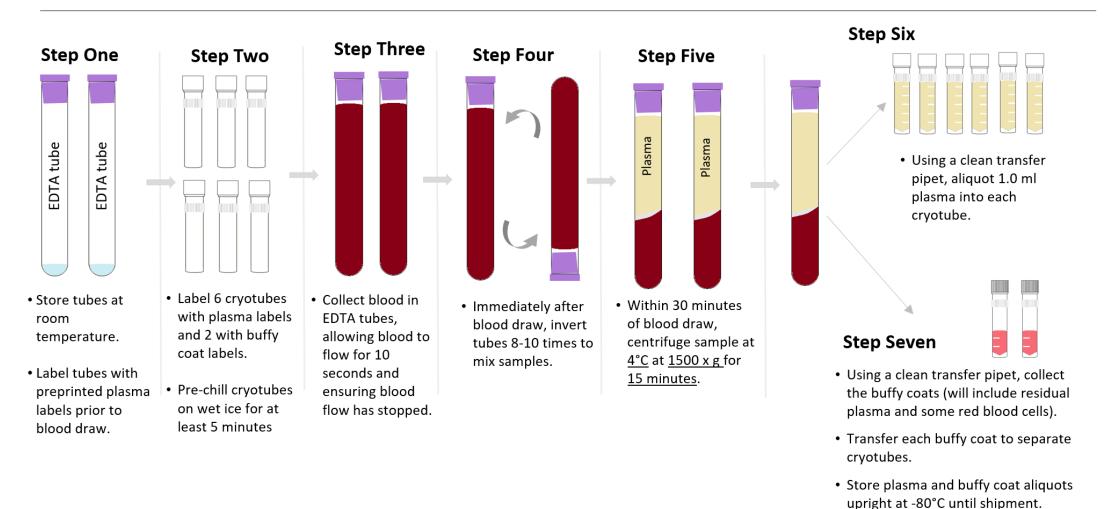
Sample Collection and Processing: Serum



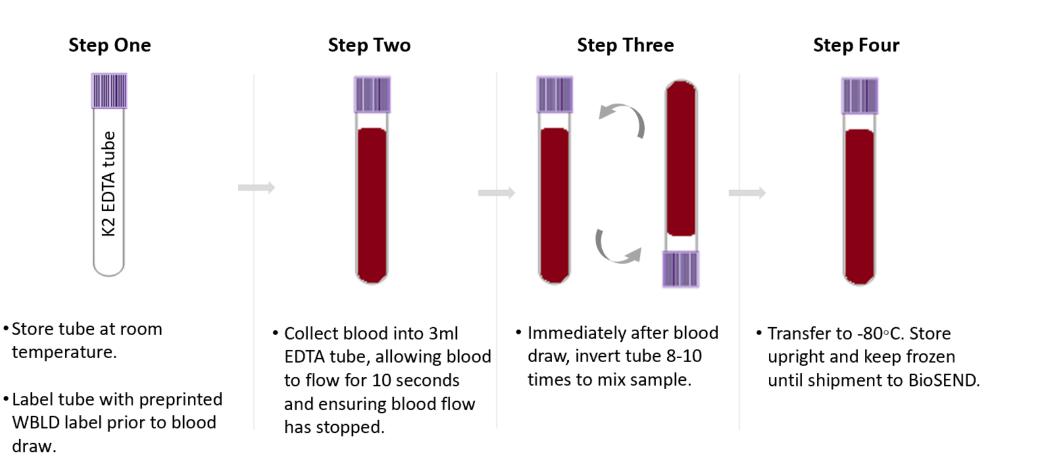
Sample Collection and Processing: RNA



Sample Collection and Processing: Plasma & Buffy Coat



Sample Collection and Processing: Whole Blood

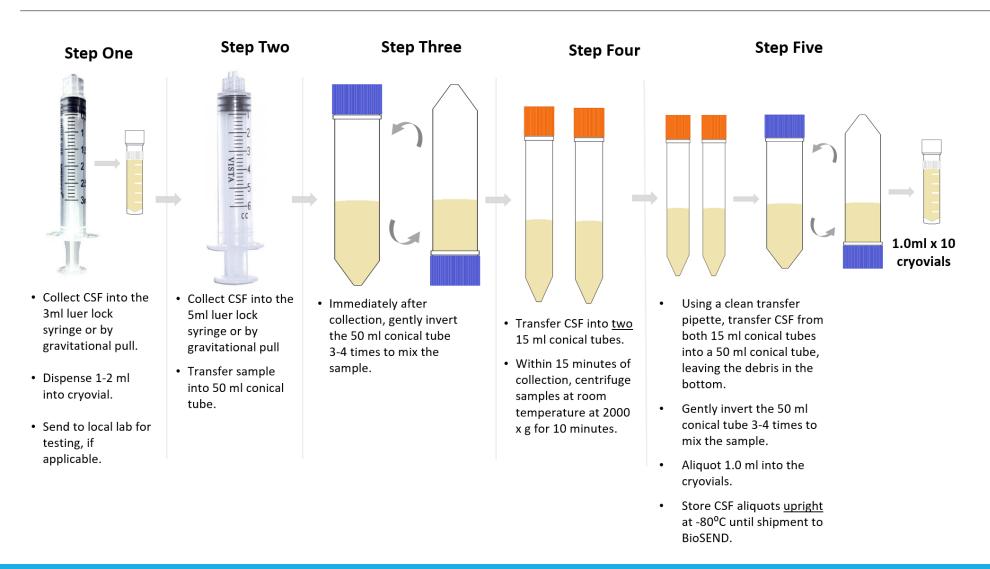


Blood Collection Troubleshooting

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

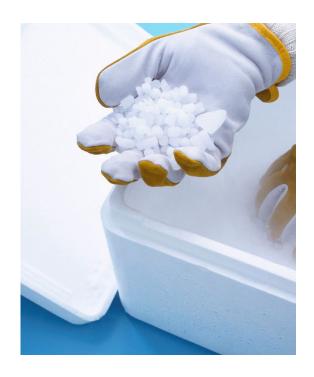
Sample Collection and Processing: CSF



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.

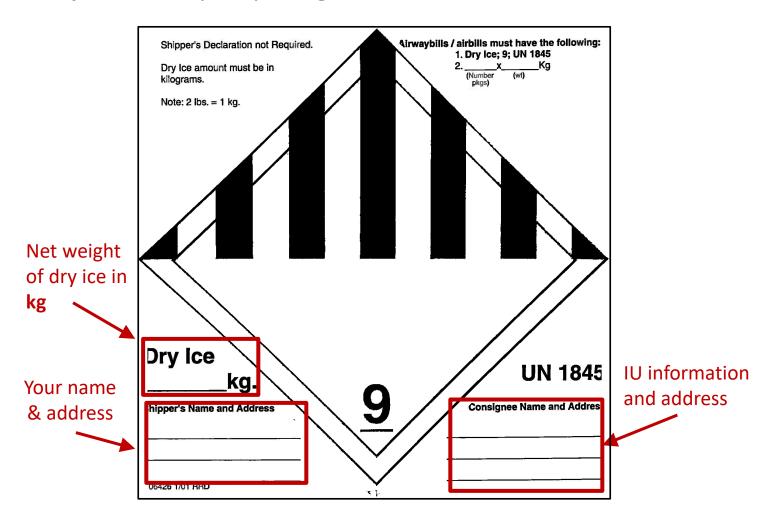
Samples should be received at BioSEND within 2 weeks of collection.



Shipping Samples

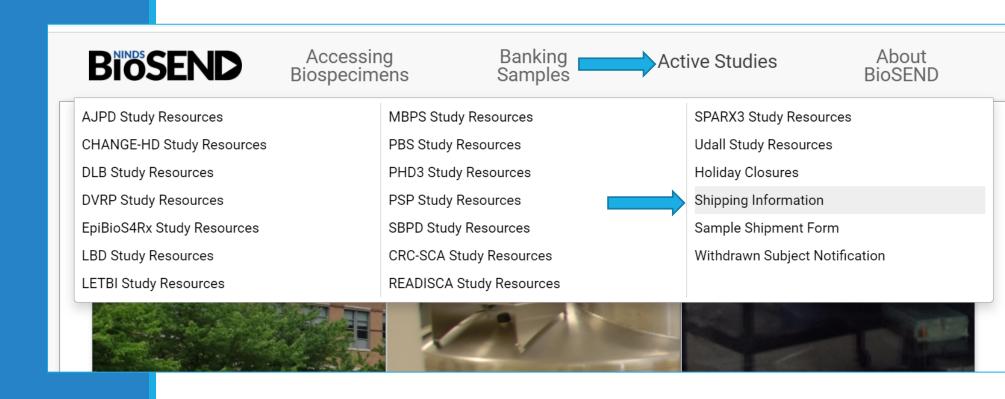
Packing and Shipping Frozen Samples

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/DLBC SampleForm

First page captures basic subject and visit information

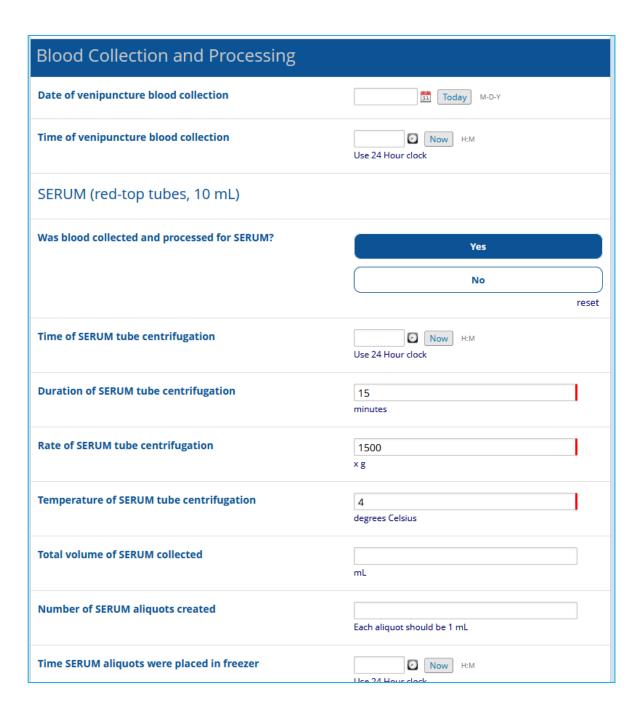


Sample Collection and Processing Form

Direct link:

http://kits.iu.edu/biosend/DLBC SampleForm

Second page captures processing information



Sample Collection and Processing Form

Direct link: Direct link: http://kits.iu.edu/biosend/DLBC
SampleForm

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 | D |
|--|--|---|
| Please verify/update the information below. When you cl Shipping Manifest will be emailed to you for Subject [sub | ick the "Submit" button below, a PDF copy of the Frozen j_id]. | |
| Please print a copy of that document and include it in the | e 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