



Dissecting Oligogenic Biomarkers in Ashkenazi Jews with
Parkinson's Disease (AJPD)

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

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

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

[illegible]

Kit Ordering – Biosend.org




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

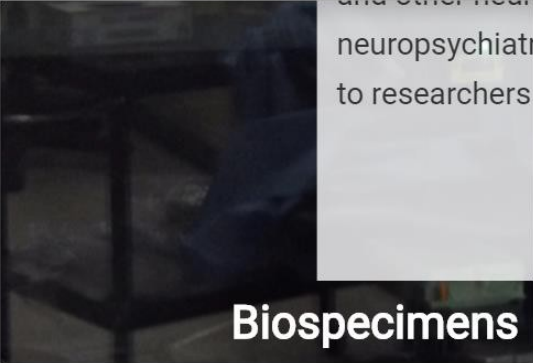
SPARX3 Study Resources
Udall Study Resources
Holiday Closures
Shipping Information
Sample Shipment Form



About BioSEND



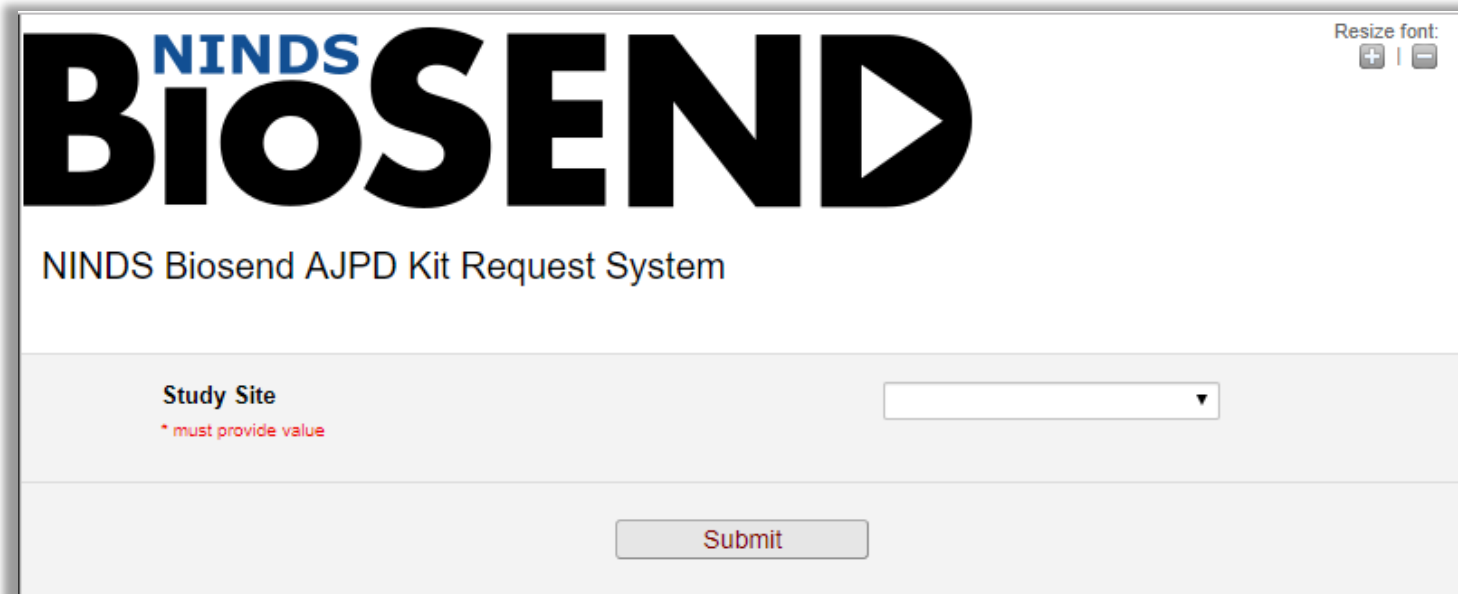
Banking Samples



Biospecimens

BioSEND Kit Request Module

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



The screenshot shows the NINDS BioSEND 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 AJPD Kit Request System" is visible. In the center, there is a form with a label "Study Site" and a red asterisk indicating a required field. To the right of the label is a drop-down menu. Below the drop-down menu is a "Submit" button. In the top right corner, there is a "Resize font" option with plus and minus icons.

NINDS BioSEND

NINDS Biosend AJPD Kit Request System

Study Site

* must provide value

Submit

Resize font: + | -

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"/>	

Multiple kit types available.
Selecting a kit will populate the
contents in that kit.

- 11 - Siliconized cryovials, sterile (2ml)
- 2 - Screw-top centrifuge tubes (15ml)
- 2 - Screw-top conical tube (50ml)
- 1 - Medication Transfer Filter Straw
- 1 - LP tray with 22 gauge Sprotte® needle

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 Visit Kit <input type="checkbox"/> Annual Visit Kit <input type="checkbox"/> Supplemental Kit <input type="checkbox"/> CSF Collection 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>

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

Automatic Kit Shipments

After subject completes baseline visit and **BioSEND receives BL samples**, BioSEND sets up automated kit sending schedule for subject's subsequent visits

Schedule gives 2 month window around the longitudinal study visit target (1 month on either side)

BioSEND will send kits prior to start of study window

- Reduces effort for study coordinators

- Sites only need to order kits if visit will occur **AHEAD** of the study visit window

All study visit target dates are determined from Baseline Visit (not from last study visit date)

CSF Kits

Labels for CSF included with every BL and Annual visit, so that CSF kit can be paired with any subject/time point.

Kit Type **Please allow two weeks for shipment** <i>* must provide value</i>	<input type="checkbox"/> Baseline Visit Kit <input type="checkbox"/> Annual Visit Kit <input type="checkbox"/> Supplemental Kit <input checked="" type="checkbox"/> CSF Collection Kit <input type="checkbox"/> Extra Supplies Please specify in comments if you need kits before the standard two week shipment time.
CSF Sprotte® Needle Gauge <i>* must provide value</i>	<input checked="" type="radio"/> 22 <input type="radio"/> 24 <div>reset</div>
CSF Collection Kit Quantity <i>* must provide value</i>	<input type="text"/> If you need more than 10 kits or labels, please use the file upload option or submit multiple requests.
Comments	<div></div> <div>Expand</div>
Each CSF Collection Kit 11 - Siliconized cryovials, sterile (2ml) 2 - Screw-top centrifuge tubes (15ml) 2 - Screw-top conical tube (50ml) 1 - Medication Transfer Filter Straw 1 - LP tray with 22 gauge Sprotte® needle	

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

Multiple Orders

Kit Type **Please allow two weeks for shipment** <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>
--	--

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

Kiesze font: [icon] [icon]

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

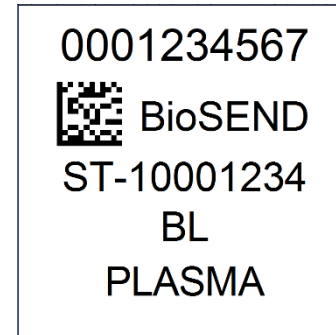
Sample Labelling

Labels are provided by Indiana University

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



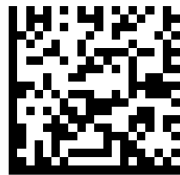
Case Labels



Specimen Labels

Case Label

ST-10001234:
AJPD-SAUND:
BL



BioSend



Subject Number



Study – PI & Visit

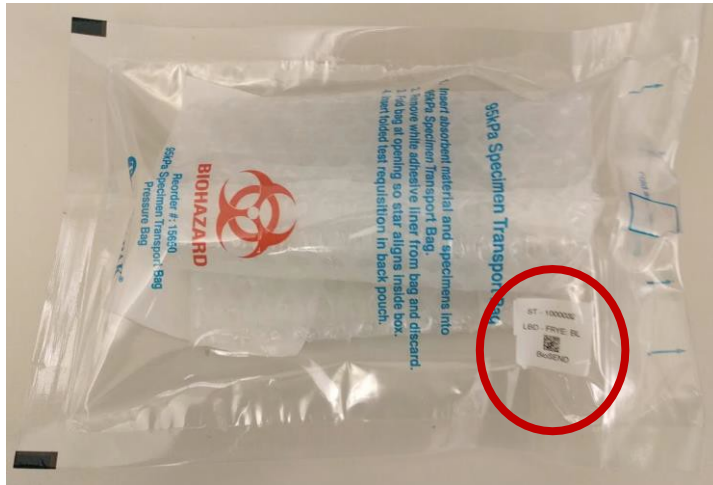


Biorepository Name

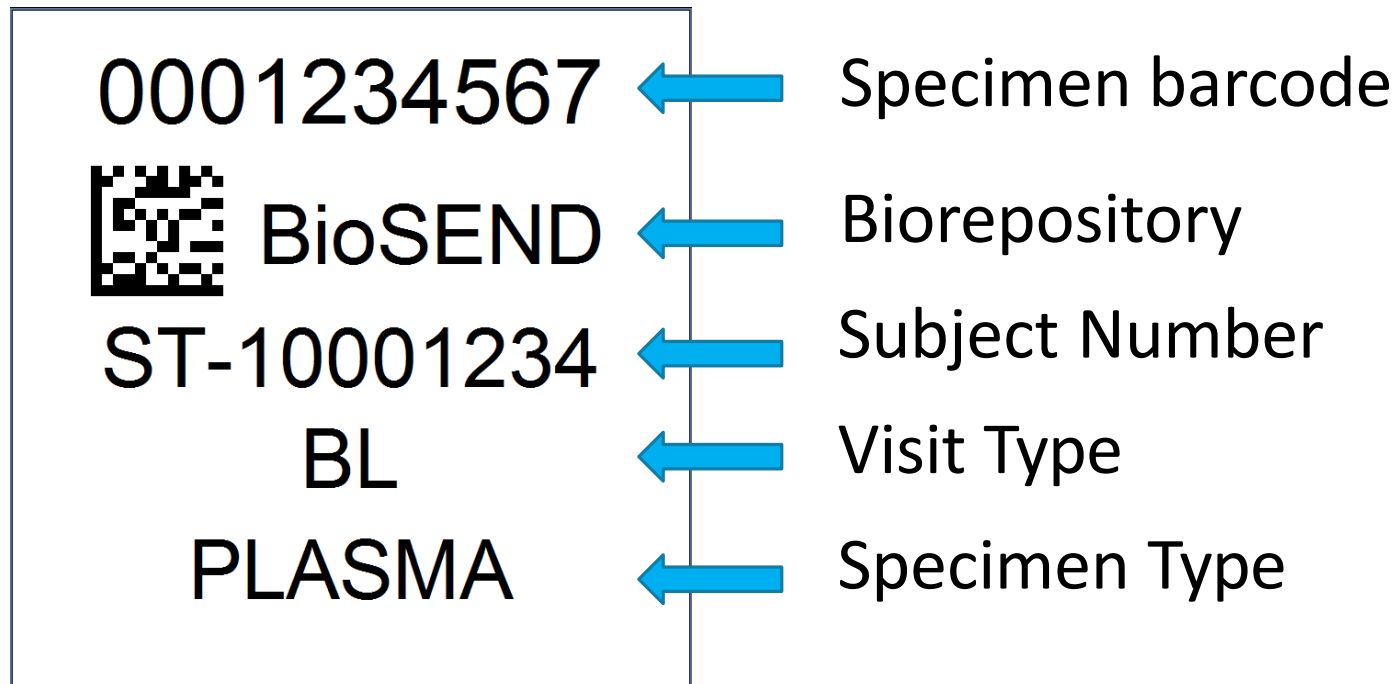
Case Labels

Case labels are placed:

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

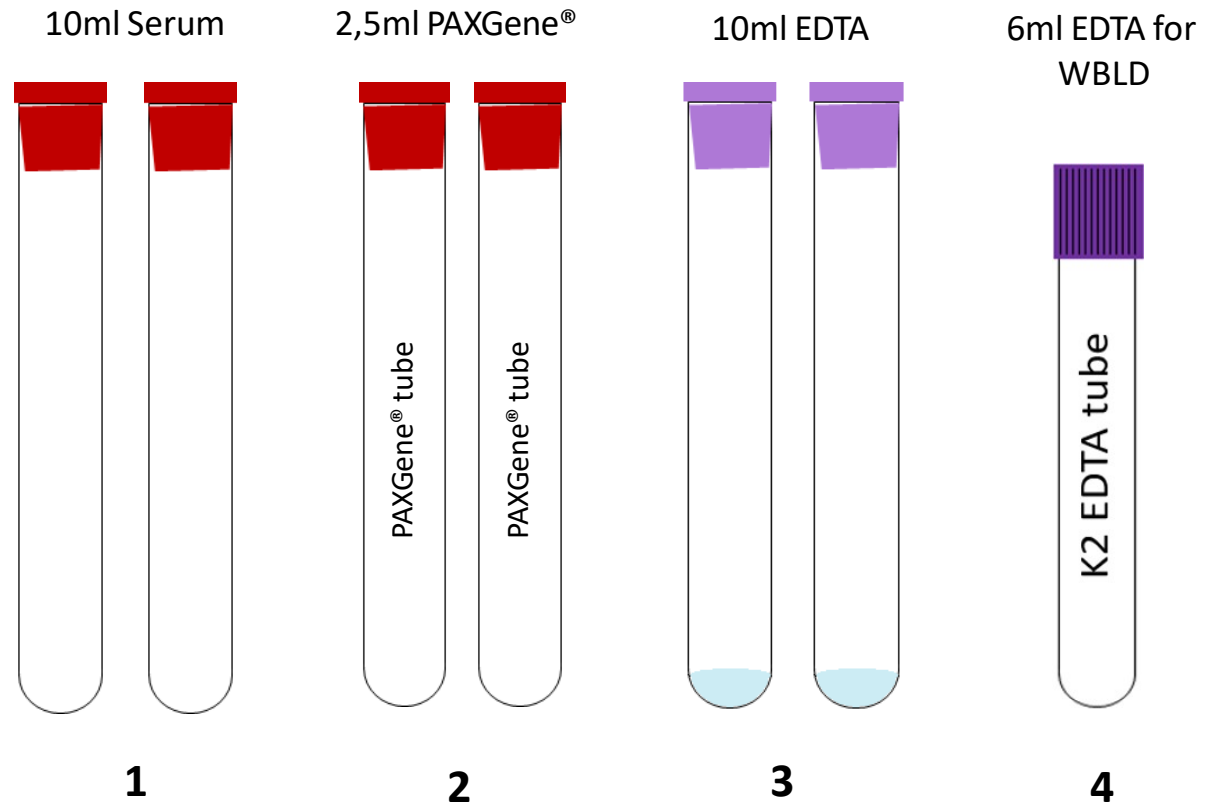


Specimen Label

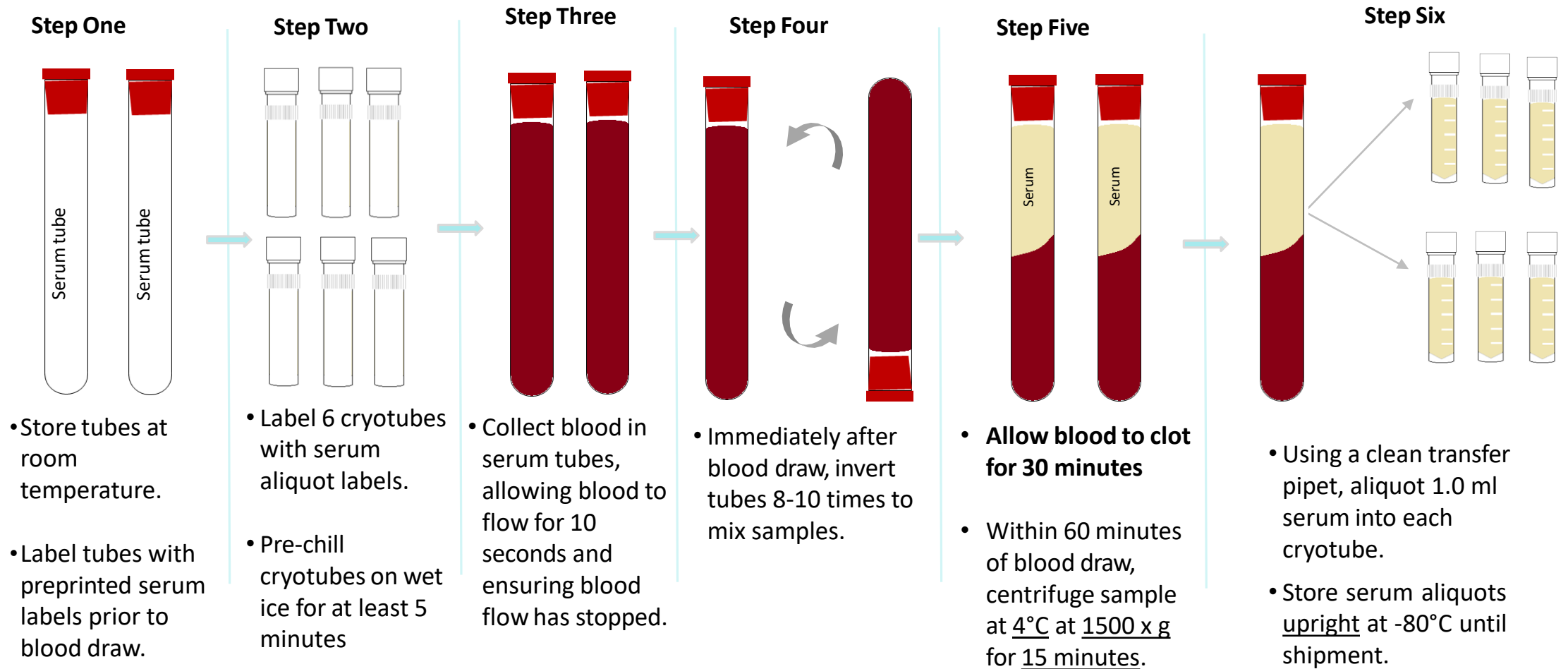


Sample Collection and Processing

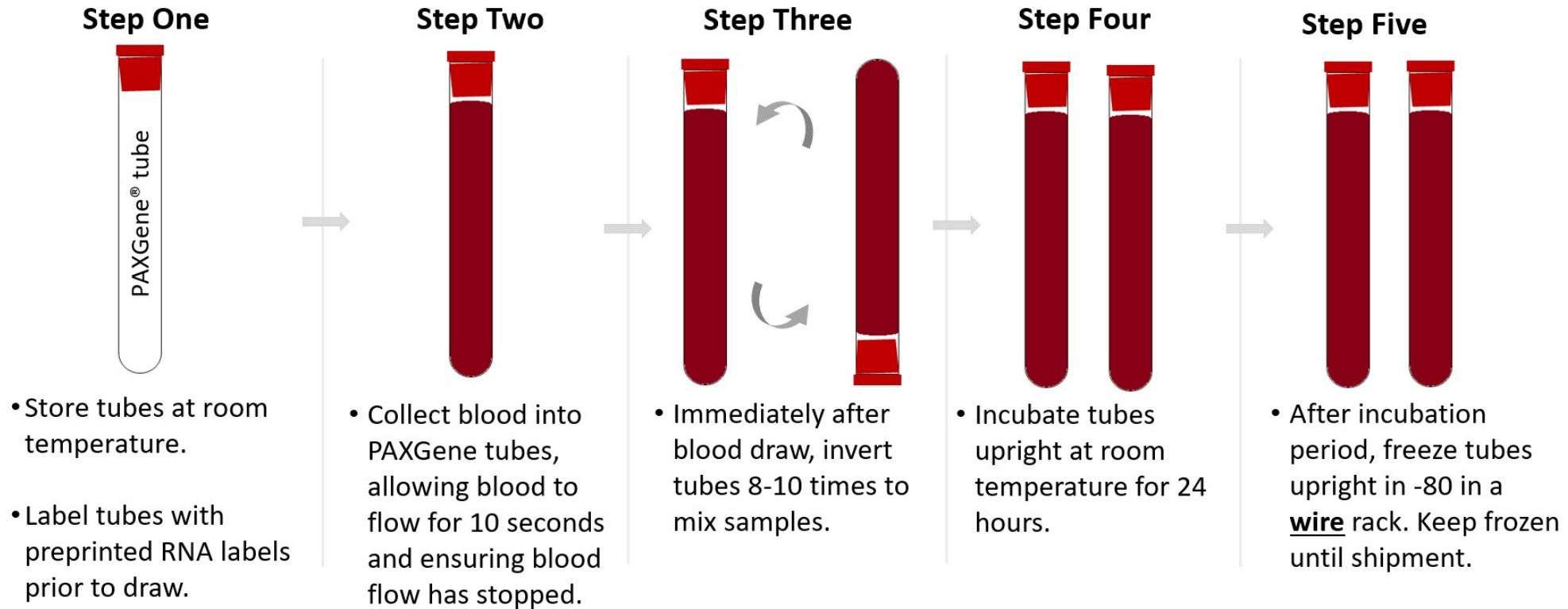
Blood Tube Draw Order



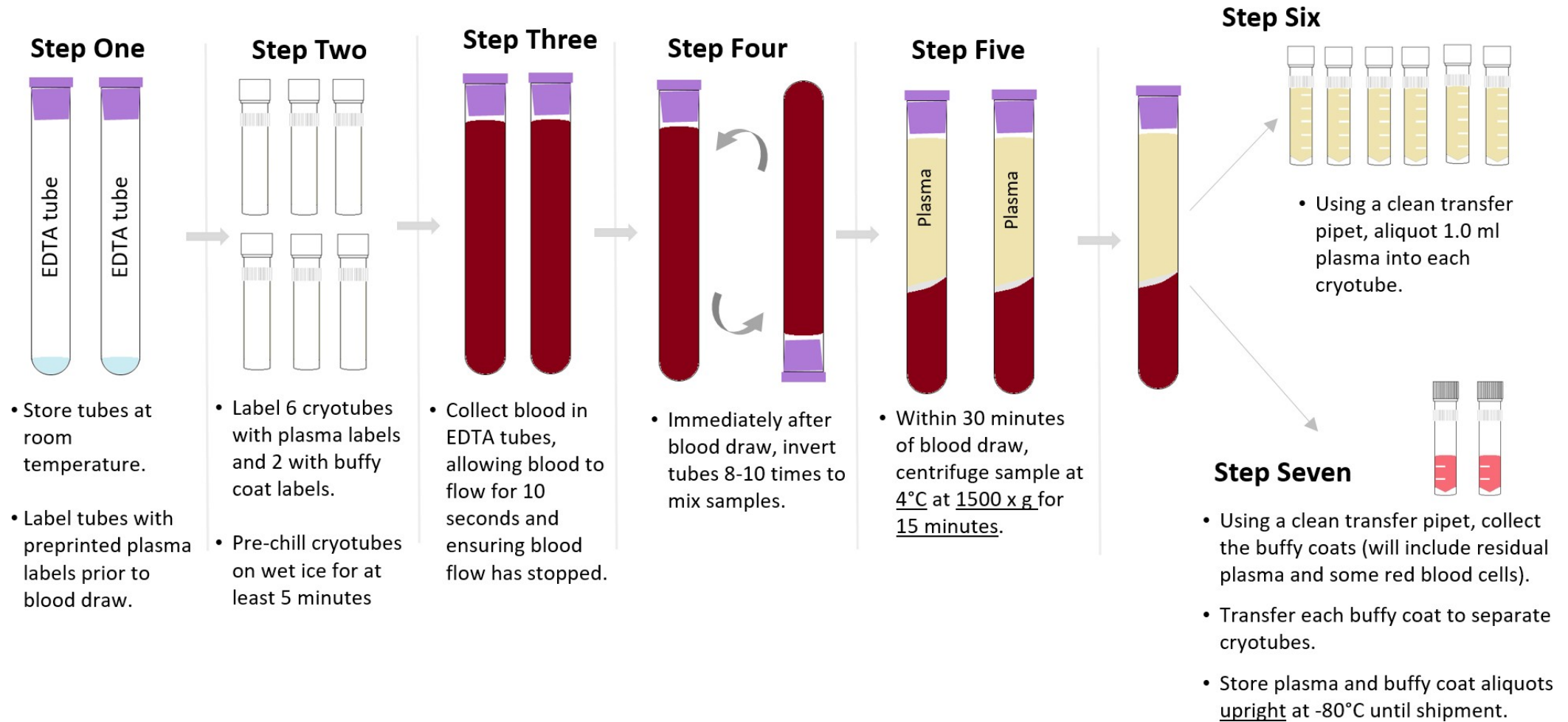
Sample Collection and Processing: Serum



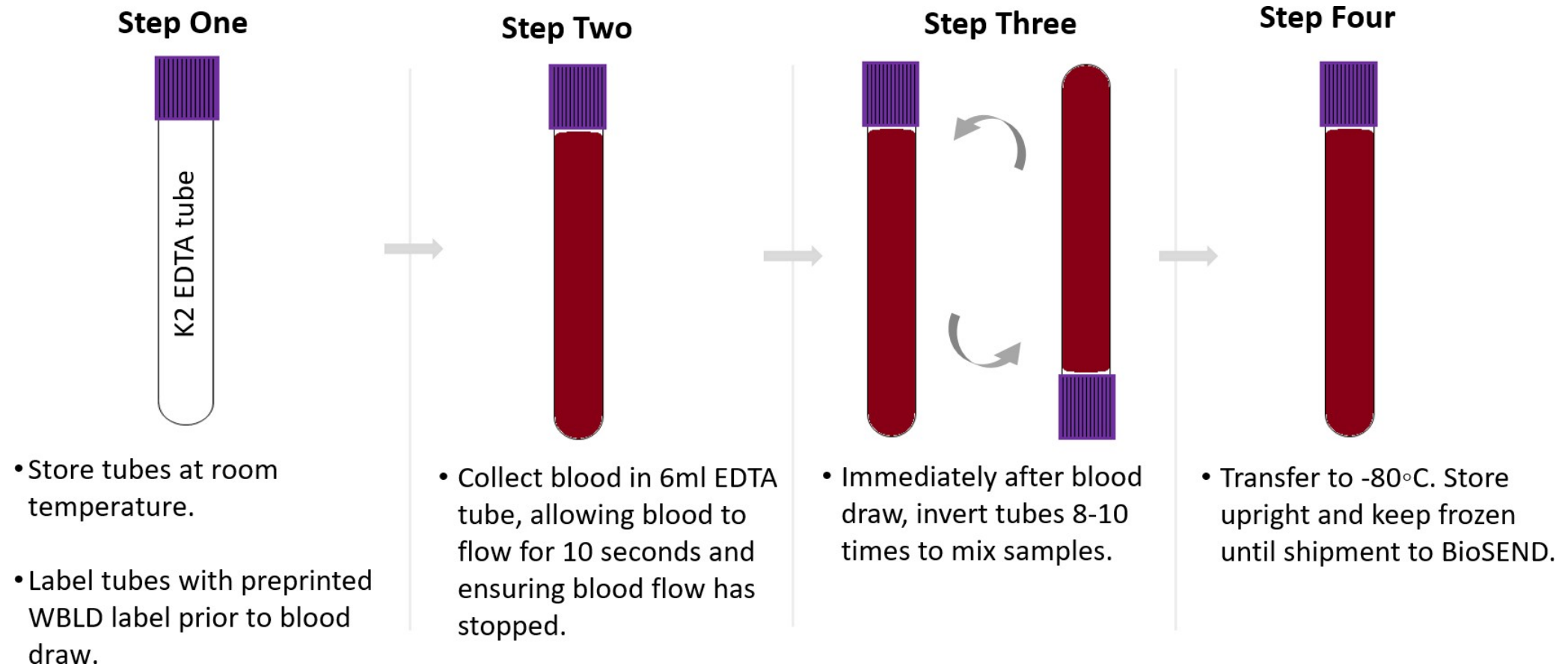
Sample Collection and Processing: RNA



Sample Collection and Processing: Plasma & Buffy Coat



Sample Collection and Processing: Whole Blood



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 & serum

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

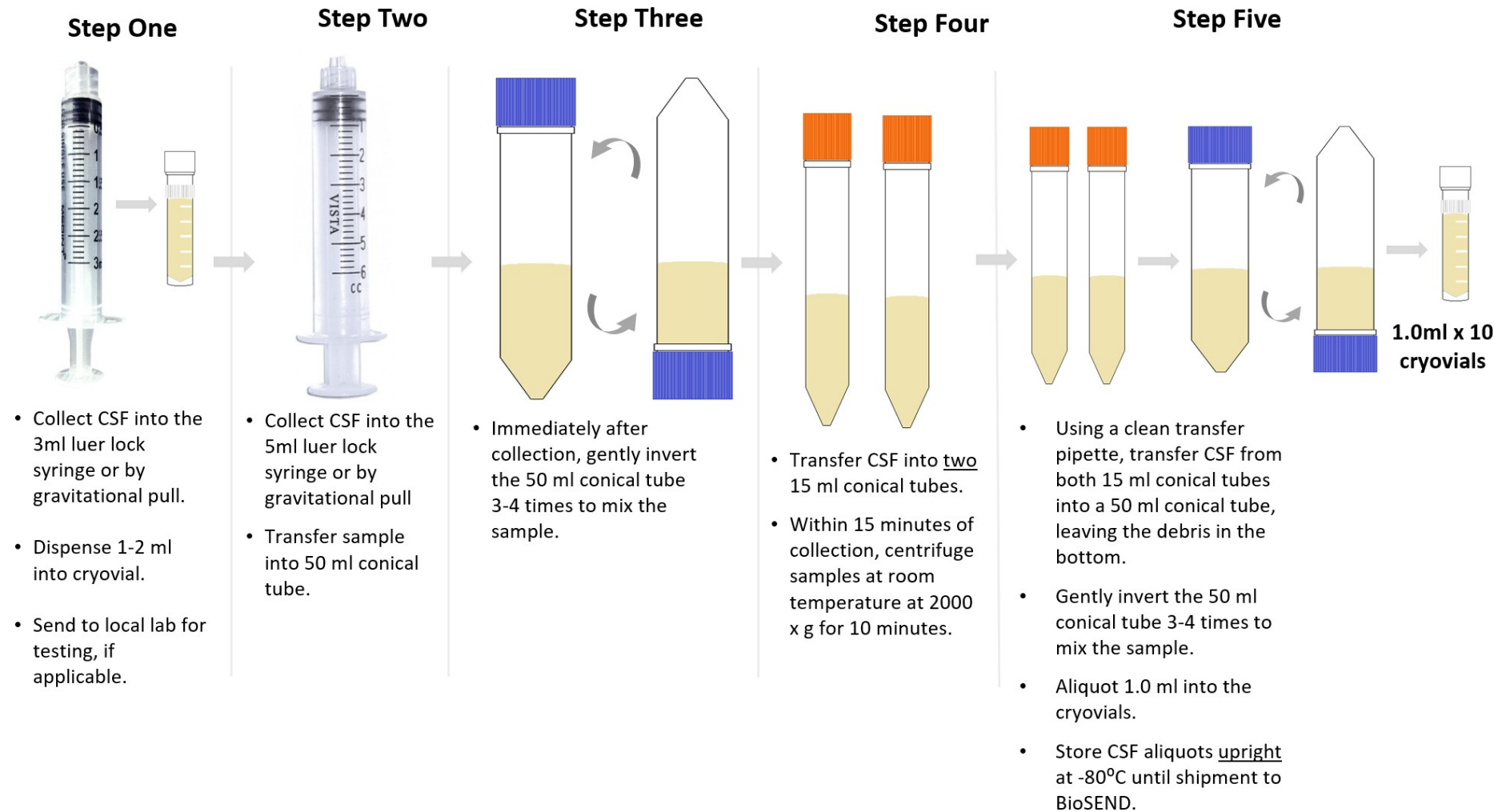
Blood Collection: Troubleshooting

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

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



Urine Sample Collection

1. Label one urine collection cup prior to urine collection with a pre-printed “URINE” label.
2. Ask study subject to collect a urine specimen in the collection cup. Urine should be collected midstream and should remain as sterile as possible.
3. Label two 15 ml conical tubes with pre-printed “URINE” labels.
4. Transfer 10mL urine from the collection cup into each of the two 15 mL conical tubes.
5. Within 60 minutes of collection, freeze and store samples **upright** at -80°C until shipment.

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

9

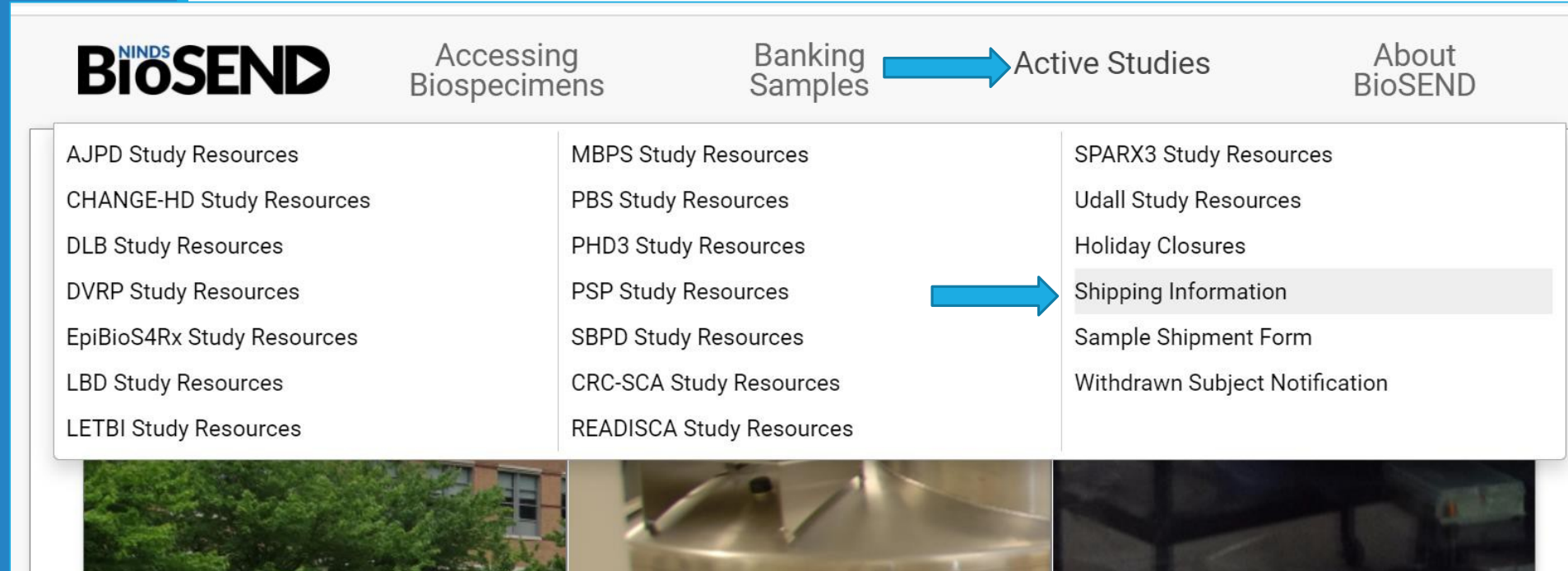
Consignee Name and Address

IU information and address

06426 1/01 RRD

Shipping Samples

UPS resources available on BioSEND website



The screenshot shows the NINDS BioSEND website navigation menu. The menu is organized into four main sections: 'Accessing Biospecimens', 'Banking Samples', 'Active Studies', and 'About BioSEND'. A blue arrow points from 'Banking Samples' to 'Active Studies'. The 'Active Studies' section is expanded, showing a list of study resources. A blue arrow points from 'PSP Study Resources' to 'Shipping Information', which is highlighted in the list.

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	Sample Shipment Form
EpiBioS4Rx Study Resources	SBPD Study Resources	Withdrawn Subject Notification
LBD Study Resources	CRC-SCA Study Resources	
LETBI Study Resources	READISCA Study Resources	

Below the menu, there are three small images: a green tree, a close-up of a metal surface, and a dark, indistinct image.

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

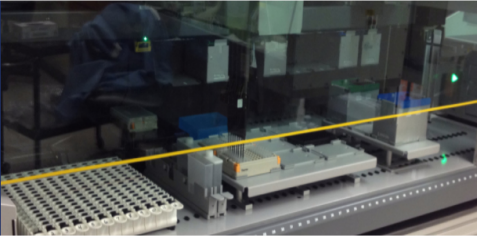
Please notify BioSEND ahead of shipment

- Email biosend@iu.edu with copy of Sample Form and tracking number
- OR use Online Sample form on biosend.org

Shipping Samples: Sample Form

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

Dissecting Oligogenic Biomarkers in Ashkenazi Jews with Parkinson's Disease (AJPD) Active Study Page



Welcome AJPD Study staff, coordinators, and PI's. This section encompasses study specific tools and resources for your reference. If you have any questions, comments, or new ideas please contact biosend@iu.edu or by phone directly at (317)278-0594.

Specimen Table

Cohort	Population	Genomic DNA	RNA	Plasma	Serum	CSF	Urine	Whole Blood
AJPD	Ashkenazi Jewish patients with Parkinson's Disease	✓	✓	✓	✓	✓	✓	✓

Study Resources

- Kit Request Module
- Study Specific Sample Notification Forms
- AJPD Manual of Procedures
- AJPD Training Slides

Downloads

- Sample Shipment Form (pdf)
- AJPD Manual of Procedures
- AJPD Training Slides

Additional Resources


- Online Sample Form

Contact Us

biosend@iu.edu
317-278-0594

Shipping Samples: Sample Form

Sample Record and Shipment Notification



Please fill out and submit this form when shipping samples to BioSEND. After submission, please print a copy of the form to include with your submission. If you prefer to not use the online system, you may download a pdf version of this form from the sidebar to the right.

Contact Information

Site Name/Number

Coordinator

Telephone

Email

Subject Information

Study

Clinical ID

GUID

Subject ID (ST# from labels)

Gender

Visit Type

Sample Information

Date Sample(s) Shipped

FedEx Tracking Number

Draw Date	Specimen Type	# of Tubes Sent	Notation of Problems
<input type="text"/>	DNA <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	RNA <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Plasma <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Serum <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	CSF <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Whole Blood <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Buffy Coat <input type="text"/>	<input type="text"/>	<input type="text"/>

Shipping 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