



# Longitudinal Imaging Biomarkers of Disease Progression in DLB

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BIOSPECIMEN COLLECTION & PROCESSING

# Overview

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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

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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

Questions? Email [biosend@iu.edu](mailto:biosend@iu.edu)

# Site Equipment

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*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

	BL	12M	24M	36M	48M
<b>Whole Blood</b> (2x3ml)	X	X	X	X	X
<b>Plasma</b> (6 x 1ml)	X	X	X	X	X
<b>Buffy coat</b> (2 aliquots)	X	X	X	X	X
<b>Serum</b> (6 x 1ml)	X	X	X	X	X
<b>RNA</b> (2 x 2.5ml)	X	X	X	X	X
<b>CSF</b> (10 x 1ml)	X	X	X	X	X

# Kit Ordering – Biosend.org




Accessing  
Biospecimens

Banking  
Samples


Active Studies

About  
BioSEND

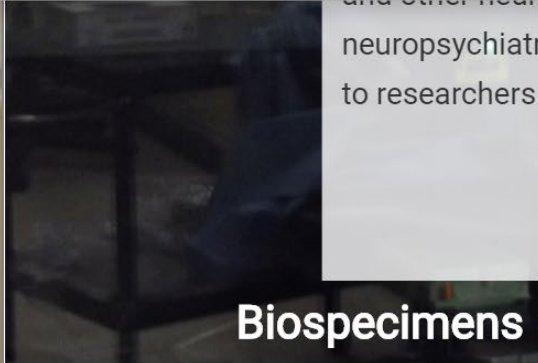
AJPD Study Resources	MBPS Study Resources	SPARX3 Study Resources
CHANGE-HD Study Resources	PBS Study Resources	Udall Study Resources
DLB Study Resources	PHD3 Study Resources	Holiday Closures
DVRP Study Resources	PSP Study Resources	Shipping Information
EpiBioS4Rx Study Resources	SBPD Study Resources	Sample Shipment Form
LBD Study Resources	CRC-SCA Study Resources	
LETBI Study Resources	READISCA Study Resources	



About BioSEND



Banking Samples

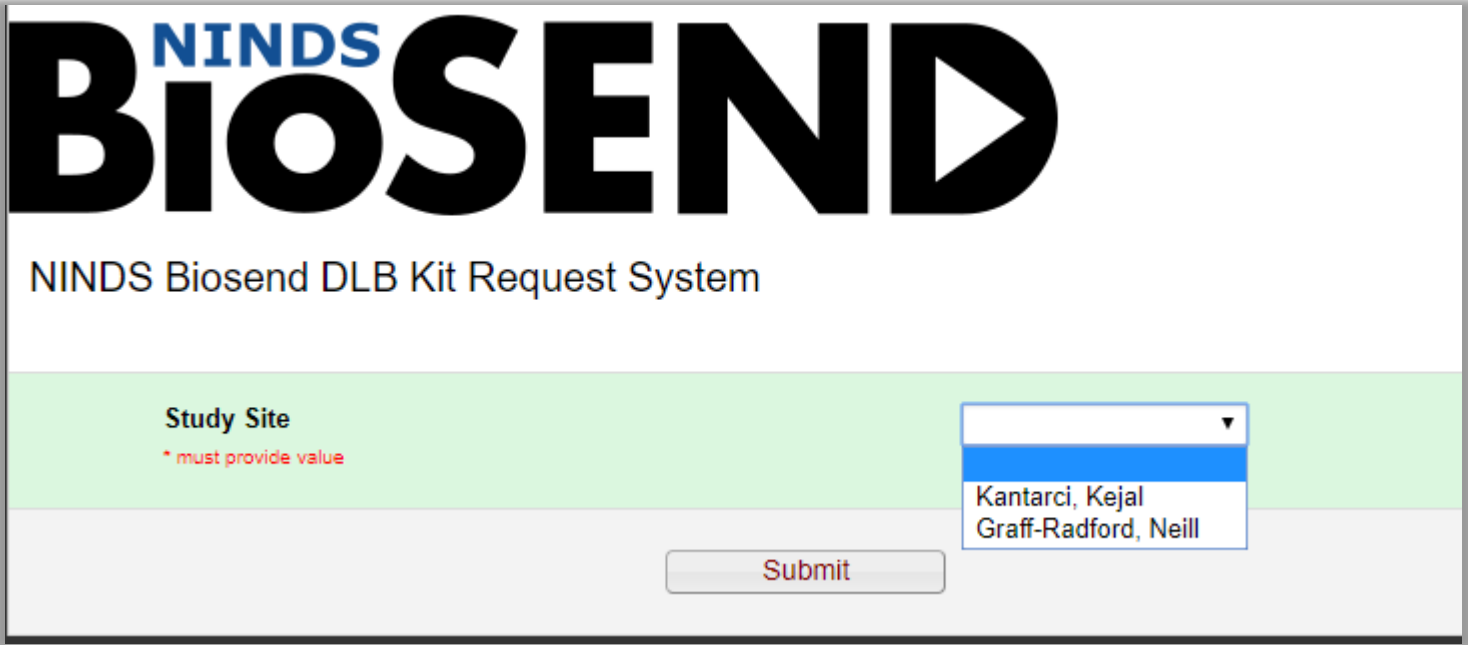


Biospecimens

# BioSEND Kit Request Module

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- <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 "NINDS BioSEND" is displayed, with "NINDS" in blue and "BioSEND" in large black letters. Below the logo, the text "NINDS Biosend DLB Kit Request System" is centered. The main form area has a light green background. On the left, the label "Study Site" is followed by a red asterisk and the text "must provide value". On the right, there is a drop-down menu with a blue header and two options: "Kantarci, Kejal" and "Graff-Radford, Neill". Below the form area, there is a grey bar containing a "Submit" button.

**NINDS BioSEND**

NINDS Biosend DLB Kit Request System

Study Site  
\* must provide value

Kantarci, Kejal  
Graff-Radford, Neill

Submit



# 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?

\* 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

<b>Is the contact name above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
<b>New Contact Name</b> <small>* must provide value</small>	<input type="text"/>	
<b>Is the shipping address above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
<b>New Shipping Address</b> <small>* must provide value</small>	<div><input type="text"/></div> <div>Expand</div>	
<b>Is the e-mail address above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
<b>New e-mail Address</b> <small>* must provide value</small>	<input type="text"/>	

# Kit Type

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**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



<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"/> 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 type="radio"/> 22 <input type="radio"/> 24  <a href="#">reset</a>
<b>Baseline or Annual Visit Kit Quantity</b> <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

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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.

# Annual Visits

Baseline or Annual Visit Kit Quantity	<input type="text" value="2"/>
<small>* must provide value</small>	<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:  <a href="#">BioSEND Kit IDs Template.xlsx</a> (0.01 MB)</p>	
<p>If you are using the provided template to upload Biorepository IDs and Visits, please upload your template file here.</p> <p> <a href="#">Upload document</a></p>	
1st Kit Visit ID (only if not using file upload option)	<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 (only if not using file upload option)	<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

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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)

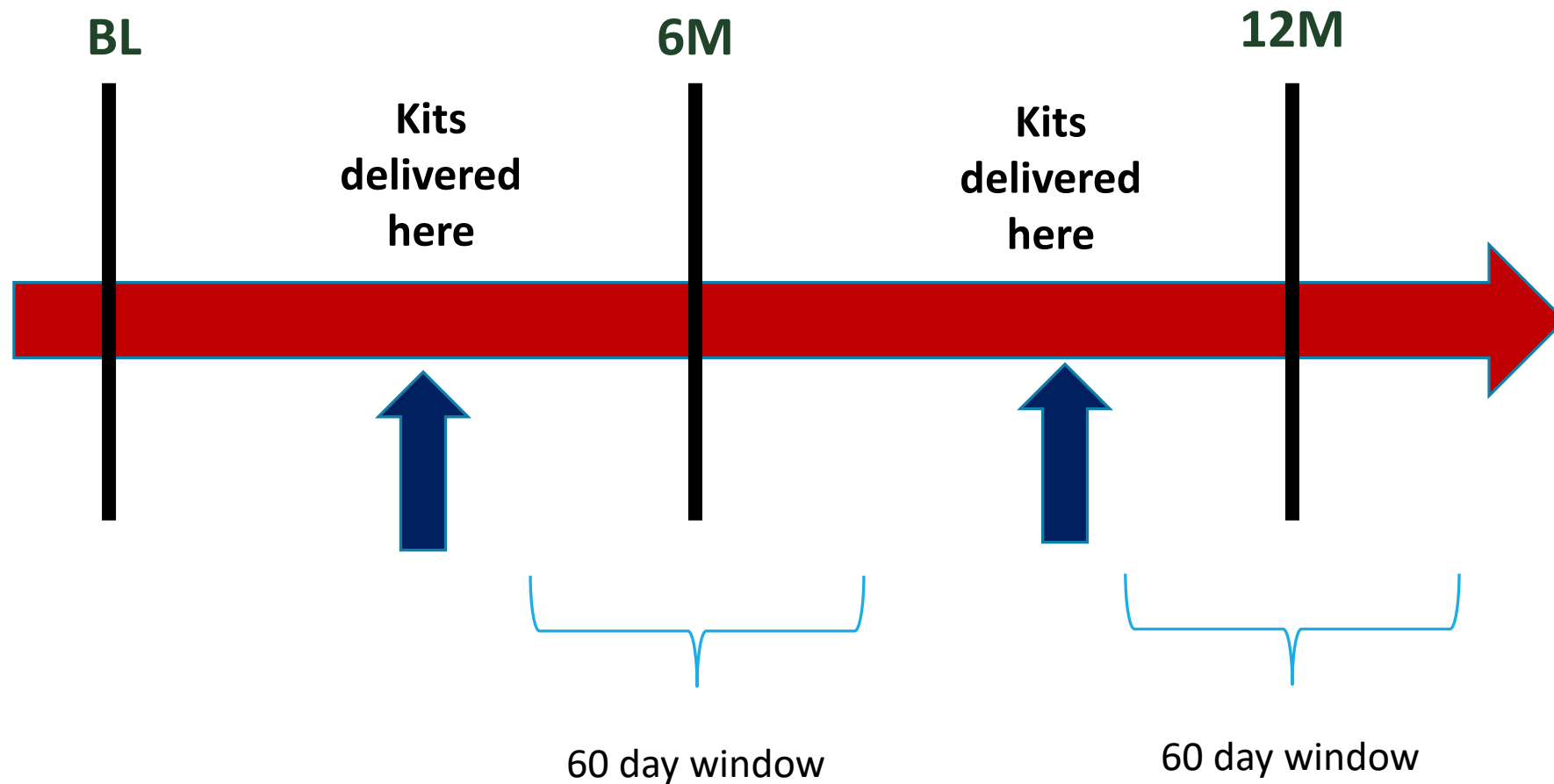
BioSEND will send kits prior to start of study window

- 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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# Supplemental Kit

Contains a variety of  
extra kit components

## 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.

## Supplemental Kit Quantity

\* must provide value

If you need more than 10 kits or labels, please use the file upload option or submit multiple requests.

## Comments

Expand

## 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

<b>Kit Type</b> **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

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<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <i>* must provide value</i>	<input checked="" type="checkbox"/> Baseline or Annual Visit Kit <input checked="" type="checkbox"/> 6-Month Visit Kit <input checked="" 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>
--	---

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  
\* must provide value

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?  
\* 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 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.

Comments

[Expand](#)

**Submit**

# Sample Labelling

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## Labels are provided by Indiana University

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

ST-10001234:  
DLB-GRAFF:BL



BioSend

Case Labels

0001234567



BioSEND

ST-10001234

BL

PLASMA

Specimen Labels

# Case Label

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ST-10001234:  
DLB-GRAFF:BL



BioSend



Subject Number



Study – PI & Visit



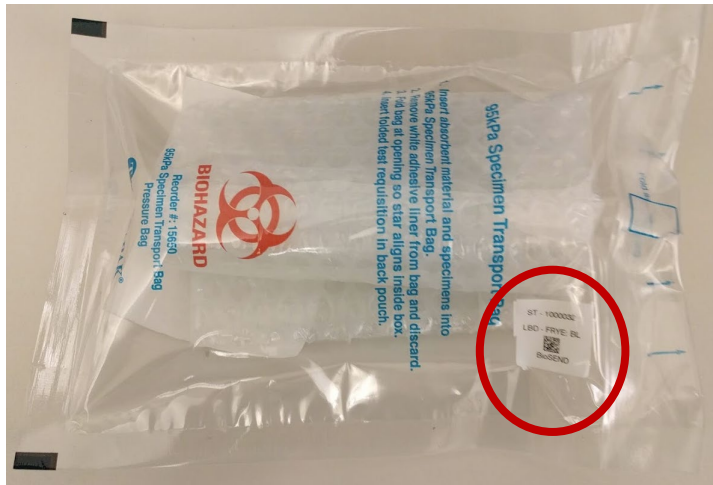
Biorepository Name

# Case Labels

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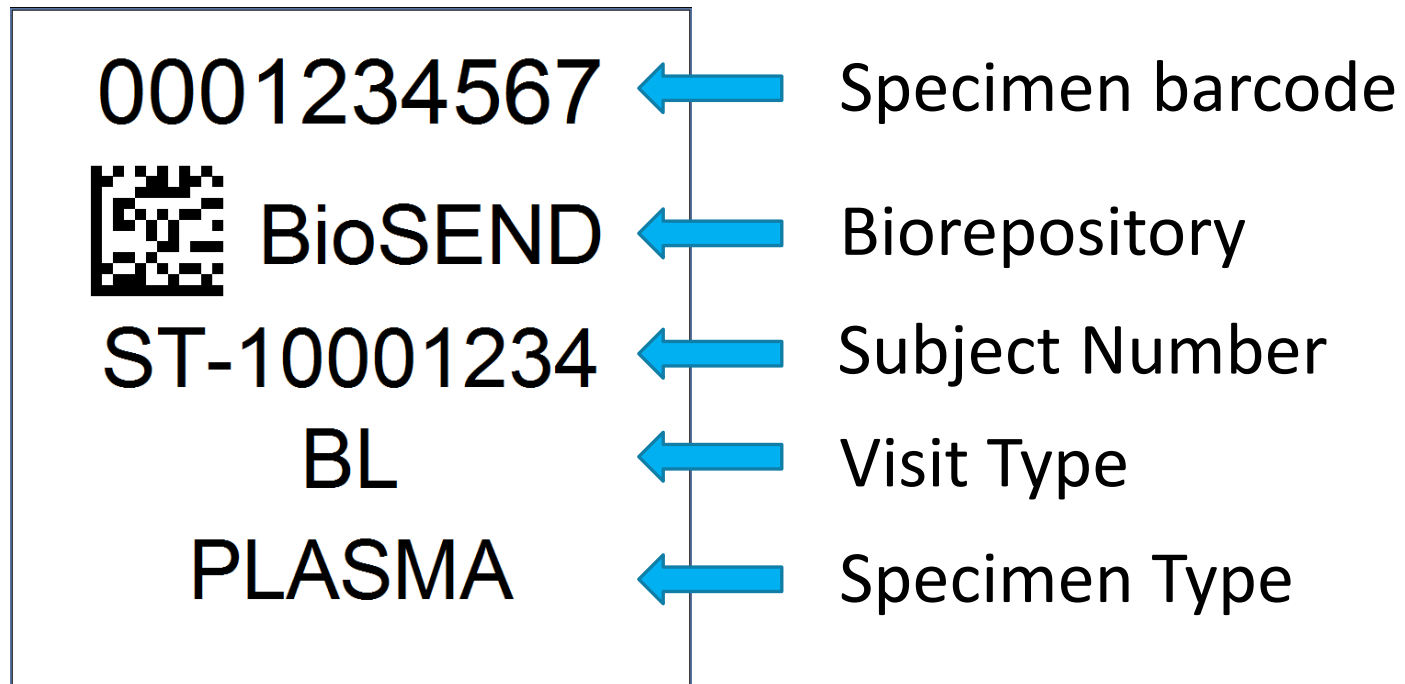
Case labels are placed:

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



# Specimen Label

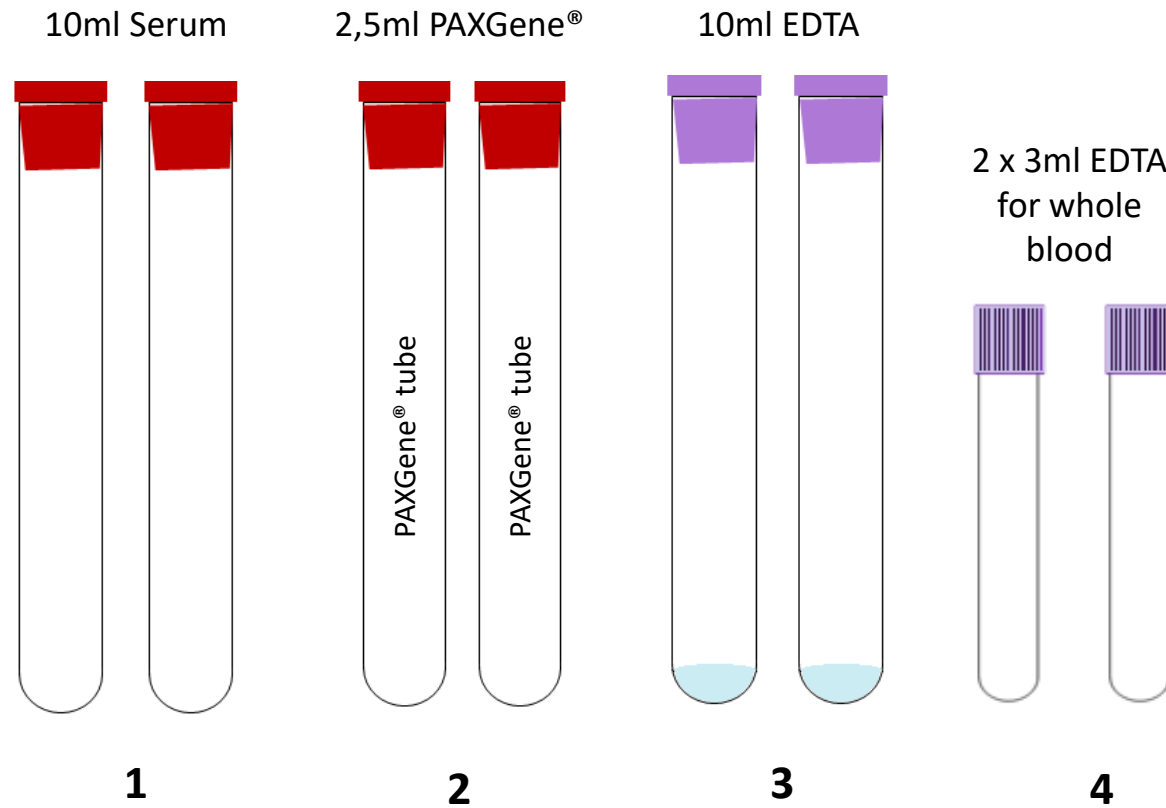
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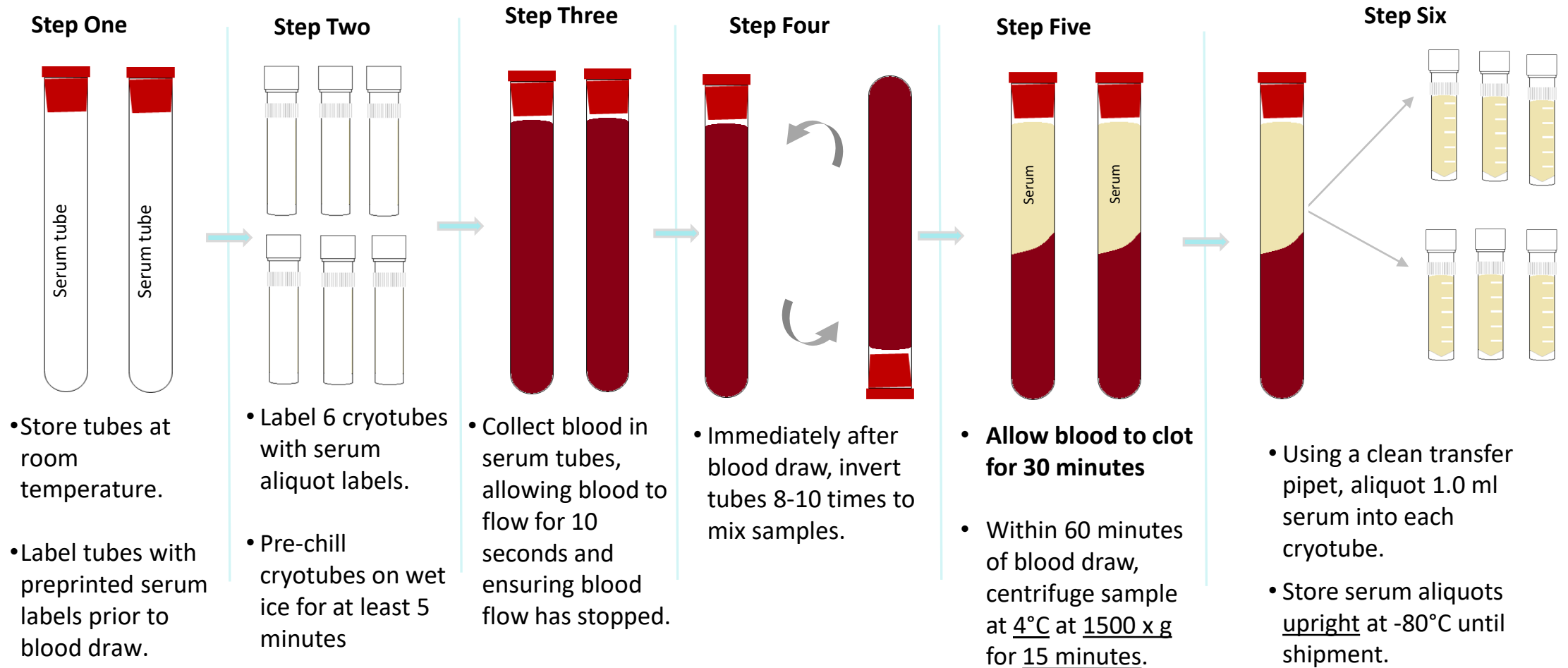


# Sample Collection and Processing

Blood Tube Draw Order

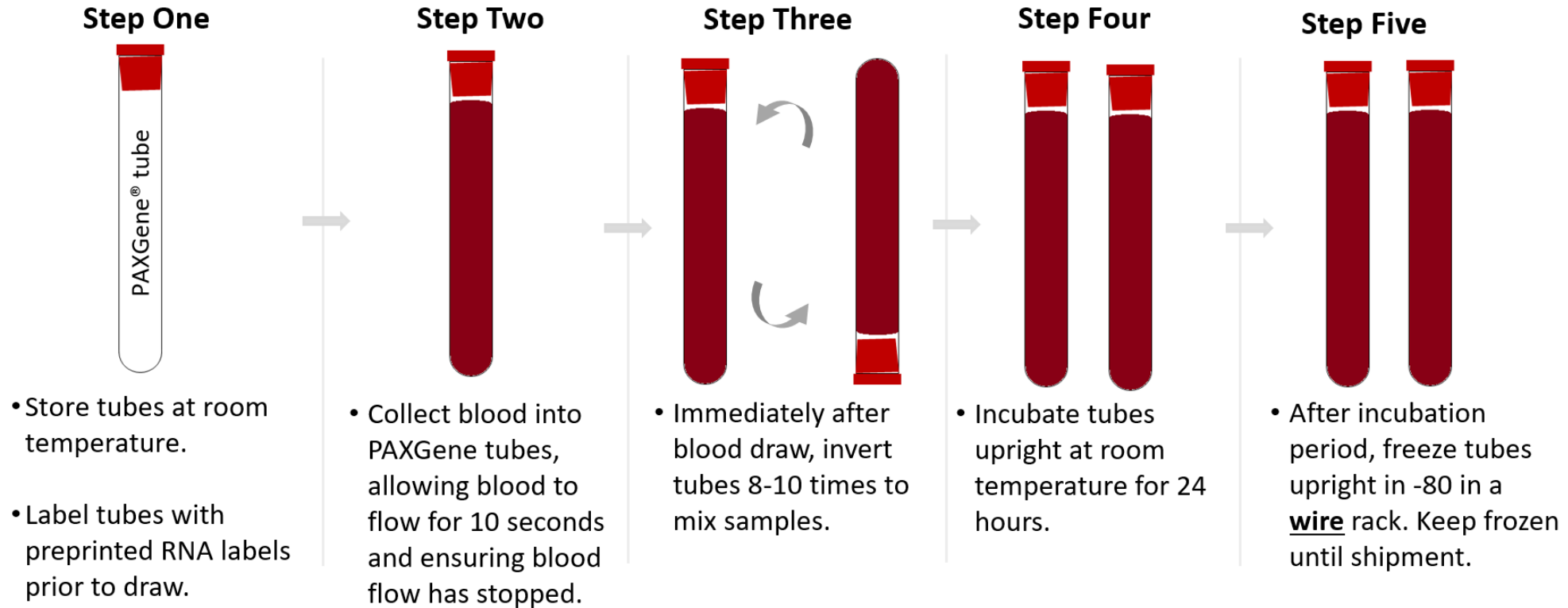


# Sample Collection and Processing: Serum

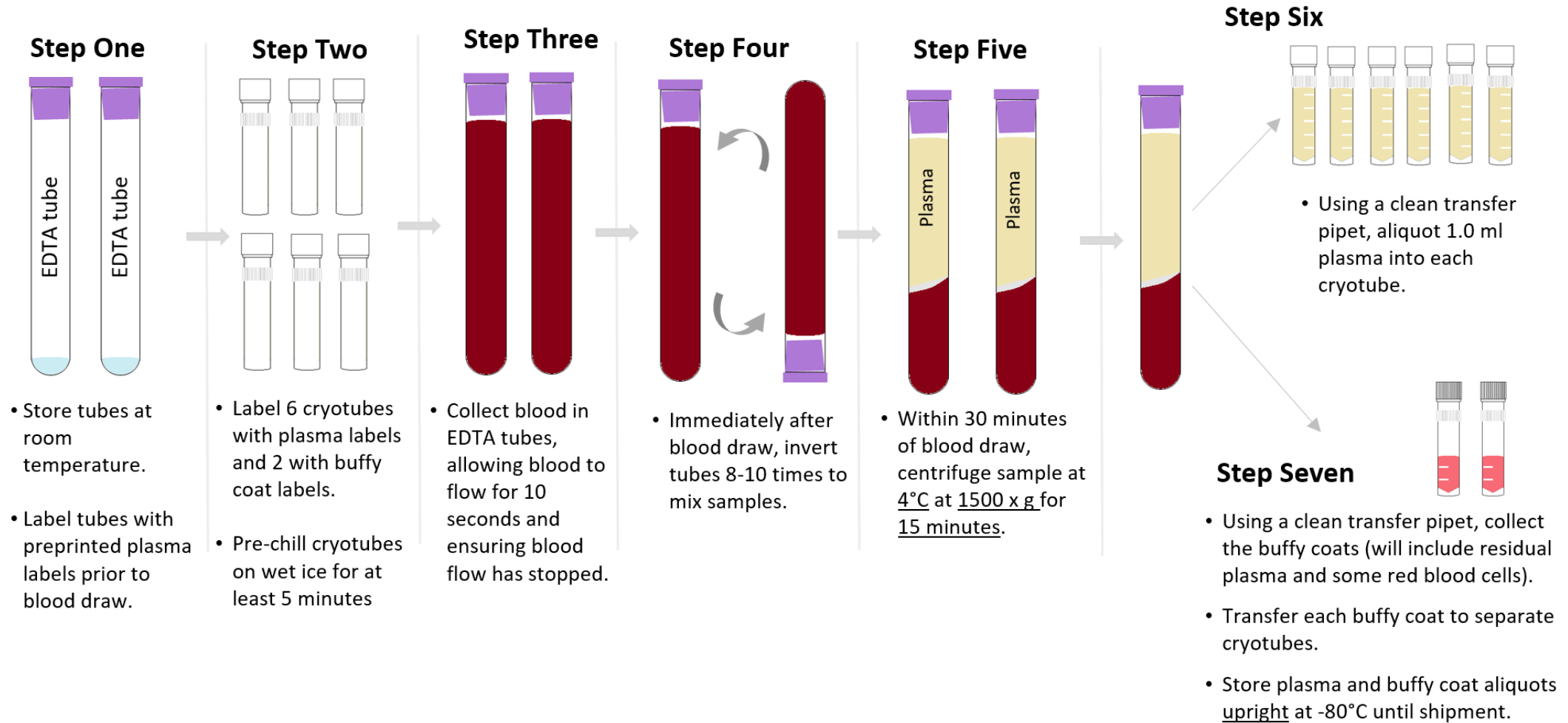


# Sample Collection and Processing: RNA

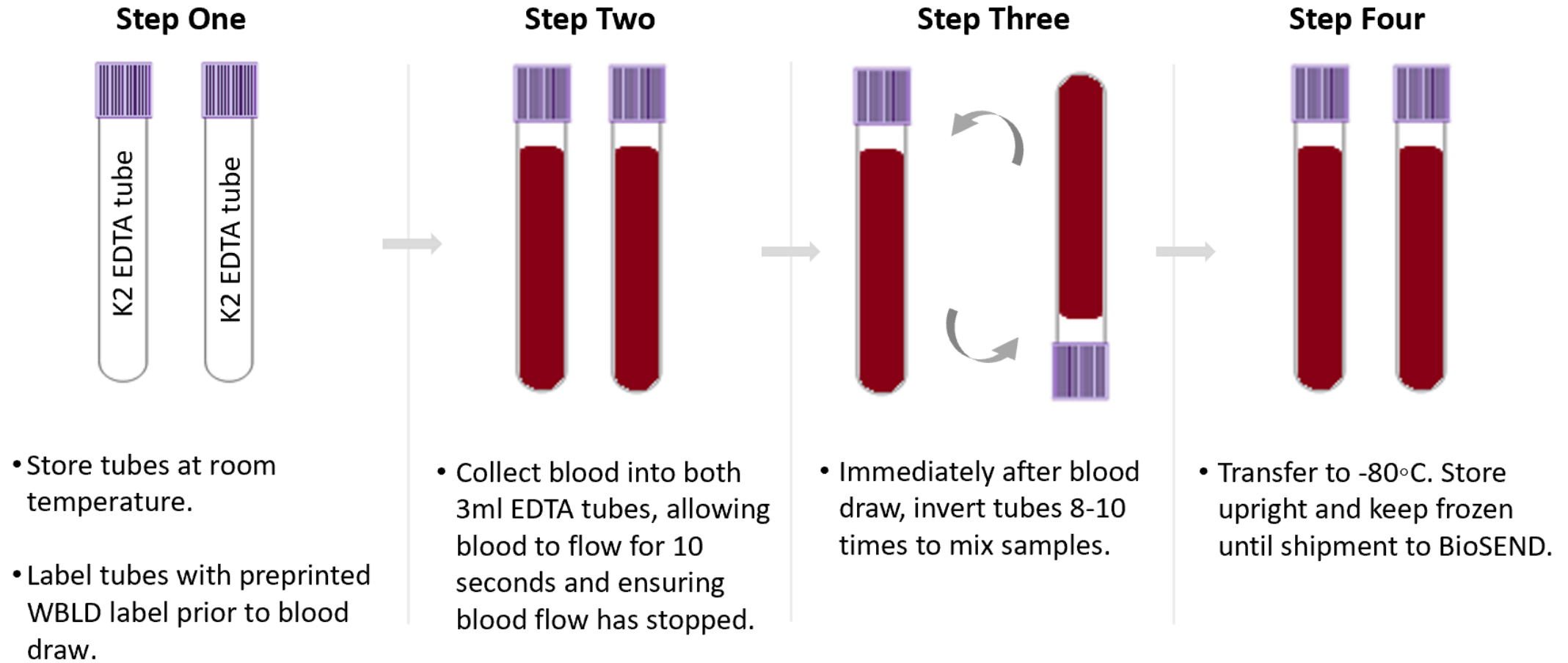
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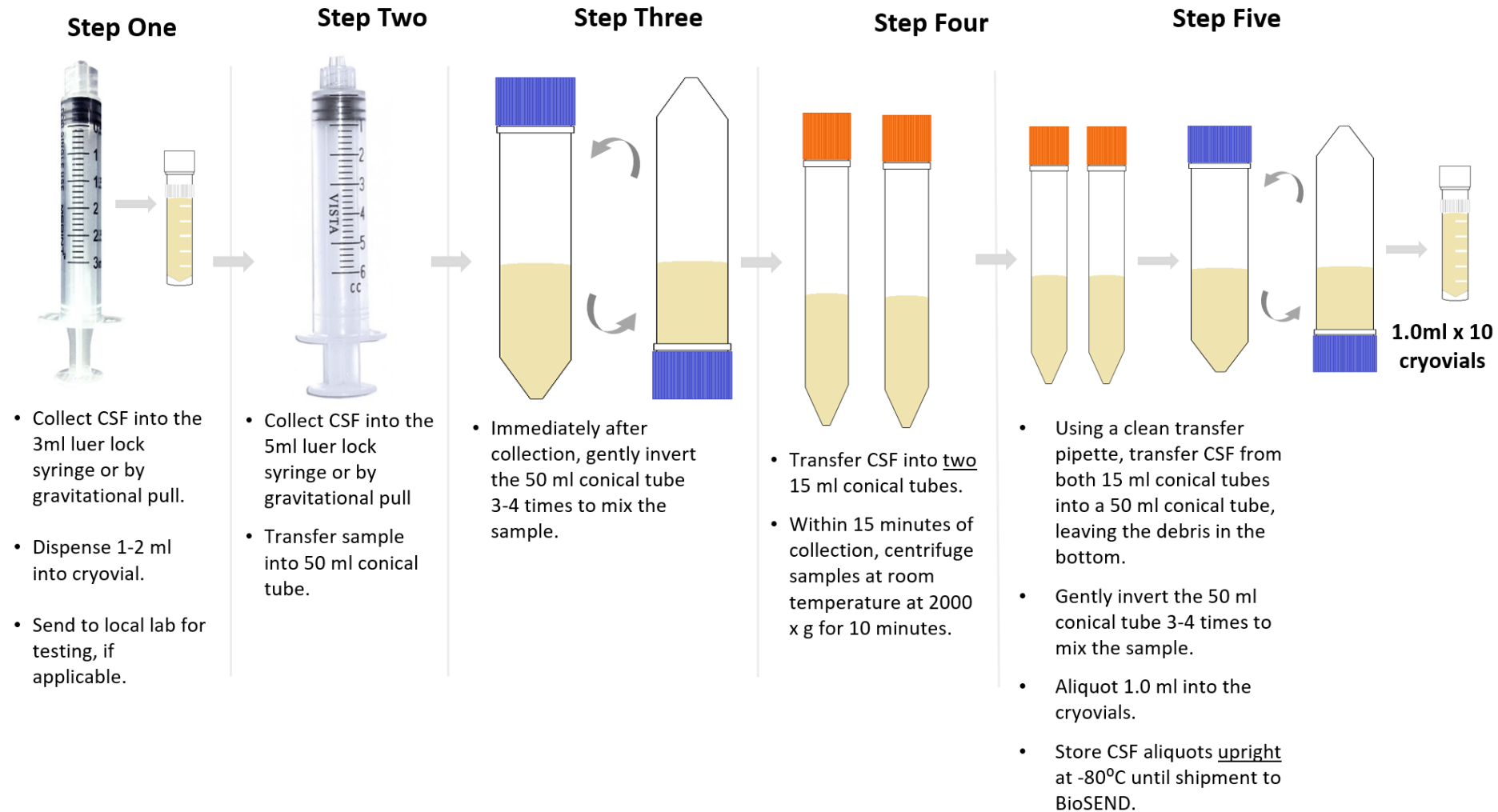
# Sample Collection and Processing: Plasma & Buffy Coat



# Sample Collection and Processing: Whole Blood



# 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 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!

Shipper's Declaration not Required.

Dry Ice amount must be in kilograms.

Note: 2 lbs. = 1 kg.

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

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

06426 1/01 RRD

# Shipping Samples

UPS resources available on BioSEND website






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	Withdrawn Subject Notification
LETBI Study Resources	READISCA Study Resources	



## 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](mailto:biosend@iu.edu)  
317-278-0594

# Shipping Samples: Frozen


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Please notify BioSEND ahead of shipment

- Email [biosend@iu.edu](mailto: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"/>	DNA <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	RNA <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Plasma <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Serum <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	CSF <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Whole Blood <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Buffy Coat <input type="text"/>	<input type="text"/>	<input type="text"/>

# Shipping Samples: Closures

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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
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.

# Non-Conformance Reporting

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Most common non-conformance issues:

- Samples shipped for weekend/holiday delivery
- Sample form incomplete/inaccurate
- Unlabeled or mislabeled tube(s)
- Sample hemolysis



# Contacts

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## Indiana University

General Questions/Shipment Notifications:

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

Biorepository Project Manager:

Claire Wegel

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

Tel: 317.278.6158

Biorepository Clinical Research Coordinator:

Carolyn Dunifon

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

Tel: 317.274.5751