

NINDS **BIOSEND**

*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

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

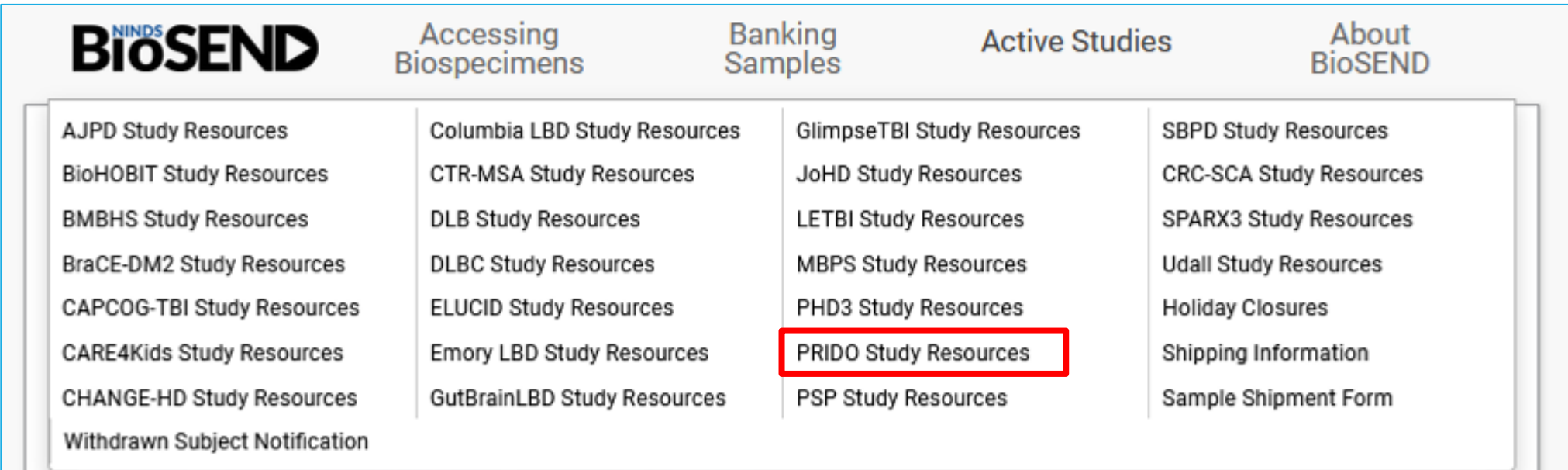
- Crushed ice
- Microcentrifuge tube rack
- Calibrated pipettes and pipette tips
- Centrifuge capable of maintaining 4°C
- -80°C Freezer
- Dry ice



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



The screenshot shows the Biosend.org website navigation menu. The logo 'NINDS BioSEND' is on the left. The menu is organized into five columns: 'Accessing Biospecimens', 'Banking Samples', 'Active Studies', and 'About BioSEND'. The 'Active Studies' column contains a list of study resource pages, with 'PRIDO Study Resources' highlighted by a red rectangular box. Below the menu, there are three small images: a building with trees, a large metal pot, and a close-up of a keyboard.

	Accessing Biospecimens	Banking Samples	Active Studies	About BioSEND
AJPD Study Resources	Columbia LBD Study Resources	GlimpseTBI Study Resources	SBPD Study Resources	
BioHOBIT Study Resources	CTR-MSA Study Resources	JoHD Study Resources	CRC-SCA Study Resources	
BMBHS Study Resources	DLB Study Resources	LETBI Study Resources	SPARX3 Study Resources	
BraCE-DM2 Study Resources	DLBC Study Resources	MBPS Study Resources	Udall Study Resources	
CAPCOG-TBI Study Resources	ELUCID Study Resources	PHD3 Study Resources	Holiday Closures	
CARE4Kids Study Resources	Emory LBD Study Resources	PRIDO Study Resources	Shipping Information	
CHANGE-HD Study Resources	GutBrainLBD Study Resources	PSP Study Resources	Sample Shipment Form	
Withdrawn Subject Notification				

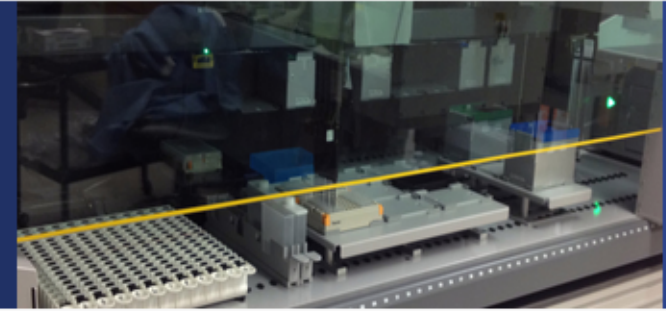
Under “Active Studies”, select the Study Resource page for your protocol

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

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



Welcome PRIDO study staff, coordinators, and PIs. This section encompasses study specific tools and resources for your reference. If you have any questions, please contact biosend@iu.edu

Specimen Table

Cohort	Population	Plasma	Genomic DNA
PRIDO	Patients with Amyotrophic Lateral Sclerosis (ALS)	✓	✓

Study Resources

Kit Request Module

Please follow the below link to access the 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

[Manual of Procedures](#)
[Training Slides](#)

Contact Us

biosend@iu.edu
317-278-6158

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
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 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

Note: Annotations in the original image include arrows pointing to the 'Study Site' dropdown, the contact information text, and the 'New Contact Name' input field, along with dashed boxes containing the text 'Select your site from the drop-down list' and 'Verify contact information and update if needed'.

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****
** 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.

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

Shipping Kits

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

Each Shipping Kit contains:

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).

- 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	<input type="radio"/> 2 <input type="radio"/> 4 reset
Cryobox	<input type="radio"/> 2 <input type="radio"/> 4 reset
Cryovial (Sarstedt®) with purple cap, 2ml	<input type="radio"/> 10 <input type="radio"/> 20 reset
Cryovial (Sarstedt®) with clear cap, 2ml	<input type="radio"/> 10 <input type="radio"/> 20 reset
Air waybill envelope	<input type="radio"/> 2 <input type="radio"/> 4 <small>Plastic envelope to affix air waybill to package</small> reset
Shipping Container for Dry Ice Shipments	<input type="radio"/> 2 <input type="radio"/> 4 reset
Biohazard bag with absorbent sheet	<input type="radio"/> 2 <input type="radio"/> 4 reset

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.

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NINDS Biosend PRIDO Kit Request System

Study Site Wake Forest University

* must provide value

SITE INFO

Is the contact name above correct? Yes No reset

* must provide value

Is the shipping address above correct? Yes No reset

* must provide value

Is the e-mail address above correct? Yes No reset

* must provide value

Is the phone number above correct? Yes No reset

* must provide value

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

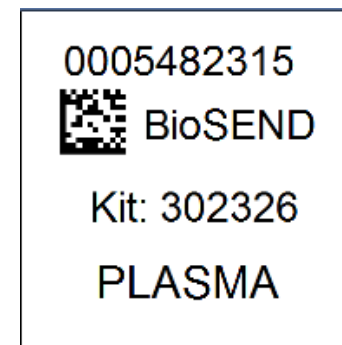
Sample Labelling

Labels are provided by Indiana University for BioSEND samples only

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



Kit Labels

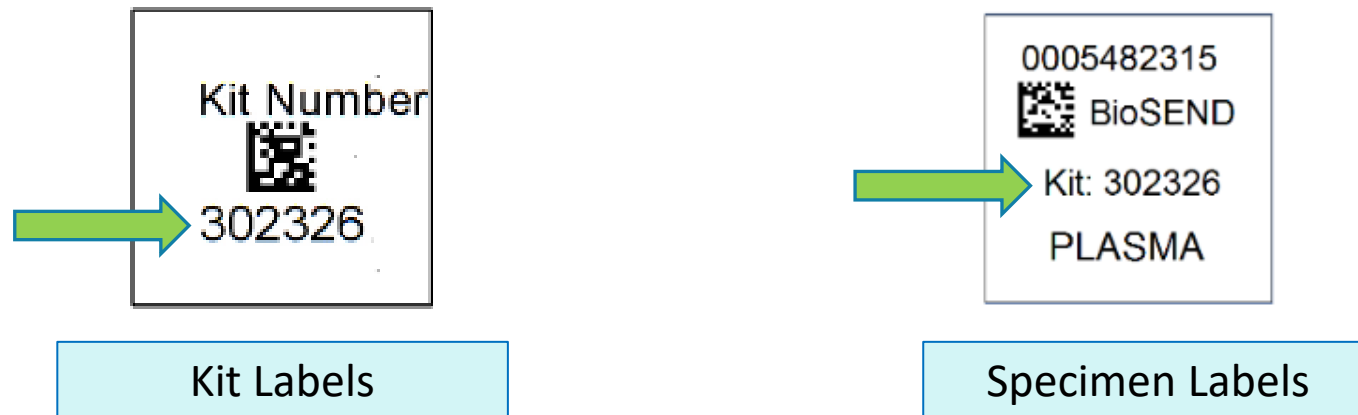


Specimen Labels

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



Sample Labelling – Kit Labels

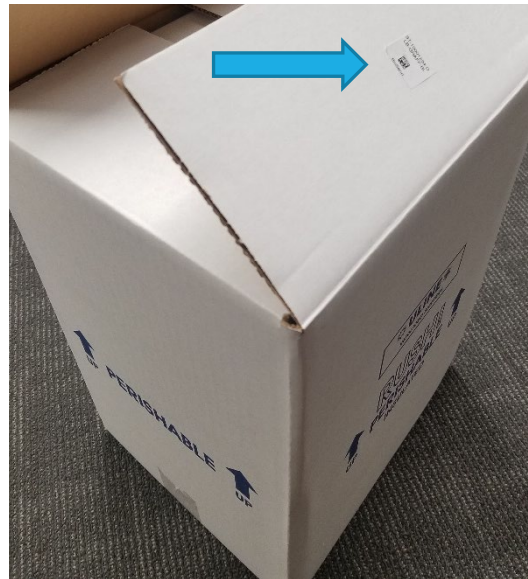
Kit Number



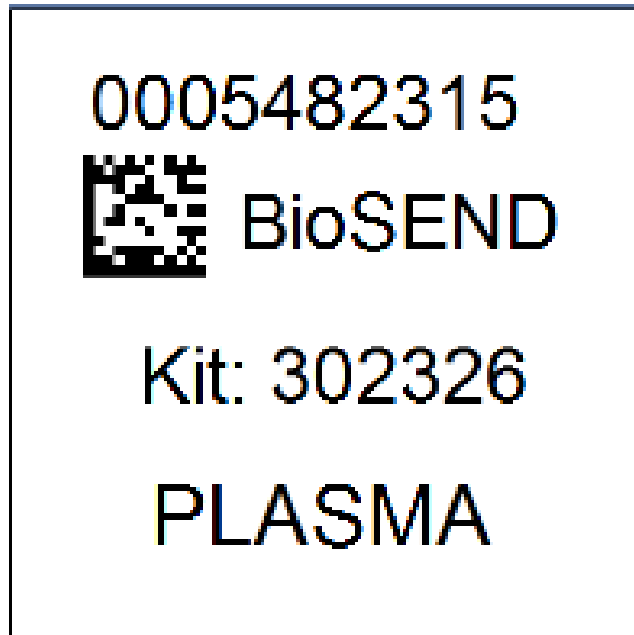
302326

Kit labels are placed:

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



Sample Labelling – Specimen Labels



Unique Barcode



Biorepository Name



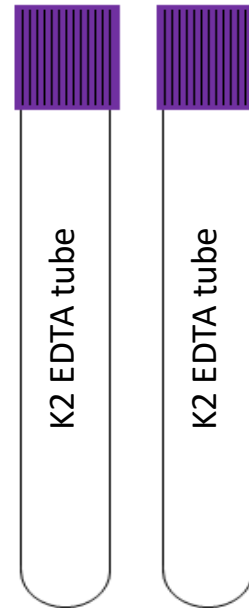
Kit Number



Sample Type

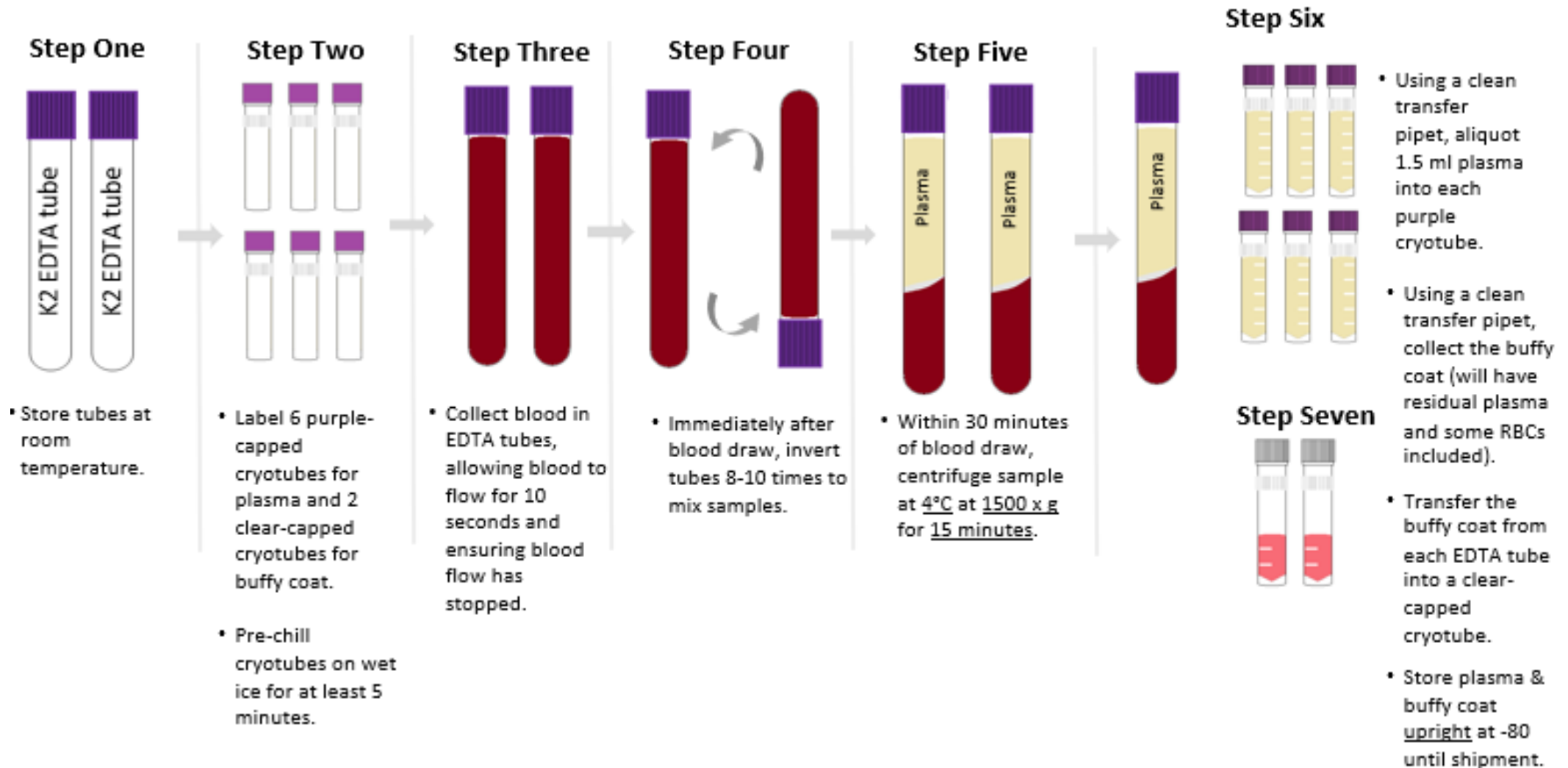
Sample Collection and Processing

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

Dry Ice kg.

9

UN 1845

Shipper's Name and Address

Consignee Name and Address

06426 1/01 RRD

Net weight of dry ice in kg

Your name & address

IU information and address

Shipping Samples

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

The screenshot shows the BioSEND website navigation menu. The logo is 'NINDS BioSEND'. The main navigation items are 'Accessing Biospecimens', 'Banking Samples', 'Active Studies', and 'About BioSEND'. A blue arrow points from 'Banking Samples' to 'Active Studies'. Below 'Active Studies' is a dropdown menu with the following items: 'SPARX3 Study Resources', 'Udall Study Resources', 'Holiday Closures', 'Shipping Information' (highlighted with a blue arrow), 'Sample Shipment Form', and 'Withdrawn Subject Notification'. Below the menu are three small images: a building with green trees, a close-up of a metal container, and a dark interior space.

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
- Withdrawn Subject Notification

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™

UPS Shipping Resources

1

To generate air waybills and schedule UPS pickups for shipments to BioSEND, please visit the UPS ShipExec™ Thin Client [website](#).

2

For instructions on how to use the UPS ShipExec™ Thin Client website, please refer to the [BioSEND UPS ShipExec™ Thin Client Guide](#)

3

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™

4

The screenshot shows the UPS ShipExec™ Thin Client Home Page. At the top, there is a navigation bar with the ShipExec logo and links for Home, My Account, and My Site. Below the navigation bar, the page is titled "Welcome to the ShipExec™ Thin Client Home Page". There are two notification sections: "System Notifications" and "Company Notifications". The "System Notifications" section contains two links: "ShipExec Documentation" and "Importing Your Personal Address Book". The "Company Notifications" section is currently empty. A large video player overlay is centered on the page, showing a play button and a progress bar at the bottom. The video player has a duration of 9:18 and is currently at 0:58. The video player also includes a volume icon, a closed captioning icon, and a full screen icon.

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
 - A completed copy of this form should be printed and retained locally
- 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

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[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	<input type="text"/>
<i>Note: A copy of the completed sample form and the shipping manifest will be sent to this address.</i>	
Clinical ID:	<input type="text"/>
Sex (used for DNA quality control)	▾
Did participant consent to the collection and storage of DNA?	<input type="button" value="Yes"/> <input type="button" value="No"/> reset
Visit	▾
IU Kit Number	<input type="text"/> 6 characters remaining

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?	<input checked="" type="button" value="Yes"/> <input type="button" value="No"/> <small>reset</small>
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. You will also have the option to download a copy of the form at the time of submission.

Print two copies – one to include with the shipment to BioSEND, and one to retain for your site records.

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 & Inventory Reporting

Most common non-conformance issues:

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



Non-Conformance & Inventory Reporting

- BioSEND will notify sites directly of any issues upon receipt
- BioSEND will email sites a monthly inventory report of all samples received from that site to date
- ***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

317-278-6158

Sample Shipping Address:

BioSEND

Indiana University School of Medicine

351 West 10th Street

TK-217

Indianapolis, IN 46202