



*Epilepsy of Late-onset Unknown etiology as a risk factor
for Cognitive Impairment and Dementia (ELUCID)*

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:

- 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

Collection Protocol

Collection Tube	Drawn At	Specimen Type	Aliquot Volume	Total Number of Aliquots	Cryovial Cap Color	Shipping Temperature
2 EDTA (glass) Blood Collection Tubes, 10ml	Visit 1	Plasma	1.5ml	6	Purple	Frozen
	Visit 1	Buffy Coat	~750ul	2	Clear	Frozen

Kit Ordering – Biosend.org

The screenshot shows the Biosend.org website navigation menu. The main navigation bar includes the **BIOSEND** logo and five menu items: **Accessing Biospecimens**, **Banking Samples**, **Active Studies**, and **About BioSEND**. Below these are four columns of links. The **Active Studies** column contains the following links: AJPD Study Resources, BioHOBIT Study Resources, BraCE-DM2 Study Resources, CAPCOG-TBI Study Resources, CARE4Kids Study Resources, CHANGE-HD Study Resources, DLB Study Resources, DVRP Study Resources, ELUCID Study Resources, EpiBioS4Rx Study Resources, GutBrainLBD Study Resources, GlimpseTBI Study Resources, JoHD Study Resources, LBD Study Resources, LETBI Study Resources, MBPS Study Resources, PBS Study Resources, PHD3 Study Resources, PSP Study Resources, SBPD Study Resources, and CRC-SCA Study Resources. A light blue callout box with a black border is overlaid on the **Active Studies** column, containing the text: "Under 'Active Studies', select the Study Resource page for your protocol". Below the navigation menu are three image-based buttons: "About BioSEND" (with a photo of a building and trees), "Banking Samples" (with a photo of a stainless steel tank), and "Biospecimens" (with a photo of a multi-well plate).

BIOSEND	Accessing Biospecimens	Banking Samples	Active Studies	About BioSEND
AJPD Study Resources	DVRP Study Resources	LETBI Study Resources	READISCA Study Resources	
BioHOBIT Study Resources	ELUCID Study Resources	MBPS Study Resources	SPARX3 Study Resources	
BraCE-DM2 Study Resources	EpiBioS4Rx Study Resources	PBS Study Resources	Udall Study Resources	
CAPCOG-TBI Study Resources	GutBrainLBD Study Resources	PHD3 Study Resources	Holiday Closures	
CARE4Kids Study Resources	GlimpseTBI Study Resources	PSP Study Resources	Shipping	
CHANGE-HD Study Resources	JoHD Study Resources	SBPD Study Resources	Sample	
DLB Study Resources	LBD Study Resources	CRC-SCA Study Resources	Withdraw	

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

About BioSEND **Banking Samples** **Biospecimens**

Kit Ordering

Direct link to ordering system :

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

On the Study Resources Page, follow Kit Request Module link

BIOSEND NINDS Accessing Biospecimens Banking Samples Active Studies About BioSEND

Epilepsy of Late-onset Unknown etiology as a risk factor for Cognitive Impairment and Dementia (ELUCID) Study Page

Welcome ELUCID 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
ELUCID	Individuals with Epilepsy	✓	✓

Study Resources

- Kit Request Module
- ELUCID Manual of Procedures
- ELUCID Training Slides

Downloads

- ELUCID Manual of Procedures
- ELUCID Training Slides

Additional Resources

- Online Sample Form

Contact Us

biosend@iu.edu
317-278-0594

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: The form includes blue arrows pointing to the 'Study Site' dropdown, the 'New Contact Name' input field, and the 'Is the contact name above correct?' radio buttons. A dashed box highlights the 'New Contact Name' input field with the text 'Verify contact information and update if needed'. Another dashed box highlights the 'Study Site' dropdown with the text 'Select your site from the drop-down list'.

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:

- 2 - EDTA tube, 10ml (glass)
- 6 - Cryovial (Sarstedt®) with purple cap, 2ml
- 2 - Cryovial (Sarstedt®) with clear cap, 2ml
- 2 - Disposable pipette, 3ml
- 2 - Resealable tube pouch
- 1 - Cryobox, 25 slot
- 1 - Specimen/Case label set

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, two cryoboxes 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 send samples for 1-2 cryoboxes

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 **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 A A A

NINDS Biosend ELUCID Kit Request System

Study Site reset

* must provide value

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 Blood Collection Kit Shipping Kit Extra Supplies

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

* must provide value

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

Comments

Expand

Submit

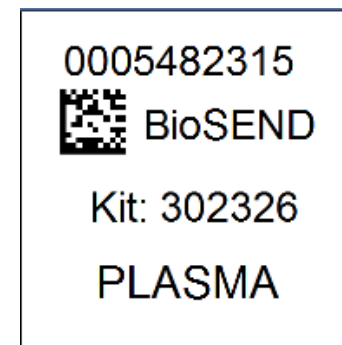
Sample Labelling

Labels are provided by Indiana University for BioSEND samples only

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



Kit Labels



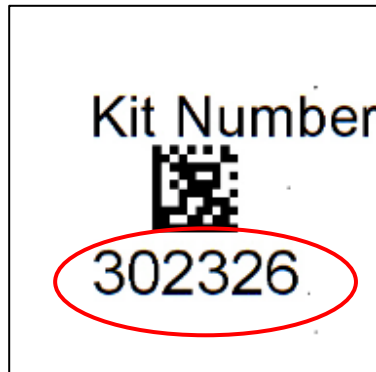
Specimen Labels

Sample Labelling

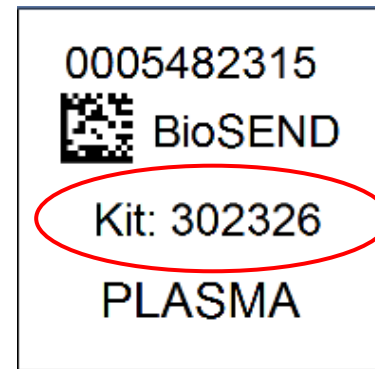
Labels are provided by Indiana University for BioSEND samples only

- 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

Each Blood Collection Kit will have a unique “Kit Number” used to track participant samples and provide quality assurance

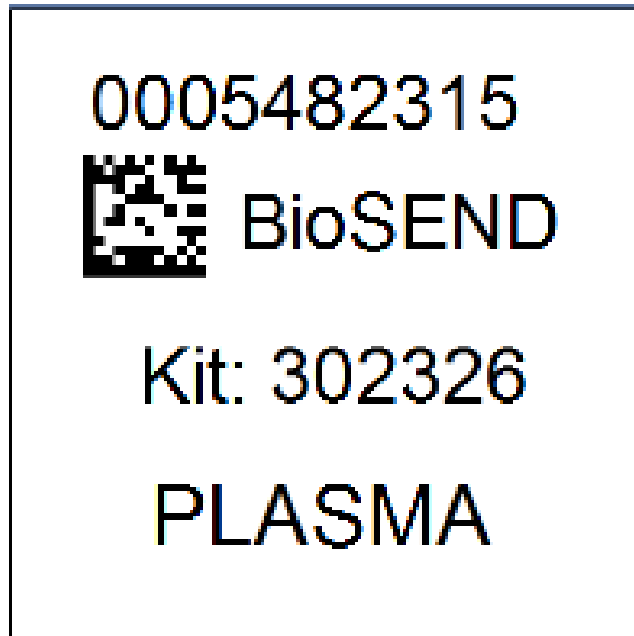


Kit Labels



Specimen Labels

Sample Labelling – Specimen Labels



Unique Barcode



Biorepository Name



Kit Number

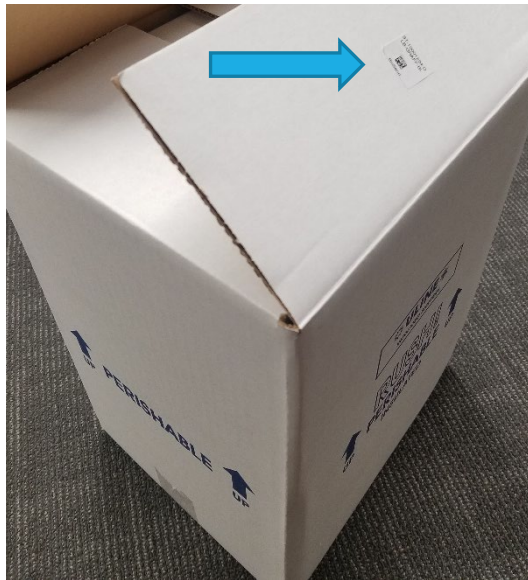


Sample Type

Sample Labelling – Kit Labels

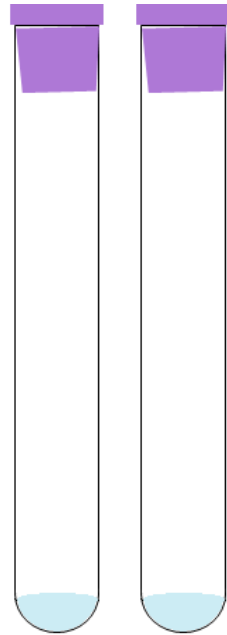
Kit labels are placed:

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

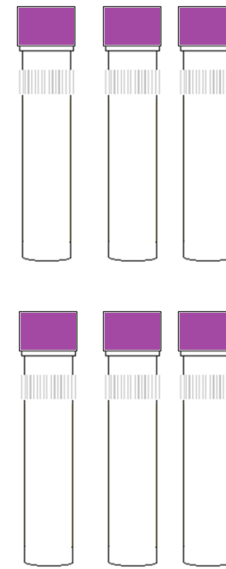


Sample Collection and Processing

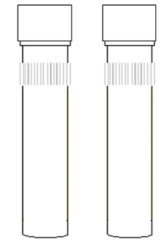
*Supplies provided for the collection of
plasma and buffy coat*



2 x 10ml EDTA (glass)
collection tubes

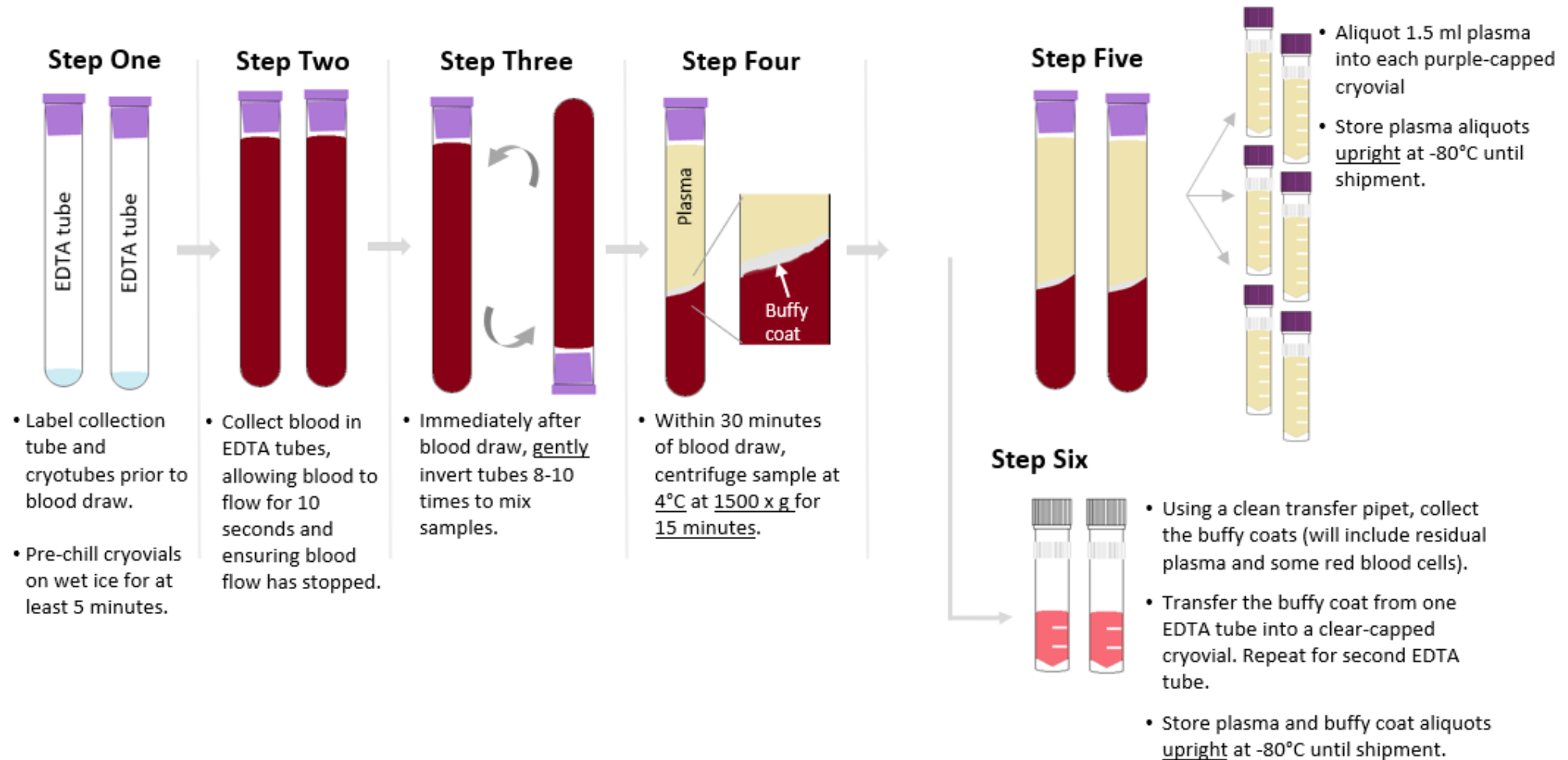


6 x 2ml Cryovials
(purple-capped) for
plasma aliquots



2 x 2ml Cryovials
(clear-capped) for
buffy coat aliquots

Sample Collection and Processing: Plasma & Buffy Coat



Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- All ELUCID samples ship frozen
- Ship frozen samples 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
- Place the cryobox in a biohazard bag
- Place layer of dry ice in between biohazard bags
- 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



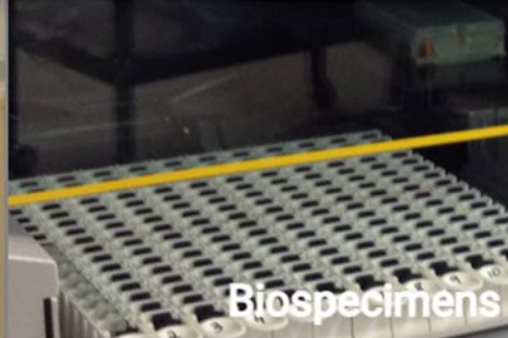
IU information and address

Shipping Samples

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

The screenshot shows the BioSEND website navigation menu. The BioSEND logo is on the left. The main navigation bar includes 'Accessing Biospecimens', 'Banking Samples', 'Active Studies', and 'About BioSEND'. A blue arrow points from 'Banking Samples' to 'Active Studies'. Below the navigation bar is a grid of study resource links. A blue arrow points from 'PSP Study Resources' to 'Shipping Information'.

Accessing Biospecimens	Banking Samples	Active Studies	About BioSEND
AJPD Study Resources	DVRP Study Resources	LETBI Study Resources	READISCA Study Resources
BioHOBIT Study Resources	ELUCID Study Resources	MBPS Study Resources	SPARX3 Study Resources
BraCE-DM2 Study Resources	EpiBioS4Rx Study Resources	PBS Study Resources	Udall Study Resources
CAPCOG-TBI Study Resources	GutBrainLBD Study Resources	PHD3 Study Resources	Holiday Closures
CARE4Kids Study Resources	GlimpseTBI Study Resources	PSP Study Resources	Shipping Information
CHANGE-HD Study Resources	JoHD Study Resources	SBPD Study Resources	Sample Shipment Form
DLB Study Resources	LBD Study Resources	CRC-SCA Study Resources	Withdrawn Subject Notification

 <p>About BioSEND</p>	 <p>Banking Samples</p>	 <p>Biospecimens</p>
--	---	--

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, Help, and User Guide. Below the navigation bar, the page title reads "Welcome to the ShipExec™ Thin Client Home Page". The main content area is divided into two columns: "System Notifications" and "Company Notifications". Under "System Notifications", there are two links: "ShipExec Documentation" and "Importing Your Personal Address Book". Under "Company Notifications", there is a message: "No Company notifications to display". A large video player overlay is centered on the page, showing a play button and a progress bar at the bottom indicating 0:58 / 9:18. The video player also includes volume, full screen, and other standard controls.

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

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

Sample Collection and Processing Form

Direct Link:

<https://kits.iu.edu/biosend/ElucidSampleForm>

First page captures basic subject and visit information

NINDS BIOSEND

Survey Queue

AAA
□ □

Please complete the Specimen Collection and Processing Form, below.

Page 1 of 2

Study

ELUCID ▼

Study Site

Email address of staff member completing this form

Note: A copy of the completed sample form and the shipping manifest will be sent to this address.

Clinical ID:

Sex (used for DNA quality control)

Visit

IU Kit Number

6 characters remaining

Next Page >>

Save & Return Later

Blood Collection and Processing

Date of venipuncture blood collection  M-D-Y

Time of venipuncture blood collection  H:M
Use 24 Hour clock

Date participant last ate  M-D-Y

Time participant last ate  H:M

2. PLASMA and BUFFY COAT (Purple-top EDTA tubes, 10 mL)

Was blood collected and processed for PLASMA EDTA?

Time of PLASMA EDTA tube centrifugation  H:M
Use 24 Hour clock

Duration of PLASMA EDTA tube centrifugation
minutes

Rate of PLASMA EDTA tube centrifugation
x g

Temperature of PLASMA EDTA tube centrifugation
degrees Celsius

Sample Collection and Processing Form

Second page captures processing
information

Sample Collection and Processing Form

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

ELUCID Frozen Shipping Manifest

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 ELUCID

Study Site: Beth Israel Deaconess Medical Center (BIDMC)
 Brigham and Women's Hospital (BWH)
 Icahn School of Medicine at Mount Sinai (ISMMS)
 Johns Hopkins Medical Institute (JHMI)
 Massachusetts General Hospital (MGH)
 University of Alabama at Birmingham (UAB)
 University of Texas Southwestern (UTSW)

Clinical ID: _____

Visit: V1

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.

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***

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.

Contacts

Indiana University

General Questions/Shipment Notifications:

biosend@iu.edu