



Biospecimen Exchange for Neurological Disorders

Reducing Falls with Varenicline in Hypocho^linergic Pa^rkin^son Dis^ease

BIOSPECIMEN COLLECTION & PROCESSING

Overview

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

GENERAL REMINDERS

Specimen Standardization and Quality

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

Site Consumables and Equipment

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

MAINTAINING SPECIMEN UNIFORMITY AND QUALITY

Biospecimen Collection Protocol

Sample Type & Volume	BL
Whole Blood, 6ml	2

Kit Contents and Ordering

- 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

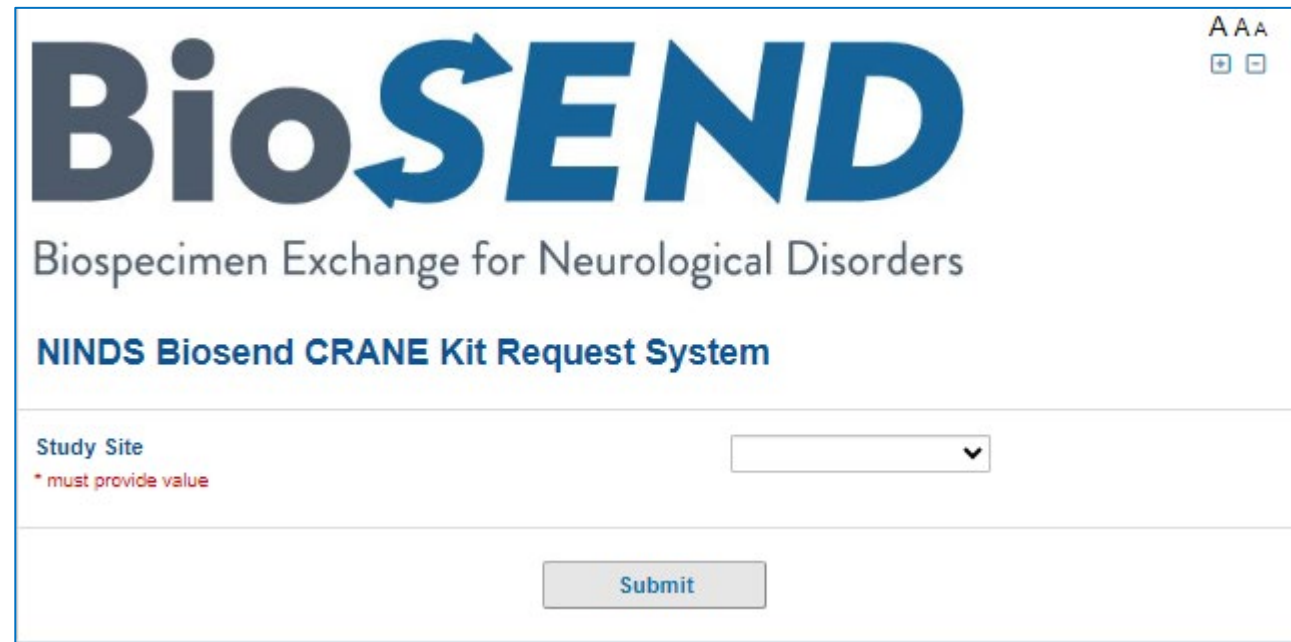
Kit Contents and Ordering – REDCap Survey

<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 'NINDS Biosend CRANE Kit Request System' form. At the top is the 'BioSEND' logo, where 'Bio' is in a dark blue sans-serif font and 'SEND' is in a larger, bold, blue sans-serif font with a blue curved arrow pointing from 'Bio' to 'SEND'. Below the logo is the text 'Biospecimen Exchange for Neurological Disorders' in a smaller, grey sans-serif font. Underneath that is the title 'NINDS Biosend CRANE Kit Request System' in a bold, blue sans-serif font. In the top right corner, there are three small icons: 'A A A' and two square icons with plus and minus signs. Below the title is a form field labeled 'Study Site' in a grey sans-serif font. To the right of the label is a dropdown menu with a downward arrow. Below the label, there is a red asterisk followed by the text '* must provide value'. At the bottom center of the form is a grey button with the word 'Submit' in a blue sans-serif font.

Kit Contents and Ordering: Confirm Site Info

CRANE Kit Request Module

Study Site <small>* must provide value</small>	Indiana Univers	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
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 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.

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

Kit Contents and Ordering: Kit Breakdown

CRANE Kit Request Module

Comments	
	<div></div> <div>Expand</div>
Each Blood Collection Kit contains:	
<ul style="list-style-type: none">2 - EDTA tube, 6ml (plastic)2 - Resealable tube pouch1 - Specimen/Case label set-- Kit numbers	
Each Shipping Kit contains:	
<p><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 style="list-style-type: none">2 - Plastic Biohazard bag with absorbent sheet (small)1 - UPS Airbill Sleeve1 - Shipping box/Styrofoam container1 - UN3373 label1 - Fragile label1 - Dry ice label	

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

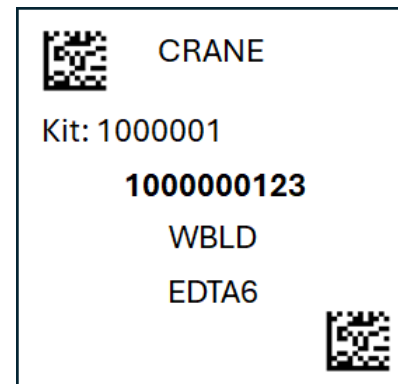
Kit and Supply Ordering

- 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

Labels are provided by Indiana University

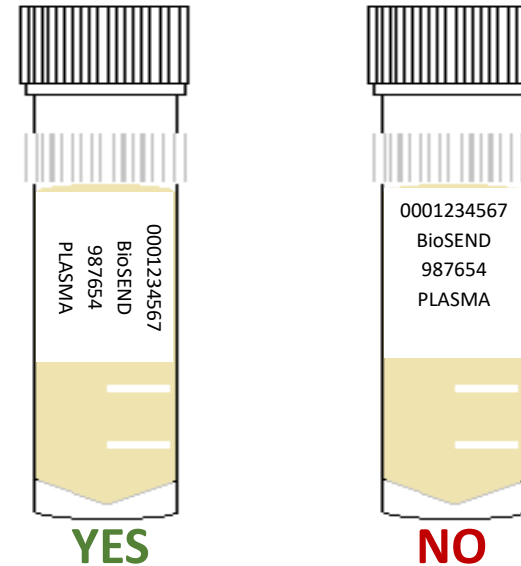
- Please check that all samples are properly labelled to ensure correct identification by IU
- If do not have enough labels to complete a visit, please contact IU *immediately*
- Labelling the tubes during processing prevents sample mix-ups



Sample Labelling: Label Placement

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

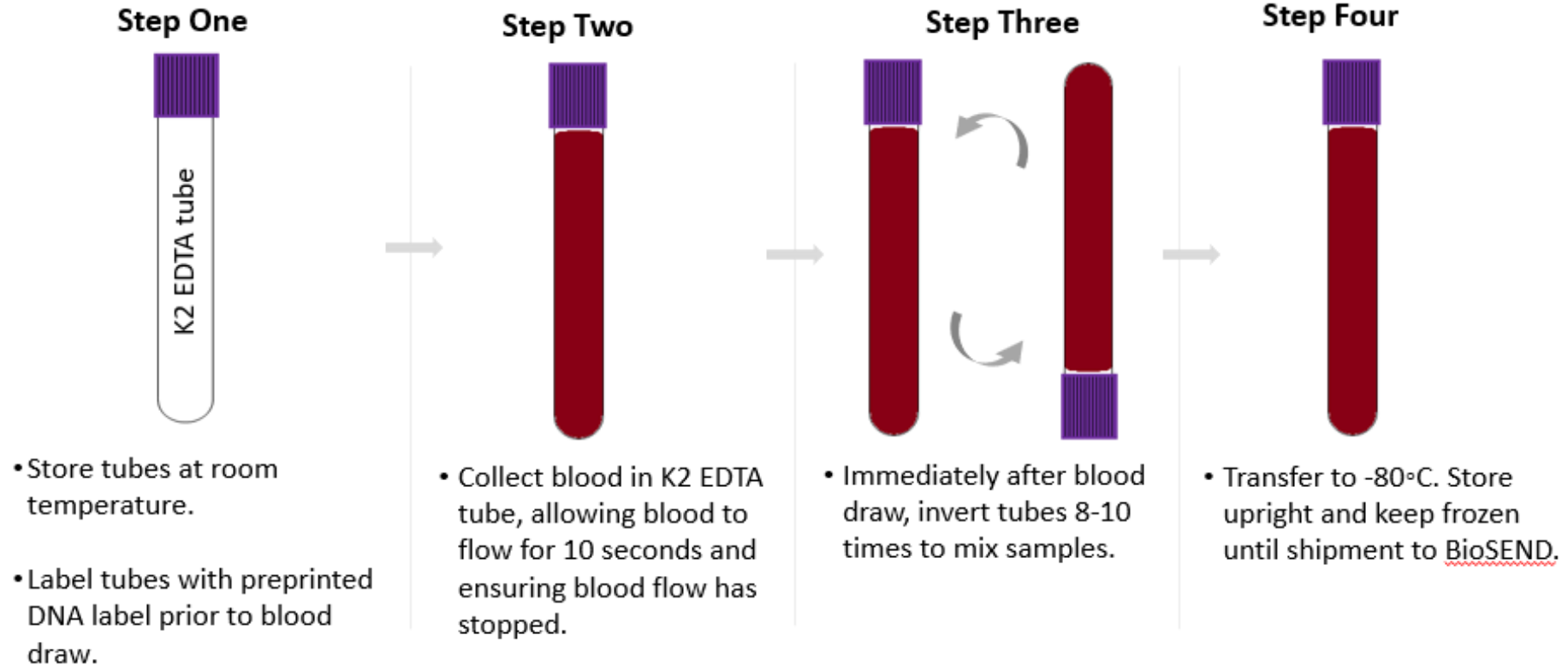
Blood Tube Draw Order

2 x 6ml EDTA
tube



1

Sample Collection and Processing: Whole Blood



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

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

Returning?

AAA

BioSEND

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 *	<div></div>
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> *	<div></div>
CRANE Study ID *	<div></div>
Kit Number *	<div></div>
Sex (used for DNA quality control) *	<div></div>
Visit *	<div></div>
Date of venipuncture blood collection *	<div></div> <div>Today</div> M-D-Y
Time of venipuncture blood collection *	<div></div> <div>Now</div> H:M Use 24 Hour clock
WHOLE BLOOD EDTA	
Number of WBLD tubes shipped: *	<div></div> 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

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

Packing and Shipping Frozen Samples

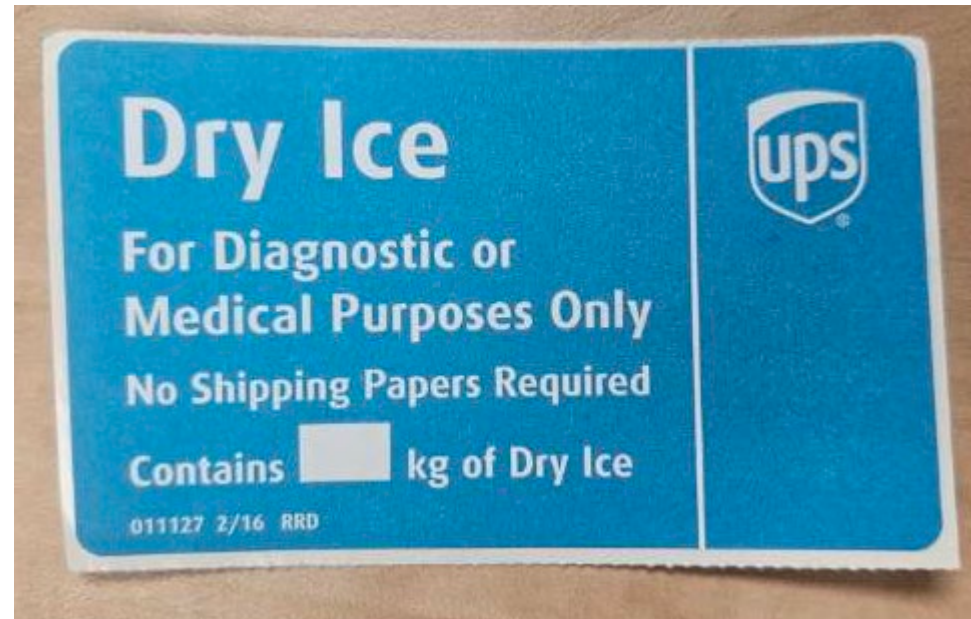
- Whole blood all ship frozen
- Ship frozen samples on dry ice
- Frozen samples should be shipped **only** Monday through Wednesday
- Always fill carton to **top** with dry ice
- Do not pack shipment until the day of pickup



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 'SHIP FROM' and 'SHIPMENT INFORMATION' sections of the IU School of Medicine shipping form. Annotations include:

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

The form contains the following data:

SHIP FROM		SHIPMENT INFORMATION	
Code		Study Group	SSBC
Company	Icahn School of Medicine - Mt. Sinai	Weight	20 LB
Contact	Kenny Persaud	Dry Ice Weight	10 LB
Address 1	1425 Madison (Icahn Building)	Description of Return	Biologic Specimens
Address 2	Icahn L4 39		
Address 3			
City	New York		
State/Province	NY		
Postal Code	10029		
Country/Territory	United States		

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		
 SAMPLE		
BILLING: P/P DESC: Biological Specimens RETURN SERVICE		
Reference No.1: 4087277		
XOL 20.03.09 NV45 83.0A 12/2019		 TM

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. Reach out to BioSEND if you are unsure if it is safe to ship.

Non-Conformance Reporting

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

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***

BioSEND.org

On the website, you can:

- Access your study's kit request module and sample submission form
- Download the most recent version of the Manual of Procedures
- View a recording of this training
- Find information about holiday closures
- Access shipping resources

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 fulfilled.

[Kit Request System →](#)

SPECIMEN COLLECTION AND PROCESSING FORM

Please use the below link to access the collection and processing form for this protocol. This form must be completed prior to shipment. We also ask that all shipments include a physical copy of the shipping manifest portion of the form.

[Specimen Collection and Processing Form →](#)

MANUAL OF PROCEDURES

The below downloadable manual was created specifically for the DxCTEII study. Please feel free to explore the manual through the hyperlinked 'Table of Contents'. Questions concerning any part of the manual may be directed to biosend@iu.edu for further clarification.

[Manual of Procedures ↓](#)

TRAINING SLIDES

These slides correspond to the BioSEND DxCTEII protocol training. Training is available upon request by contacting biosend@iu.edu.

[Training Slides ↓](#)

SAMPLE SHIPPING

BioSEND can receive samples Monday-Friday, excluding holidays. Frozen samples should be shipped M-W. Ambient samples may be shipped on Th.

[Generate UPS airbill or schedule pickup →](#)
[Check holiday closures →](#)
[What do I do for Friday blood draws →](#)

Contacts

Indiana University

General Questions/Shipment Notifications:

biosend@iu.edu

317-278-6158

Request kits:

<https://redcap.link/CRANEKits>