



Clinical Trial Readiness for SCA1 and SCA3

READISCA

BIOSPECIMEN COLLECTION & PROCESSING

A solid blue horizontal bar at the bottom of the slide.

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

	BL	12M	24M	36M	48M
DNA ** (6ml)	X				
Plasma (6 x 1ml)	X	X	X	X	X
Buffy Coat (2 aliquots)	X	X	X	X	X
CSF * (10 x 1ml)	X				X

*CSF will be collected at two timepoints throughout the study. They will not necessarily occur during the baseline visit and year 5 follow up visit.

**DNA collection will occur only once, at either the first or the second CSF collection visit.

Kit Ordering – Biosend.org


NINDS BioSEND


[Accessing Biospecimens](#)[Banking Samples](#)[Active Studies](#)[About BioSEND](#)

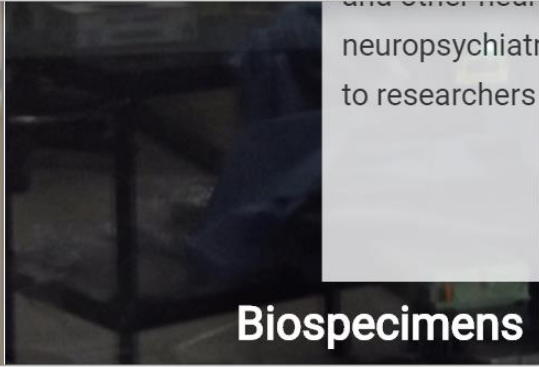
[AJPD Study Resources](#)[CHANGE-HD Study Resources](#)[DLB Study Resources](#)[DVRP Study Resources](#)[EpiBioS4Rx Study Resources](#)[LBD Study Resources](#)[LETBI Study Resources](#)

[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](#)

**About BioSEND**

**Banking Samples**

**Biospecimens**

BioSEND Kit Request Module

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

The screenshot shows the NINDS BioSEND SCA Kit Request System interface. At the top, the logo "NINDS BioSEND" is displayed in large, bold letters. Below the logo, the text "NINDS Biosend SCA Kit Request System" is visible. The main form area has a light green header with the label "Study Site" and a red asterisk indicating a required field. A "Submit" button is located below the form. A drop-down menu is open, showing a list of study sites. The footer of the page includes the text "REDCap 8.1.18 - © 2018 Vanderbilt University".

NINDS BioSEND

NINDS Biosend SCA Kit Request System

Study Site
* must provide value

Submit

REDCap 8.1.18 - © 2018 Vanderbilt University

Drop-down list contents:

- Columbia University
- Emory University
- Houston Methodist Hospital
- Johns Hopkins University
- Massachusetts General Hospital (Harvard Medical School)
- Northwestern University
- Stanford University
- University of Alabama-Birmingham
- University California-Los Angeles
- University California-San Francisco
- University of Chicago
- University of Colorado
- University of Florida
- University of Michigan
- University of Minnesota
- University of Rochester
- University of South Florida

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****

* must provide value

- ☐ Baseline/ Annual Visit Kit
- ☐ CSF Kit
- ☐ DNA 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/ Annual Visit Kit <input type="checkbox"/> CSF Kit <input type="checkbox"/> DNA 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>
Baseline 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>
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	<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:  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.</p> <p> Upload document</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

CSF Kits

- Select needle gauge and enter kit quantity
- Can be used for any subject, do not need to specify
- Labels will be in BL/Annual Kit

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input type="checkbox"/> Baseline/ Annual Visit Kit <input checked="" type="checkbox"/> CSF Kit <input type="checkbox"/> DNA 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 checked="" type="radio"/> 22 <input type="radio"/> 24 <small>reset</small>
CSF 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>
Comments	<div></div> <small>Expand</small>
CSF Collection Kit Contents: 11 - Siliconized cryovials, sterile (2ml) 2 - Blue screw-top centrifuge tubes (15ml) 2 - Blue screw-top conical tube (50ml) 1 - LP tray with 22 gauge Sprotte® needle	

DNA Kits

- Enter kit quantity
- Can be used for any subject, do not need to specify
- Labels will be in BL/Annual Kit

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input type="checkbox"/> Baseline/ Annual Visit Kit <input type="checkbox"/> CSF Kit <input checked="" type="checkbox"/> DNA 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>
DNA 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>
Comments	<div></div> <div>Expand</div>
DNA Collection Kit Contents: 1 - Purple-top EDTA tube (6 ml) 1 - FedEx® return Airbill 1 - Ambient shipper 1 - FedEx® ClinPak	

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

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

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 SPARX3 Kit Request System

Study Site

* must provide value

Northwestern University ▼

Northwestern University

Contact Name

Shipment Address

Email

Phone

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 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

Labels are provided by Indiana University

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

ST-10000123:

SCA:BL



BioSend

Case Labels

0001234567



BioSEND

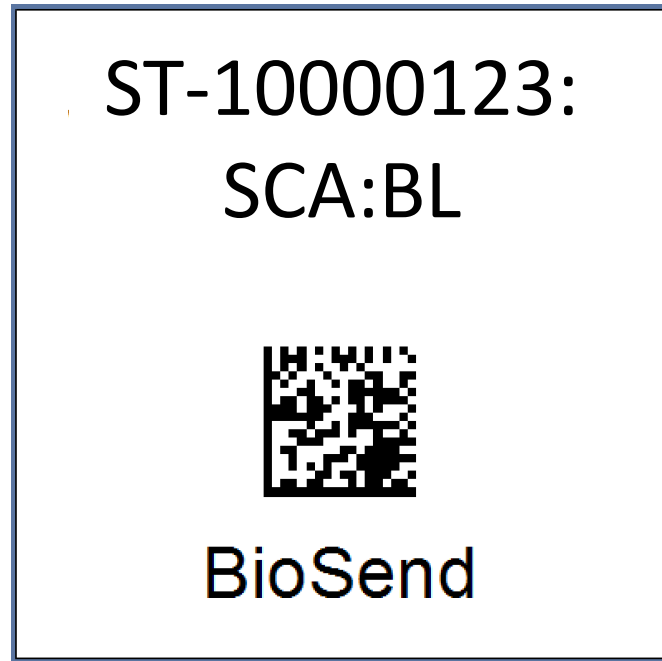
ST-10001234

BL

PLASMA

Specimen Labels

Case Label



← Subject Number

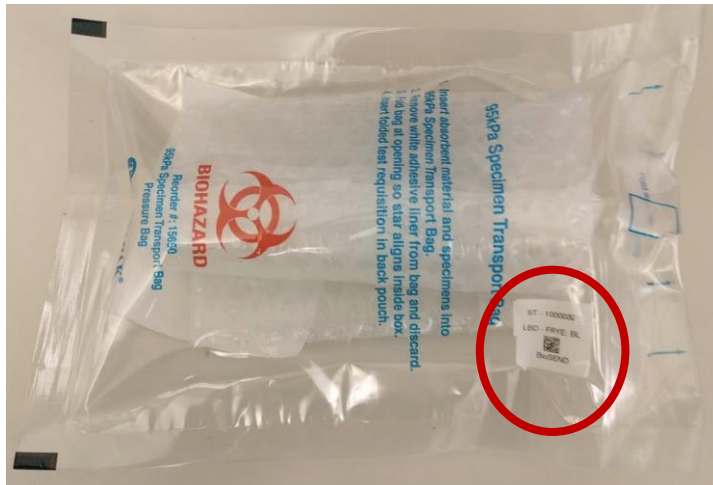
← Study & Visit

← Biorepository Name

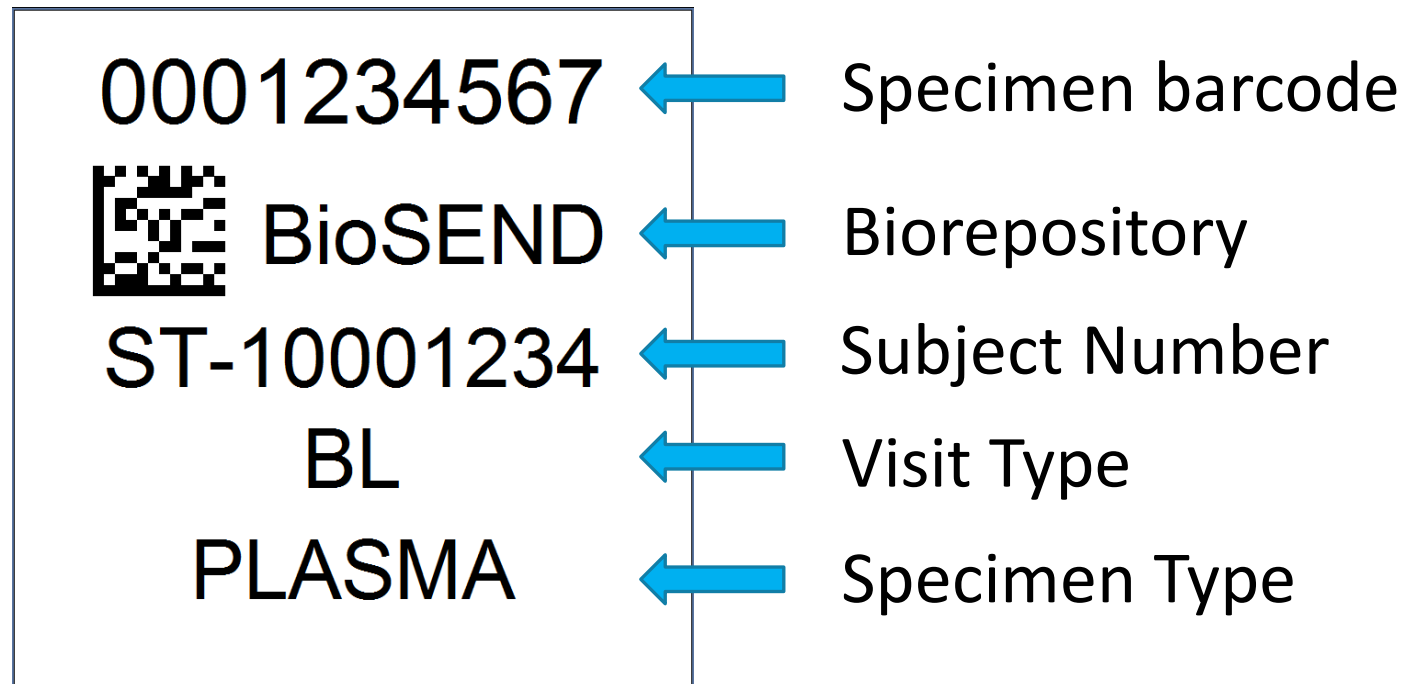
Case Labels

Case labels are placed:

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



Specimen Label



Sample Collection and Processing

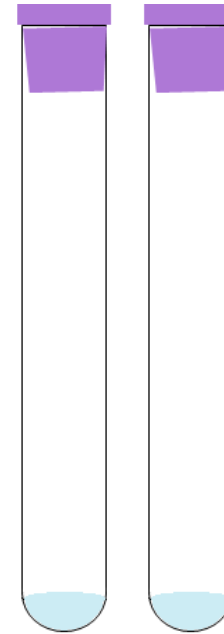
Blood Tube Draw Order

6ml EDTA*



1

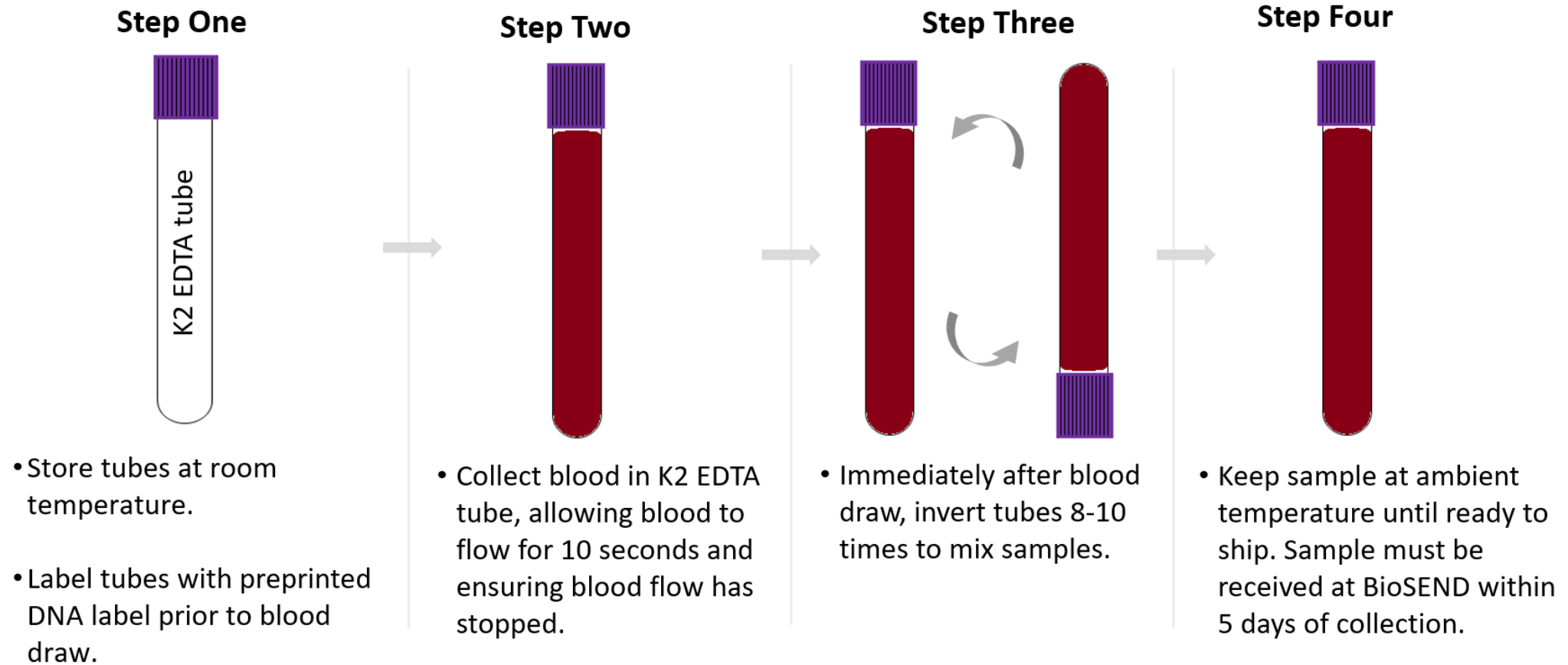
10ml EDTA



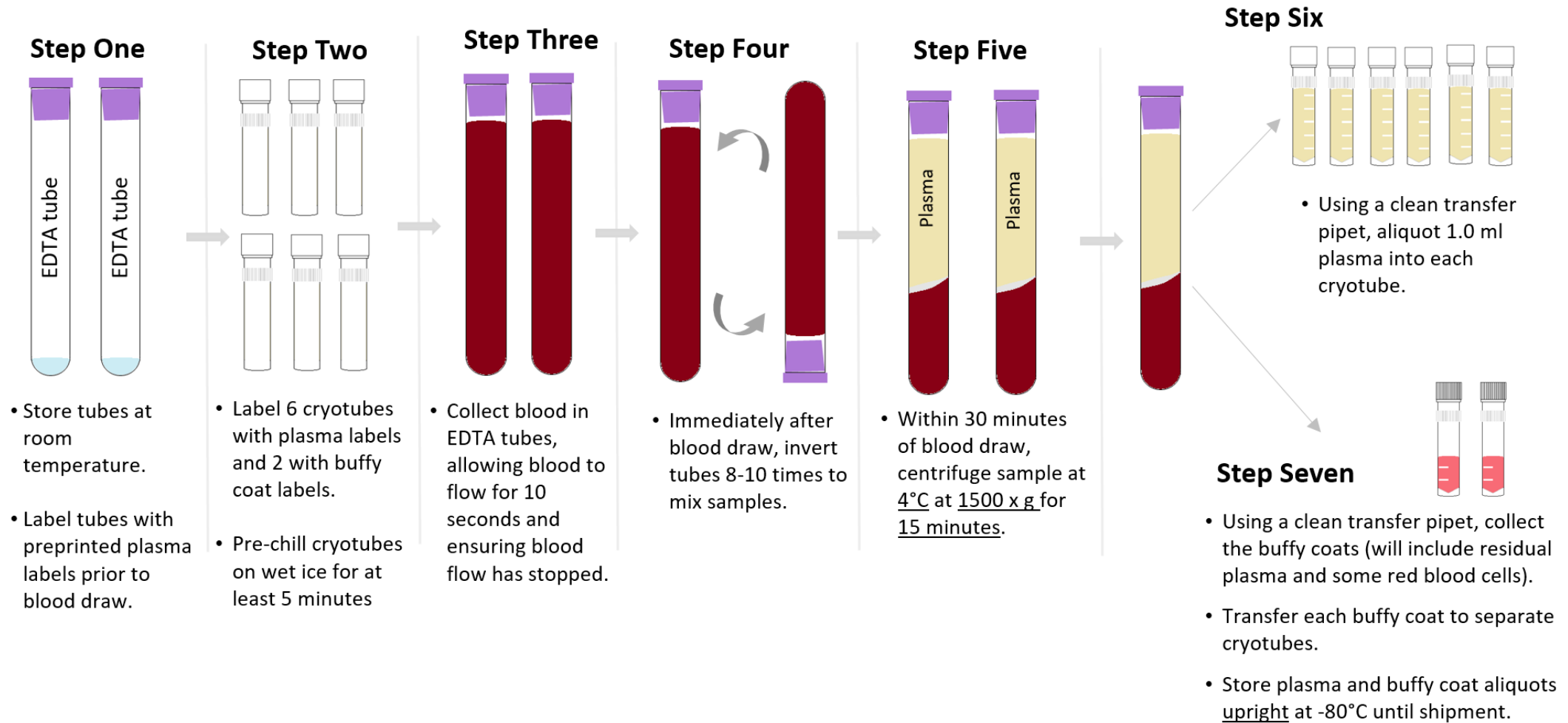
2

**6ml EDTA for DNA collected at one visit only*

Sample Collection and Processing: DNA



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

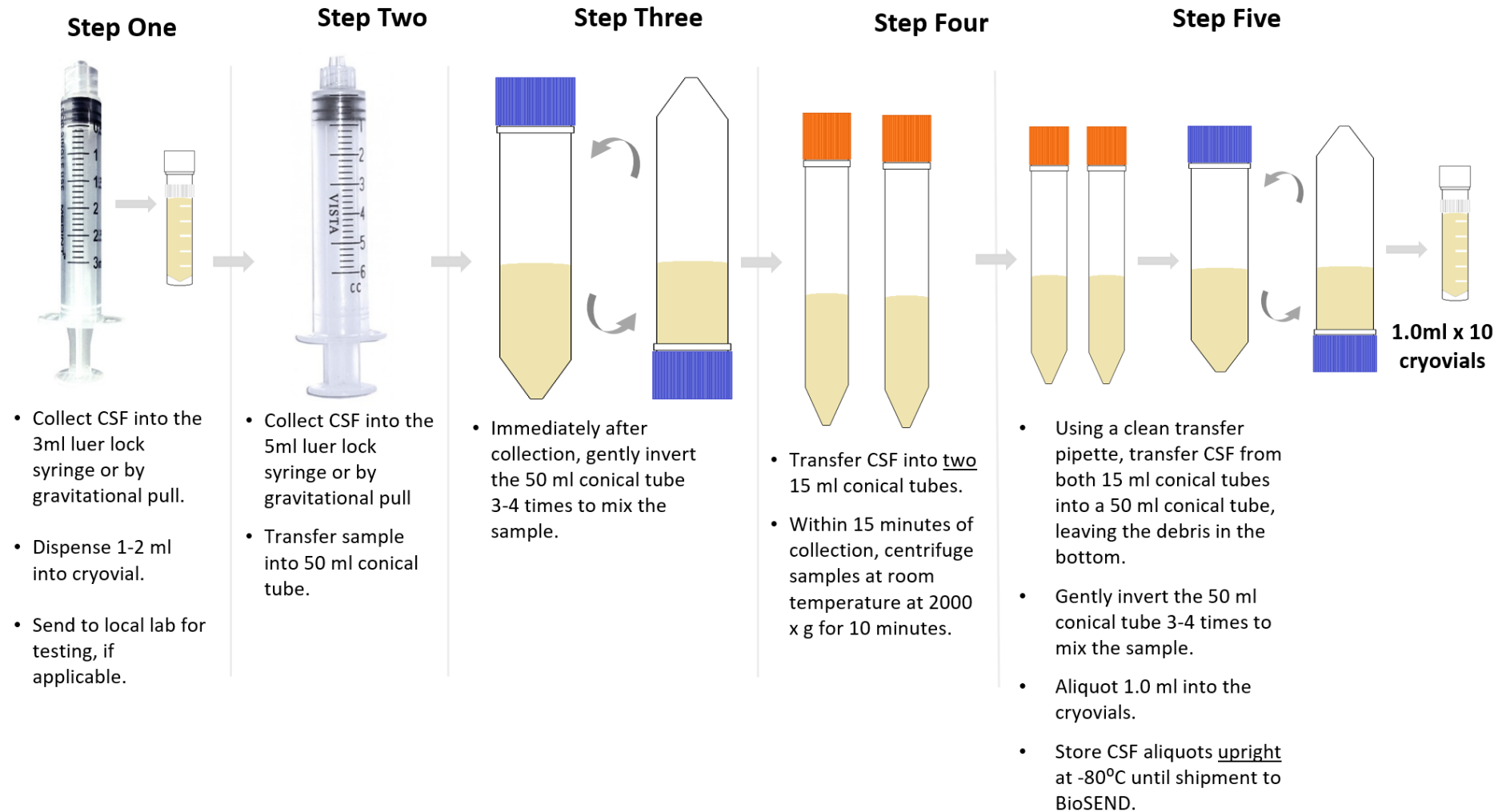
Blood Collection: Troubleshooting

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)

Sample Collection and Processing: CSF



Shipping Samples: Ambient

6ml EDTA for DNA is the only sample shipped ambient

- Ambient samples should be shipped Monday-Thursday only
- If collected on a Friday, hold sample at room temperature and ship to BioSEND the following Monday
- Sample(s) must be received at BioSEND within 5 days of collection

Shipping Samples

Ambient Shipper Contents

Styrofoam shipper with outer cardboard box

IATA Contents Sheet



Biohazard bag with absorbent material

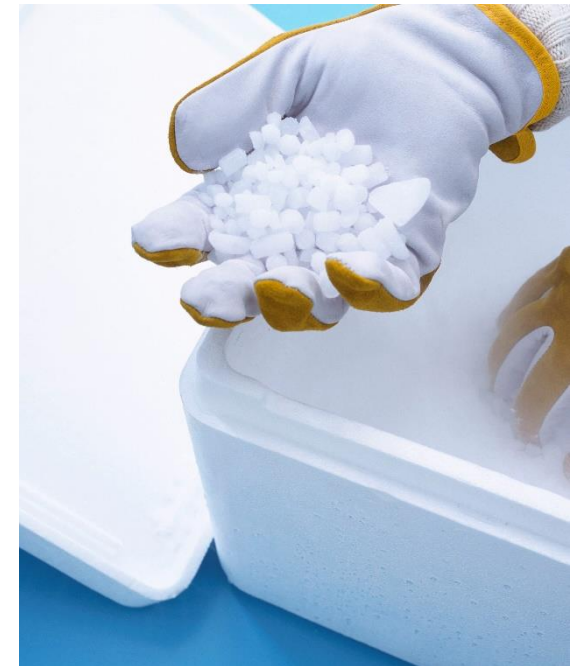
Cool pack (place in fridge prior to collection/shipment)

Collection tube will be in blood kit

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



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

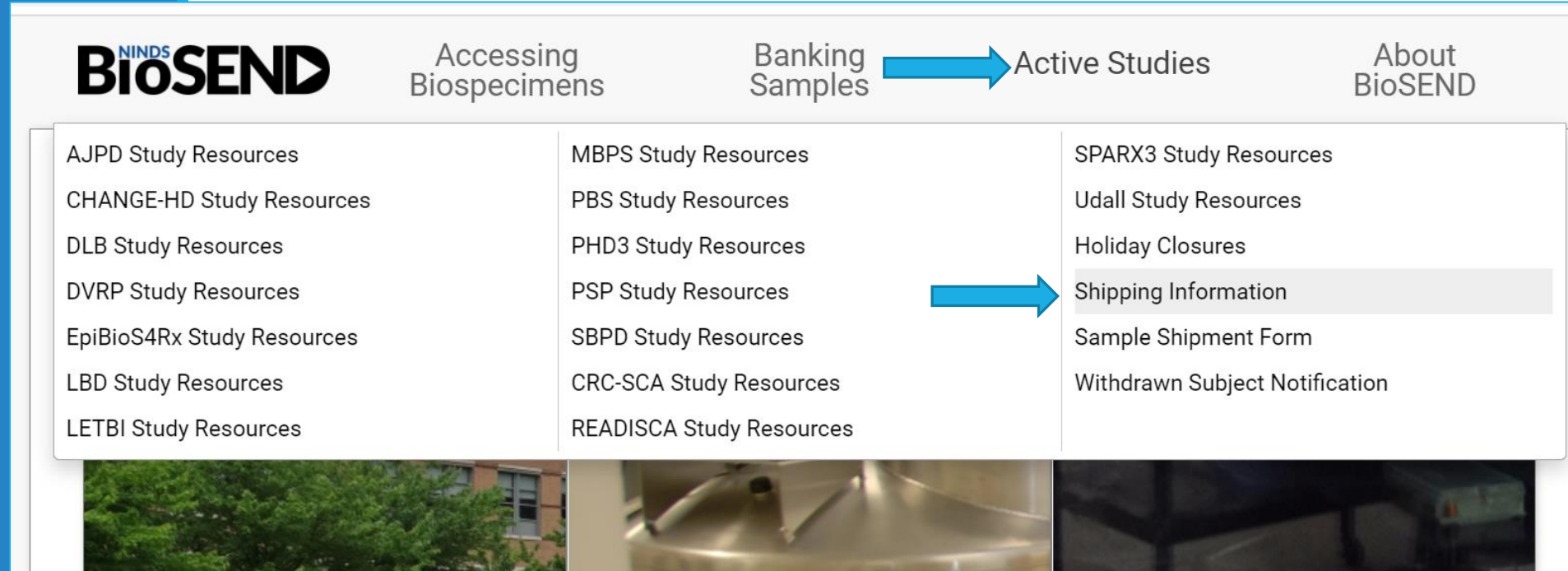
Consignee Name and Address

IU information and address

06426 1/01 RRD

Shipping Samples

UPS resources available on BioSEND website

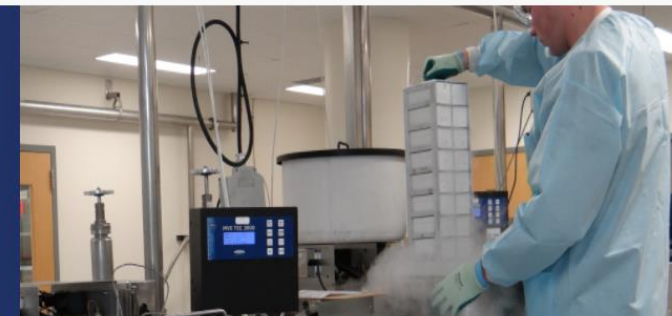


The screenshot shows the NINDS BioSEND website navigation bar and a dropdown menu. The navigation bar includes the BioSEND logo, 'Accessing Biospecimens', 'Banking Samples', 'Active Studies' (highlighted with a blue arrow), and 'About BioSEND'. The dropdown menu lists various study resources and shipping-related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

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 Frozen Samples

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

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



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

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