

BioSpecimen Exchange for Neurological Disorders (BioSEND) Training Webinar


***Study in Parkinson Disease
of Exercise Phase 3 Clinical
Trial: SPARX3***

BioSEND Training Webinar Overview

1. Study Reminders
2. Site Equipment
3. Biospecimen Collection Protocol
4. Kits & Samples
 - Requesting Kits
 - Labels
 - Sample Collection & Processing
 - Sample Shipment
5. BioSEND Website
6. Contact Information

Study Reminders

Please remember...

- Biospecimens are limited, valuable resources.
- Standardization and quality are key! 
- Reference the BioSEND Manual of Procedures as needed.
- Do not replace or supplement any kit components without first receiving approval from BioSEND.

Site Equipment

The following items are to be supplied by the site:

- Personal protective equipment
- Alcohol prep pads
- Butterfly needles and hubs
- Tourniquet
- Gauze pads
- Bandages
- Sharps bin and lid
- Microcentrifuge tube rack
- Test tube rack
- Pipettes and pipette tips
- 4°C Centrifuge
- -80°C Freezer
- Crushed/wet ice
- Dry ice

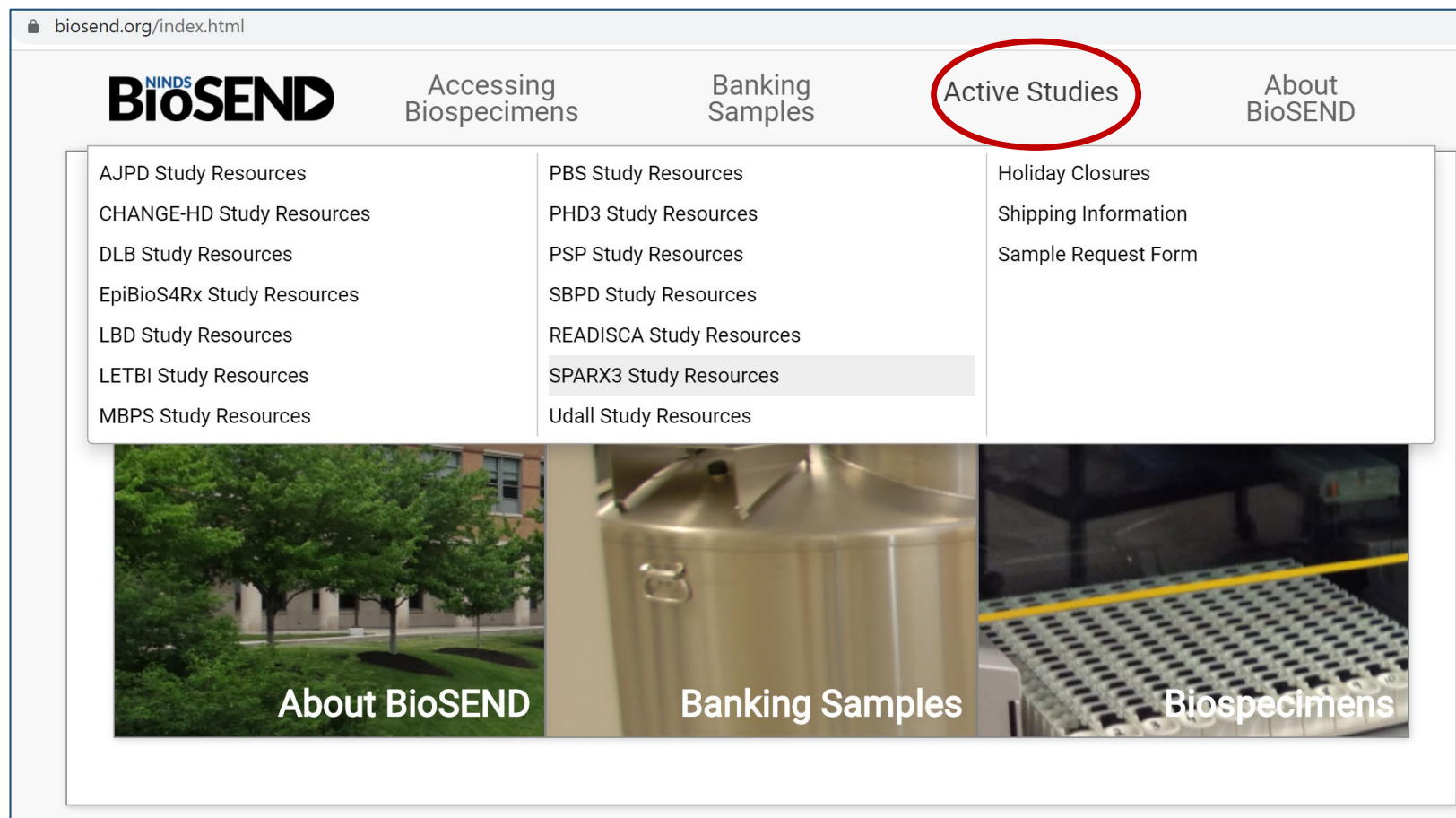
Biospecimen Collection Protocol

All specimen types FROZEN

	BL	6M	12M	18M	24M
Plasma (6 x 1.5ml)	X	X	X	X	X
Buffy Coat (2 aliquots)	X	X	X	X	X
Whole Blood (1 x 6ml)	X	X	X	X	X

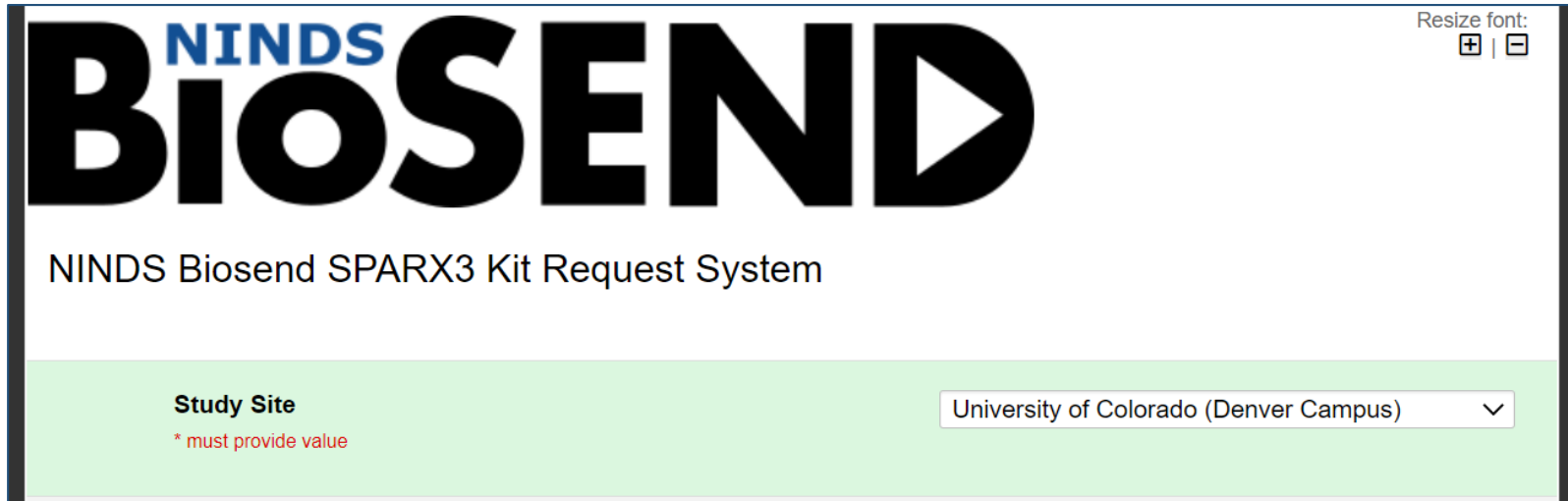
Requesting Kits

NINDS BioSEND Website



<https://www.biosend.org/>

BioSEND Kit Request Module



The screenshot shows the NINDS BioSEND SPARX3 Kit Request System interface. At the top, the NINDS BioSEND logo is displayed in large, bold letters. Below the logo, the text "NINDS Biosend SPARX3 Kit Request System" is visible. In the top right corner, there is a "Resize font:" option 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". On the right, there is a drop-down menu showing "University of Colorado (Denver Campus)" with a downward arrow.

- <http://kits.iu.edu/biosend/sparx3>
- **Choose your site from the drop-down list.**

BioSEND Kit Request Module

University of Colorado

Katherine Balfany
University of Colorado Denver Anschutz Medical Campus
Department of Physical Therapy
13121 E 17th Ave. Mail Stop C244
Aurora, CO 80045

Katherine.balfany@cuanschutz.edu
Phone Office: 303.724.9101
Phone Cell: 608.317.6222

Confirm site information:

- Study site
- Shipping address
- Contact name
- Email

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

BioSEND Kit Request Module

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>Option to correct/update contact and shipping address, if needed</div> <input type="text"/>	
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"/>	

BioSEND Kit Request Module: Kit Type

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

BioSEND Kit Request Module: Baseline Kit


Kit Type **Please allow two weeks for shipment** <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>
Baseline Visit Kit Quantity <small>* must provide value</small>	<input type="text"/>

- BioSEND creates ST numbers for baseline kits
- ST#s serve as the biorepository subject identifier
- Enter kit quantity

BioSEND Kit Request Module: Baseline Kit

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.

BioSEND Kit Request Module: Annual Visits

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input type="checkbox"/> Baseline Visit Kit <input checked="" 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>
Annual Visit Kit Quantity <small>* must provide value</small>	<input type="text" value="1"/> <small>If requesting annual kits, you must provide the ST-numbers of all kits needed. Not doing so will cause delay in shipment, as we are unable to complete your request without this information.</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"/> <small>e.g. ST-00012345</small>
1st Kit Visit Month	<input type="text" value="▼"/>
Comments	<input type="text"/>

- Please provide ST# and visit type for follow-up kits. We cannot complete your request without this information.

BioSEND Kit Request Module: Supplemental Kit

Kit Type **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>
Supplemental Kit Quantity <small>* must provide value</small>	<input type="text" value="1"/>
Comments	<div></div> <div>Expand</div>
Each Supplemental Kit Contains: 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)	

- Contains a variety of extra kit components

BioSEND Kit Request Module: Extra Supplies

Kit Type **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"/> <input type="radio"/>

- Allows you to choose specific supplies and particular quantities

BioSEND Kit Request Module: Multiple Orders

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.

- You can order more than one type of kit in a single kit request

BioSEND Kit Request Module: Submit

- Click “Submit” to turn in your request.
- The BioSEND staff will notify you that your request has been received and address any issues.

NINDS BioSEND
NINDS Biosend SPARX3 Kit Request System

Study Site: 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

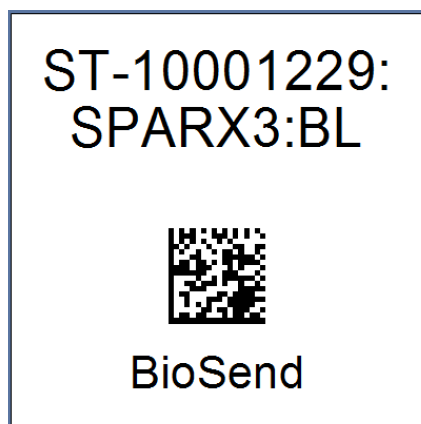
Expand

Submit

Labels

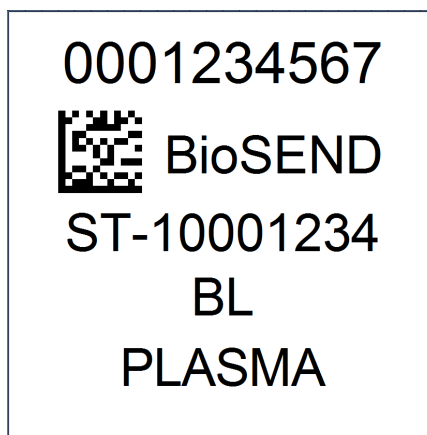
Types of Labels

Case Label



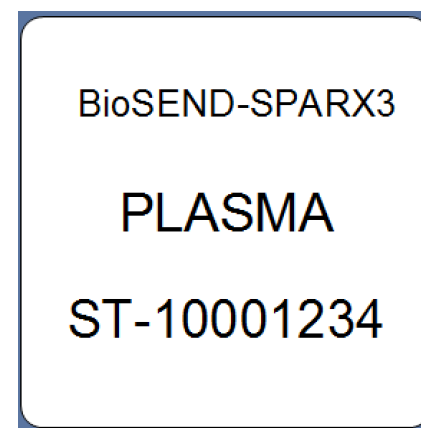
Identify study and Visit

Collection Tube Label



For collection tubes

Aliquot Label



For cryovials

Case Label

ST-10001229:
SPARX3:BL



BioSend



Subject Number



Study and Visit



Biorepository Name

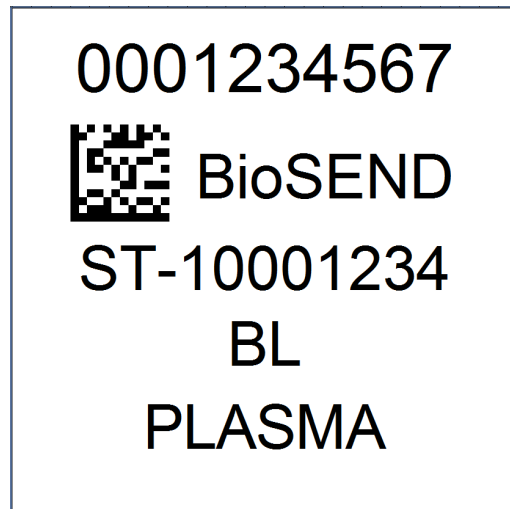
Case Labels

Case labels are placed:

- On the biohazard bag of the cryovial transport box and biohazard bag with EDTA.
- *On the lid of frozen shippers*



Collection Tube Label



Unique Barcode



Subject Number



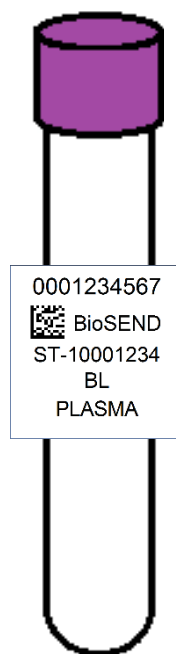
Visit Type



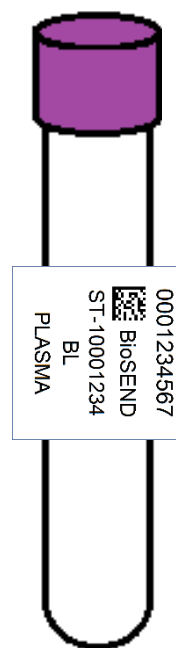
Specimen Type

Collection Tube Labels

Collection Tube Labels are placed on all collection tubes

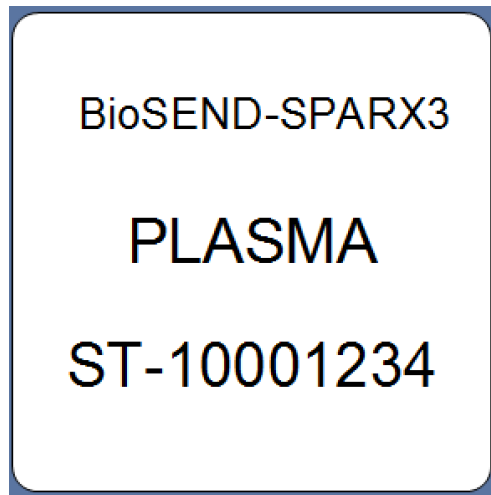


Incorrect



Correct

Aliquot Tube Label



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).

Aliquot Labels

Note: cryovial 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 cryovials from another.**

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



BioSEND-SPARX3
BUFFY COAT
ST-10001234

Aliquot Labels

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

Grey cryovials are used for
Buffy Coat aliquots



BioSEND-SPARX3
BUFFY COAT
ST-10001234

Purple cryovials are used for
plasma aliquots



BioSEND-SPARX3
PLASMA
ST-10001234

Sample Collection & Processing

Reminders:

- All specimens should be frozen and stored UPRIGHT
 - For plasma and buffy coat aliquots, please freeze samples upright in the cryobox provided

Order of Specimen Collection

1. EDTA 10 ml (**lavender top**) blood collection for plasma and buffy coat
2. EDTA 6 ml (**purple top**) blood collection for banking

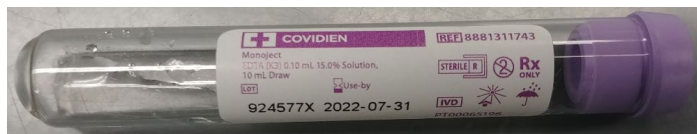


**EDTA, 10ml
(Plasma and
Buffy Coat)**

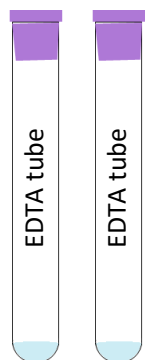


**EDTA, 6ml
(Whole Blood)**

Plasma Preparation –10 ml EDTA (Purple Top) Tube



Step One



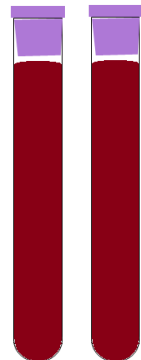
- Store tubes at room temperature.
- Label tubes with preprinted plasma labels prior to blood draw.

Step Two



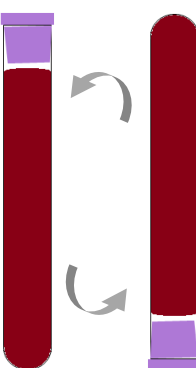
- Label purple cryovials with plasma labels.
- Pre-chill cryotubes on wet ice for at least 5 minutes.

Step Three



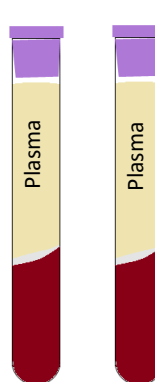
- Collect blood in EDTA tubes, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Four



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

Step Five



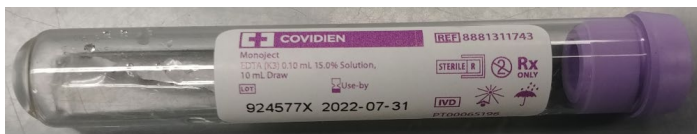
- Within 30 minutes of blood draw, centrifuge sample at 1500 x g at 4°C for 15 minutes.

Step Six

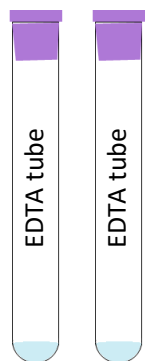


- Using a clean transfer pipet, aliquot 1.5 ml plasma into each purple cryotube.
- Store plasma aliquots upright at -80°C until shipment.
- See Appendix C for instructions on buffy coat collection.

Buffy Coat Preparation –10 ml EDTA (Purple Top) Tube



Step One



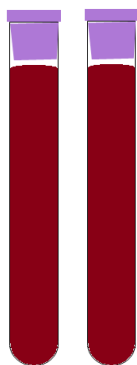
- Store tubes at room temperature.
- Label tubes with preprinted plasma labels prior to blood draw.

Step Two



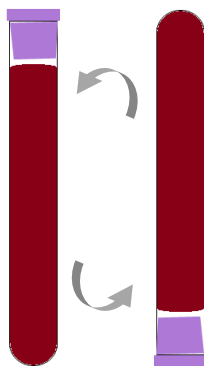
- Label grey cryovials with buffy coat labels.
- Pre-chill cryotubes on wet ice for at least 5 minutes.

Step Three



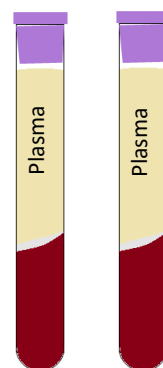
- Collect blood in EDTA tubes, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Four



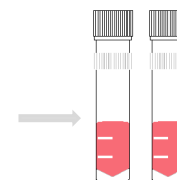
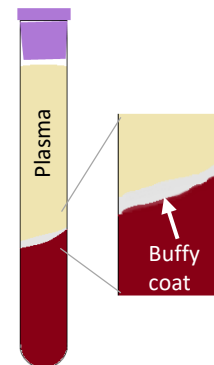
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

Step Five



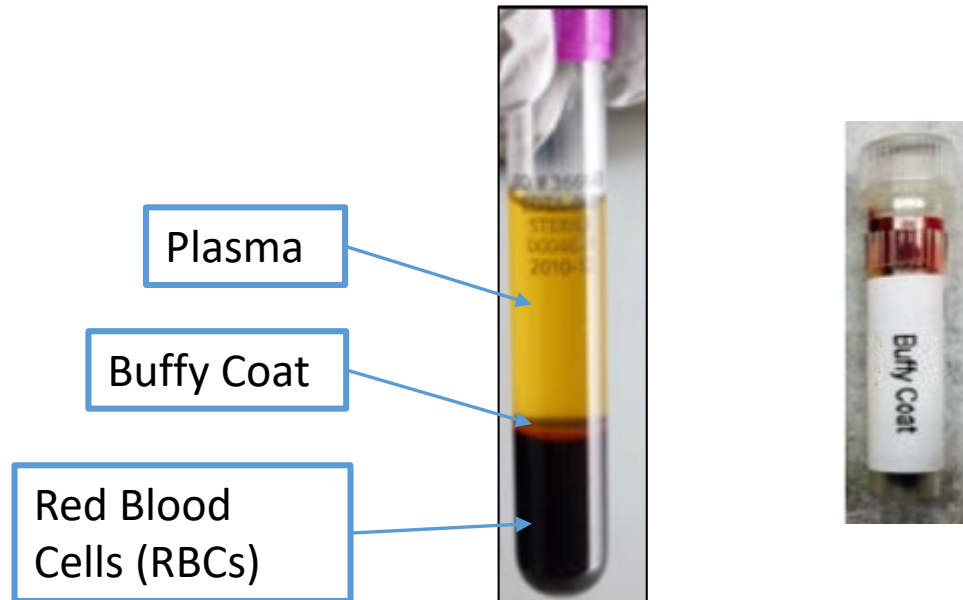
- Within 30 minutes of blood draw, centrifuge sample at 1500 x g at 4°C for 15 minutes.

Step Six



- Using a clean transfer pipet, collect the buffy coat (will have residual plasma and some RBCs included).
- Transfer the buffy coat from each EDTA tube into a grey cryotube.
- Store plasma aliquots upright at -80°C until shipment.

Buffy Coat Collection



Collect the buffy coat layer using the transfer pipet provided. Residual plasma as well as some RBCs will be included in this collection. A buffy coat will be reddish in color due to RBCs. Freeze buffy coats upright on dry ice or -80 freezer. Store in -80 freezer until shipment to BioSEND.

Whole Blood (6 ml Lavender Top Tube)



Step One



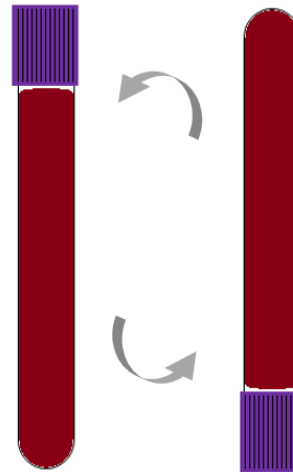
- Store tubes at room temperature.
- Label tubes with preprinted WBLD label prior to blood draw.

Step Two



- Collect blood in 6ml EDTA tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



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

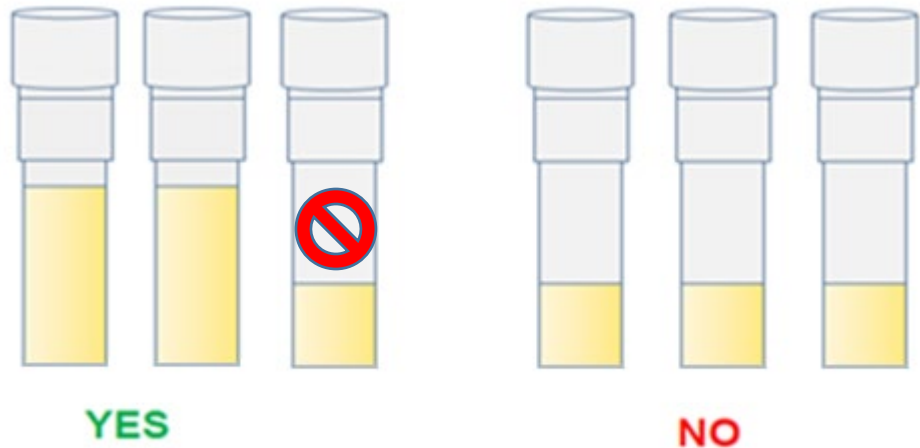
Step Four



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

Plasma and Buffy Coat Aliquots

- Fill plasma cryovials to 1.5ml
- Over-filled vials may burst in freeze
- Do NOT send residual volumes to BioSEND



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
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 Shipment

Frozen Samples

- **All samples are shipped frozen**
 - Plasma, buffy coat, and whole blood
- **Ship Monday-Wednesday Only via FedEx Priority Overnight**
- Schedule FedEx® pickup
 - UPS for international shipments
- Email Sample Record and Shipment Notification Form including tracking number **AHEAD OF SHIPMENT**



Packaging and Shipping Frozen Samples



Place plasma and buffy coats in cryobox



Place cryobox in biohazard bag with absorbent sheet, seal, and label with case label.

Packaging and Shipping Frozen Samples



Place whole blood in
bubble-sleeve and seal



Place frozen tube in
second biohazard bag
with absorbent sheet,
seal, and label with
case label.

Packaging and Shipping Frozen Samples



Place approx. 2-3 inches
of dry ice in bottom of
shipper



Place biohazard bags upright in box



FILL dry ice to top
of box

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 the tubes are securely placed into the bubble wrap pouch and are placed in a separate bag from the boxed aliquots.
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 Frozen Samples

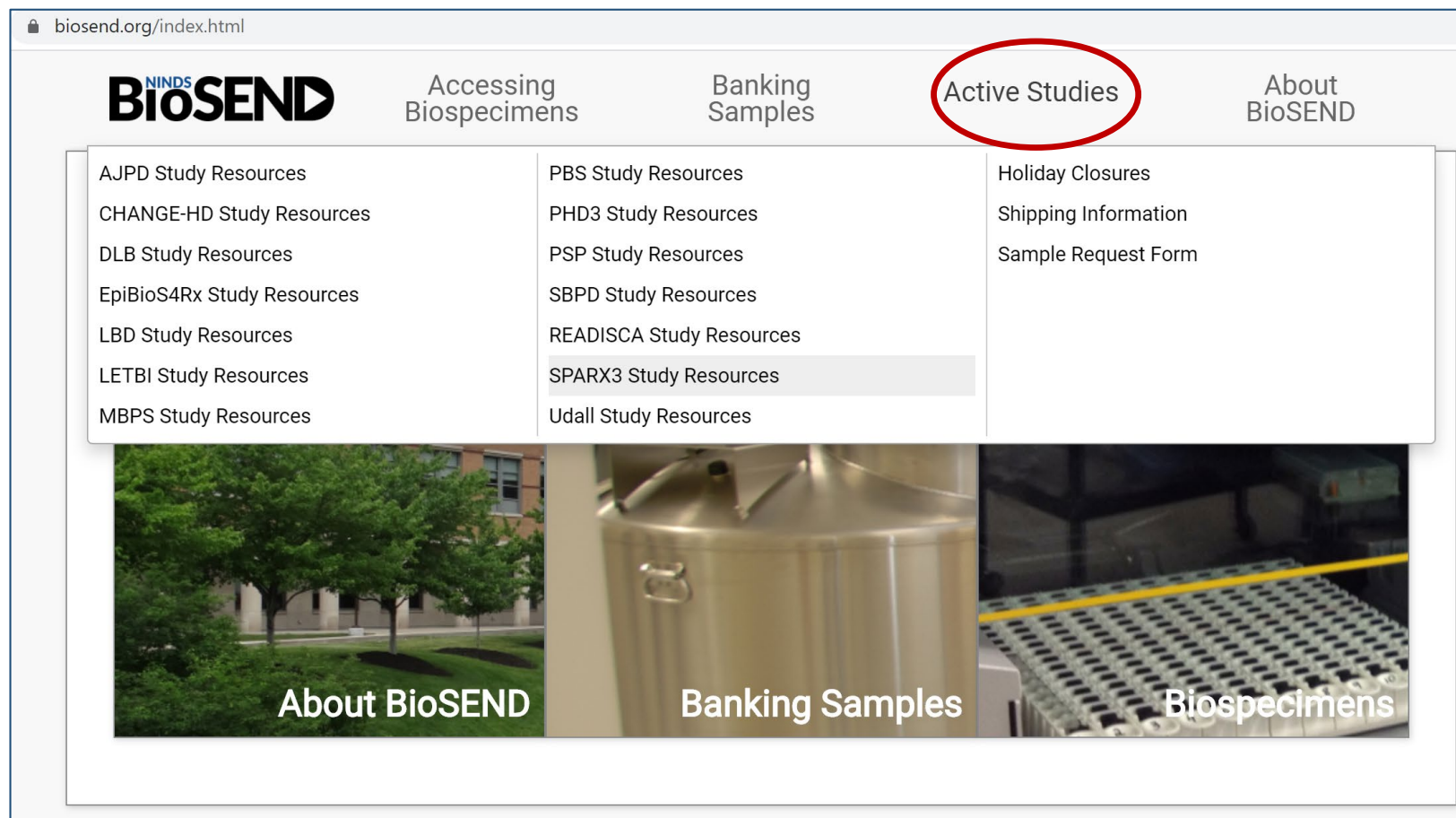
- Hold packaged samples in a -80°C freezer until pickup.
- ***Samples should be received at BioSEND within 2 weeks of collection.***



Sample Shipment Notification Form

Sample Record and Shipment Notification			
Study:			
Site Name:		Principal Investigator:	
Coordinator:		Telephone:	Email:
Please list only ONE subject per Sample Record Summary and Shipment Notification Form			
Clinical ID:		Subject ID (ST# from pre-printed labels):	
Gender:		Visit Type:	
Age in Years:		Plus Months:	
Instructions: Ship Frozen Shipments Monday- Wednesday ONLY! Ambient Shipments (purple-top EDTA tube) may be shipped Monday- Thursday (preferably Monday- Wednesday) provided they are received at Indiana University within five days of collection. This form must be completed for shipment of all research samples. Notify Indiana University (email preferred) and the DMR in advance of shipment using contact information below. Place a copy in the shipment box and file a copy of the completed form in the study binder. <u>Ensure all frozen shipments are completely filled with dry ice.</u>			
Date Sample(s) Shipped:		FedEx Tracking Number:	
In the table below, please indicate the date of specimen collection and number of tubes/aliquots submitted.			
Completed by Submitter/Site			
Dates of Draw	Specimen Type	Number of Tubes/ Aliquots sent to BioSEND	Notation of Problems
	DNA		
	RNA		
	Buffy Coat		
	Plasma		
	Serum		
	CSF		
	Whole Blood		
Contact Information: Indiana University; Email: biosend@iu.edu Ph: 317-278-0594			

NINDS BioSEND Website



<https://www.biosend.org/>

Sample Shipment Notification Form, Online

NINDS
BioSEND


Accessing
Biospecimens

Banking
Samples

Active Studies

About
BioSEND

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

Principal Investigator

Coordinator

Telephone

Email

Subject Information

Study

Clinical ID

GUID

Subject ID (ST# from labels)

Subject ID (ST#)

Gender

Visit Type

Age (In Years)

Plus Months

Ship Frozen Shipments Monday-Wednesday ONLY! Ambient Shipments (purple-top EDTA tube) may be shipped Monday-Thursday (preferably Monday- Thursday) provided they are received at Indiana University within five days of collection. This form must be completed for shipment of all research samples. This form will serve as notification to Indiana University and the DMR of sample shipment. Place a copy in the shipment box and file a copy of the completed form in the study binder. **Ensure all frozen shipments are filled with dry ice.**

Downloads

Sample Shipment Form (pdf)
Sample Shipment Form (xlsx)

Additional Resources

Shipping Information

Contact Us

biosend@iu.edu
317-278-0594

Sample Information

Date Sample(s) Shipped

FedEx Tracking Number

07/27/2017

FedEx Tracking #

Draw Date	Specimen Type	# of Tubes Sent	Notation of Problems
<div>Draw Date</div>	<div>DNA</div>	<div># of Tubes</div>	<div>Notation of Problems</div>
<div>Draw Date</div>	<div>RNA</div>	<div># of Tubes</div>	<div>Notation of Problems</div>
<div>Draw Date</div>	<div>Plasma</div>	<div># of Tubes</div>	<div>Notation of Problems</div>
<div>Draw Date</div>	<div>Serum</div>	<div># of Tubes</div>	<div>Notation of Problems</div>
<div>Draw Date</div>	<div>CSF</div>	<div># of Tubes</div>	<div>Notation of Problems</div>
<div>Draw Date</div>	<div>Whole Blood</div>	<div># of Tubes</div>	<div>Notation of Problems</div>
<div>Draw Date</div>	<div>Buffy Coat</div>	<div># of Tubes</div>	<div>Notation of Problems</div>

Reset Sample Form

Submit Sample Form

Holiday 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 Day

Note that BioSEND has extended closures surrounding the Thanksgiving, Christmas, and New Year's Holidays. BioSEND will send notification of these dates prior to the holiday season.

BioSEND Contact Information

- Questions?

Please contact:

- General Email: biosend@iu.edu
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Questions?