



*An Intermediate-Size Expanded Access Protocol for
Amyotrophic Lateral Sclerosis with Pridopidine
(Pridopidine EAP2)*

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:

Phlebotomy

- Gloves
- Alcohol wipes
- Butterfly needles
- Tourniquet
- Gauze pads
- Bandages
- Sharps bin and lid



Site Equipment

Sites will need to supply the following items:

Processing

- Crushed ice
- Microcentrifuge tube rack
- Calibrated pipettes and pipette tips
- Centrifuge capable of maintaining 4°C
- -80°C Freezer
- Dry ice



Collection Protocol

Collection Tube	Drawn At	Specimen Type	Aliquot Volume	Total Number of Aliquots/Tubes Shipped to BioSEND	Cryovial Cap Color
2 EDTA (plastic) Blood Collection Tubes, 10ml	BL, Week 12, Week 52, Week 104	Plasma	1.5ml	6	Purple
	BL, Week 12, Week 52, Week 104	Buffy Coat	~500-750ul	2	Clear

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

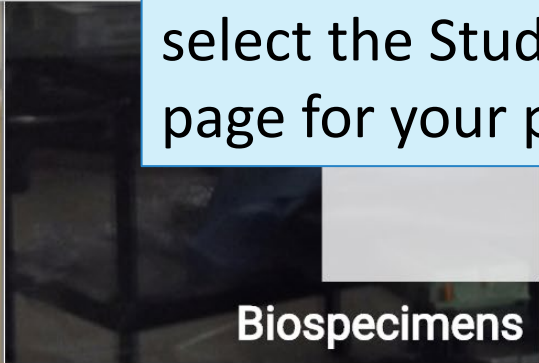
Holiday Closures

Shipping Information

Sample Shipment Form

**About BioSEND**

**Banking Samples**

**Biospecimens**

Under “Active Studies”,
select the Study Resource
page for your protocol



Kit Ordering – Study Resource Page

Study-specific resource page available.
Will include:

- Link to Kit Request Module:
<http://kits.iu.edu/biosend/prido>
- Link to Sample Collection & Processing Form
- Manual of Procedures
- Training Slides

BioSEND^{NINDS}


Accessing Biospecimens

Banking Samples

Active Studies

About BioSEND

Clinical Research Consortium for SCA (CRC-SCA) Study Page



Welcome CRC-SCA Study staff, coordinators, and PIs. 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	Plasma	Genomic DNA	Serum	CSF
MBPS	Participants with a diagnosis of SCA 1, 2, 3, 6, or 7	✓	✓	✓	✓

Study Resources

Kit Request Module

Please follow the below link to access the CRC-SCA Kit Request Module. This link will direct you to a REDCap database where study coordinators and staff may request kits, individual supplies, and/or labels. Please allow a total of two weeks for kit requests to be compiled and delivered to your site.

[Kit Request System](#)

Downloads

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

Additional Resources

- Online Sample Form
- Kit Request System

Contact Us

biosend@iu.edu
317-278-0594

Example Study Resource Page

Confirm/Update Shipping Information

Select your Study Site from the drop down box to populate the most current information we have for your site. Please confirm or update your site's information as needed.

Study Site <small>* must provide value</small>	Indiana University	Select your site from the drop-down list
Indiana University School of Medicine Carolyn Dunifon Dept. of Medical & Molecular Genetics 351 West 10th Street, TK-318 Indianapolis, IN 46202-3002 (317) 274-5751 cdunifon@iu.edu		
Is the contact name above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	Verify contact information and update if needed
		reset
New Contact Name <small>* must provide value</small>	Claire Wegel	
Is the shipping address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	reset
Is the e-mail address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	reset
Is the phone number above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	reset

Kit Ordering – Kit Options

Selecting a kit option will populate contents

Kit Type

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

* must provide value

☒ Blood Collection Kit

☐ Shipping Kit

☐ Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

Each Blood Collection Kit contains:

6 - Cryovial (Sarstedt®) with purple cap, 2ml

2 - Cryovial (Sarstedt®) with clear cap, 2ml

2 - EDTA (plastic) tube, 10ml

2 - Disposable pipet, 3ml

1 - Cryobox, 25 cell

1 - Label set (kit & specimen labels)

Kit Ordering – Blood Collection Kit

Kit Type **Please allow two weeks for shipment** <i>* must provide value</i>	<input checked="" type="checkbox"/> Blood Collection Kit <input type="checkbox"/> Shipping Kit <input type="checkbox"/> Extra Supplies
Please specify in comments if you need kits before the standard two week shipment time.	

Standard collection kit for plasma and buffy coat. Contains supplies for one subject-visit.

Shipping Kits

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input type="checkbox"/> Blood Collection Kit <input checked="" type="checkbox"/> Shipping 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 Shipping Kit contains: <i>Shipping kits contain the supplies to ship up to two subject visits' worth of samples (that is, up to 2 biohazard bags may be shipped in a single shipper).</i> 2 - Plastic Biohazard bag with absorbent sheet (small) 1 - UPS Airbill Sleeve 1 - Shipping box/Styrofoam container 1 - UN3373 label 1 - Fragile label 1 - Dry ice label	

- Shipping Kits are ordered independently of Blood Kits
- A single Shipping Kit may be used to up to 2 biohazard bags

Extra Supplies

This option allows you to order individual kit components. For ex, if you have a kit with blood tubes that have expired, you may order new collection tubes to replace them.

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input type="checkbox"/> Blood Collection Kit <input type="checkbox"/> Shipping Kit <input checked="" type="checkbox"/> Extra Supplies <small>Please specify in comments if you need kits before the standard two week shipment time.</small>
Individual tube bubble pouch	<div><input type="radio"/> 2 <input type="radio"/> 4</div> <div>reset</div>
Cryobox	<div><input type="radio"/> 2 <input type="radio"/> 4</div> <div>reset</div>
Cryovial (Sarstedt®) with purple cap, 2ml	<div><input type="radio"/> 10 <input type="radio"/> 20</div> <div>reset</div>
Cryovial (Sarstedt®) with clear cap, 2ml	<div><input type="radio"/> 10 <input type="radio"/> 20</div> <div>reset</div>
Air waybill envelope	<div><input type="radio"/> 2 <input type="radio"/> 4</div> <div>Plastic envelope to affix air waybill to package reset</div>
Shipping Container for Dry Ice Shipments	<div><input type="radio"/> 2 <input type="radio"/> 4</div> <div>reset</div>
Biohazard bag with absorbent sheet	<div><input type="radio"/> 2 <input type="radio"/> 4</div> <div>reset</div>

Submit Request

- Click “Submit” to send order to BioSEND; staff will confirm receipt of your order
- Please allow a **two week** turn-around time for kit shipments
- If urgent request needed, please note date needed by in comments and email BioSEND. We cannot guarantee urgent requests, but will do our best to accommodate.

NINDS BioSEND AAA

NINDS Biosend PRIDO Kit Request System

Study Site Wake Forest University
* must provide value

SITE INFO

Is the contact name above correct? Yes No
* must provide value reset

Is the shipping address above correct? Yes No
* must provide value reset

Is the e-mail address above correct? Yes No
* must provide value reset

Is the phone number above correct? Yes No
* must provide value reset

Kit Type
****Please allow two weeks for shipment****
* must provide value

☐ Blood Collection Kit
☐ Shipping Kit
☐ Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

Comments

Expand

Submit

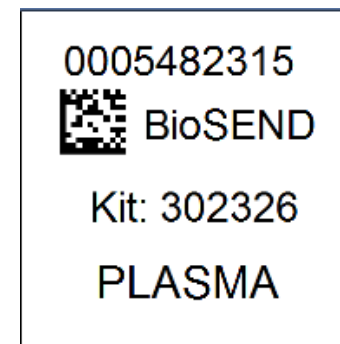
Sample Labelling

Labels are provided by Indiana University for BioSEND samples only

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



Kit Labels

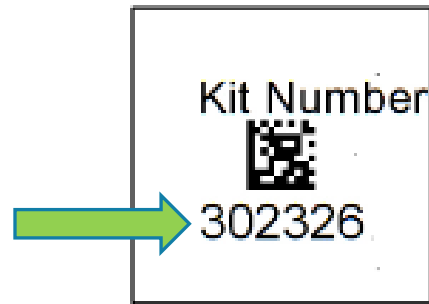


Specimen Labels

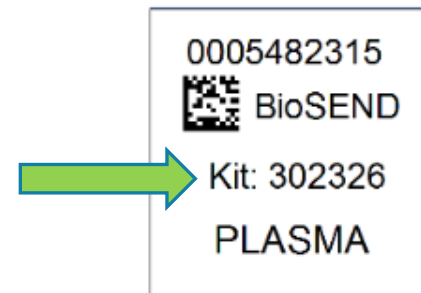
Sample Labelling – Kit Number

Kit Number

- Each Blood Collection Kit will have a unique “Kit Number” used to track participant samples and provide quality assurance
- Any kit number can be used for any subject or visit—which is why it is very important to document which kit number was used for which subject and visit



Kit Labels



Specimen Labels

Sample Labelling – Kit Labels

Kit Number



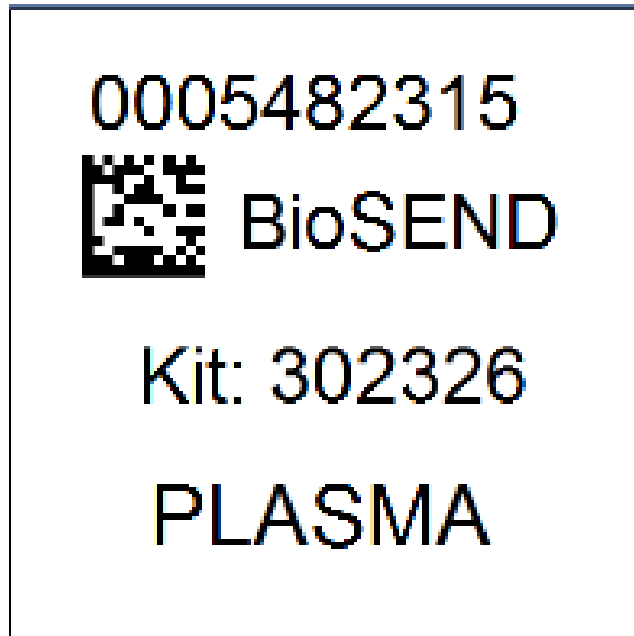
302326

Kit labels are placed:

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



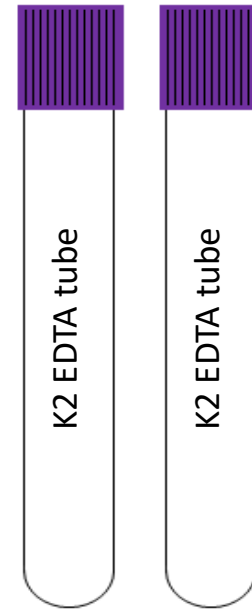
Sample Labelling – Specimen Labels



- ← **Unique Barcode**
- ← **Biorepository Name**
- ← **Kit Number**
- ← **Sample Type**

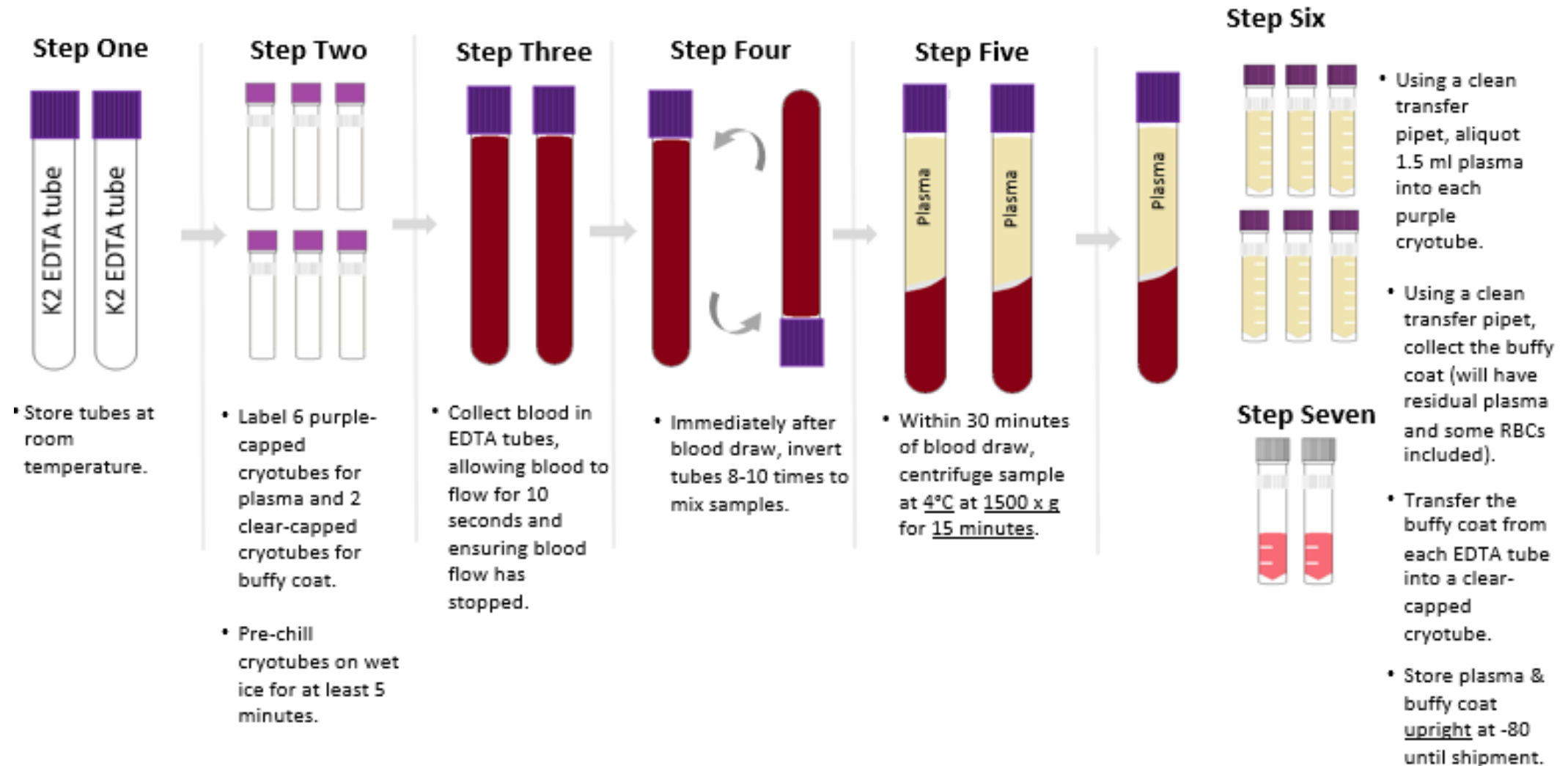
Sample Collection and Processing

*Supplies provided for the collection of
plasma and buffy coat*



2 x 10ml EDTA
(plastic) collection
tubes

Sample Collection and Processing: Plasma & Buffy Coat



Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- Please ship samples as they are collected (within two weeks of collection)
- All samples ship frozen on dry ice
- Frozen samples should be shipped **Monday through Wednesday only**



Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- Fill shippers with a minimum of 10lbs of dry ice
- Do not package more than 2 visits (ie, 2 biohazard bags) into a single shipper
- Do not pack shipment until the day of pickup



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

Shipping Samples

Labeling frozen shippers

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. $\frac{\text{Number}}{\text{(Number pkgs)}} \times \frac{\text{wt}}{\text{(wt)}} \text{ Kg}$

Net weight of dry ice in kg

Dry Ice kg.

Your name & address

Shipper's Name and Address

UN 1845

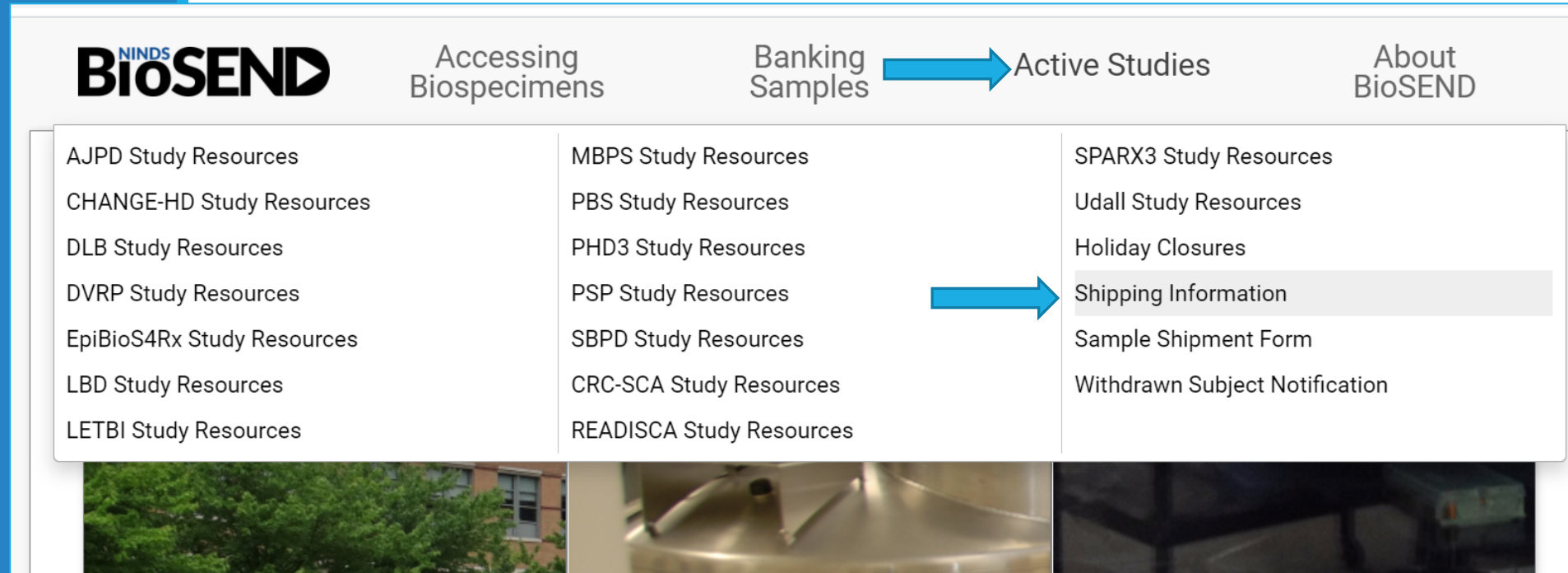
Consignee Name and Address

IU information and address

06426 1/01 RRD

Shipping Samples

UPS resources available on BioSEND website on the “**Shipping Information**” page



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

NINDS BioSEND

Accessing Biospecimens Banking Samples → Active Studies About BioSEND

AJPD Study Resources	MBPS Study Resources	SPARX3 Study Resources
CHANGE-HD Study Resources	PBS Study Resources	Udall Study Resources
DLB Study Resources	PHD3 Study Resources	Holiday Closures
DVRP Study Resources	PSP Study Resources →	Shipping Information
EpiBioS4Rx Study Resources	SBPD Study Resources	Sample Shipment Form
LBD Study Resources	CRC-SCA Study Resources	Withdrawn Subject Notification
LETBI Study Resources	READISCA Study Resources	

Three small images are displayed below the menu: a green tree, a close-up of a metal container, and a dark scene with a light source.

Shipping Information Page

Links on this page to:

1. Generate airwaybills & schedule pickups
2. View printed guide on how to use ShipExec™
3. Request user account and update site address in system
4. View video tutorial for using UPS ShipExec™

1

2

3

4

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.

Navigating UPS ShipExec™



Shipping Samples – UPS ShipExec™

If you will be assisting in shipping samples, please request a user account and familiarize yourself with the system well in advance of your first sample shipment

Shipping Samples: Frozen

Please notify BioSEND ahead of shipment

- Please complete the Sample Collection and Processing Form in REDCap ahead of shipment (can be completed day of shipment).
 - A completed copy of this form should be included in the sample shipper
- If you are having trouble with REDCap, please notify BioSEND directly of shipment at biosend@iu.edu

Sample Collection and Processing Form

<http://kits.iu.edu/biosend/PRIDOSampleForm>

First page captures basic subject and visit information

NINDS
BIOSEND

Returning?

AAA
+ -

Please complete the Specimen Collection and Processing Form, below.

Protocol: An Intermediate-Size Expanded Access Protocol for Amyotrophic Lateral Sclerosis with Pridopidine (Pridopidine EAP2)




Page 1 of 2

Study	PRIDO ▾
Study Site	▾
Email address of staff member completing this form	
<i>Note: A copy of the completed sample form and the shipping manifest will be sent to this address.</i>	
Clinical ID:	
Sex (used for DNA quality control)	▾
Did participant consent to the collection and storage of DNA?	<div>Yes</div> <div>No</div> <div>reset</div>
Visit	▾
IU Kit Number	<div>6 characters remaining</div>

Sample Collection and Processing Form

<http://kits.iu.edu/biosend/PRIDOSampleForm>

Second page captures processing information

Blood Collection and Processing	
Date of venipuncture blood collection	<input type="text"/>  Today M-D-Y
Time of venipuncture blood collection	<input type="text"/>  Now H:M Use 24 Hour clock
1. PLASMA and BUFFY COAT (Purple-top EDTA tubes, 10 mL)	
Was blood collected and processed for PLASMA EDTA?	<div>Yes</div> <div>No</div> <div>reset</div>
Time of PLASMA EDTA tube centrifugation	<input type="text"/>  Now H:M Use 24 Hour clock
Duration of PLASMA EDTA tube centrifugation	<input type="text" value="15"/> minutes
Rate of PLASMA EDTA tube centrifugation	<input type="text" value="1500"/> x g
Temperature of PLASMA EDTA tube centrifugation	<input type="text" value="4"/> degrees Celsius
Total volume of PLASMA EDTA collected	<input type="text"/> mL

Sample Collection and Processing Form

<http://kits.iu.edu/biosend/PRIDOSampleForm>

PDF form of responses will be emailed to you.
Print a copy and include with shipment.

PRIDO Frozen Shipping Manifest

Page 6

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the Frozen Shipping Manifest will be emailed to you for Subject [subj_id].

Please print a copy of that document and include it in the Kit #[kit_num] shipping container.

Study

☐ PRIDO

Study Site:

☐ Massachusetts General Hospital

Clinical ID:

Visit:

☐ Baseline
☐ 12 Week
☐ 52 Week
☐ 104 Week

IU Kit Number:

Date of blood collection:

PLASMA EDTA

Number of PLASMA EDTA aliquots shipped:

Number of BUFFY COAT aliquots shipped:

Shipping Information - Please complete.

Frozen shipments should be sent Monday-Wednesday only. Please check for holiday closures prior to shipping. Contact us at biosend@iu.edu if you are unsure whether or not it is safe to ship.

Date of shipment:

Did/will you use the IU UPS interface to generate the shipping label?

☐ Yes
☐ No

Which shipping service did you use?

☐ UPS
☐ FedEx
☐ World Courier
☐ Other

What is the shipment tracking number?

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
June 19	Juneteenth (observed)
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

Most common non-conformance issues:

- Samples shipped for weekend/holiday delivery
- Sample form incomplete/inaccurate
- Unlabeled or mislabeled tube(s)
- Sample hemolysis



Non-Conformance

- BioSEND will notify sites directly of any issues upon receipt
- *If you are experiencing issues, please reach out to us for help! It is much easier to prevent an issue before sample collection & shipment than trying to fix it after the fact*

Contact Information

BioSEND at Indiana University

biosend@iu.edu

317-278-0594

Sample Shipping Address:

BioSEND

Indiana University School of Medicine

351 West 10th Street

TK-217

Indianapolis, IN 46202