



PREDICT-HD 3.0

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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

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	301 (BL)	302 (12M)	303 (24M)
<b>Whole Blood</b> (1 x 6ml)	X	X	X
<b>Plasma</b> (12 x 1.5ml)	X	X	X
<b>Buffy Coat</b> (4 aliquots)	X	X	X
<b>CSF</b> (13 x 1.5ml)	X	X	X
<b>RNA</b> (2 x 2.5ml)	X	X	X

# Kit Ordering – Biosend.org

**NINDS BioSEND**


Accessing Biospecimens


Banking Samples

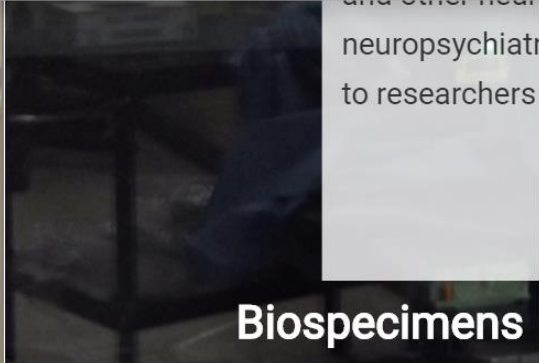
Active Studies

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	

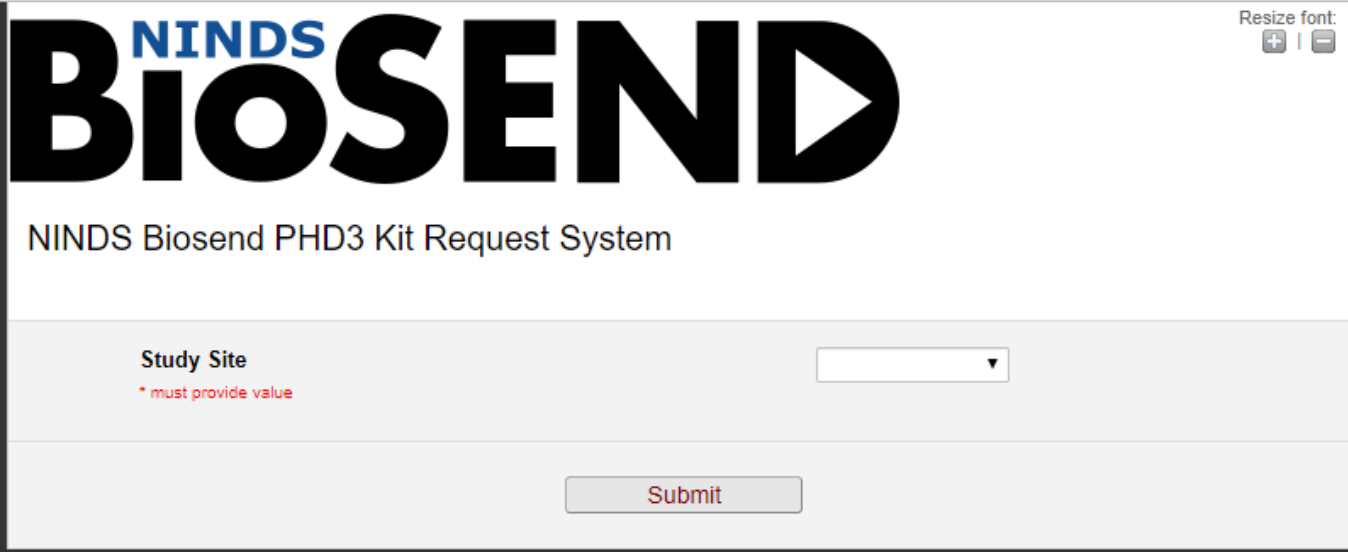
**About BioSEND**

**Banking Samples**

**Biospecimens**

# Select Site

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The screenshot shows the NINDS BioSEND PHD3 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 PHD3 Kit Request System" is visible. In the top right corner, there is a "Resize font:" label with plus and minus icons. The main form area has a light gray background. It contains a "Study Site" label, a red asterisk with the text "must provide value", and a white drop-down menu with a black arrow. Below this, there is a "Submit" button.

- <http://kits.iu.edu/biosend/phd3>
- **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](#)

# 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 Visit Kit
- ☐ Annual 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

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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 Visit Kit <input type="checkbox"/> Annual 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>Baseline Visit Kit Quantity</b> <small>* must provide value</small>	<input type="text"/>

# 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

# Supplemental Kit

Contains a variety of  
extra kit components

<b>Kit Type</b> **Please allow two weeks for shipment** <small>* must provide value</small>	<input type="checkbox"/> Baseline Visit Kit <input type="checkbox"/> Annual 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>
<b>Supplemental Kit Quantity</b> <small>* must provide value</small>	<input type="text" value="1"/>
<b>Comments</b>	<div></div> <div>Expand</div>
<b>Each Supplemental Kit Contains:</b> 10 - Purple-top EDTA tubes (Plastic, 10 ml) 10 - Purple cryogenic vials (2 ml) 10 - Grey cryogenic vials (2 ml) 10 - Disposable transfer pipettes (3ml) 2 - Cryobox, 25-slot 5 - Biohazard bag with absorbent sheet 5 - Shipping label packet (incl. waybill)	

# 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 Visit Kit <input type="checkbox"/> Annual 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>
Resealable Tube Pouches	<input type="radio"/> 2 <input type="radio"/> 4	reset
Cryobox	<input type="radio"/> 2 <input type="radio"/> 4	reset
Cryogenic Vial (2 ml) - Grey	<input type="radio"/> 10 <input type="radio"/> 20	reset
Cryogenic Vial (2 ml) - Purple	<input type="radio"/> 10 <input type="radio"/> 20	reset
FedEx® return Airbill	<input type="radio"/> 2 <input type="radio"/> 4	reset
Shipping Container for Dry Ice Shipments (includes shipping labels & airbill)	<input type="radio"/> 2 <input type="radio"/> 4	reset



# Multiple Orders

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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 Visit Kit <input checked="" type="checkbox"/> Annual 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>
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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**

Resize font:  
+ | -

NINDS Biosend PHD3 Kit Request System

Study Site

Paulsen, Jane ▼

\* must provide value

University of Iowa

Jane Paulsen

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

Kit Type

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

\* must provide value

☐ Baseline Visit Kit

☐ Annual 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

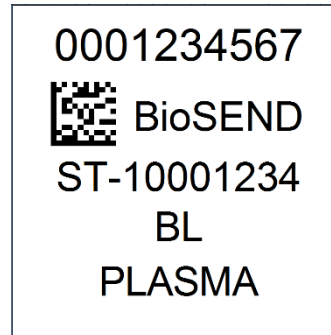
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**Labels are provided by Indiana University**

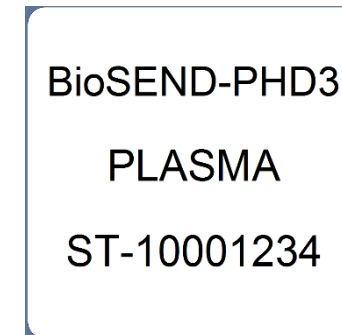
- Please check that all samples are properly labelled with correct specimen type and visit



Case Labels



Collection Tube  
Labels



Cryotube labels

# Case Labels

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ST-10012345:  
PHD3:301



BioSend



Subject Number



Study & Visit



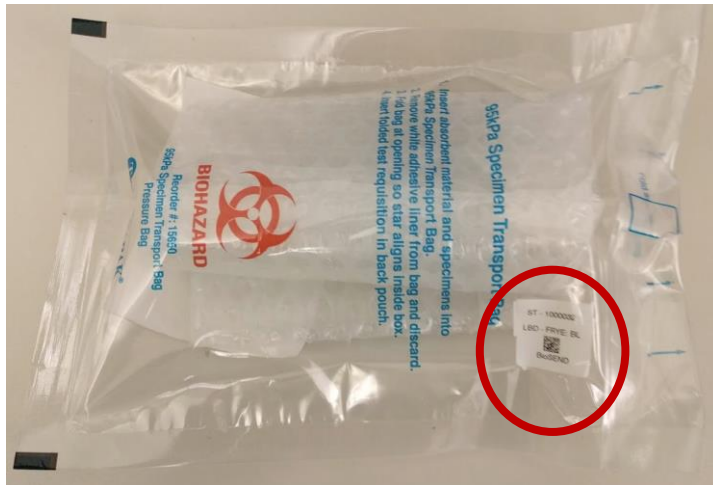
Biorepository Name

# Case Labels

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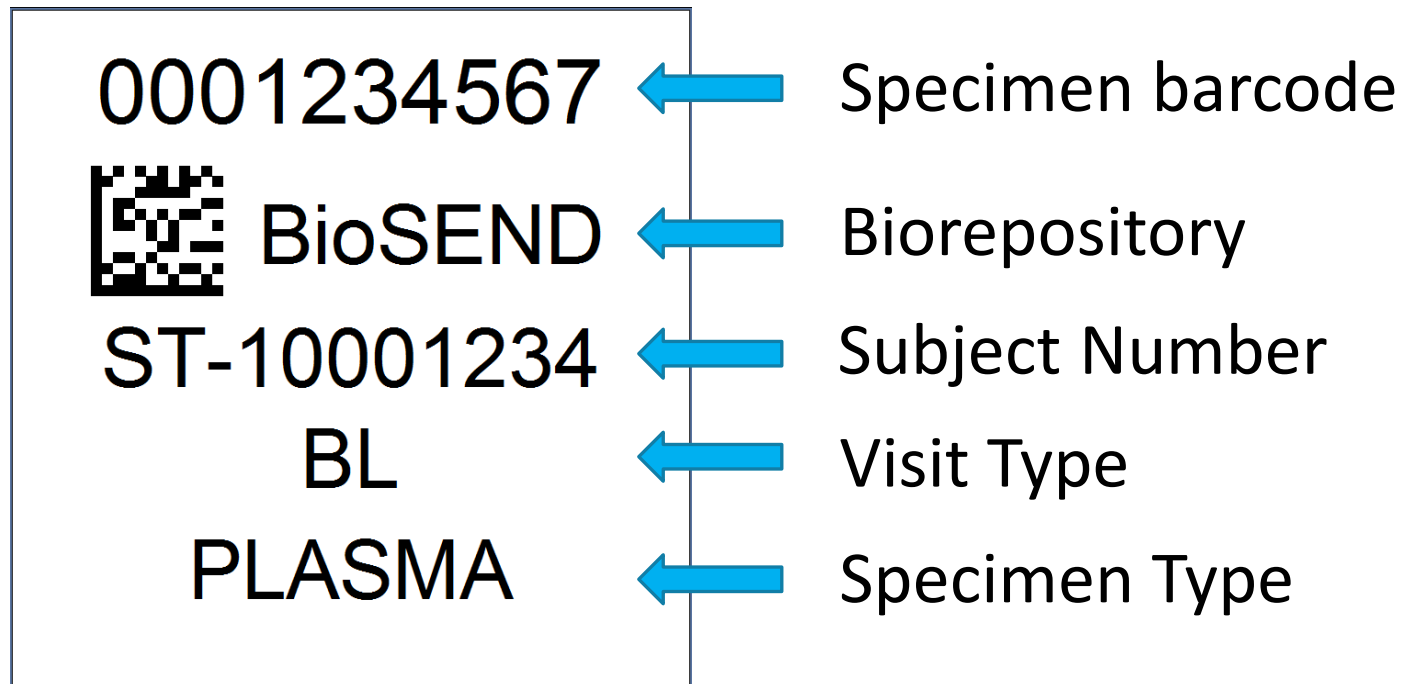
Case labels are placed:

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



# Collection Tube Labels

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# Cryotube Labels

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BioSEND-PHD3

PLASMA

ST-10001234



Study Abbreviation



Specimen Type



Subject Number

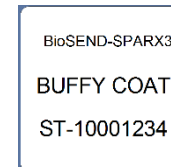
\*Note: The tube itself will have a unique barcode printed in both 2D format (on bottom of tube) and human readable format (alongside of tube).

# Cryotube Labels

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Note: cryotube barcodes are printed on tube, not on the label. Barcodes are tied to the specific kit they arrive in (ie, a specific subject and visit). **Please do not mix the labels from one kit with the cryotubes from another.**

- Barcode is in human readable format on side of tube, 2D format on bottom of tube





# Cryotube Labels

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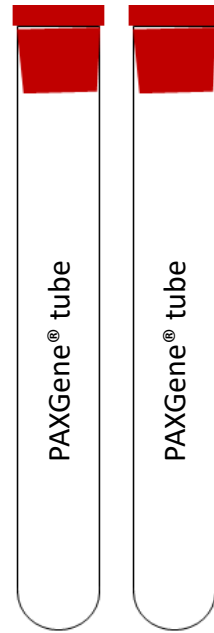
Please verify that you are using the correct cryotube for the correct specimen type

Specimen Type	Cryotube Color
Plasma	Purple
Cerebrospinal Fluid	Orange
Buffy Coat	Grey

# Sample Collection and Processing

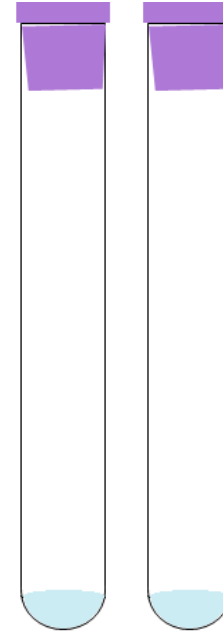
Blood Tube Draw Order

2,5ml PAXGene®



**1**

10ml EDTA



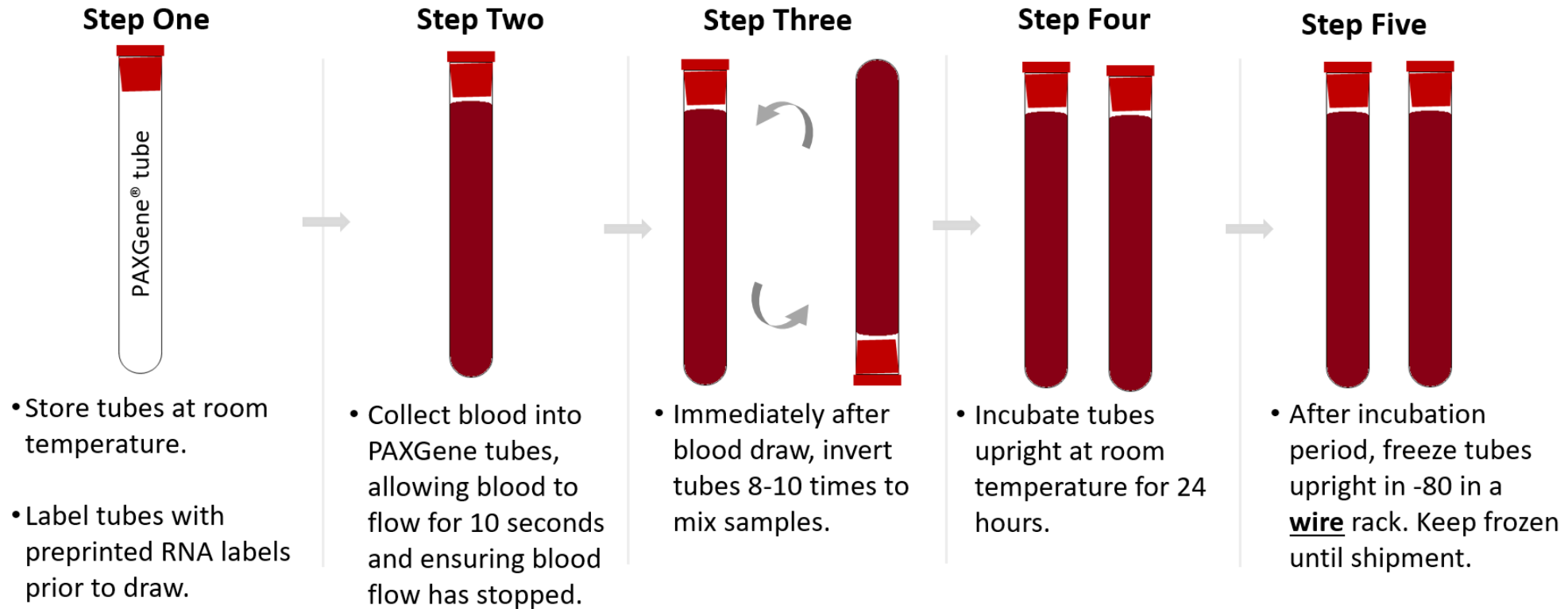
**2**

6ml EDTA

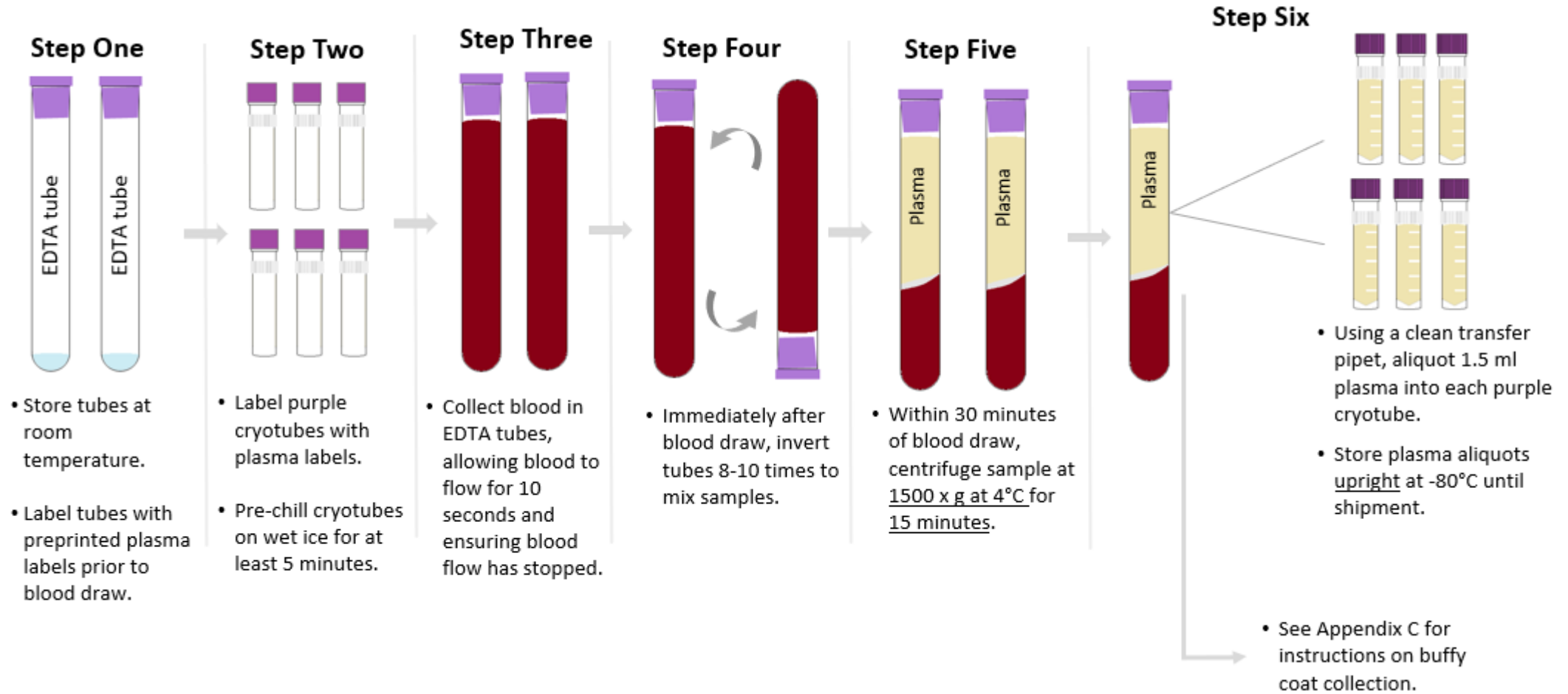


**3**

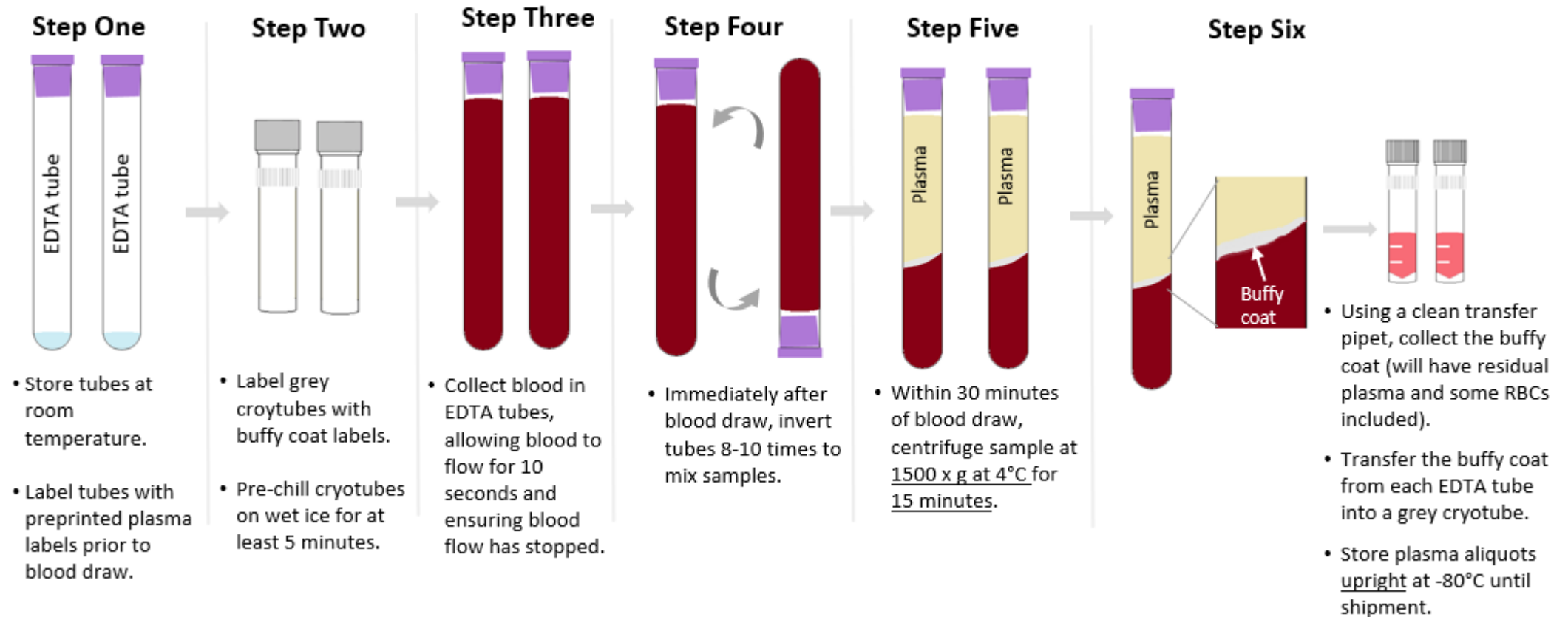
# Sample Collection and Processing: RNA



# Sample Collection and Processing: Plasma & Buffy Coat

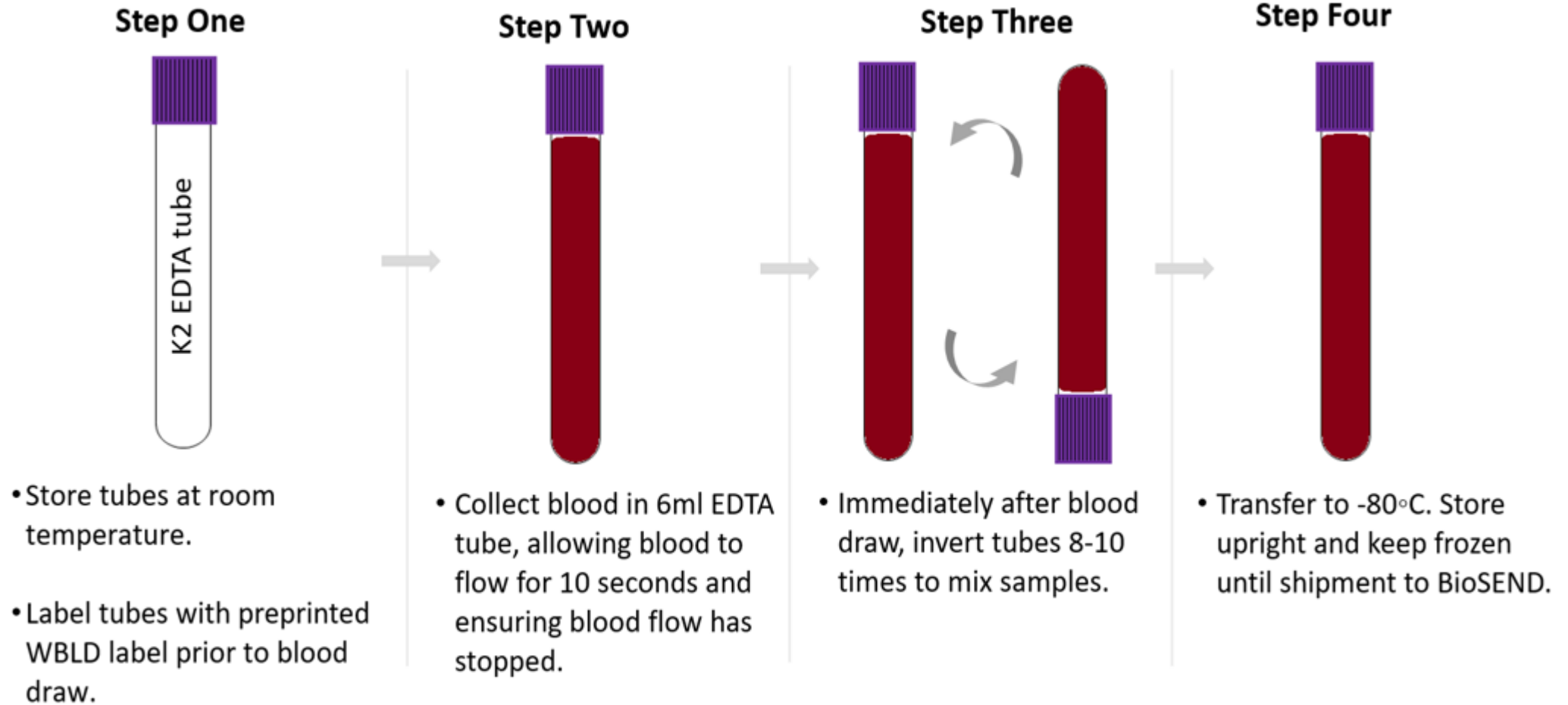


# Sample Collection and Processing: Plasma & Buffy Coat



# Sample Collection and Processing: Whole Blood

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# Blood Collection: Troubleshooting

## Issue #1: Collection tube with little/no vacuum

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**Always check expiration dates before beginning blood draw and discard expired tubes**

*- Tubes expire on last day of month printed on tube*

**Store tubes at ambient temperature**

*- Extreme temperatures can affect vacuum*

**Keep extra collection tubes from supplemental kit nearby during blood draw to replace “bad” tubes. These can also be requested through the Kit Request Module.**

**If frequent occurrence, report tube type and lot numbers to Indiana University**

# Blood Collection: Troubleshooting

## Issue #2: Hemolyzed (pink/red) plasma

Cause: Blood Collection Methods	Corrective Action
Improper venipuncture site	Draw from median cubital, basalic, and cephalic veins from antecubital region of arm
Prolonged tourniquet use	Tourniquet should be released after no more than 1 min, excessive fist clenching should be avoided
Not allowing alcohol to dry on skin before venipuncture	Without touching, allow the venipuncture site to air dry
Lumen of needle too close to inner wall of vein (indicated by slow blood flow)	
Use of too large/small bore needle resulting in excess force applied to blood	Avoid using too small/large needle. Needle size dependent on the subject's physical characteristics & amount of blood to be drawn. Most commonly used sizes are 19 – 23.
Pulling/pushing plunger too fast while drawing/transferring blood	Avoid drawing the syringe plunger too forcefully when collecting blood
	Ensure all blood collection assemblies are fitted securely, to avoid frothing



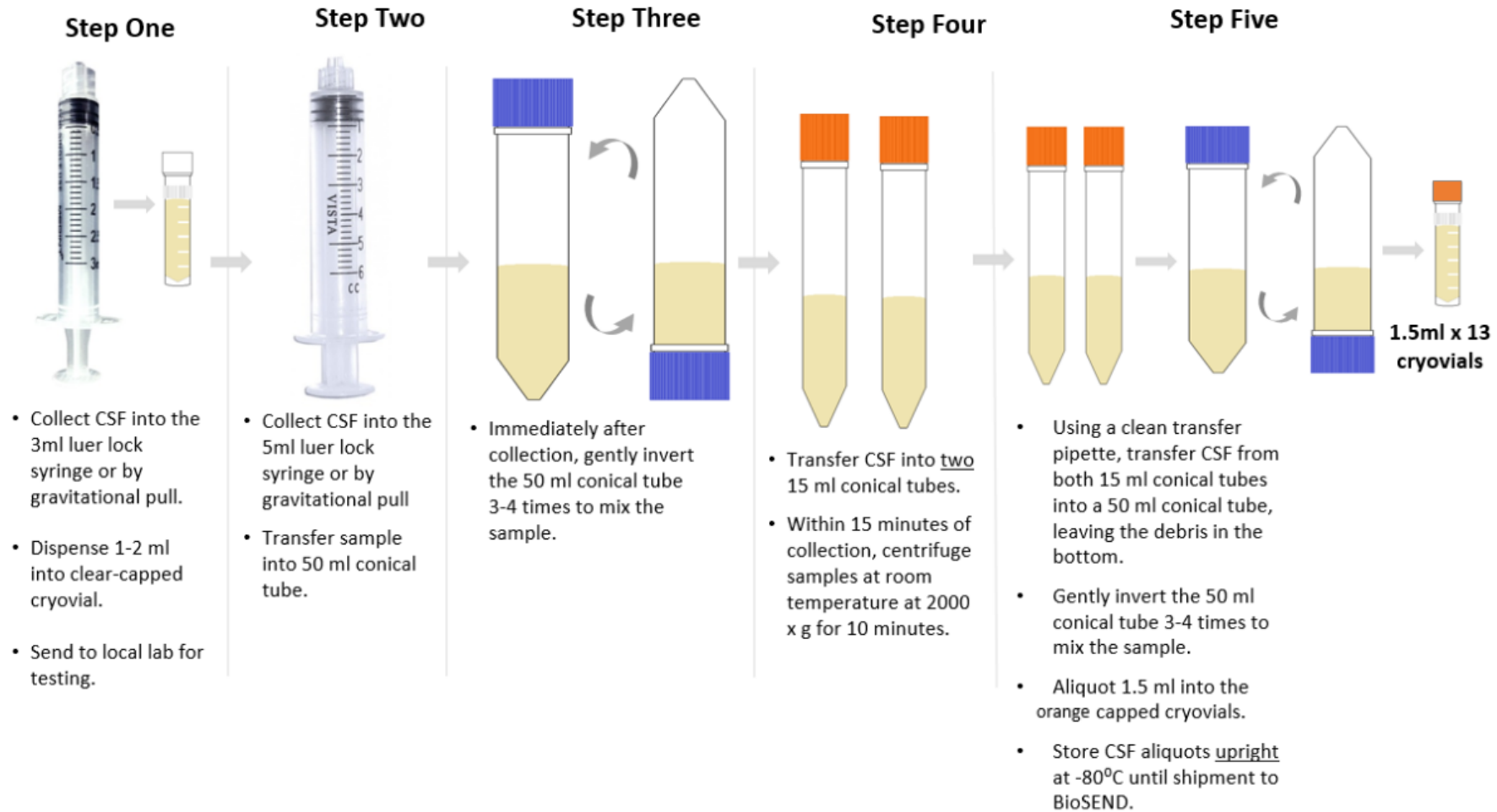
# Blood Collection: Troubleshooting

## Issue #2: Hemolyzed (pink/red) plasma

Cause: Sample Processing Methods	Corrective Actions
Vigorous mixing/shaking	Gently invert blood collection tube when mixing additive with specimen, follow guidelines in Biologics Manual regarding number of times to invert each type of tube
Not allowing serum to clot for recommended time	Serum tubes without clot activator should be allowed to clot for 60 min in a vertical position
Exposure to excessive heat or cold	Keep samples at ambient temp
Prolonged contact of serum/plasma with cells	Do not store uncentrifuged samples beyond recommended time

Reference: BD's "Tech Talk" newsletter, Vol. 2, No. 2, October 2003  
([http://www.bd.com/vacutainer/pdfs/techtalk/TechTalk\\_Jan2004\\_VS7167.pdf](http://www.bd.com/vacutainer/pdfs/techtalk/TechTalk_Jan2004_VS7167.pdf))

# Sample Collection and Processing: CSF



# Shipping Samples: Frozen

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## Packing and Shipping Frozen Samples

- All 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

9

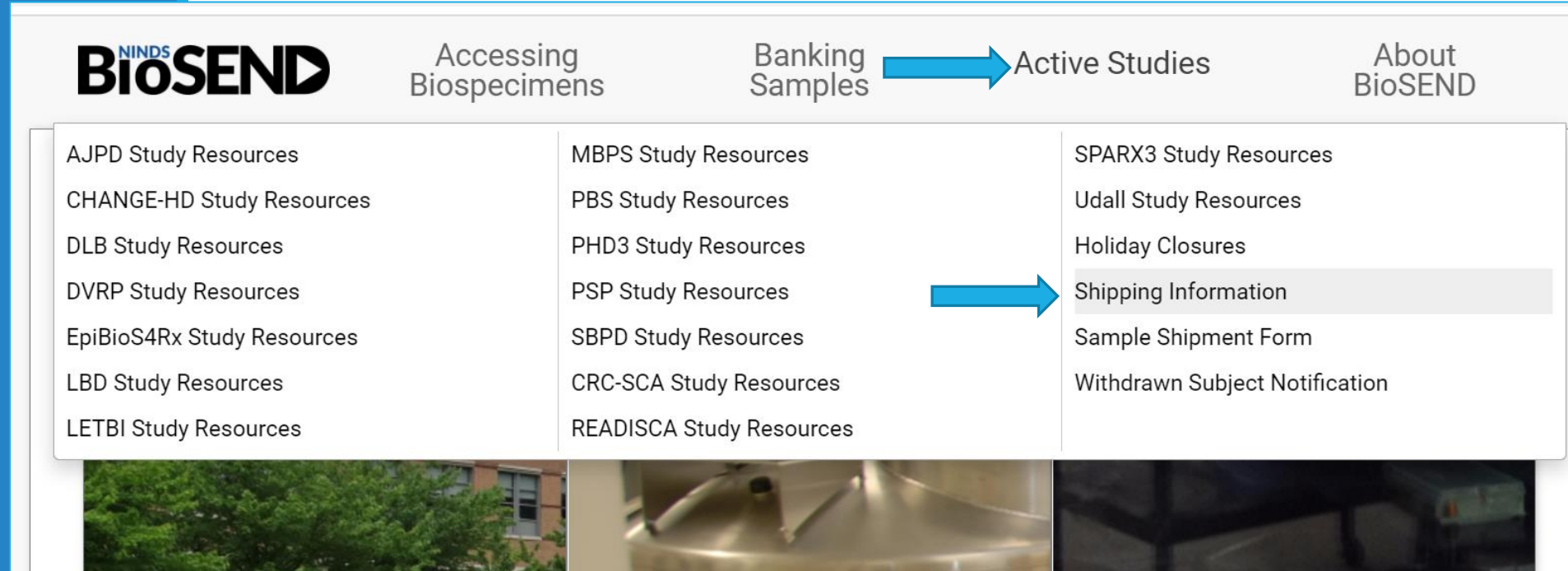
Consignee Name and Address

IU information and address

06426 1/01 RRD

# Shipping Samples

UPS resources available on BioSEND website



The screenshot shows the BioSEND website navigation bar and a dropdown menu. The navigation bar includes the NINDS BioSEND logo, and links for 'Accessing Biospecimens', 'Banking Samples', 'Active Studies', and 'About BioSEND'. A blue arrow points from 'Banking Samples' to 'Active Studies'. The 'Active Studies' dropdown menu is open, showing a list of study resources. A blue arrow points from 'PSP Study Resources' to 'Shipping Information', which is highlighted in the menu. Below the menu, there are three small images: a green tree, 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	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	

Three small images are displayed below the menu: a green tree, a close-up of a metal container, and a dark interior space.

## 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 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.***





# 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"/>	<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"/>

# Packaging & Shipping Troubleshooting

## Issue: Broken/Damaged Tubes

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Cause	Preventative Action
Over filling tubes	Fill tubes to suggested volume. If any sample still remains, place in an additional tube
Improper packaging	Ensure any tubes are securely placed into the bubble wrap pouch and are placed in a separate bag from the cryobox
Rough shipping conditions	Extra bubble wrap may be needed to pad blood tubes
Extreme changes in temperature (ambient→freezer; freezer→dry ice)	Wrapping the tubes in bubble wrap before freezing may help slow the cooling process

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# 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