



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

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BIOSPECIMEN COLLECTION & PROCESSING

# Specimen Uniformity and Quality

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GENERAL REMINDERS

# Specimen Uniformity and Quality

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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

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Sites will need to supply the following items:

## Phlebotomy

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



# Site Equipment

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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





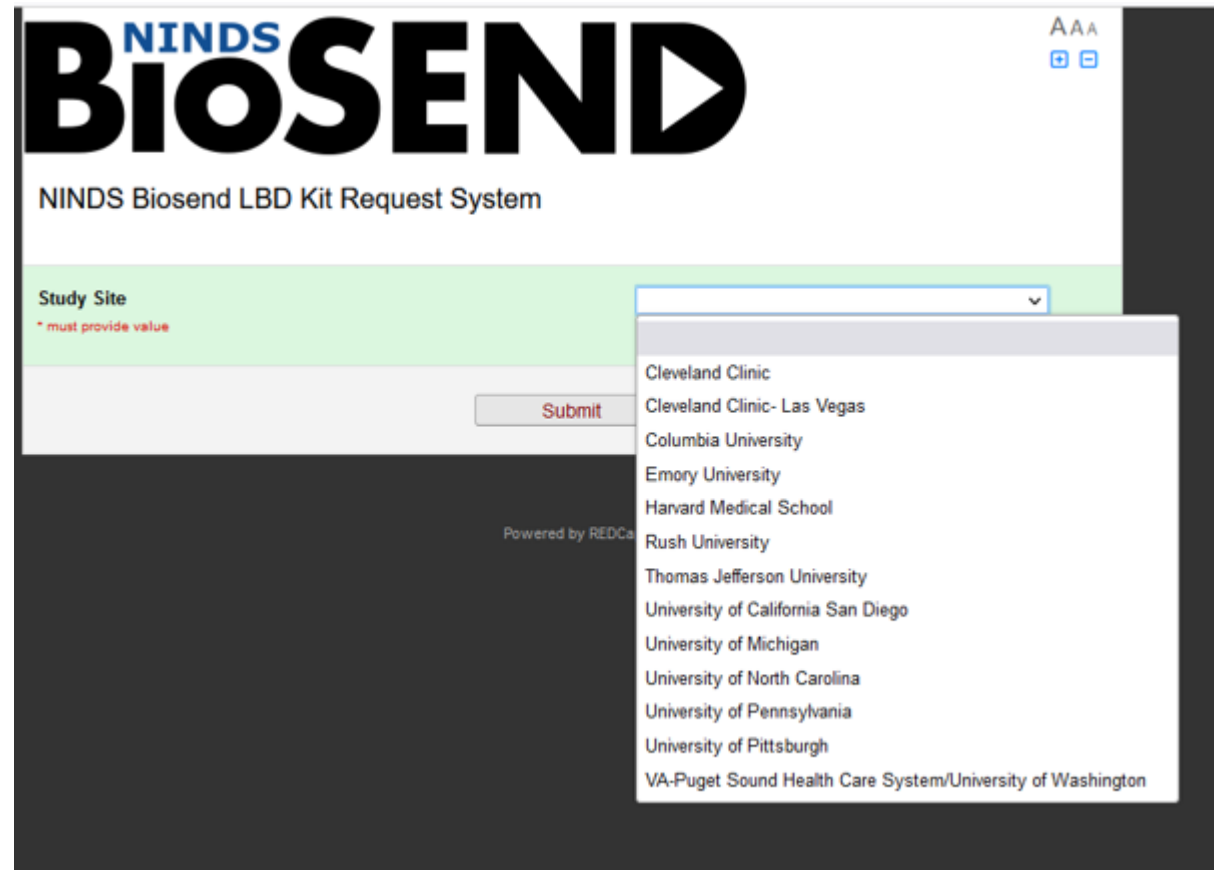
# Kit Ordering – Biosend.org

The screenshot shows the Biosend.org website navigation menu. At the top left is the **NINDS BioSEND** logo. To its right are five main menu categories: **Accessing Biospecimens**, **Banking Samples**, **Active Studies**, and **About BioSEND**. A white dropdown menu is open under 'Active Studies', listing the following resources: AJPD Study Resources, CHANGE-HD Study Resources, DLB Study Resources, DVRP Study Resources, EpiBioS4Rx Study Resources, **LBD Study Resources** (highlighted with a blue arrow), 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, and Sample Shipment Form. Below the menu are three image-based navigation buttons: 'About BioSEND' (with a photo of a building), 'Banking Samples' (with a photo of a metal container), and 'Biospecimens' (with a photo of a dark container). A partial text box on the right side of the image reads 'and other neuropsychiatr to researchers'.

# BioSEND Kit Request Module

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



The screenshot displays the NINDS BioSEND LBD Kit Request System interface. At the top, the logo "NINDS BioSEND" is prominent, with "NINDS" in blue and "BioSEND" in large black letters. Below the logo, the text "NINDS Biosend LBD Kit Request System" is visible. In the top right corner, there are accessibility icons labeled "AAA".

The main form area has a light green background. It contains a "Study Site" label, a red asterisk, and the text "\* must provide value". Below this is a dropdown menu that is currently open, showing a list of study sites:

- Cleveland Clinic
- Cleveland Clinic- Las Vegas
- Columbia University
- Emory University
- Harvard Medical School
- Rush University
- Thomas Jefferson University
- University of California San Diego
- University of Michigan
- University of North Carolina
- University of Pennsylvania
- University of Pittsburgh
- VA-Puget Sound Health Care System/University of Washington

To the right of the dropdown menu is a "Submit" button. At the bottom of the form, it says "Powered by REDCap".



# Confirm Shipping Info

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## 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? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">reset</a>
Is the shipping address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">reset</a>
Is the e-mail address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">reset</a>

# Kit Contents and Ordering

Kit Request Module

<b>Study Site</b> <small>* must provide value</small>	Indiana University
Indiana University School of Medicine Carolyn Dunifon Dept. of Medical & Molecular Genetics 351 West 10th Street, TK-318 Indianapolis, IN 46202-3002 (317) 274-5751 cdunifon@iu.edu	
<b>Is the contact name above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No <a href="#">reset</a>
<b>New Contact Name</b> <small>* must provide value</small>	Claire Wegel
<b>Is the shipping address above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <a href="#">reset</a>
<b>Is the e-mail address above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <a href="#">reset</a>
<b>Is the phone number above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <a href="#">reset</a>

Select your site from the drop-down list

Verify contact information and update if needed

# Kit Type

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**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

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

<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <small>* must provide value</small>	<input checked="" type="checkbox"/> Baseline or Annual Visit Kit <input type="checkbox"/> 6-Month Visit Kit <input type="checkbox"/> CSF Kit <input type="checkbox"/> Supplemental Kit <input type="checkbox"/> Extra Supplies
<b>Baseline or Annual Visit Kit Quantity</b> <small>* must provide value</small>	<input type="text" value="1"/> <small>If annual kit is selected, please provide the ST number of the subject for which you need a kit. Omitting this information will delay shipment, as we cannot complete your request without it.</small>

# Important Note: ST-Numbers

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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

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After subject completes baseline visit and BioSEND receives BL samples, 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)

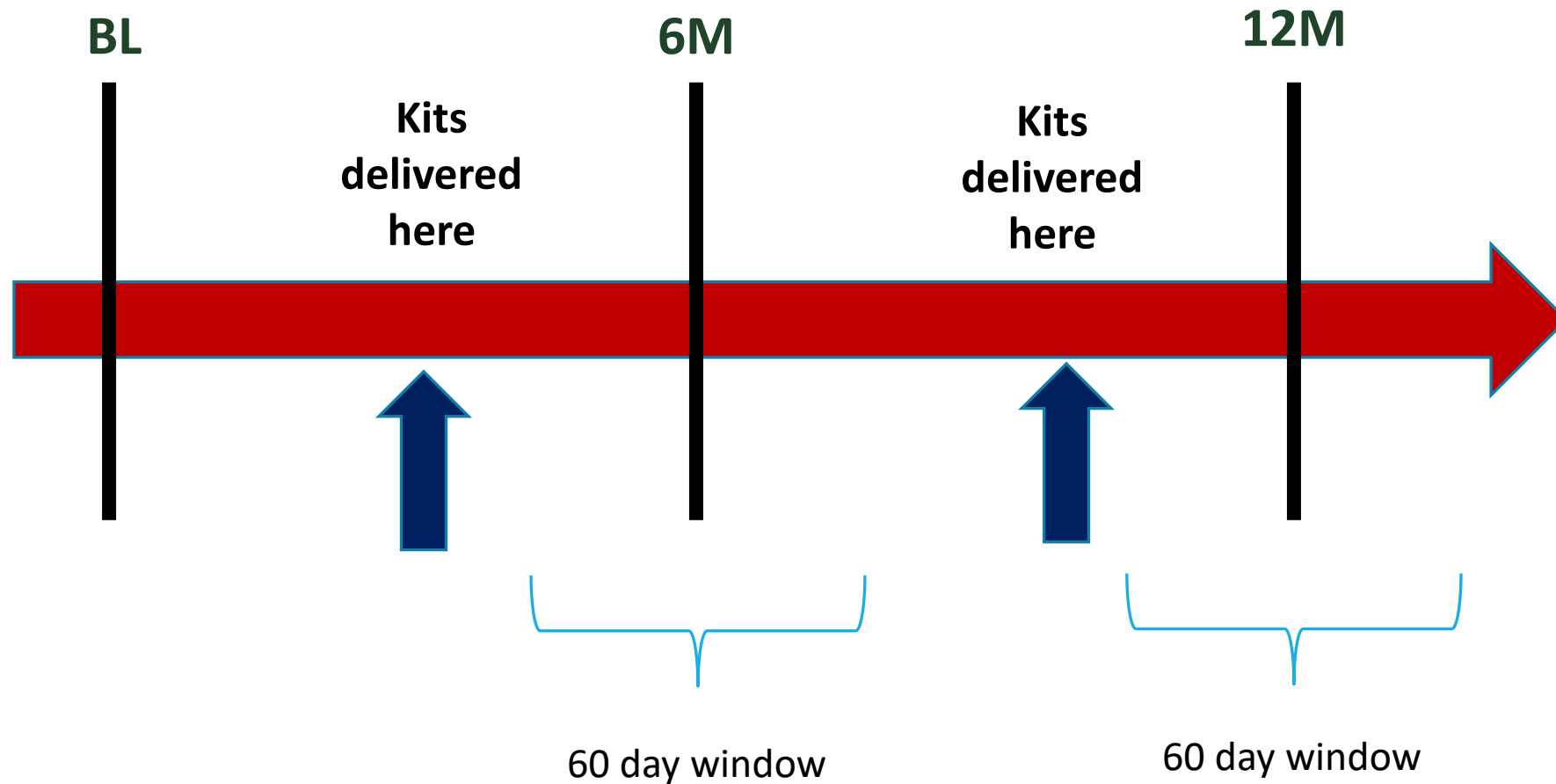
BioSEND will send kits prior to start of study window

- 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

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# Annual Visits

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<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <small>* must provide value</small>	<input checked="" type="checkbox"/> Baseline or Annual Visit Kit <input type="checkbox"/> CSF Kit <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>
<b>Baseline or Annual Visit Kit Quantity</b> <small>* must provide value</small>	<input type="text" value="2"/> <small>If annual kit is selected, please provide the ST number of the subject for which you need a kit. Omitting this information will delay shipment, as we cannot complete your request without it.</small>
<b>1st Kit Visit ID</b>	<input type="text" value="ST-00012345"/> <small>e.g. ST-00012345</small>
<b>1st Kit Visit Month</b>	<input type="text" value="12 Month"/>
<b>2nd Kit Visit ID</b>	<input type="text" value="ST-00012346"/> <small>e.g. ST-00012345</small>
<b>2nd Kit Visit Month</b>	<input type="text" value="48 Month"/>

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

<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <small>* must provide value</small>	<input type="checkbox"/> Baseline or Annual Visit Kit <input type="checkbox"/> 6-Month Visit Kit <input checked="" type="checkbox"/> CSF Kit <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>
<b>CSF Sprotte® Needle Gauge</b> <small>* must provide value</small>	<input checked="" type="radio"/> 22 <input type="radio"/> 24 <small>reset</small>
<b>CSF Visit Kit Quantity</b> <small>* must provide value</small>	<input type="text" value="2"/>

# Supplemental Kit

Contains a variety of extra kit components

<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <small>* must provide value</small>	<input type="checkbox"/> Baseline or Annual Visit Kit <input type="checkbox"/> CSF Kit <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>
<b>Supplemental Kit Quantity</b> <small>* must provide value</small>	<input type="text" value="1"/>
<b>Comments</b>	<div style="border: 1px solid #ccc; height: 100px;"></div> <p style="text-align: right;"><a href="#">Expand</a></p>
<b>Each Supplemental Kit Contains:</b>  10 - individual tube bubble pouch 2 - 25-slot cryobox 20 - Siliconized cryovial (2ml) 2 - 15ml conical tube (individually wrapped) 2 - 50ml conical tube (individually wrapped) 2 Biohazard bag with absorbent sheet 2 Purple-top EDTA tube (3ml), plastic 2 PAXGene® tube (2.5ml) 2 Lavender-top EDTA tube (10ml), glass 2 Purple-top EDTA tube (6ml), plastic 2 Red-top serum tube (10ml), glass 2 Disposable transfer pipette (3ml) 2 Shipping label packet 2 Airway bill envelope	

# Extra Supplies

Allows you to choose specific supplies and particular quantities

<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <small>* must provide value</small>	<input type="checkbox"/> Baseline or Annual Visit Kit <input type="checkbox"/> CSF Kit <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>	
Individual Tube Bubble Pouch	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
25-Slot Cryobox	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
Siliconized Cryoial (2 ml)	<input checked="" type="radio"/> 10 <input type="radio"/> 20 <a href="#">reset</a>
Lumbar Puncture Trays with Lidocaine, 22g	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
Airway bill envelope	<input type="radio"/> 2 <input type="radio"/> 4 <small>Plastic envelope to affix air waybill to package</small> <a href="#">reset</a>
Lumbar Puncture Trays with Lidocaine, 24g	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
Medication Transfer Filter Straws (for LP)	<input checked="" type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
15ml Conical Tube, individually wrapped	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>

# 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** AAA

NINDS Biosend LBD Kit Request System

Study Site  \* must provide value

University of Miami - Galvin, James, MD, MPH

Site Contact  
Shipping Address

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

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

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

Is the phone number above correct?  Yes  No \* must provide value [reset](#)

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.

CSF Sprotte® Needle Gauge  22  24 \* must provide value [reset](#)

CSF Visit Kit Quantity  \* must provide value

Comments  [Expand](#)

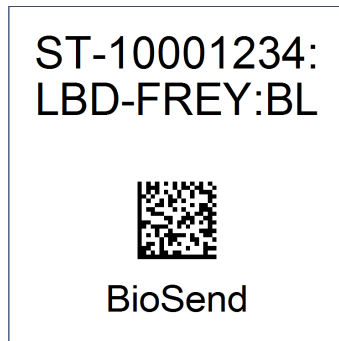
CSF Collection Kit Contents:  
11 - Siliconized cryovial (2ml)  
2 - 15ml conical tubes- (individually wrapped)  
2 - 50ml conical tubes- (individually wrapped)  
1 - Medication Transfer Filter Straw  
1 - LP tray with 22 gauge Sprotte® needle

# Sample Labeling

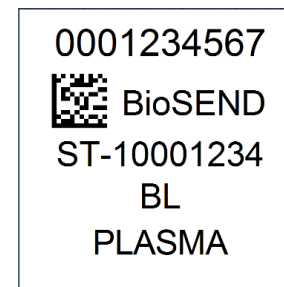
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## Labels are provided by Indiana University

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



Case Labels



Specimen Labels

# Case Label

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ST-10001234:  
LBD-FREY:BL



BioSend



Subject Number



Study – PI & Visit



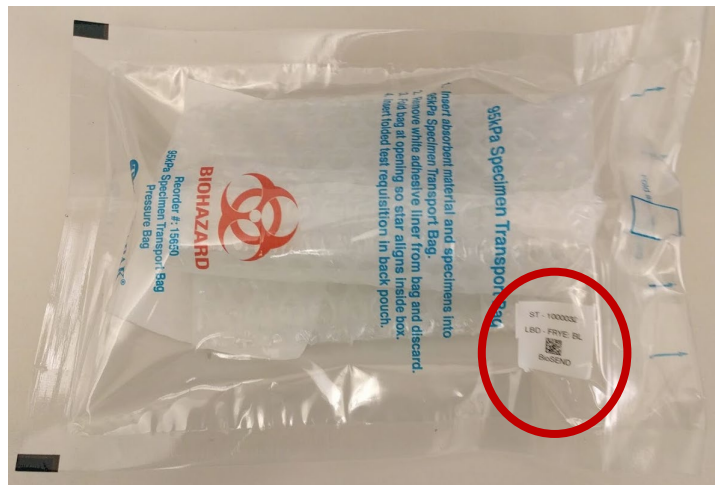
Biorepository Name

# Case Labels

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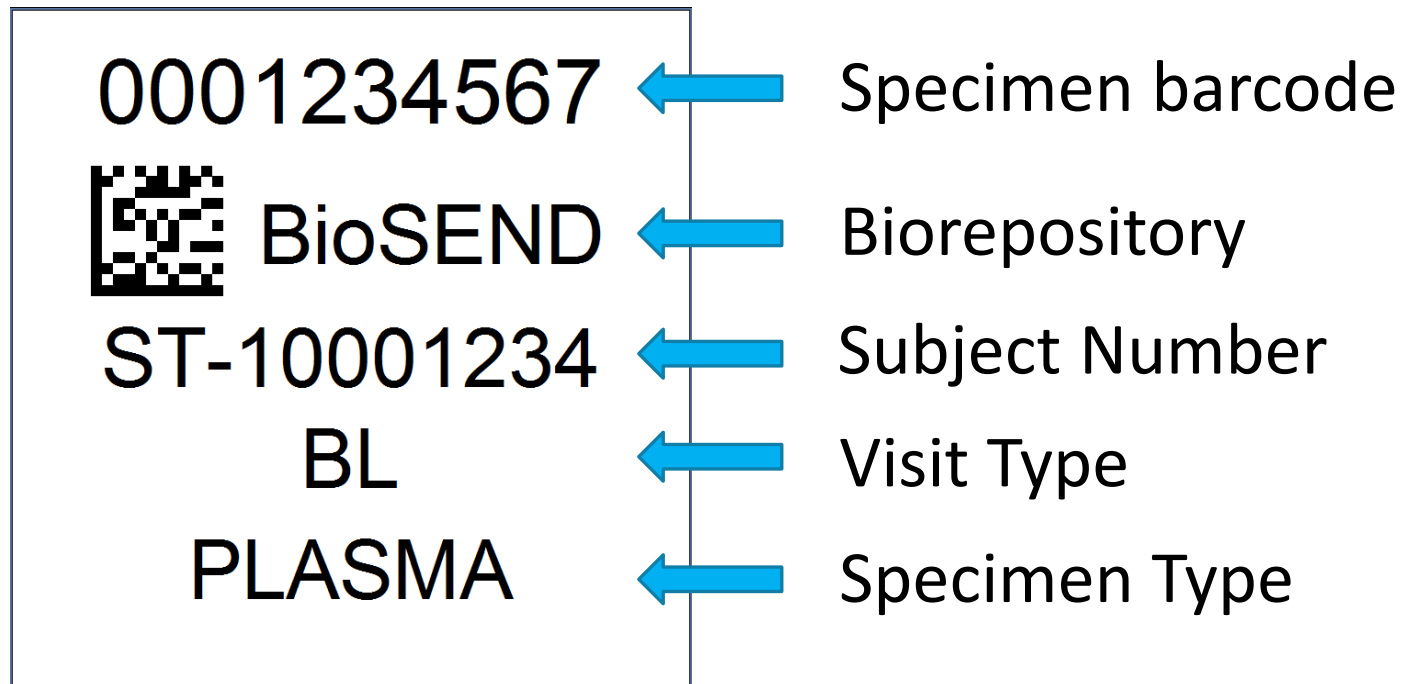
Case labels are placed:

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



# Specimen Label

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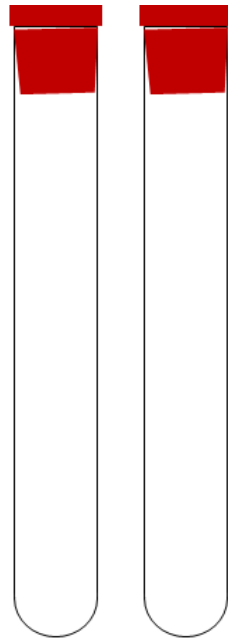




# Sample Collection and Processing

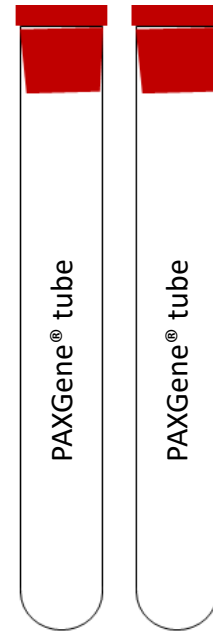
Blood Tube Draw Order for PDBP Study 233

2 x 10ml Serum Tubes



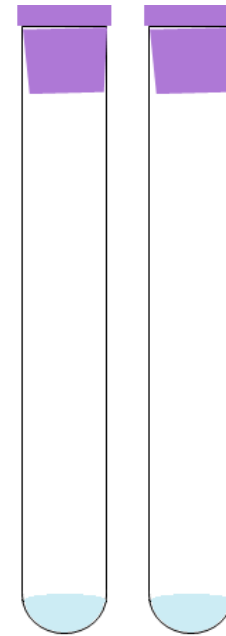
1

2 x 2,5ml PAXGene® Tubes



2

2 x 10ml EDTA Tubes



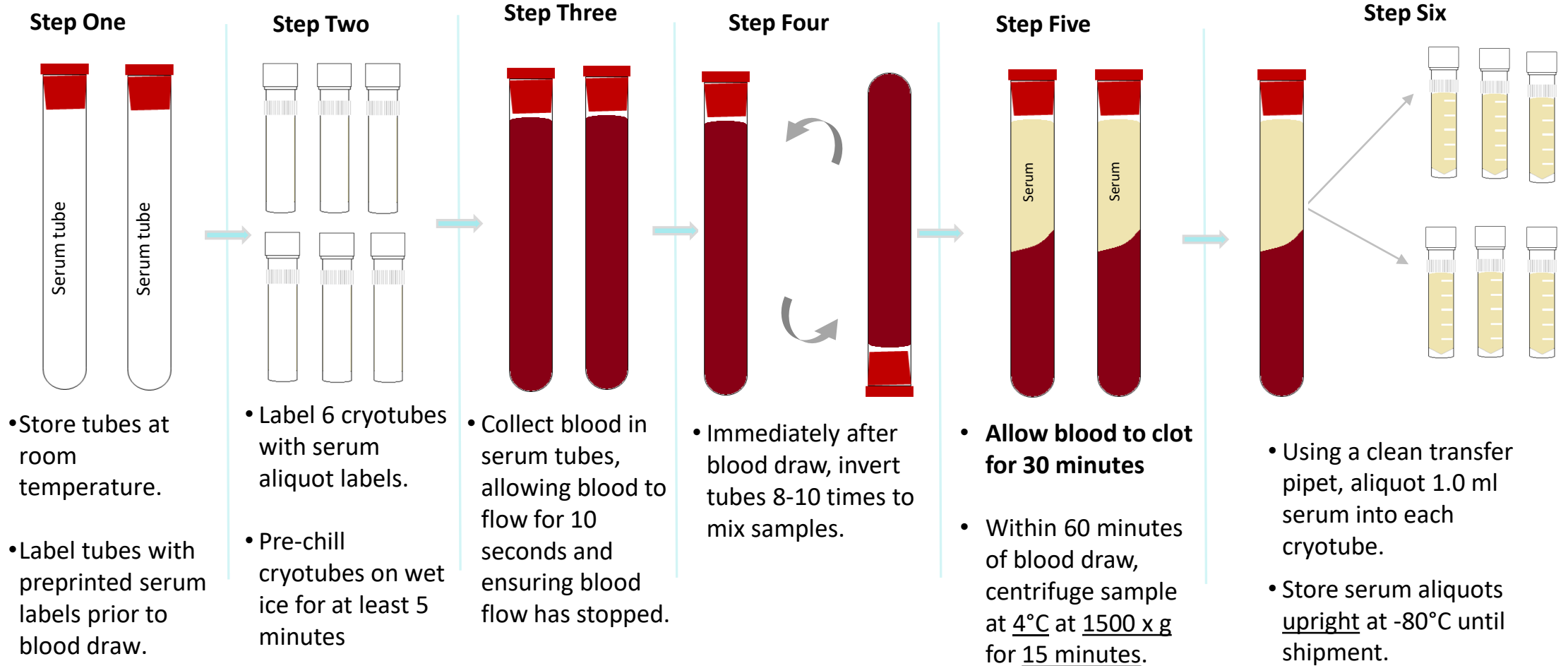
3

1 x 3ml EDTA Tube



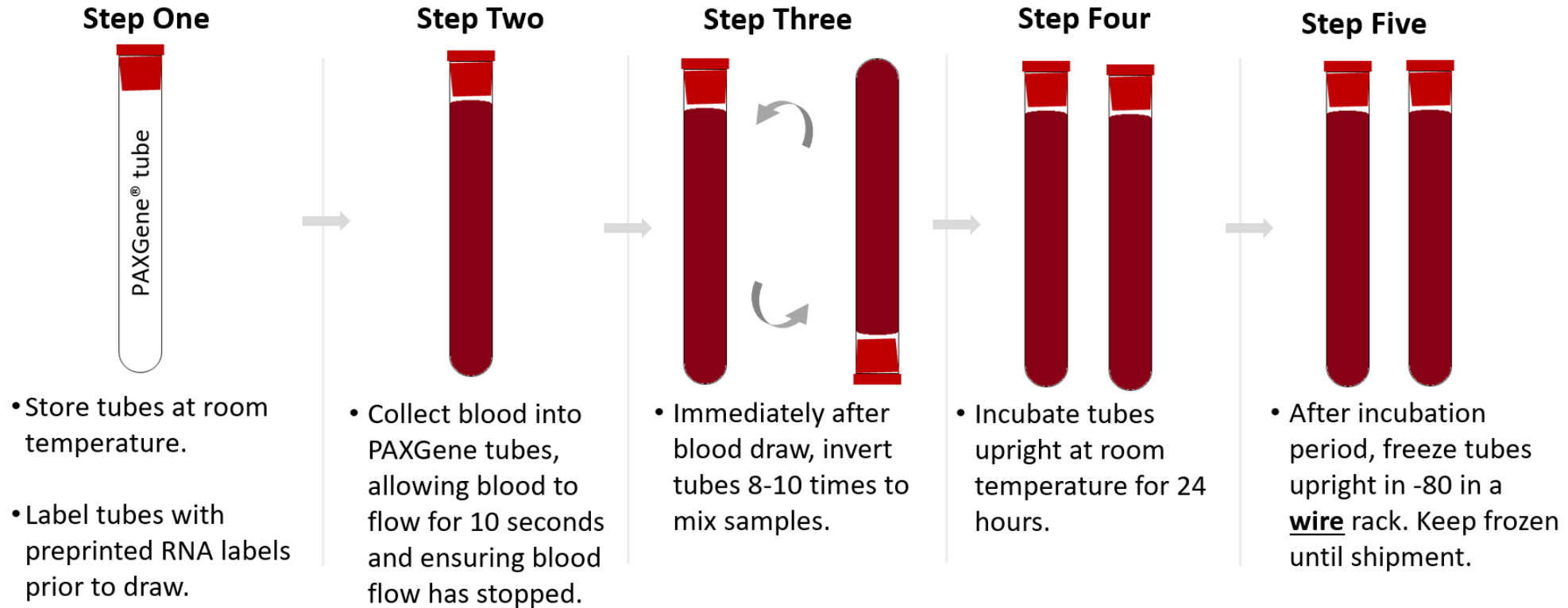
4

# Sample Collection and Processing: Serum

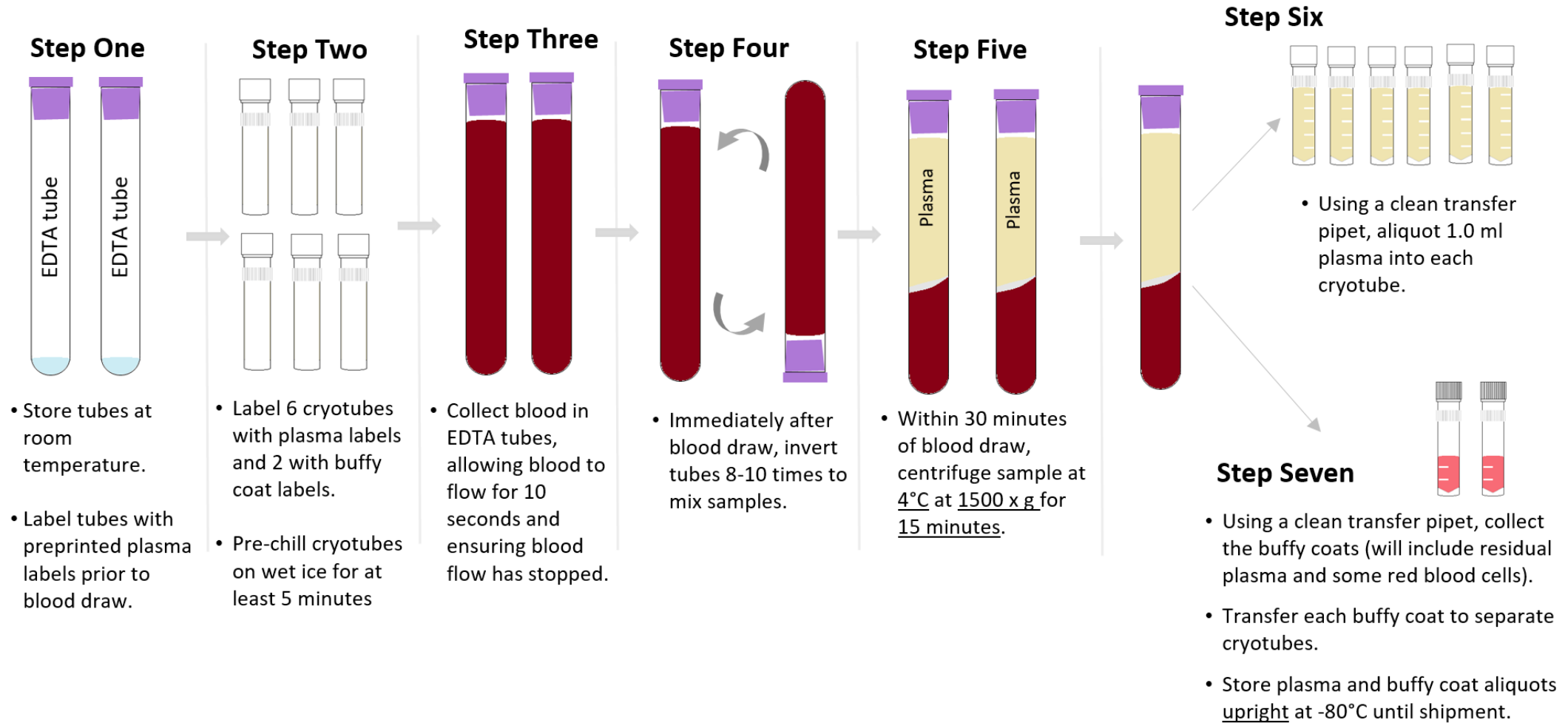


# Sample Collection and Processing: RNA

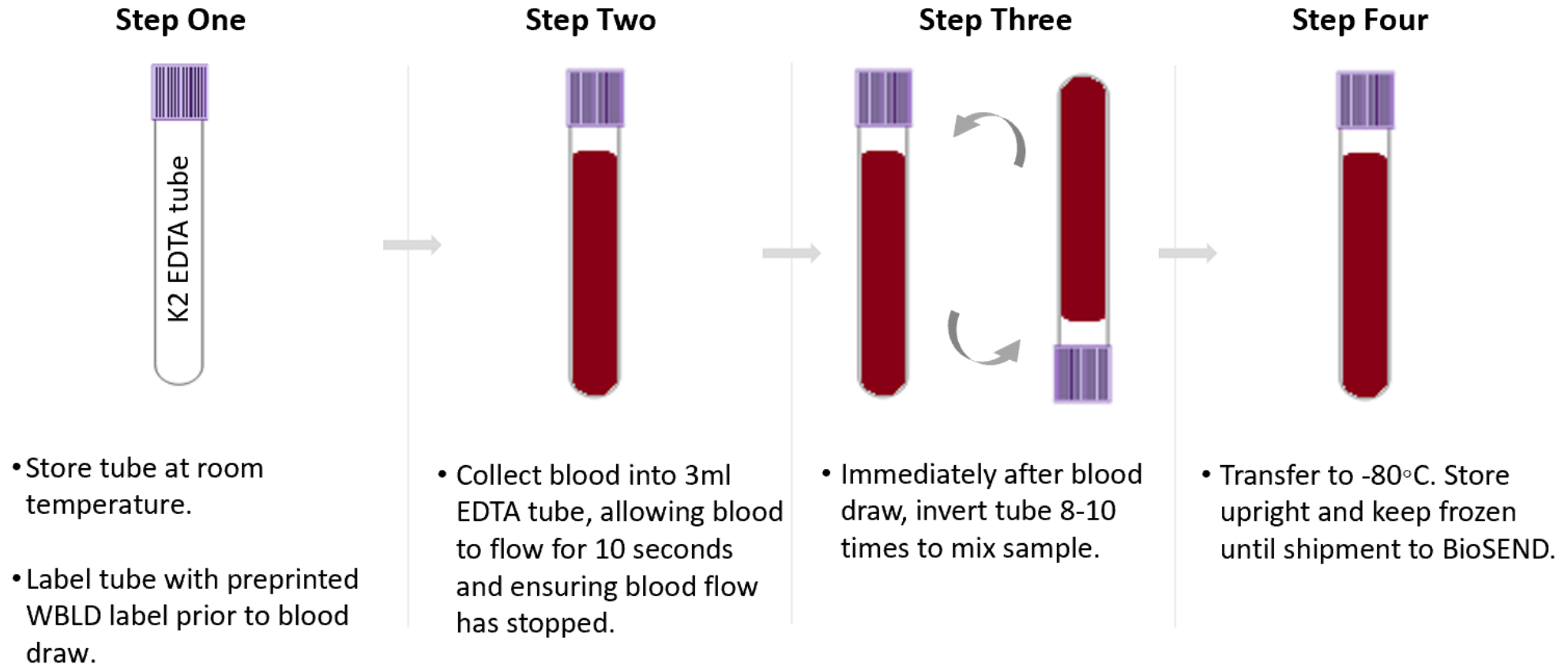
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# Sample Collection and Processing: Plasma & Buffy Coat



# Sample Collection and Processing: Whole Blood



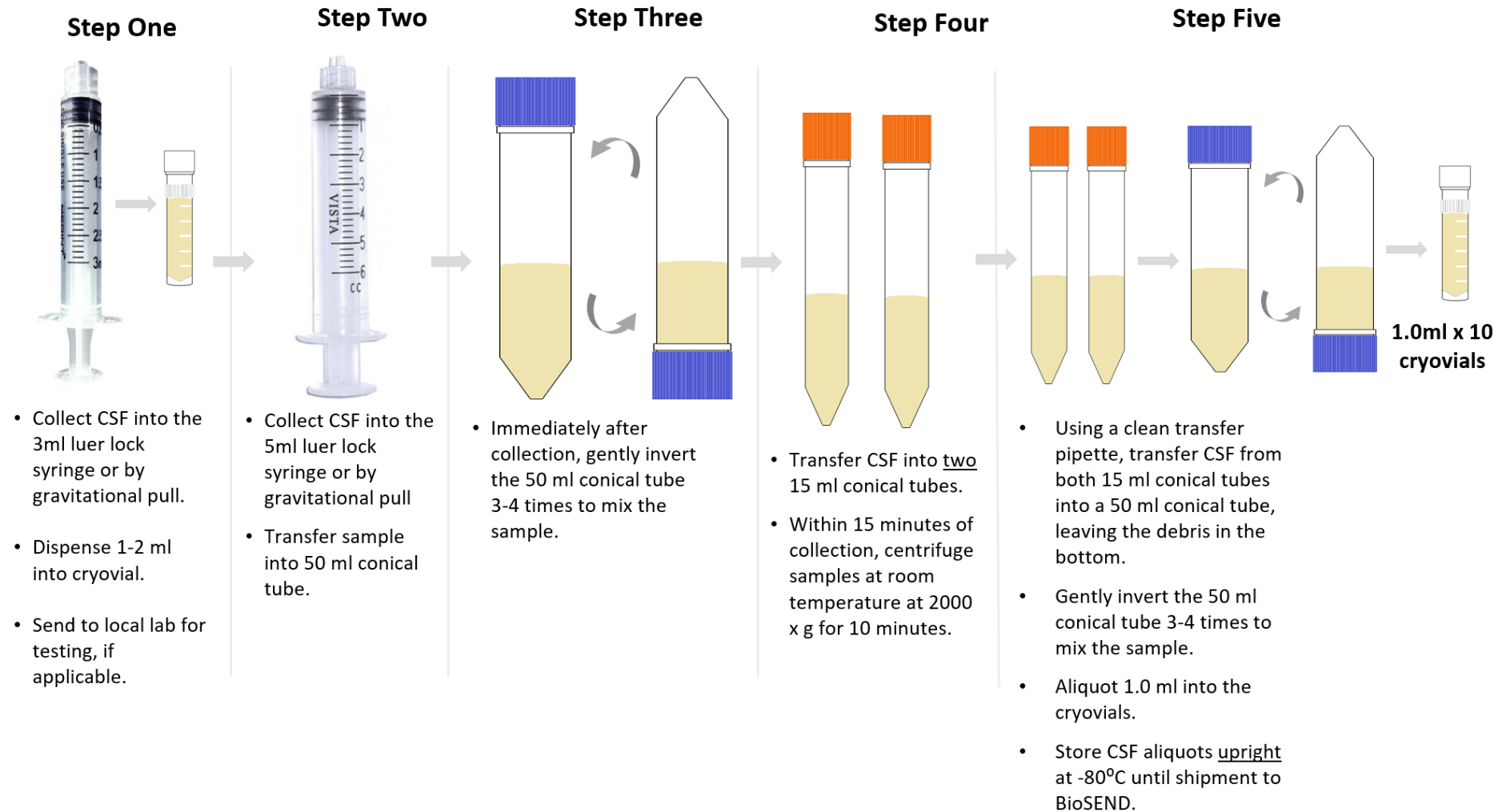
# Blood Collection Troubleshooting

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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

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## 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

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

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



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

Packing and Shipping Frozen Samples

Shipper's Declaration not Required.

Dry Ice amount must be in kilograms.

Note: 2 lbs. = 1 kg.

Airwaybills / airmails must have the following:  
1. Dry Ice; 9; UN 1845  
2.  $\frac{\text{Number}}{\text{(Number pkgs)}} \times \frac{\text{wt}}{\text{(wt)}} \text{ Kg}$

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

9

06426 1/01 FRD

The form is a diamond-shaped label with a black and white striped pattern. It contains fields for shipper and consignee information, a large '9' in the center, and the UN 1845 hazard code. Red arrows point to specific fields with explanatory text.

# Shipping Samples


UPS resources available on BioSEND website

The screenshot shows the BioSEND website navigation menu. The logo is 'NINDS BioSEND'. The main navigation items are 'Accessing Biospecimens', 'Banking Samples', 'Active Studies', and 'About BioSEND'. A blue arrow points from 'Banking Samples' to 'Active Studies'. Below 'Active Studies' is a dropdown menu with the following items: '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', and 'Withdrawn Subject Notification'. A blue arrow points to 'Shipping Information', which is highlighted in a grey box. Below the menu are three small images: a building with green trees, a close-up of a metal container, and a dark interior space.

**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
- Withdrawn Subject Notification



# Shipping Information Page

Links on this page to:

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

## UPS Shipping Resources

1 →

To generate air waybills and schedule UPS pickups for shipments to BioSEND, please visit the UPS ShipExec™ Thin Client [website](#).

2 →

For instructions on how to use the UPS ShipExec™ Thin Client website, please refer to the [BioSEND UPS ShipExec™ Thin Client Guide](#)

3 →

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™

4 →

The screenshot shows the UPS ShipExec™ Thin Client Home Page. At the top, there is a navigation bar with the ShipExec logo and links for Home, My Account, and My Site. Below the navigation bar, the page title reads "Welcome to the ShipExec™ Thin Client Home Page". The main content area is divided into two columns: "System Notifications" and "Company Notifications". Under "System Notifications", there are two links: "ShipExec Documentation" and "Importing Your Personal Address Book". Under "Company Notifications", there is a message: "No Company Notifications to display". A large video player overlay is centered on the page, showing a play button and a progress bar at the bottom indicating 0:58 / 9:18. The video player also includes volume, full screen, and other standard controls.

# Shipping Samples – UPS ShipExec™

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**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

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Please notify BioSEND ahead of shipment

- Please complete the Sample Collection and Processing Form in REDCap ahead of shipment (can be completed 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](mailto: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

# NINDS BIOSEND

[Returning?](#)

AAA  
+ -

Please complete the Specimen Collection and Processing Form, below.

Page 1 of 3

LBD Emory Study (PDBP Study ID 238)

**Study Site**

**Email address of staff member completing this form**

*Note: A copy of the completed sample form and the shipping manifest will be sent to this address.*

**GUID**

**Sex (used for DNA quality control)**

**Visit**

**ST Number**   
eg, ST-1001234

[Next Page >>](#)

[Save & Return Later](#)



# Sample Collection and Processing Form

Direct link:

<http://kits.iu.edu/biosend/DLBCSampleForm>


Second page captures processing information

## Blood Collection and Processing

Date of venipuncture blood collection

 Today M-D-Y

Time of venipuncture blood collection

 Now H:M  
Use 24 Hour clock

SERUM (red-top tubes, 10 mL)


Was blood collected and processed for SERUM?

Yes

No

reset

Time of SERUM tube centrifugation

 Now H:M  
Use 24 Hour clock

Duration of SERUM tube centrifugation

minutes

Rate of SERUM tube centrifugation

x g

Temperature of SERUM tube centrifugation

degrees Celsius

Total volume of SERUM collected

mL

Number of SERUM aliquots created

Each aliquot should be 1 mL

Time SERUM aliquots were placed in freezer

 Now H:M  
Use 24 Hour clock

# Sample Collection and Processing Form

Direct link: <http://kits.iu.edu/biosend/DLBCSampleForm>

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

Page 6

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the Frozen Shipping Manifest will be emailed to you for Subject [subj\_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 <sup>rd</sup> Monday in January	Martin Luther King, Jr Day
4 <sup>th</sup> Monday in May	Memorial Day
June 19	Juneteenth (observed)
July 4	Independence Day (observed)
1 <sup>st</sup> Monday in September	Labor Day
4 <sup>th</sup> Thursday in November	Thanksgiving
4 <sup>th</sup> 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.

# Contact Info

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Indiana University

[biosend@iu.edu](mailto:biosend@iu.edu)

317-278-0594

<https://biosend.org>