



EpiBioS4Rx Training Webinar

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

Biospecimen Collection Protocol

	D1	D3	D5	D15	D30	D90	D180
Buffy Coat (2 aliquots)	X	X	X	X	X	X	X
Plasma (6 x 250ul)	X	X	X	X	X	X	X
RNA (2 x 2.5ml)			X	X			

Kit Ordering – Biosend.org



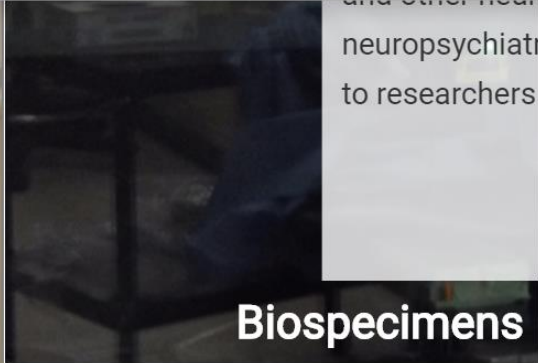


Accessing
Biospecimens

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	



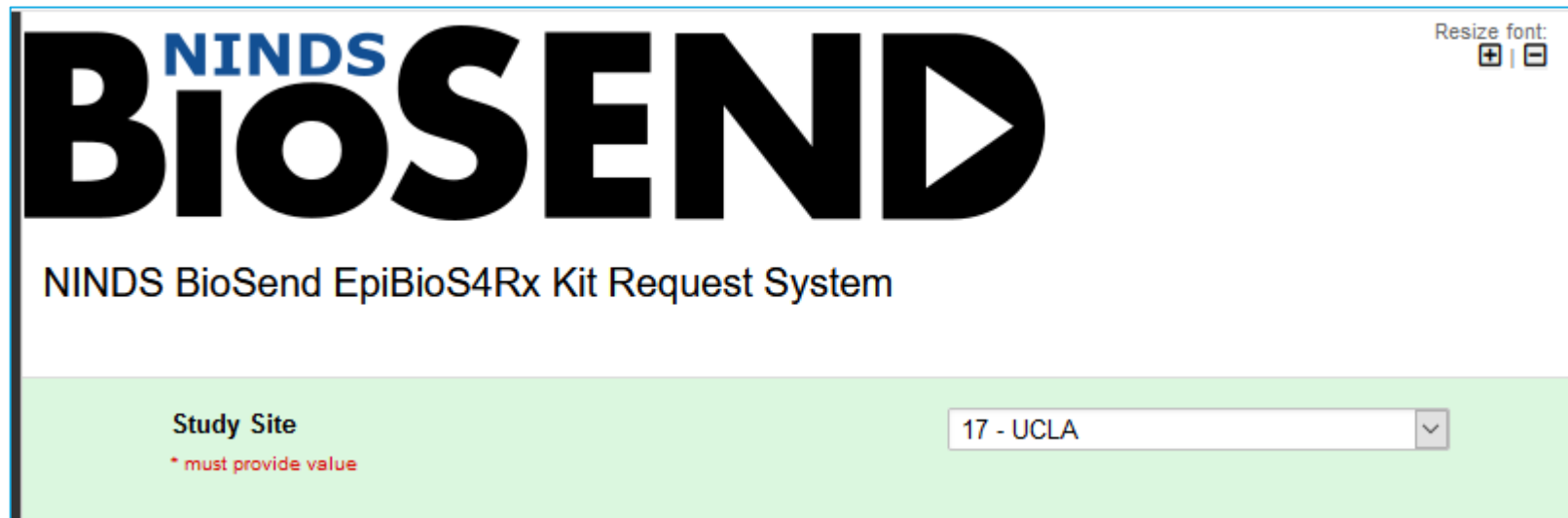
About BioSEND

Banking Samples

Biospecimens

BioSEND Kit Request Module

- <http://kits.iu.edu/biosend/EPIBIO4RX>
- **Choose your site from the drop-down list.**



The screenshot shows the NINDS BioSEND EpiBioS4Rx Kit Request System interface. At the top, the logo "NINDS BioSEND" is displayed in large, bold letters, with "NINDS" in blue and "BioSEND" in black. Below the logo, the text "NINDS BioSend EpiBioS4Rx 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 green background. On the left, the label "Study Site" is followed by a red asterisk and the text "* must provide value". To the right of this is a drop-down menu showing "17 - UCLA" with a downward arrow icon.

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

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>	<div><input type="text"/></div> <div>Expand</div>	
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** <small>* must provide value</small>	<input checked="" type="checkbox"/> Standard 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>
Standard 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>

Multiple kit types available

Standard Kits

- Contains supplies and labels for all visits for a subject

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input checked="" type="checkbox"/> Standard 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>
Standard 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></div> <div>Expand</div>
Each Standard Collection Kit Contains: Blood Collection Kit Contents: 7 - Lavender-top K2 EDTA tube (10 ml) 4 - PAXGene® tubes (2.5 ml) 50 - Siliconized cryovials, sterile (0.5ml) 10 - Siliconized Sterile Cryogenic Vial (2.0 ml) 7 - Disposable transfer pipette (1ml) 2 - Cryobox 1 - Warning label packet (incl. dry ice label) 1 - FedEx® return Airbills 1 - Shipping container for dry ice shipments 2 - Biohazard bag 2 - 100 ml absorbent sheet	

Standard Kits

Standard Kit Quantity <small>* must provide value</small>	<input type="text" value="1"/> <small>If you need more than 10 kits or labels, please use the file upload option or submit multiple requests.</small>
1st Kit Visit ID <small>(only if not using file upload option)</small>	<input type="text"/> <small>e.g. ST-00012345</small>
1st Kit Visit	<input type="text"/> 

- Only need to request specific ST-Number if requesting replacement labels

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.

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"/> Standard 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>
Comments	<div></div> <div>Expand</div>
Each Supplemental Kit Contains: 5 100 ml absorbent sheets 5 6-tube bubble pouches 5 Cryoboxes 50 Siliconized sterile cryogenic vials (0.5 ml) 5 Siliconized Sterile Cryogenic Vial (2.0 ml) 5 Biohazard bags 5 PAXGene® tubes (2.5 ml) 10 Lavender-top K2EDTA tubes (10 ml) 10 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

- ☒ Standard 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
* 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

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

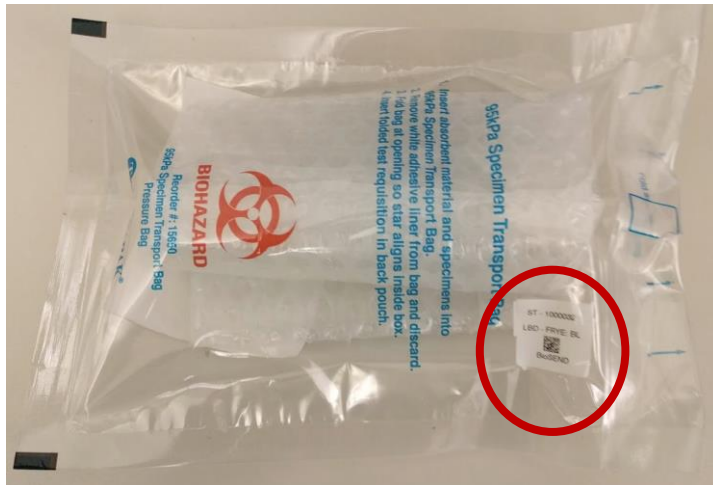


- ← Subject Number
- ← Study – Site & Visit
- ← Biorepository Name

Case Labels

Case labels are placed:

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



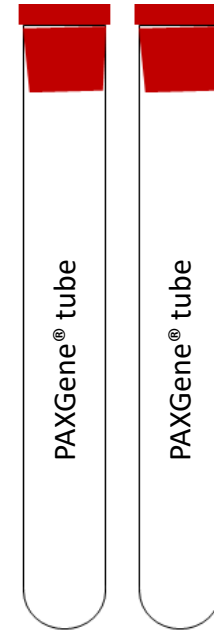
Specimen Label

0003374183	← Specimen barcode
 BioSEND	← Biorepository
ST-10000352	← Subject Number
D1	← Visit Type
PLASMA	← Specimen Type

Sample Collection and Processing

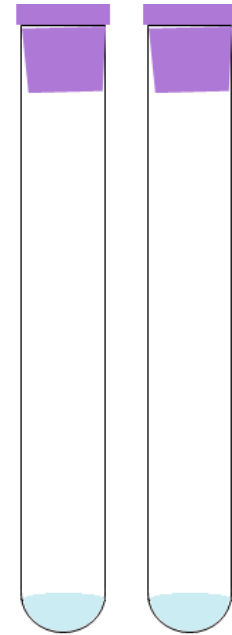
Blood Tube Draw Order

2.5ml PAXGene®



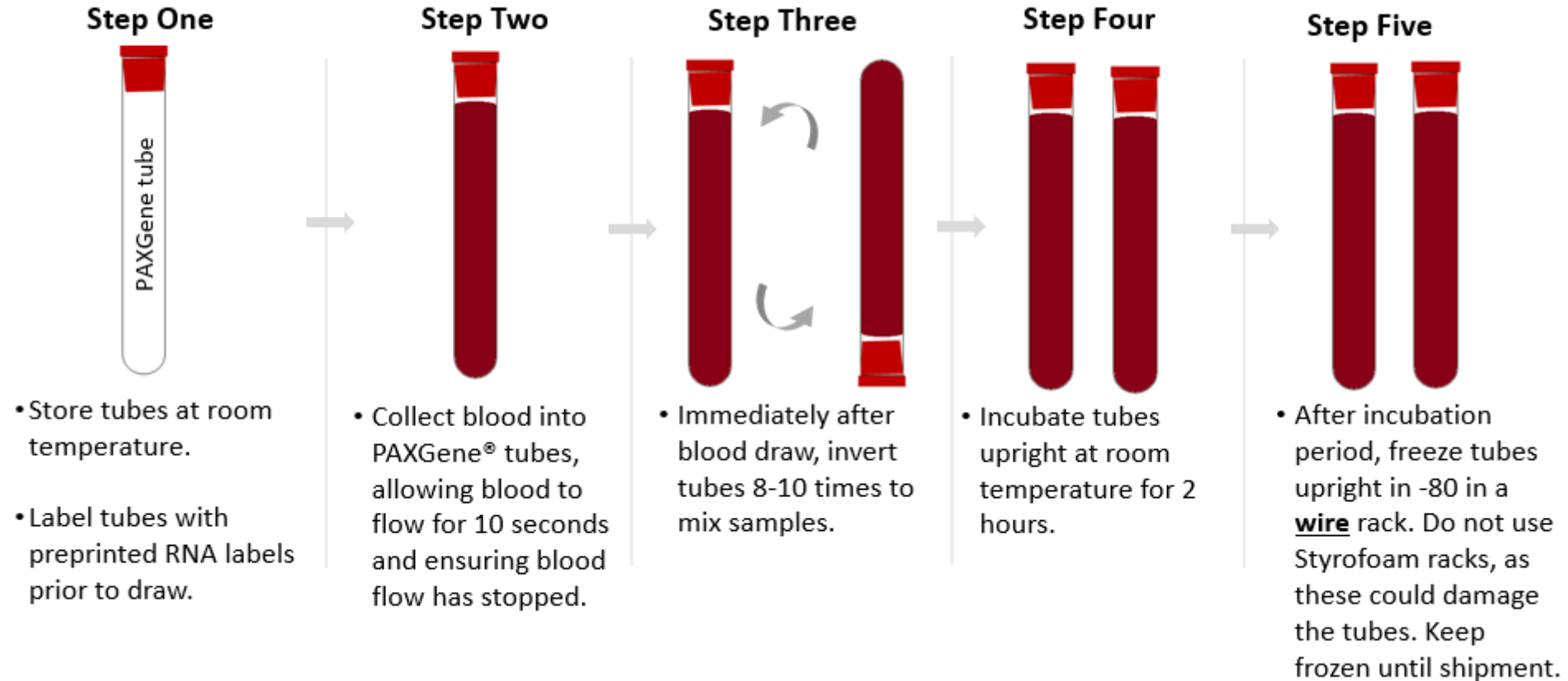
1

10ml EDTA

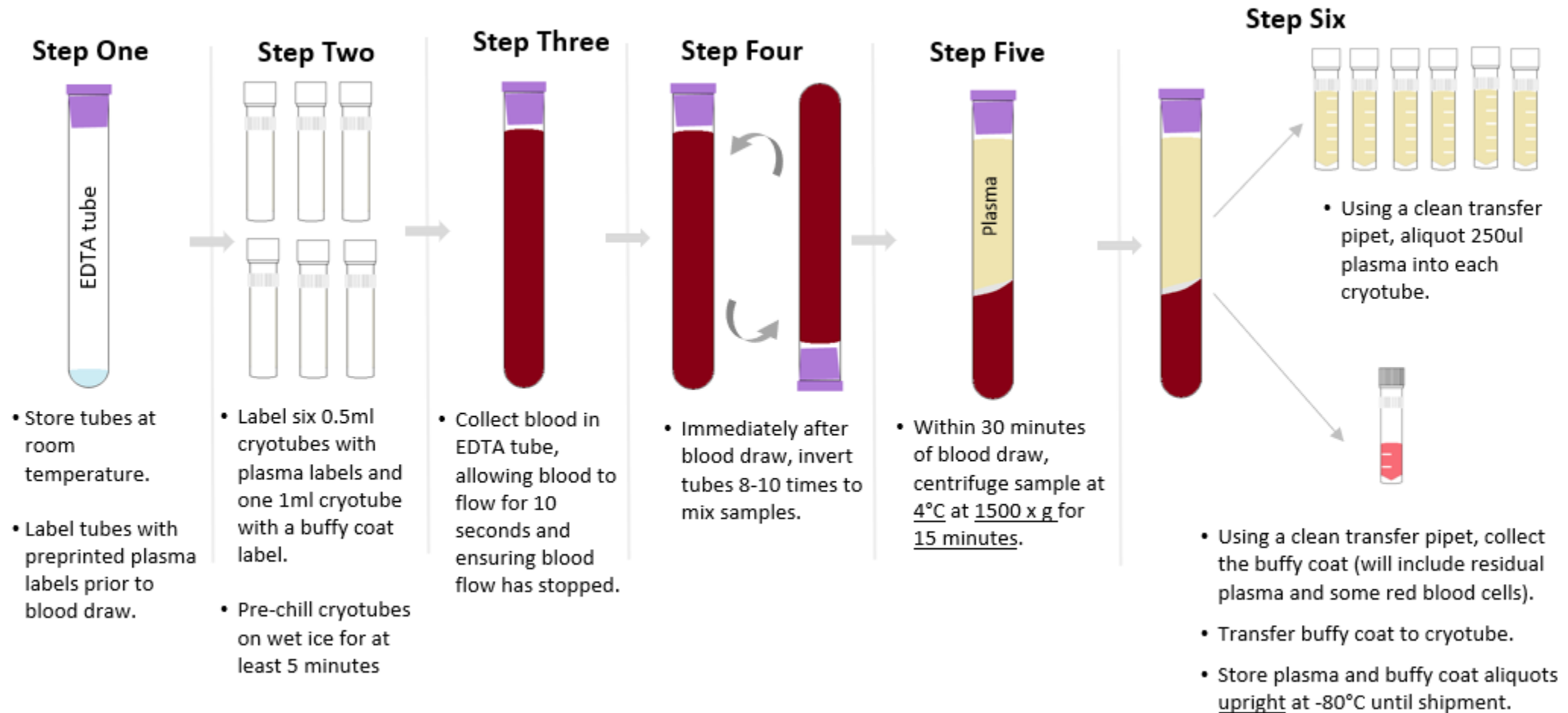


2

Sample Collection and Processing: RNA



Sample Collection and Processing: Plasma & Buffy Coat



Blood Collection: Troubleshooting

Issue #1: Collection tube with little/no vacuum

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)

Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- All samples ship frozen
- Ship frozen samples on dry ice
- Frozen samples should be shipped **only** Monday through Wednesday
- International shipments should be shipped **only** Monday
- 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

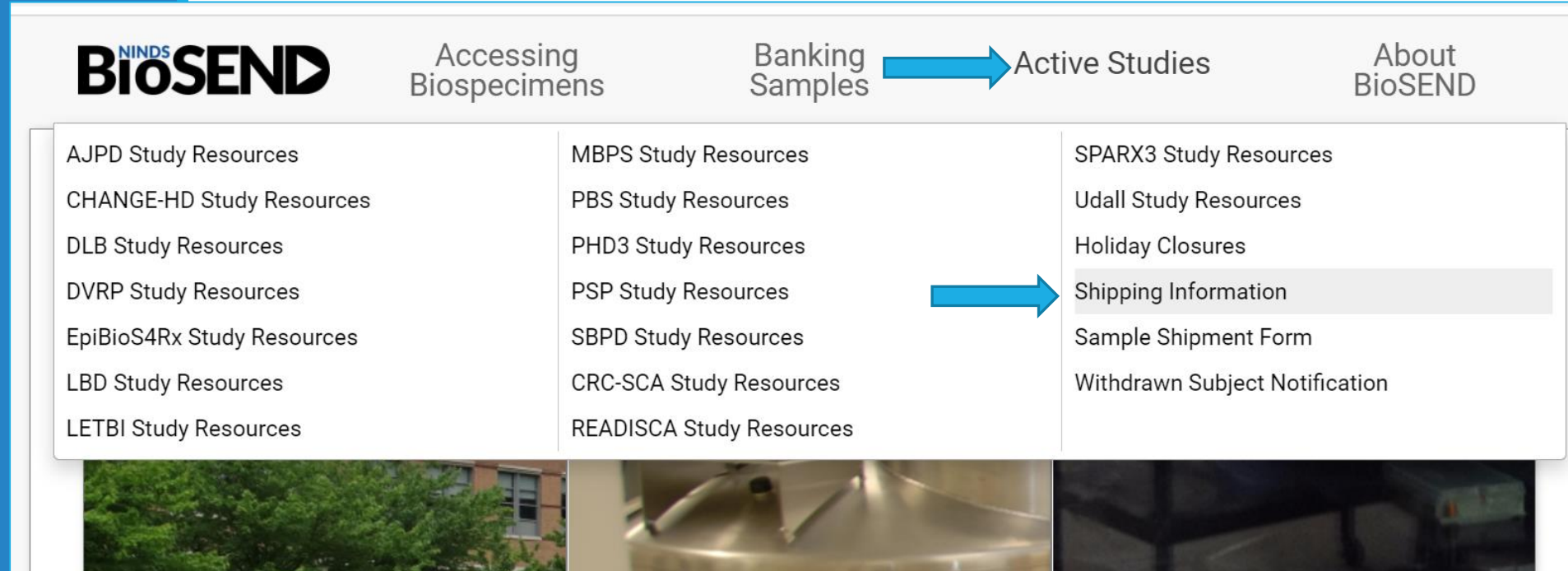
Class 9 Dry Ice Label should not be covered with other stickers and must be completed, or courier will reject/return your package!

The image shows a Class 9 Dry Ice Label template. It features a large diamond shape with a black and white striped pattern. The label includes the following text and fields:

- 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 (indicated by a red arrow pointing to the "Dry Ice" field)
- Dry Ice kg.
- Your name & address (indicated by a red arrow pointing to the "Shipper's Name and Address" field)
- Shipper's Name and Address
- UN 1845
- Consignee Name and Address (indicated by a red arrow pointing to the "Consignee Name and Address" field)
- 9
- 06426 1/01 RRD

Shipping Samples

UPS resources available on BioSEND website

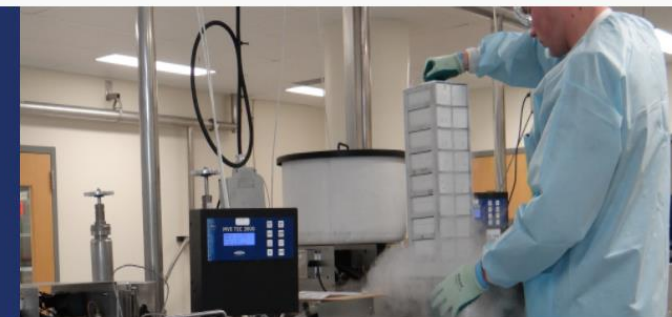


The screenshot shows the NINDS BioSEND website navigation bar and a dropdown menu. The navigation bar includes the BioSEND logo, 'Accessing Biospecimens', 'Banking Samples', 'Active Studies' (highlighted with a blue arrow), and 'About BioSEND'. The dropdown menu lists various study resources and shipping-related links. 'Shipping Information' is highlighted with a blue arrow.

Accessing Biospecimens	Banking Samples	Active Studies	About BioSEND
<ul style="list-style-type: none">AJPD Study ResourcesCHANGE-HD Study ResourcesDLB Study ResourcesDVRP Study ResourcesEpiBioS4Rx Study ResourcesLBD Study ResourcesLETBI Study Resources	<ul style="list-style-type: none">MBPS Study ResourcesPBS Study ResourcesPHD3 Study ResourcesPSP Study ResourcesSBPD Study ResourcesCRC-SCA Study ResourcesREADISCA Study Resources	<ul style="list-style-type: none">SPARX3 Study ResourcesUdall Study ResourcesHoliday ClosuresShipping InformationSample Shipment FormWithdrawn Subject Notification	

Below the navigation bar, there are three small images: a green tree, a close-up of a metal container, and a dark image of a sample shipment box.

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
- Include physical copy of sample form in shipment

Shipping Samples: Sample Form

STUDY: EPIBIOS4RX**SHIP FROZEN SHIPMENTS MONDAY - WEDNESDAY ONLY!**

Ensure all frozen shipments are completely filled with dry ice.

This form must be completed for shipment of all research samples.

Prior to shipping, email a PDF copy of this completed form to BioSEND at biosend@iu.edu.
Also place a hard copy of this form in the shipment box and in the study binder.

Site Name:

Site #

(The site # is the 2 digit number in your patient's study ID. Ex. 17 for UCLA, study ID = 3_17_0000)

Principal Investigator:

Coordinator Name:

Coordinator Telephone:

Coordinator Email:

PATIENT INFORMATION

Patient's Study ID:

(ex. 3_17_0000)

ST Number

(FOR ONE PATIENT, ALL VIAL LABELS FROM ALL 6 DRAW TIME POINTS MUST HAVE THE SAME ST NUMBER.)

Patient's Gender

☐ Male ☐ Female ☐ Unknown
☐ Not reported

Patient's Age

(years)

Please complete:

- One form for each subject shipped
- Coordinator contact information
- Patient Information

Shipping Samples: Sample Form

SHIPPING INFORMATION:	
Date samples were shipped?	_____
Time samples were shipped?	_____
FedEx Tracking #:	_____
Which visit days for this patient are included in the shipment?	<input type="checkbox"/> Day 1 <input type="checkbox"/> Day 3 <input type="checkbox"/> Day 5 <input type="checkbox"/> Day 15 <input type="checkbox"/> Day 30 <input type="checkbox"/> Day 90 <input type="checkbox"/> Day 180
Notation of storage or shipping problems	_____
DAY 1	
Blood draw date	_____
# of plasma vials	_____
# of buffy coat vials	_____
DAY 3	
Blood draw date	_____
# of plasma vials	_____
# of buffy coat vials	_____
DAY 5	
Blood draw date	_____
# of plasma vials	_____
# of buffy coat vials	_____
# of PAX tubes	_____

Please complete:

- Date of sample shipment
- Tracking Number
- Quantity of each sample type shipped
- Collection Date
- Any issues

Shipping Schedule

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

Samples should be shipping to BioSEND on a quarterly basis.



Packaging & Shipping Troubleshooting

Issue: Broken/Damaged Tubes

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

Shipping Samples: Closures

Date	Holiday
January 1	New Year's Day
3 rd Monday in January	Martin Luther King, Jr Day
4 th Monday in May	Memorial Day
July 4	Independence Day (observed)
1 st Monday in September	Labor Day
4 th Thursday in November	Thanksgiving
4 th Friday in November	Friday after Thanksgiving
December 25	Christmas

*Please also consider weather when shipping. UPS will post service updates on their webpage. Please reach out to BioSEND if you are unsure if it is safe to ship.

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

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cwegel@iu.edu

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Biorepository Clinical Research Coordinator:

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cdunifon@iu.edu

Tel: 317.274.5751