



Biospecimen Exchange for Neurological Disorders

## Reducing Falls with Varenicline in Hypocho<sup>l</sup>inergic Pa<sup>r</sup>kin<sup>s</sup>on Dis<sup>e</sup>ase

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BIOSPECIMEN COLLECTION & PROCESSING

# Overview

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1. Specimen uniformity and quality
2. Site Equipment
3. Procedures
  - Kit Contents and Ordering
  - Sample Labelling
  - Sample Collection and Processing
  - Shipping Samples
  - Non-Conformance
4. Contact Information

# Specimen Uniformity and Quality

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GENERAL REMINDERS



# Specimen Standardization and Quality

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Most biomarkers are sensitive to *time* and *temperature*

- Standardization of processing across sites is key
- Reference the *BioSEND Biomarker 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](mailto:biosend@iu.edu)

# Site Consumables and Equipment

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*Sites will need to supply the following items:*

- Gloves
- Alcohol wipes
- Butterfly needles
- Tourniquet
- Gauze pads
- Bandages
- Sharps bin and lid
- -80°C Freezer
- Dry ice

# Procedures

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MAINTAINING SPECIMEN UNIFORMITY AND QUALITY

# Biospecimen Collection Protocol

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Sample Type & Volume	BL
Whole Blood, 6ml	2

# Kit Contents and Ordering

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- All sites will be sent a Supplemental Kit with their first kit shipment
  - Contains extra blood collection tubes
  - May be used to replace items in study visit kits
- Study Visit Kits should be ordered as soon as visits are planned
  - Contains collection, processing, and shipping supplies specific to each visit
  - Includes barcoded labels
  - The supplies/labels in each study visit kit are intended for that visit only



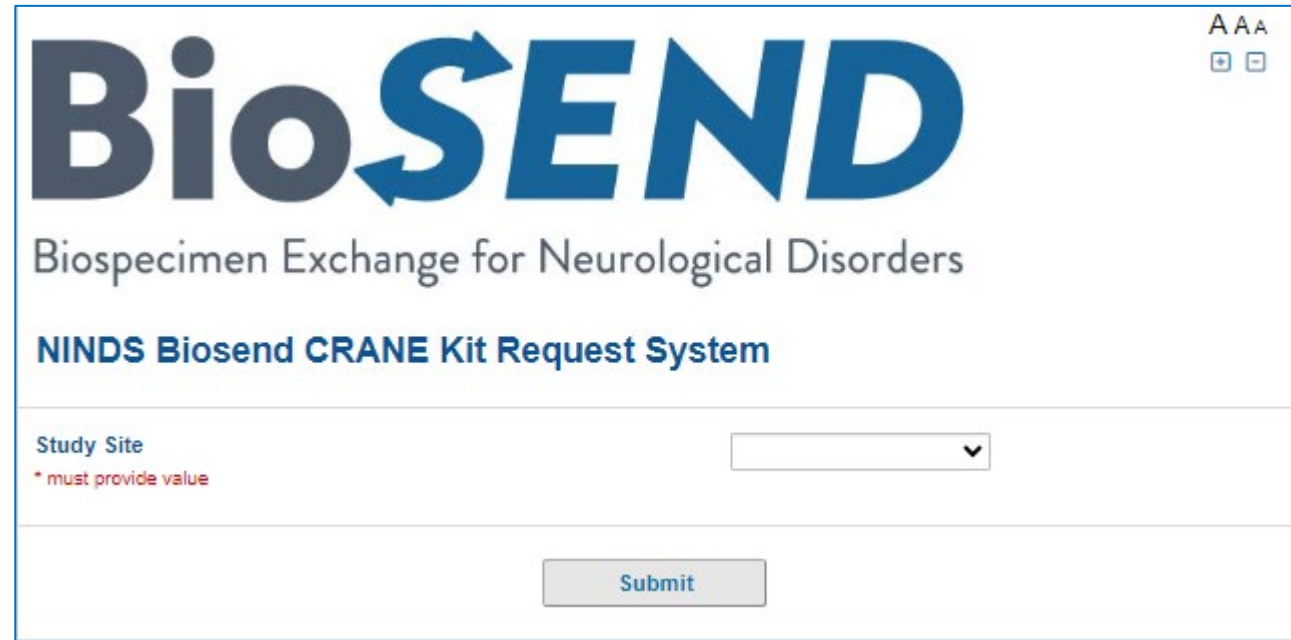
# Kit Contents and Ordering – REDCap Survey

<https://redcap.link/CRANEKits>

Order kits online through the Kit Request Module for:

- Blood kits
- Shipping kits
- Extra Supplies

Please provide as much notice as possible when ordering kits and/or supplies.



The screenshot shows the BioSEND logo with a blue arrow pointing to the 'S' in 'SEND'. Below the logo is the text 'Biospecimen Exchange for Neurological Disorders' and 'NINDS Biosend CRANE Kit Request System'. There is a dropdown menu for 'Study Site' with a red asterisk and the text '\* must provide value' below it. A 'Submit' button is located at the bottom of the form.

AAA  
⊕ ⊞

# BioSEND

Biospecimen Exchange for Neurological Disorders

**NINDS Biosend CRANE Kit Request System**

Study Site

\* must provide value

Submit

# Kit Contents and Ordering: Confirm Site Info

CRANE Kit Request Module

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

# Kit Contents and Ordering: Kit Types

## CRANE Kit Request Module

- Kits are not specific to a subject or time point. After collection, sites will indicate the subject and time point to which BioSEND should link the samples.


<b>Kit Type</b> **Please allow two weeks for shipment** * must provide value	<input checked="" type="radio"/> Blood Collection Kit <input type="radio"/> Shipping Kit <input type="radio"/> Extra Supplies
<b>Blood Collection Kit Quantity</b> * must provide value	<input type="text"/>
<b>Comments</b>	<input type="text"/> <a href="#">Expand</a>

# Kit Contents and Ordering: Kit Breakdown

CRANE Kit Request Module

<b>Comments</b>	<div data-bbox="1778 242 2331 421" style="border: 1px solid gray; height: 125px; width: 217px;"></div> <p data-bbox="2331 421 2400 449">Expand</p>
<p data-bbox="1006 506 1426 535"><b>Each Blood Collection Kit contains:</b></p> <ul data-bbox="1006 578 1477 685" style="list-style-type: none"><li data-bbox="1006 578 1312 606">2 - EDTA tube, 6ml (plastic)</li><li data-bbox="1006 614 1299 642">2 - Resealable tube pouch</li><li data-bbox="1006 649 1477 685">1 - Specimen/Case label set-- Kit numbers</li></ul>	
<p data-bbox="1006 749 1337 778"><b>Each Shipping Kit contains:</b></p> <p data-bbox="1006 842 2382 906"><i>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).</i></p> <ul data-bbox="1006 935 1605 1149" style="list-style-type: none"><li data-bbox="1006 935 1605 963">2 - Plastic Biohazard bag with absorbent sheet (small)</li><li data-bbox="1006 971 1248 999">1 - UPS Airbill Sleeve</li><li data-bbox="1006 1006 1414 1035">1 - Shipping box/Styrofoam container</li><li data-bbox="1006 1042 1197 1071">1 - UN3373 label</li><li data-bbox="1006 1078 1184 1106">1 - Fragile label</li><li data-bbox="1006 1113 1184 1149">1 - Dry ice label</li></ul>	

Kit contents of selected kit will appear at the bottom of the page



# Kit Contents and Ordering: Kits

Blood Kit (frozen):



Shipping Kit:



# Collection Volumes

Total blood volumes

Sample Type	Amount
Whole Blood for DNA	6 ml
Whole Blood for Banking	6 ml

# Kit and Supply Ordering

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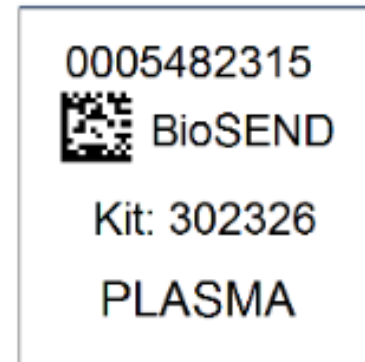
- Click “Submit” to send order to BioSEND; staff will confirm receipt of your order
- Please allow two-week turn-around time for kit shipments
- If urgent request needed, please note date needed by in comments and email BioSEND. We cannot guarantee urgent orders, but we will do our best to accommodate.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

# Sample Labelling: Example Labels

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## Labels are provided by Indiana University

- Please check that all samples are properly labelled to ensure correct identification by IU
- If do not have enough labels to complete a visit, please contact IU *immediately*
- Labelling the tubes during processing prevents sample mix-ups



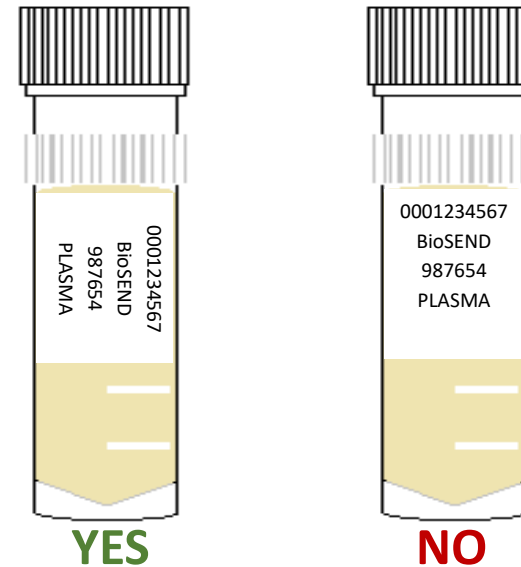


# Sample Labelling: Label Placement

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Please...

- Label all collection tubes before collecting or freezing samples
- Label only 1 subject's tubes at a time to avoid mix-ups
- Wrap the label around the tube horizontally - label position is important for all tube types
- Make sure the label is completely adhered by rolling between your fingers



# Sample Collection and Processing

Blood Tube Draw Order

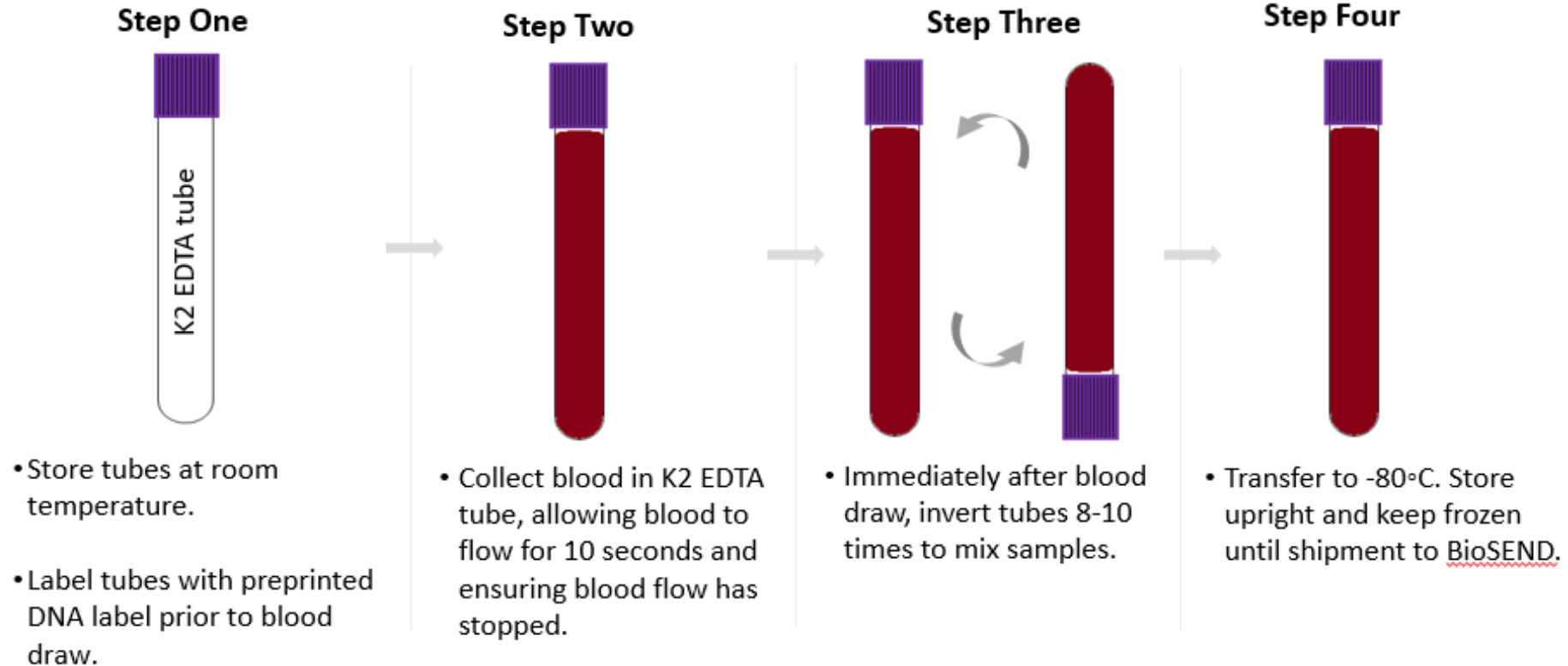
2 x 6ml EDTA  
tube



**1**

# Sample Collection and Processing: Whole Blood

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# Sample Collection and Processing: Timeline

Timeline for blood processing

**Blood  
Collection**

Invert all  
tubes 8x to  
mix

**90-120  
Minutes**

Freeze  
whole  
blood tubes

# Sample Collection and Processing: Issue #1

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## Troubleshooting Blood Collection

### Issue #1: Tube with little/no vacuum

- Always check expiration date on the tube before beginning blood draw and discard expired tubes
- Store tubes at “room temperature” – extreme temperature can affect vacuum
- Keep extra vacutainer tubes from supplemental kit nearby during blood draw to replace “bad” tubes
- If this is a frequent occurrence, report tube type and lot number to IU.

# Sample Collection and Processing Form

Specimen Collection and Processing Form

Direct Link:

<https://redcap.link/CRANESampleForm>

First part captures basic subject and visit information

**BioSEND** Returning?  
A A A

## Biospecimen Exchange for Neurological Disorders

Please complete the Specimen Collection and Processing Form, below, to ship samples to BioSEND for *Reducing Falls with Varenicline in Hypocholinergic Parkinson Disease (CRANE)*.  
Copies of the completed forms will be automatically emailed to you after submission.

### BioSEND CRANE Study

**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.*

**CRANE Study ID** \*

**Kit Number** \*

**Sex (used for DNA quality control)** \*

**Visit** \*

**Date of venipuncture blood collection** \*

**Time of venipuncture blood collection** \*

**WHOLE BLOOD EDTA**

**Number of WBLD tubes shipped:** \*

Two 6ml EDTA tubes expected

# Sample Collection and Processing Form

Second page captures collection and shipping information

## WHOLE BLOOD EDTA

Number of WBLD tubes shipped:

Two 6ml EDTA tubes expected

## NOTES

Please record any issues with collection/processing:

Expand

## Shipping Information - Please complete.

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

Date of shipment:

  Today D-M-Y

Did/will you use the IU UPS interface (ShipExec®) to generate the shipping label?

Yes

No

reset

Which shipping service did you use?

What is the shipment tracking number?

Submit

Save & Return Later

# Sample Collection and Processing Form

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

Confidential

Page 1

## CRANE Sample Record and Shipment Notification Form

Please complete the Specimen Collection and Processing Form, below, to ship samples to BioSEND for Reducing Falls with Varenicline in Hypocholinergic Parkinson Disease (CRANE). Copies of the completed forms will be automatically emailed to you after submission.

BioSEND CRANE Study

Study Site

University of Michigan

Email address of staff member completing this form

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

CRANE Study ID

\_\_\_\_\_

Kit Number

\_\_\_\_\_

Sex (used for DNA quality control)

Male  
 Female  
 Other

Visit

BL

Date of venipuncture blood collection

\_\_\_\_\_

Time of venipuncture blood collection

\_\_\_\_\_  
(Use 24 Hour clock)

### WHOLE BLOOD EDTA

Number of WBLD tubes shipped:

\_\_\_\_\_  
(Two 6ml EDTA tubes expected)

### NOTES

Please record any issues with collection/processing:

\_\_\_\_\_



# Sample Collection and Processing Form

Submission of the Shipping Manifest portion of the form serves as shipment notification to BioSEND

- Must be completed prior to shipment
- If samples are shipped and not received, BioSEND will follow-up with courier. It is recommended that sites also track shipment to ensure safe delivery

# Shipping Frozen Samples: Tips

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## Packing and Shipping Frozen Samples

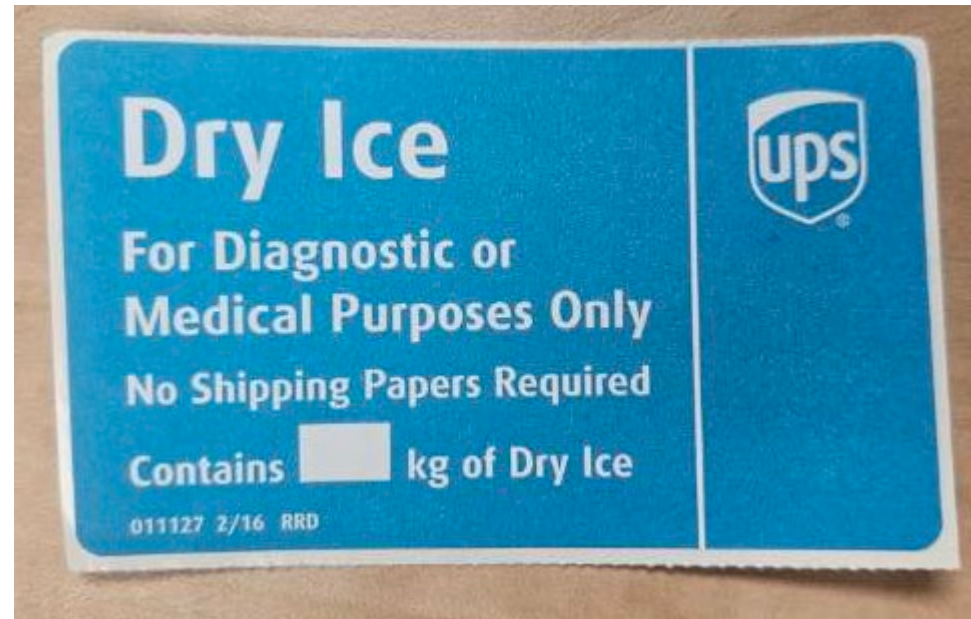
- Whole blood all ship frozen
- Ship frozen samples on dry ice
- Frozen samples should be shipped **only** Monday through Wednesday
- Always fill carton to **top** with dry ice
- Do not pack shipment until the day of pickup



# Shipping Samples

Packing and Shipping Frozen Samples

UPS Dry Ice label should not be covered with other stickers and must be completed, or UPS will reject/return your package!



# Shipping Samples: Frozen

Do not ship more than 6 biohazard bags in a single shipper\* (equivalent to six subject-visits).

- Allows room for dry ice to keep samples frozen in transit
- Minimizes loss in the rare but unfortunate event of courier issues



# Shipping Samples – UPS: <https://kits.iu.edu/UPS>

The screenshot shows the shipping interface for Indiana University School of Medicine. The header includes the IU logo and the text "INDIANA UNIVERSITY SCHOOL OF MEDICINE". Below the header, the text "and Affiliated Biorepositories" is displayed. The interface is divided into two main sections: "Ship From" and "Shipment Information".

**Ship From Section:**

- Search for address: A search bar with a magnifying glass icon and a "Clear" button.
- Code: Input field.
- Company: Icahn School of Medicine - Mt. Sinai
- Contact: Kenny Persaud
- Address 1: 1425 Madison (Icahn Building)
- Address 2: Icahn L4 39
- Address 3: Input field.
- City: New York
- State/Province: NY
- Postal Code: 10029
- Country/Territory: United States

**Shipment Information Section:**

- Study Group: SSBC (dropdown menu)
- Weight: 20 (input field) LB (dropdown menu)
- Dry Ice Weight: 10 (input field) LB (dropdown menu)
- Description of Return: Biologic Specimens
- Pickup Request: Button

**Annotations:**

- "Search for address": Points to the search bar.
- "Choose Study": Points to the Study Group dropdown.
- "Enter weight": Points to the Weight and Dry Ice Weight input fields.
- "Schedule Pickup": Points to the Pickup Request button.
- "Click 'Ship'": Points to the Ship button at the bottom right.

**Buttons:** Clear, Pickup Request, Reset, Ship.

# Shipping Samples via UPS

IU UPS ShipExec Shipping Portal

- Print out UPS air waybill
- Ensure all elements (barcode, return address, etc.) printed clearly
- Fold and insert UPS air waybill into clear plastic sleeve on package

JOHN SMITH  
INDIANA UNIVERSITY  
410 WEST 10TH STREET  
INDIANAPOLIS IN 46202

2 LBS

1 OF 1

RS

SHIP TO:

SCHOOL OF MEDICINE  
317-278-2694  
INDIANA UNIVERSITY  
TK 217  
351 W 10TH ST  
INDIANAPOLIS IN 46202



IN 461 9-01



UPS NEXT DAY AIR

1

TRACKING #: 1Z 976 R8W 84 3985 8595



BILLING: P/P  
DESC: Biological Specimens  
RETURN SERVICE

Reference No. 1: 4087277

XOL 20.03.09 NV45 83.0A 12/2019



# Shipping Samples: Closures

Date	Holiday
January 1	New Year's Day
3 <sup>rd</sup> Monday in January	Martin Luther King, Jr Day
4 <sup>th</sup> Monday in May	Memorial Day
June 19	Juneteenth (observed)
July 4	Independence Day (observed)
1 <sup>st</sup> Monday in September	Labor Day
4 <sup>th</sup> Thursday in November	Thanksgiving
4 <sup>th</sup> Friday in November	Friday after Thanksgiving
December 25	Christmas

Please also consider weather when shipping. UPS will post service updates on their webpage. Reach out to BioSEND if you are unsure if it is safe to ship.

# Non-Conformance Reporting

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Most common non-conformance issues:

- Shipment notification not sent
- Samples shipped for weekend/holiday delivery
- Sample form incomplete/inaccurate
- Low volume
- Unlabeled or mislabeled tube(s)





# Non-Conformance and Inventory Reporting

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Most common non-conformance issues:

- 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***

# Contacts

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## Indiana University

General Questions/Shipment Notifications:

[biosend@iu.edu](mailto:biosend@iu.edu)

317-278-6158

Request kits:

<https://redcap.link/CRANEKits>