



Longitudinal Imaging Biomarkers of Disease Progression in DLB

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

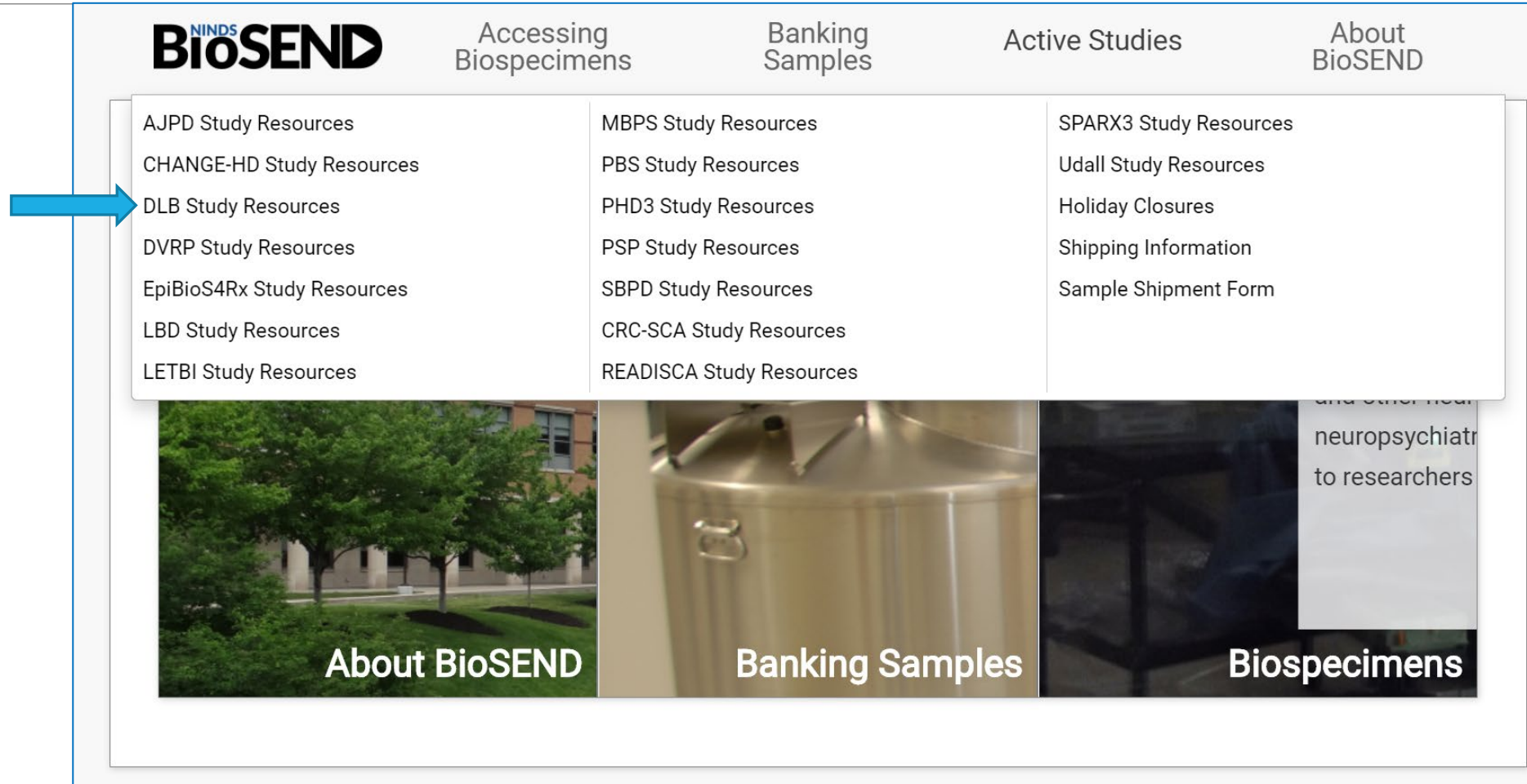
Questions? Email biosend@iu.edu

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

Kit Ordering – Biosend.org



The screenshot shows the Biosend.org website navigation menu. The logo is **NINDS BioSEND**. The main navigation tabs are: **Accessing Biospecimens**, **Banking Samples**, **Active Studies**, and **About BioSEND**. A blue arrow points to the **DLB Study Resources** link in the **Accessing Biospecimens** dropdown menu.

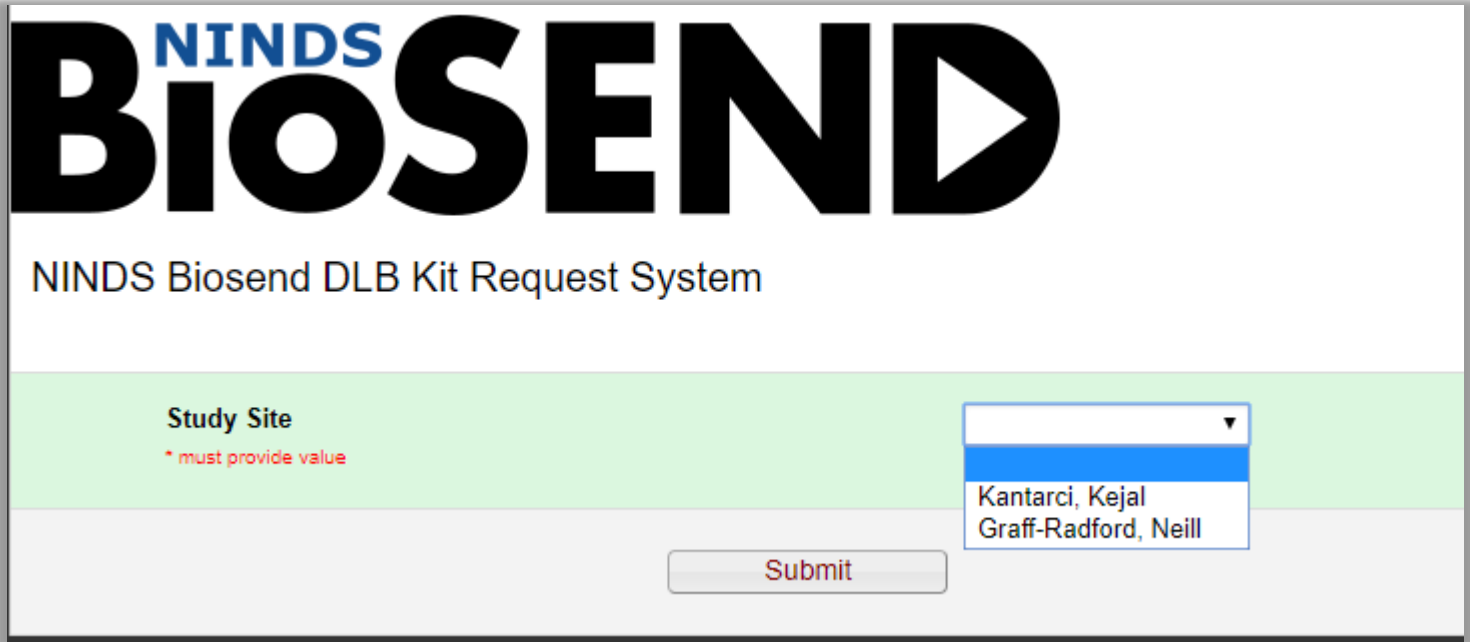
Accessing Biospecimens	Banking Samples	Active Studies	About BioSEND
AJPD Study Resources	MBPS Study Resources	SPARX3 Study Resources	
CHANGE-HD Study Resources	PBS Study Resources	Udall Study Resources	
DLB Study Resources	PHD3 Study Resources	Holiday Closures	
DVRP Study Resources	PSP Study Resources	Shipping Information	
EpiBioS4Rx Study Resources	SBPD Study Resources	Sample Shipment Form	
LBD Study Resources	CRC-SCA Study Resources		
LETBI Study Resources	READISCA Study Resources		

Below the navigation menu are three image-based sections:

- About BioSEND**: Image of a building and trees.
- Banking Samples**: Image of a large metal storage tank.
- Biospecimens**: Image of a laboratory setting with a sign that reads "and other neuropsychiatr to researchers".

BioSEND Kit Request Module

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



The screenshot shows the NINDS BioSEND DLB Kit Request System interface. At the top, the logo reads "NINDS BioSEND" in large, bold letters, with "NINDS" in blue and "BioSEND" in black. Below the logo, the text "NINDS Biosend DLB Kit Request System" is displayed. The main form area has a light green background and contains a "Study Site" label with a red asterisk and the text "* must provide value". To the right of this label is a drop-down menu with a blue header and two options: "Kantarci, Kejal" and "Graff-Radford, Neill". Below the form area is a grey "Submit" button.

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? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	reset
Is the shipping address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	reset
Is the e-mail address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> 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>	<input type="text"/>	Expand
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 or Annual Visit Kit
- 6-Month Visit 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

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input checked="" type="checkbox"/> Baseline or Annual Visit Kit <input type="checkbox"/> 6-Month Visit 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>	
CSF Sprotte® Needle Gauge <small>* must provide value</small>	<input type="radio"/> 22 <input type="radio"/> 24 reset
Baseline or Annual Visit Kit Quantity <small>* must provide value</small>	<input type="text"/> <small>If you need more than 10 kits or labels, please use the file upload option or submit multiple requests.</small>

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

Baseline or Annual Visit Kit Quantity <small>* must provide value</small>	<input type="text" value="2"/> <small>If you need more than 10 kits or labels, please use the file upload option or submit multiple requests.</small>
<p>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.</p> <p>Attachment:  BioSEND Kit IDs Template.xlsx (0.01 MB)</p>	
<p>If you are using the provided template to upload Biorepository IDs and Visits, please upload your template file here.  Upload document</p>	
1st Kit Visit ID <small>(only if not using file upload option)</small>	<input type="text" value="ST-00012345"/> <small>e.g. ST-00012345</small>
1st Kit Visit Month	<input type="text" value="12 Month"/>
2nd Kit Visit ID <small>(only if not using file upload option)</small>	<input type="text" value="ST-0012346"/> <small>e.g. ST-00012345</small>
2nd Kit Visit Month	<input type="text" value="36 Month"/>

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

Automatic Kit Shipments

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

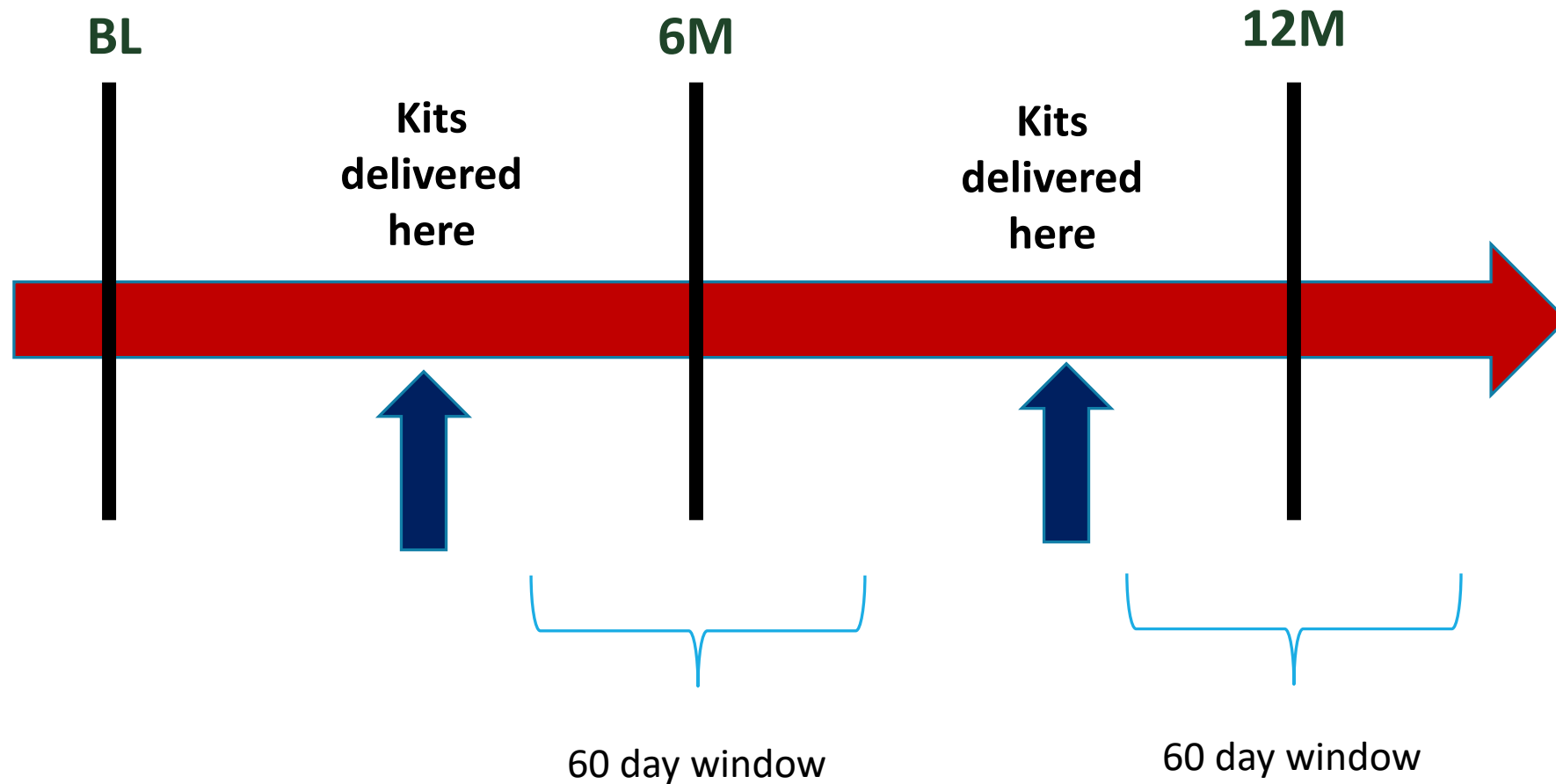
Schedule gives 2 month window around the longitudinal study visit target (1 month on either side)

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



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 or Annual Visit Kit <input type="checkbox"/> 6-Month Visit 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>
Supplemental Kit Quantity <small>* must provide value</small>	<input type="text"/> <small>If you need more than 10 kits or labels, please use the file upload option or submit multiple requests.</small>
Comments	<div style="border: 1px solid #ccc; height: 100px;"></div> <p style="text-align: right;">Expand</p>
Each Supplemental Kit Contains: 2 100 ml absorbent sheets 2 6-tube bubble pouches 2 Cryoboxes 20 Siliconized sterile cryogenic vials (2 ml) 2 Screw-top centrifuge tubes (15 ml) 2 Screw-top centrifuge tubes (50 ml) 2 Biohazard bags 2 Vacutainer® - PAXGene® tubes (2.5 ml) 2 Monoject- Lavender-top EDTA tubes (10 ml) 2 Vacutainer® - Purple-top EDTA tubes (6 ml) 2 Vacutainer® - Red-top serum tubes (10 ml) 2 Disposable transfer pipettes (1ml) 2 Warning label packets	

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 or Annual Visit Kit <input type="checkbox"/> 6-Month Visit 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>	
6-Tube Bubble Pouch	<input type="radio"/> 2 <input type="radio"/> 4 reset
Cryobox	<input type="radio"/> 2 <input type="radio"/> 4 reset
Siliconized Sterile Cryogenic Vial (2 ml)	<input type="radio"/> 10 <input type="radio"/> 20 reset
FedEx® return Airbill	<input type="radio"/> 2 <input type="radio"/> 4 reset
Lumbar Puncture Trays with Lidocaine	<input type="radio"/> 2 <input type="radio"/> 4 reset
Needles - Introducer	<input type="radio"/> 5 reset

Multiple Orders

Kit Type

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

* must provide value

- Baseline or Annual Visit Kit
- 6-Month Visit Kit
- Supplemental Kit
- Extra Supplies

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

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
Ninds Biosend LDB Kit Request System

Study Site: Scherzer, Clemens

Harvard Medical School - Scherzer, Clemens
Kara Page
65 Landsdowne St
Rm #327
Cambridge, MA 02139
(617) 768-8677
kjpage@partners.org
ksburke@partners.org

Is the contact name above correct? Yes No

Is the shipping address above correct? Yes No

Is the e-mail address above correct? Yes No

Kit Type
Please allow two weeks for shipment

Baseline or Annual Visit Kit
 6-Month Visit Kit
 Supplemental Kit
 Extra Supplies

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

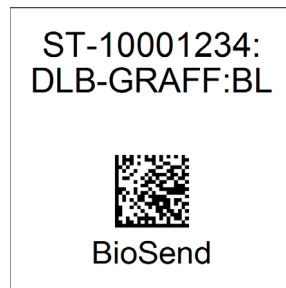
Comments

Submit

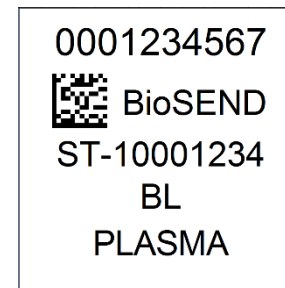
Sample Labelling

Labels are provided by Indiana University

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

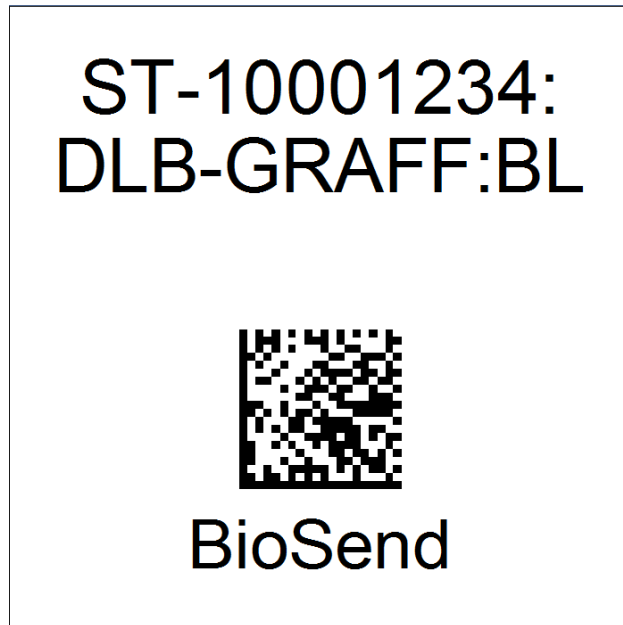


Case Labels



Specimen Labels

Case Label



Subject Number



Study – PI & Visit

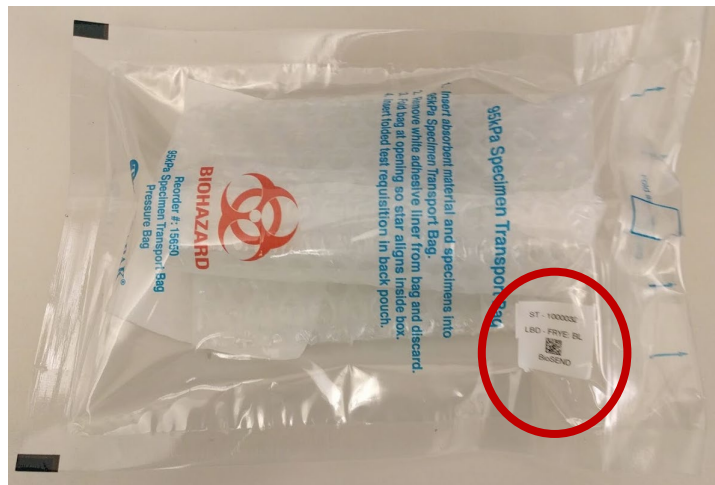


Biorepository Name

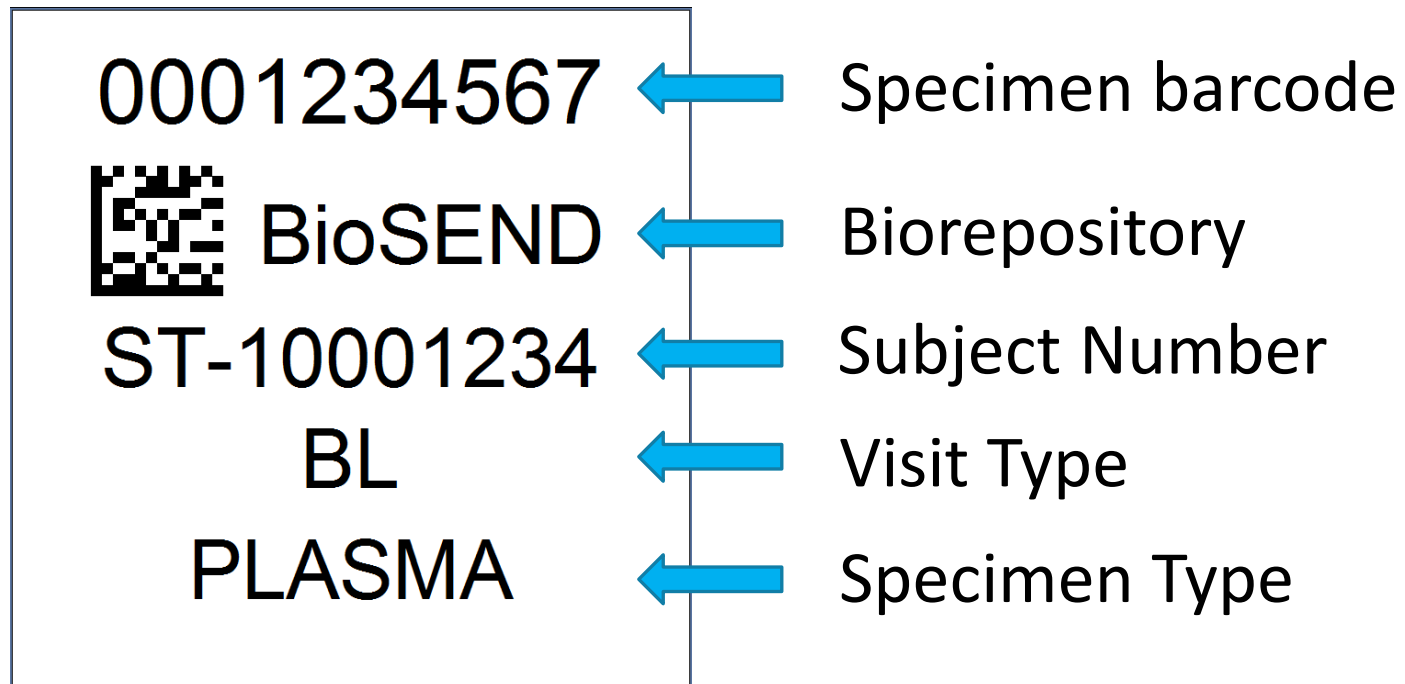
Case Labels

Case labels are placed:

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

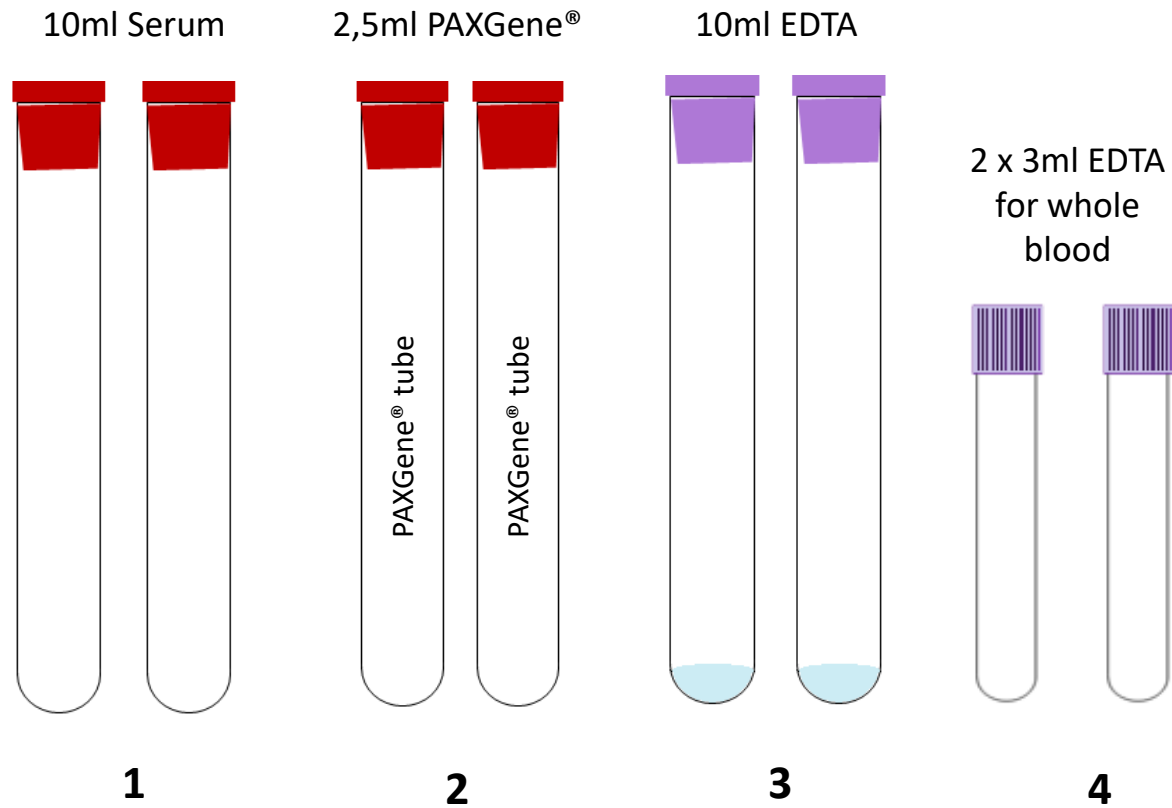


Specimen Label

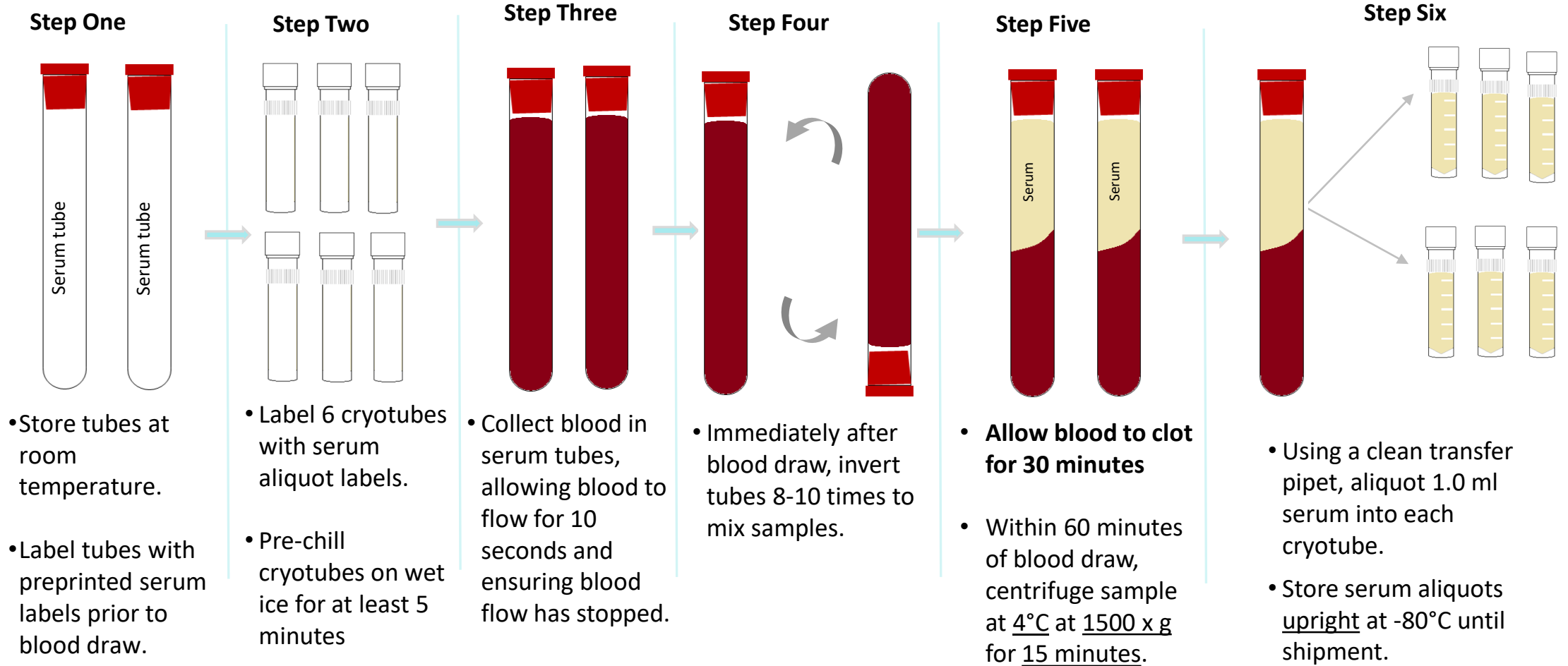


Sample Collection and Processing

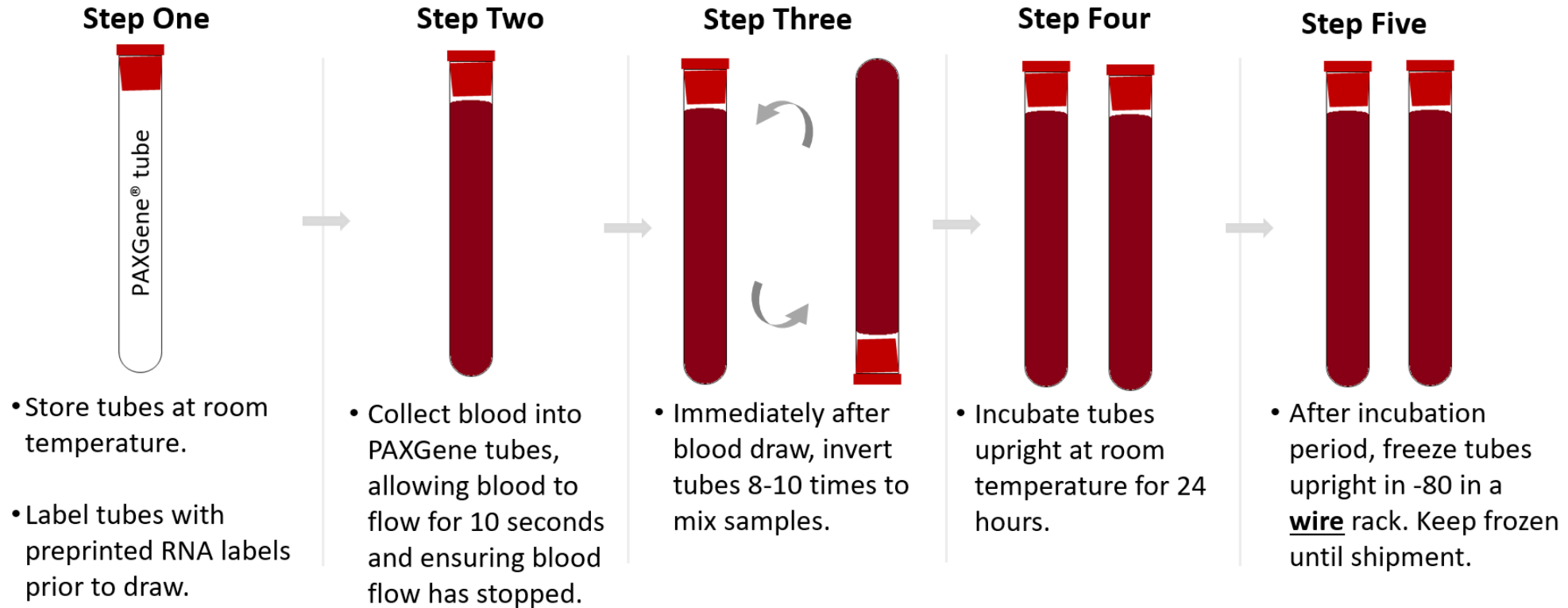
Blood Tube Draw Order



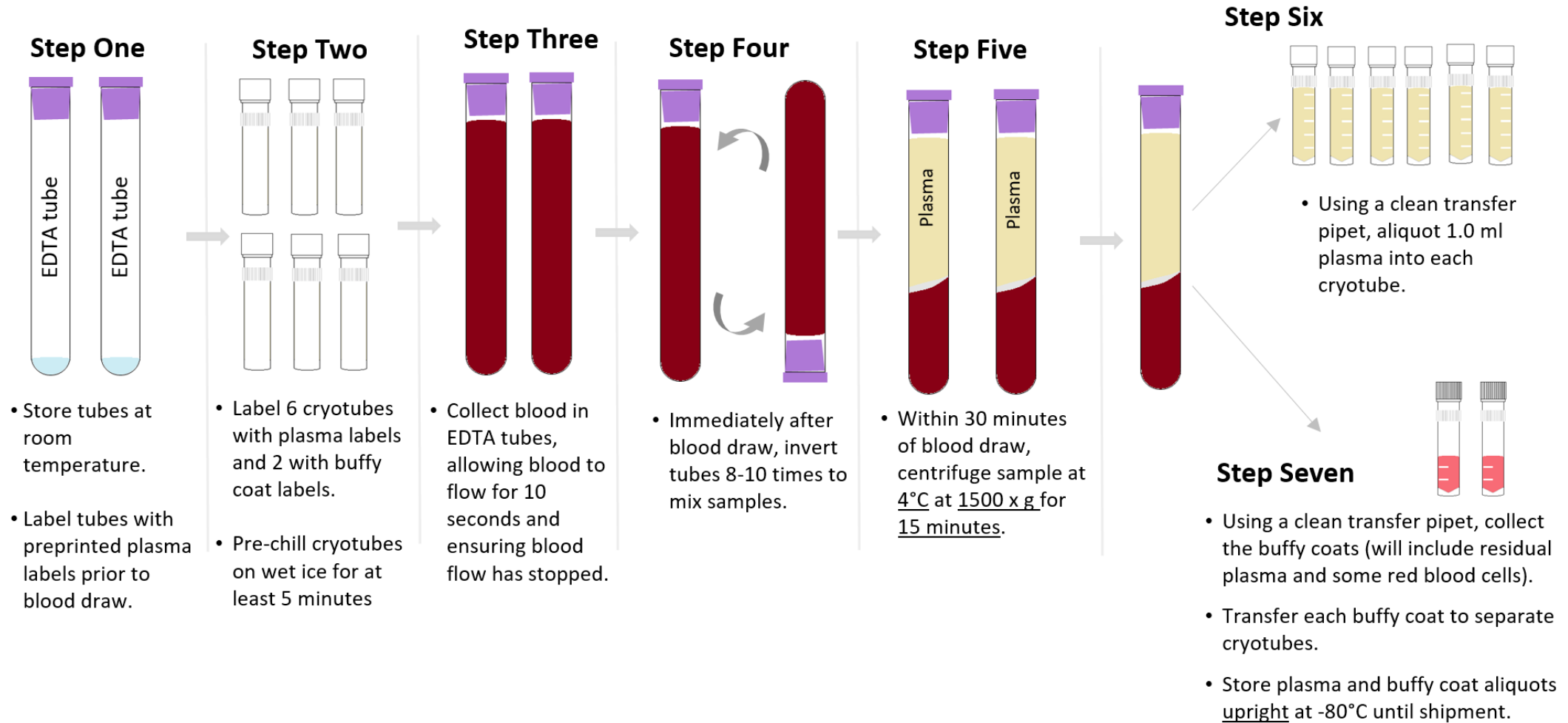
Sample Collection and Processing: Serum



Sample Collection and Processing: RNA



Sample Collection and Processing: Plasma & Buffy Coat



Sample Collection and Processing: Whole Blood

Step One



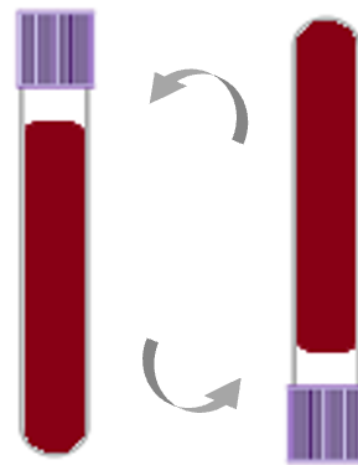
- Store tubes at room temperature.
- Label tubes with preprinted WBLD label prior to blood draw.

Step Two



- Collect blood into both 3ml EDTA tubes, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



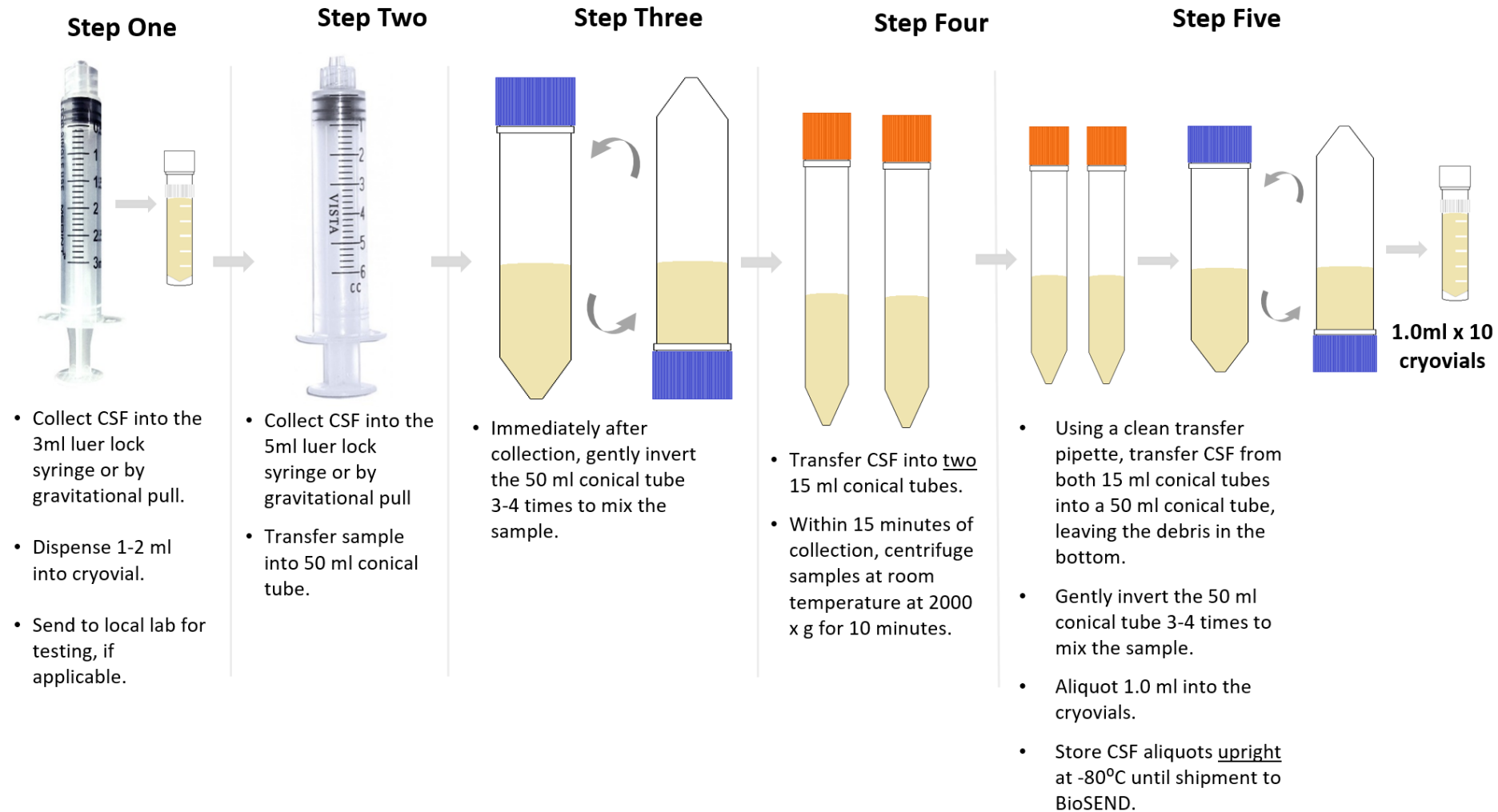
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

Step Four



- Transfer to -80°C. Store upright and keep frozen until shipment to BioSEND.

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



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

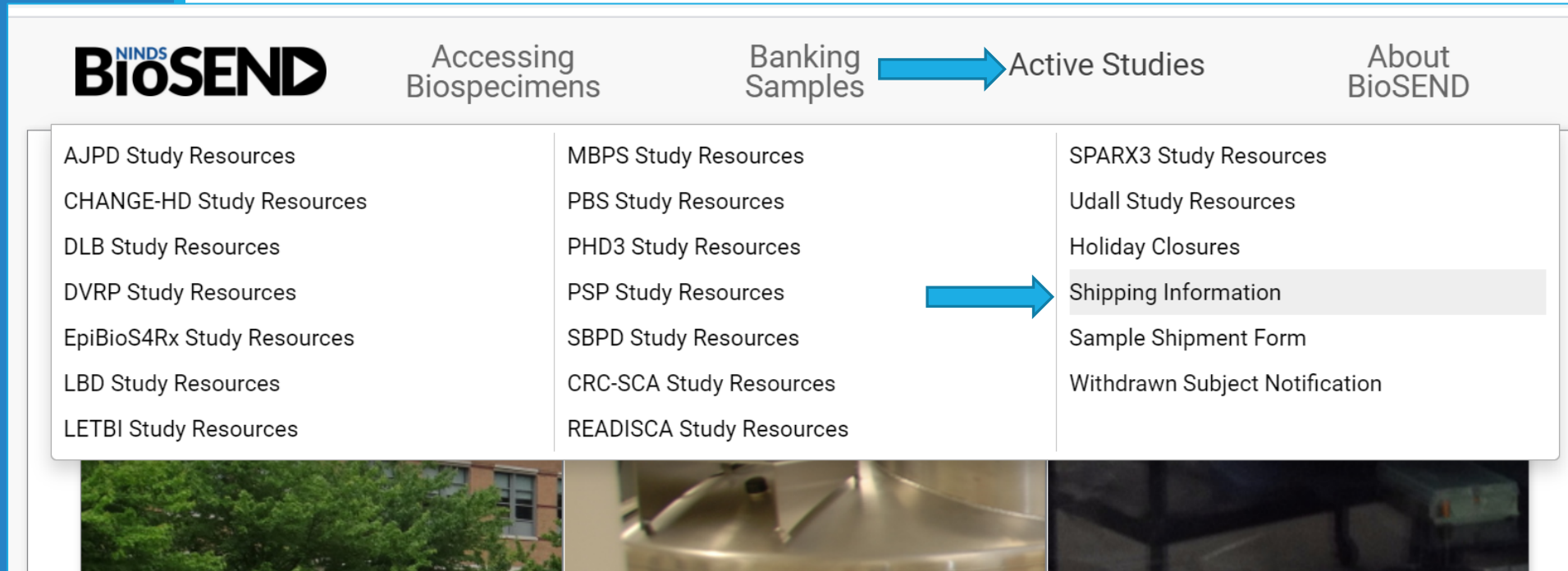
9

06426 1/01 RRD

The form is a diamond-shaped label with a black and white striped pattern. It contains text for shipper's declaration, dry ice amount, and airwaybill requirements. Red arrows point to specific fields: 'Net weight of dry ice in kg' points to the 'Dry Ice' field; 'Your name & address' points to the 'Shipper's Name and Address' field; and 'IU information and address' points to the 'Consignee Name and Address' field. The number '9' is prominently displayed in the center.

Shipping Samples

UPS resources available on BioSEND website



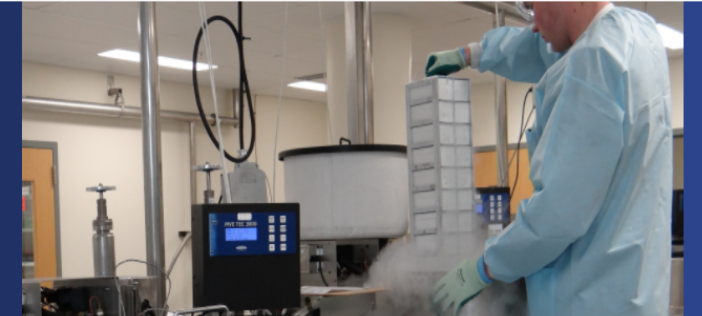
The screenshot shows the BioSEND website navigation menu. The logo is 'NINDS BioSEND'. The main navigation items are 'Accessing Biospecimens', 'Banking Samples', 'Active Studies', and 'About BioSEND'. A blue arrow points from 'Banking Samples' to 'Active Studies'. Below 'Active Studies', a dropdown menu is open, listing various study resources. A blue arrow points to 'Shipping Information', which is highlighted in grey. Below the menu, there 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



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 Samples: Closures

Date	Holiday
January 1	New Year's Day
3 rd Monday in January	Martin Luther King, Jr Day
5 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. Reach out to BioSEND if you are unsure if it is safe to ship. **Last day to ship to BioSEND in 2022 is Wednesday, 12/14. Shipments may resume on January 3rd, 2023.**

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