



Microbiome-gut-brain dysfunction in prodromal and symptomatic
Lewy body diseases (GutBrainLBD)

BIOSPECIMEN COLLECTION & PROCESSING

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



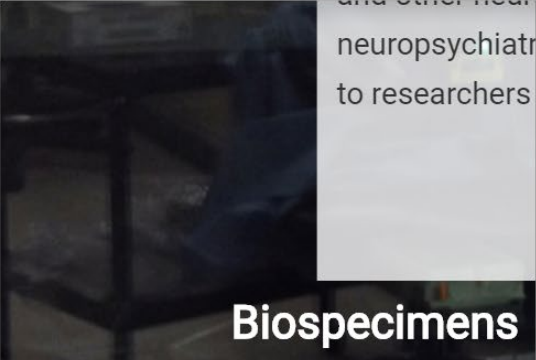


Sample Collection

| | BL |
|-----------------------------------|-----------|
| Buffy coat (2 aliquots) | X |
| Plasma (6 x 1.5ml) | X |
| Urine (2 x 10ml) | X |
| Stool | X |

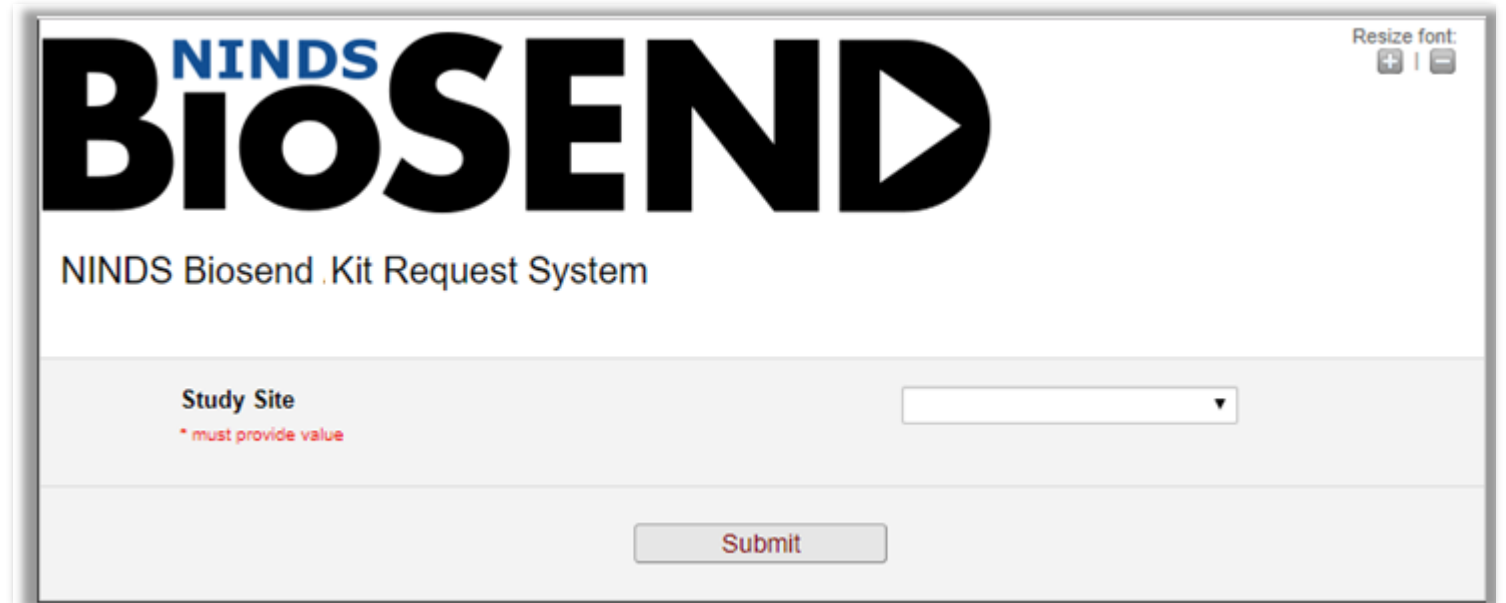
Note that BioSEND will provide an additional collection tube and cryovials for plasma and buffy coat to be retained at site. Those samples should be labeled and stored according to local site protocol.

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 | | |
|  <p>About BioSEND</p> |  <p>Banking Samples</p> |  <p>Biospecimens</p> | and other neuropsychiatr to researchers | |

BioSEND Kit Request Module

- <http://kits.iu.edu/biosend/gutbrainlbd>
- 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, black letters, with "NINDS" in blue. Below the logo, the text "NINDS Biosend Kit Request System" is visible. In the top right corner, there is a "Resize font" option with plus, minus, and refresh icons. The main form area contains a "Study Site" label, a red asterisk indicating a required field, and a drop-down menu. Below the form, a "Submit" button is centered.

Kit Contents and Ordering

Kit Request Module – confirm shipping and contact information

| | |
|---|---|
| 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 |

Select your site from the drop-down list

Verify contact information and update if needed

Kit Type

Kit Type

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

** must provide value*

- Specimen Collection Kit
- Ambient (Stool) Shipping Kit
- Frozen (Blood/Urine) Shipping Kit
- Supplemental Kit
- Extra Supplies

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

Select kit type needed—
selecting a kit type will
populate the kit contents

Specimen Collection Kits

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

Specimen Collection Kit
 Ambient (Stool) Shipping Kit
 Frozen (Blood/Urine) Shipping Kit
 Supplemental Kit
 Extra Supplies

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

Specimen Collection Kit Quantity
** must provide value*

1

Standard collection kit for all sample types. Contains supplies for one participant visit.

Shipping Kits

| | |
|--|--|
| Kit Type **Please allow two weeks for shipment** <small>* must provide value</small> | <input type="checkbox"/> Specimen Collection Kit <input checked="" type="checkbox"/> Ambient (Stool) Shipping Kit <input type="checkbox"/> Frozen (Blood/Urine) Shipping 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> |
| Ambient (Stool) Shipping Kit Quantity <small>* must provide value</small> | <input type="text" value="1"/> |

Ambient (Stool) Shipping Kit contains the shipping supplies for one participant at-home stool collection

Shipping Kits

| | |
|--|--|
| Kit Type **Please allow two weeks for shipment** <i>* must provide value</i> | <input type="checkbox"/> Specimen Collection Kit <input type="checkbox"/> Ambient (Stool) Shipping Kit <input checked="" type="checkbox"/> Frozen (Blood/Urine) Shipping 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> |
| Frozen (Blood/Urine) Shipping Kit Quantity <i>* must provide value</i> | <input type="text" value="1"/> |

Frozen (Blood/Urine) Shipping Kit contains the shipping supplies for up to two participant visits

Supplemental Kit

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

Specimen Collection Kit
 Ambient (Stool) Shipping Kit
 Frozen (Blood/Urine) Shipping Kit
 Supplemental Kit
 Extra Supplies

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

Contains a variety of extra kit components

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"/> CSF 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> | |
| Individual Tube Bubble Pouch | <input type="radio"/> 2 <input type="radio"/> 4 reset |
| 25-Slot Cryobox | <input type="radio"/> 2 <input type="radio"/> 4 reset |
| Siliconized Cryoial (2 ml) | <input checked="" type="radio"/> 10 <input type="radio"/> 20 reset |
| Lumbar Puncture Trays with Lidocaine, 22g | <input type="radio"/> 2 <input type="radio"/> 4 reset |
| Airway bill envelope | <input type="radio"/> 2 <input type="radio"/> 4 <small>Plastic envelope to affix air waybill to package</small> reset |
| Lumbar Puncture Trays with Lidocaine, 24g | <input type="radio"/> 2 <input type="radio"/> 4 reset |
| Medication Transfer Filter Straws (for LP) | <input checked="" type="radio"/> 2 <input type="radio"/> 4 reset |
| 15ml Conical Tube, individually wrapped | <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

NINDS BioSEND AAA

NINDS Biosend LBD Kit Request System

Study Site * must provide value

University of Miami - Galvin, James, MD, MPH

Site Contact
Shipping Address

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

Baseline or Annual Visit Kit
 CSF Kit
 Supplemental Kit
 Extra Supplies

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

CSF Sprotte® Needle Gauge 22 24 * must provide value [reset](#)

CSF Visit Kit Quantity * must provide value

Comments [Expand](#)

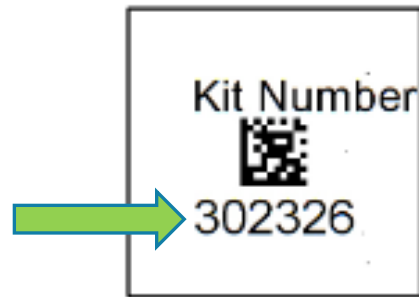
CSF Collection Kit Contents:
11 - Siliconized cryovial (2ml)
2 - 15ml conical tubes- (individually wrapped)
2 - 50ml conical tubes- (individually wrapped)
1 - Medication Transfer Filter Straw
1 - LP tray with 22 gauge Sprotte® needle

Submit

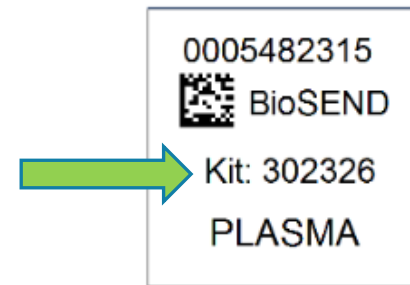
Sample Labeling

Kit Number

- 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

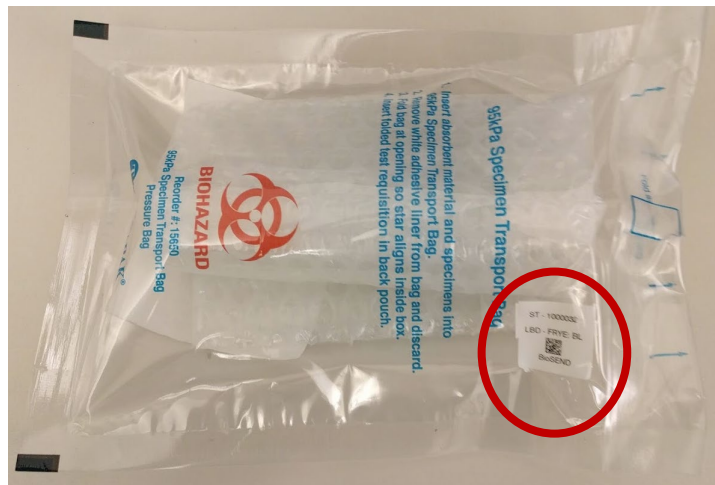


Each Blood Collection Kit will have a unique “Kit Number” used to track participant samples and provide quality assurance

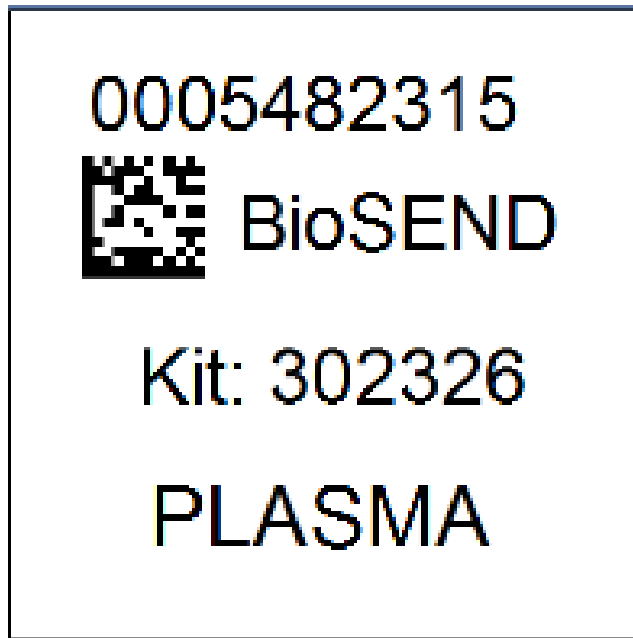
Sample Labelling – Kit Labels

Kit labels are placed:

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



Specimen Label



Unique Barcode



Biorepository Name



Kit Number



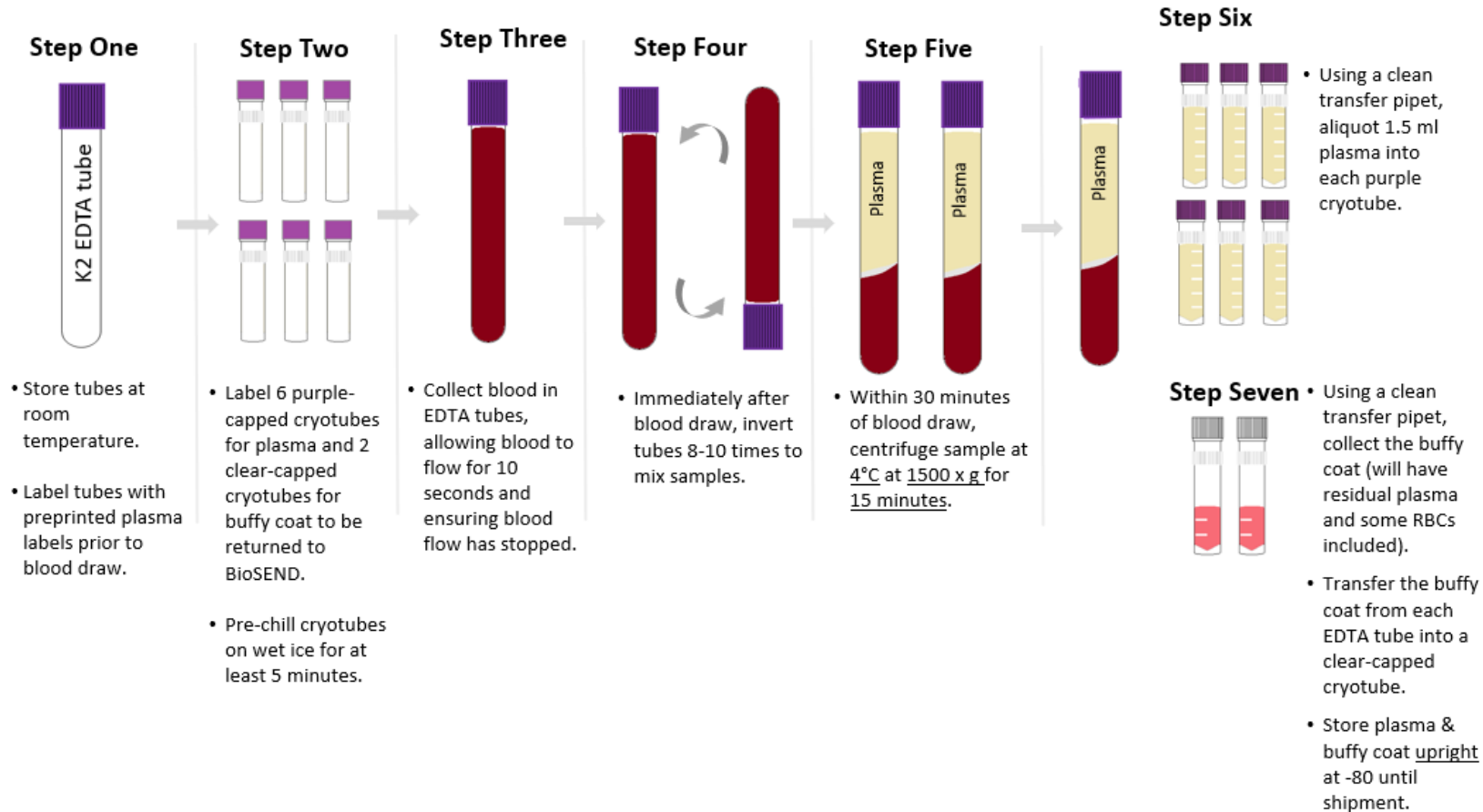
Sample Type

Sample Collection and Processing

GutBrainLBD Collection Schedule

| | BL |
|-----------------------------------|----|
| Buffy coat (2 aliquots) | X |
| Plasma (6 x 1.5ml) | X |
| Urine (2 x 10ml) | X |
| Stool | X |

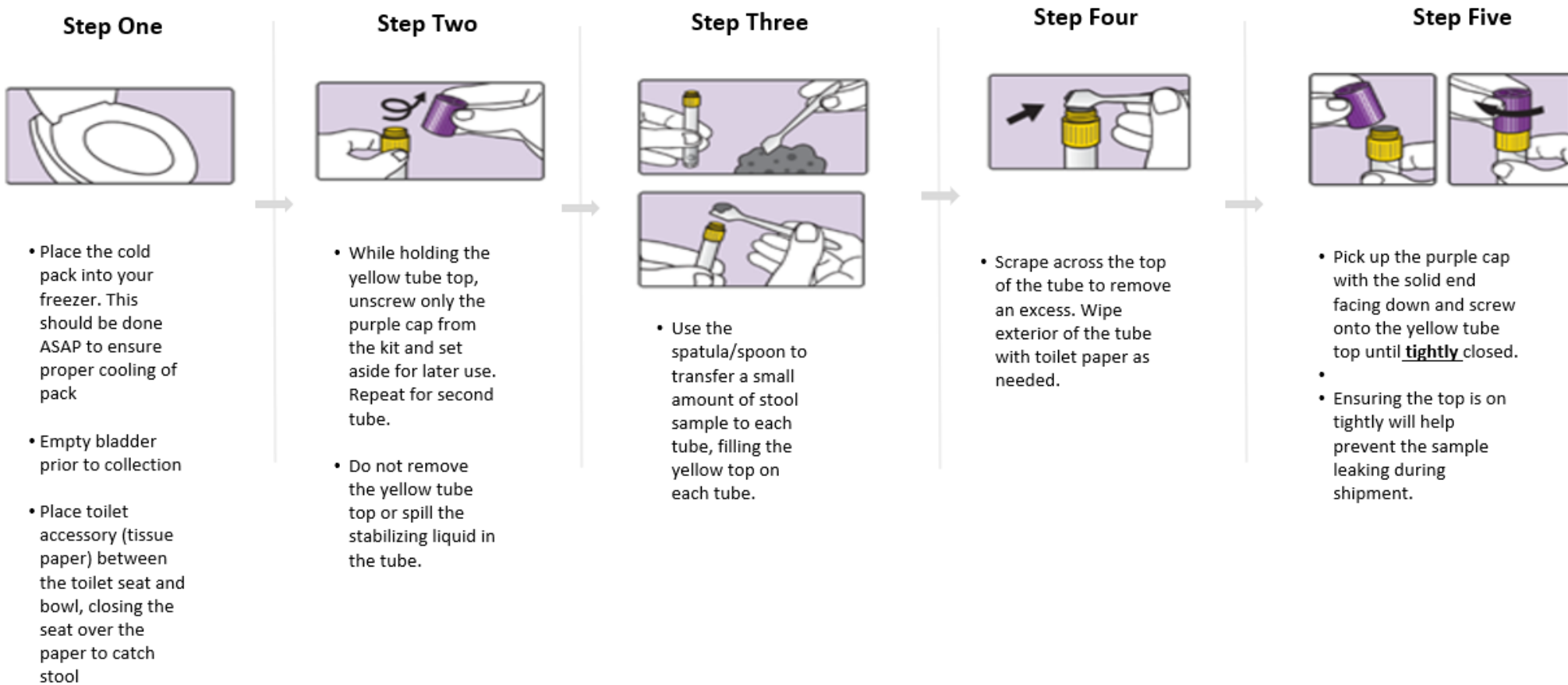
Plasma and Buffy Coat Preparation



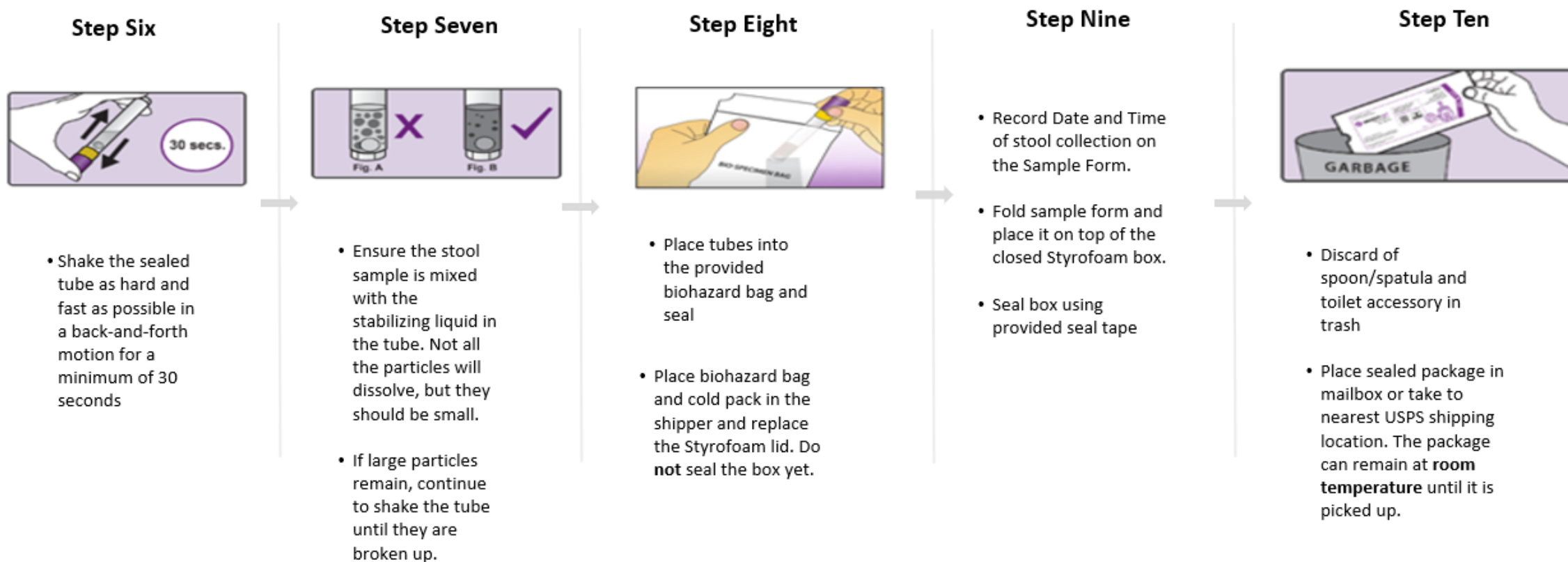
Urine Sample Collection

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.

At-Home Stool Collection – Participant Instructions



At-Home Stool Collection – Participant Instructions



Stool Collection – Prepare Supplies for Participant

Ensure all supplies are ready for the participant to take home

- Label the stool collection tubes prior to giving them to participant
- The participant should take home the stool collection tubes, spoon/spatula accessory, toilet accessory, seal tape, cold pack (for shipper), pre-labeled shipper, and partially completed sample form
- Cold pack can be placed in the participant's freezer prior to shipping



Stool Collection – Prepare Supplies for Participant

- Place the UN3373 and "E" Hazardous Materials in Exempt Quantity labels to the side of the ambient/stool shipper
- Place biohazard and fragile labels on box, taking care to not overlap labels



Stool Collection – Prepare Supplies for Participant

- Apply the BioSEND USPS Express shipping label (1) and the USPS postage sticker (2) to the bottom of the ambient shipper
- The USPS postage sticker must be placed above the barcode (3) and must not be covered it up



Shipping Stool Samples

Stool samples should be shipped **the same day** of collection

- Participants can either place the package in their mailbox or take it to a local USPS shipping location

Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- Ship Plasma, Buffy Coat, and Urine samples frozen 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 minimum 10lbs of dry ice
- Place layer of dry ice in between cryoboxes



Shipping Frozen Samples

Hold packaged samples in a -80°C freezer until pickup.

Samples should be received at BioSEND within 2 weeks of collection.



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

Shipping Samples

Packing and Shipping Frozen Samples

Shipper's Declaration not Required.

Dry Ice amount must be in kilograms.

Note: 2 lbs. = 1 kg.

Airwaybills / airmails 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

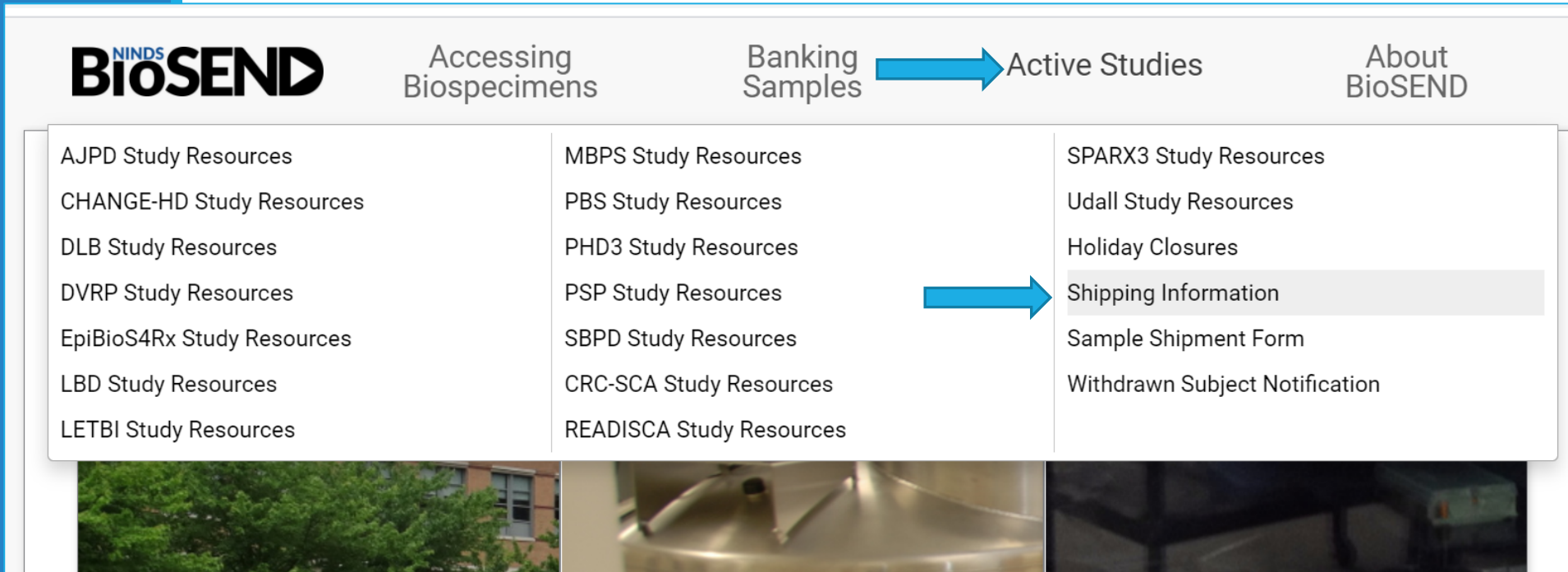
9

06426 1/01 RRD

The form is a diamond-shaped label with a black and white striped pattern. It contains fields for shipper and consignee information, a large number '9' in the center, and a field for dry ice weight. Red arrows point to specific fields with explanatory text.

Shipping Samples

UPS resources available on BioSEND website






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', a dropdown menu is open, listing various study resources. A blue arrow points to 'Shipping Information', which is highlighted in grey. Below the menu are three small images: a building with green trees, a laboratory flask, and a laboratory setting.

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, Help, and User Profile. 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: Frozen

Please notify BioSEND ahead of shipment

- A Sample Collection and Processing Form must be completed for each subject-visit submitted to BioSEND. This form includes a Frozen Shipping Manifest that should be completed in advance of shipping to BioSEND also be **physically included in the shipper.**

The form can be completed via REDCap by following the bellow link:

- <https://redcap.uits.iu.edu/surveys/?s=YWR4D48J847YTYMJ>

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

- BioSEND will notify sites directly of any issues upon receipt
- Non-conformance is reported on a weekly basis to NINDS and will be included in the monthly inventory reports your site receives from BioSEND
- ***If you are experiencing issues, please reach out to us for help! We are here to provide support. It is much easier to prevent an issue before sample collection & shipment than trying to fix it after the fact***

Contacts

Indiana University

General Questions/Shipment Notifications:

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Biorepository Clinical Research Coordinator:

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