



Biospecimen Exchange for Neurological Disorders

Reducing Falls with Varenicline in Hypocho^linergic Parkin^son Disea^se

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

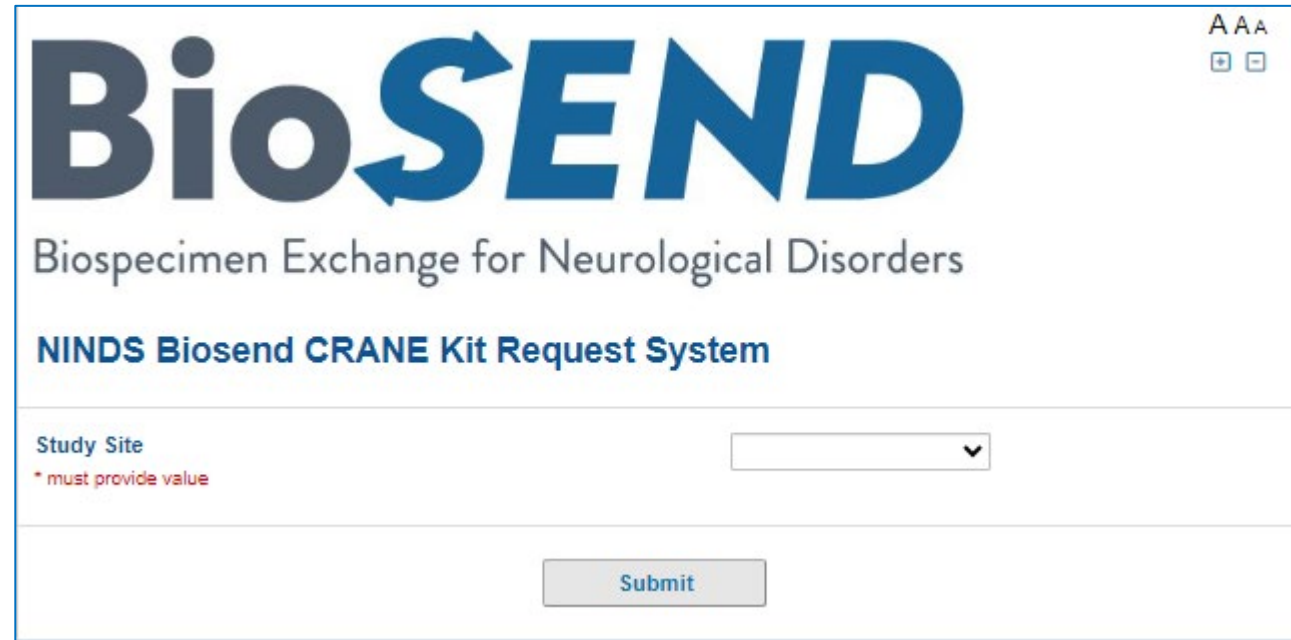
Kit Contents and Ordering – REDCap Survey

<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 BioSEND logo at the top, with the text "Biospecimen Exchange for Neurological Disorders" below it. Underneath is the title "NINDS Biosend CRANE Kit Request System". There is a dropdown menu labeled "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.

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

| | | |
|--|--|---|
| 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 | | Verify contact information and update if needed |
| 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 |

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** <i>* must provide value</i> | <input checked="" type="radio"/> Blood Collection Kit <input type="radio"/> Shipping Kit <input type="radio"/> Extra Supplies |
| Blood Collection Kit Quantity <i>* must provide value</i> | <input type="text"/> |
| Comments | <input type="text"/> <small>Expand</small> |


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

Kit Contents and Ordering: Kit Breakdown

CRANE Kit Request Module

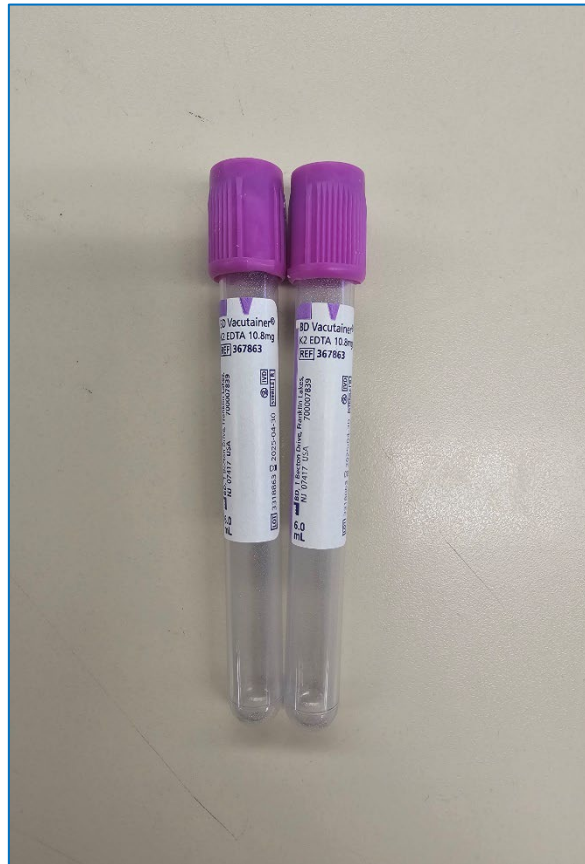
| | |
|---|--|
| Comments | <div data-bbox="1778 242 2331 421" style="border: 1px solid gray; height: 125px; width: 217px;"></div> <p data-bbox="2331 421 2400 449">Expand</p> |
| <p data-bbox="970 499 1426 535">Each Blood Collection Kit contains:</p> <ul data-bbox="970 571 1477 685" style="list-style-type: none"><li data-bbox="970 571 1312 606">2 - EDTA tube, 6ml (plastic)<li data-bbox="970 606 1299 642">2 - Resealable tube pouch<li data-bbox="970 642 1477 685">1 - Specimen/Case label set-- Kit numbers | |
| <p data-bbox="970 742 1337 778">Each Shipping Kit contains:</p> <p data-bbox="970 835 2400 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="970 928 1605 1156" style="list-style-type: none"><li data-bbox="970 928 1605 963">2 - Plastic Biohazard bag with absorbent sheet (small)<li data-bbox="970 963 1248 999">1 - UPS Airbill Sleeve<li data-bbox="970 999 1414 1035">1 - Shipping box/Styrofoam container<li data-bbox="970 1035 1197 1071">1 - UN3373 label<li data-bbox="970 1071 1184 1106">1 - Fragile label<li data-bbox="970 1106 1184 1142">1 - 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 |

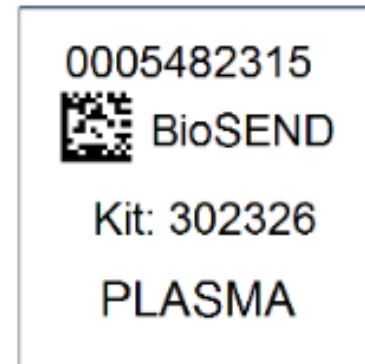
Kit and Supply Ordering

- 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

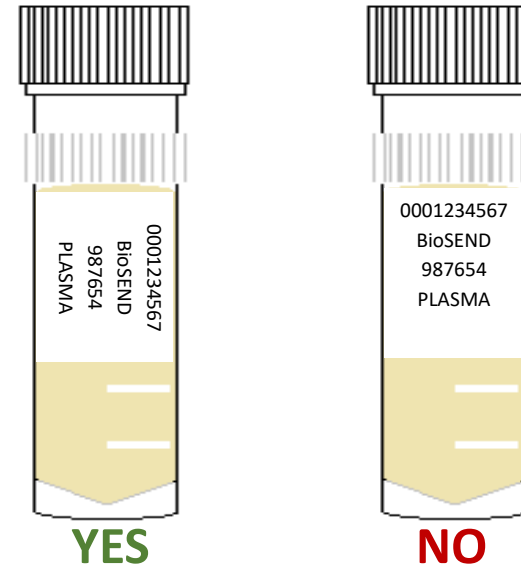
- Please check that all samples are properly labelled to ensure correct identification by IU
- If do not have enough labels to complete a visit, please contact IU *immediately*
- Labelling the tubes during processing prevents sample mix-ups



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

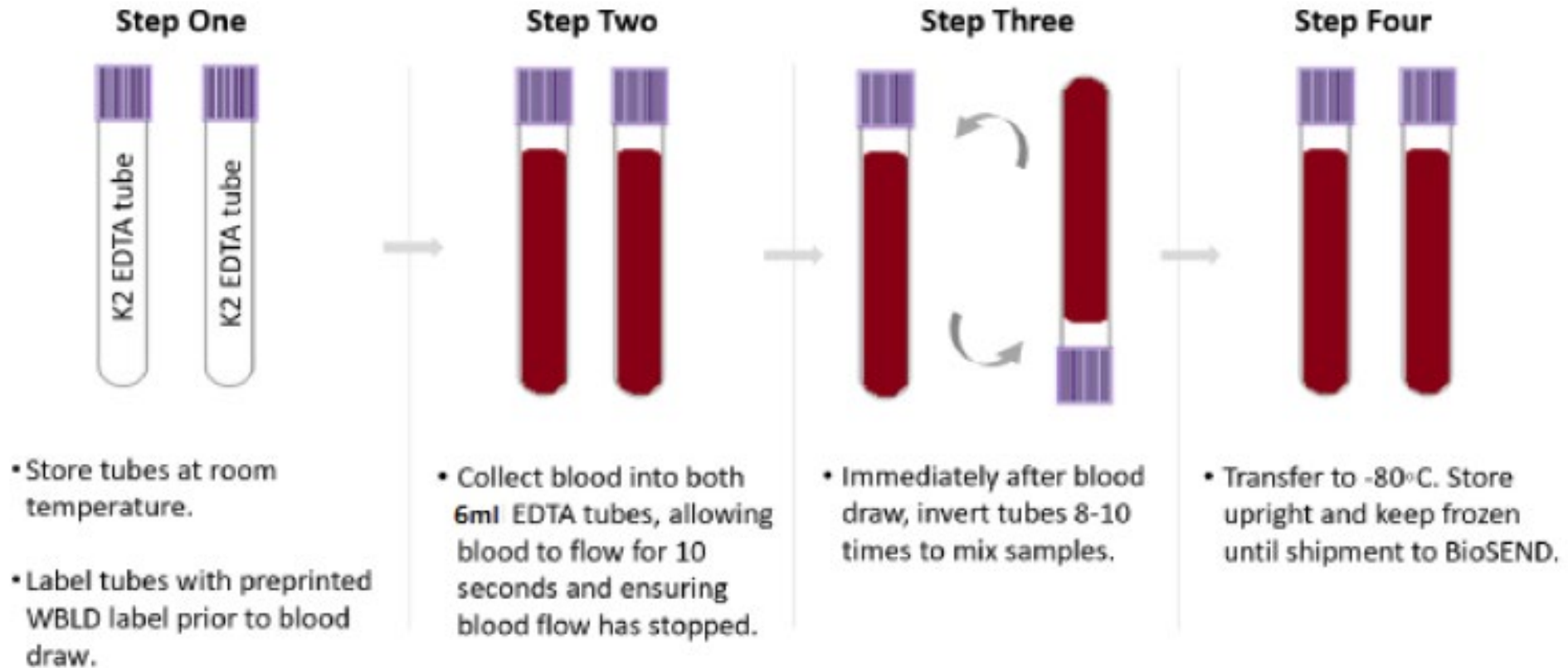
2 x 6ml EDTA
tube



1

Sample Collection and Processing: Whole Blood

WBLD Preparation – 2 x 6 ml K2 EDTA (Purple Top) Tube



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

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

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



Class 9 Dry Ice Label should not be covered with other stickers and must be completed, or UPS 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. _____ x _____ Kg
(Number of pkgs) (wt)

Net weight of dry ice in kg

Dry Ice _____ kg.

Your name & address

Shipper's Name and Address

UN 1845

IU information and address

Consignee Name and Address

9

06426 1/01 FRD

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 the Indiana University School of Medicine. The header features 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: A blue button.

Annotations:

- "Search for address": A dashed box around the search bar with a blue arrow pointing to it.
- "Choose Study": A dashed box around the "Study Group" dropdown with a blue arrow pointing to it.
- "Enter weight": A dashed box around the "Weight" and "Dry Ice Weight" input fields with a blue arrow pointing to them.
- "Schedule Pickup": A dashed box around the "Pickup Request" button with a blue arrow pointing to it.
- "Click 'Ship'": A dashed box around the "Ship" button at the bottom right with a blue arrow pointing to it.

Buttons:

- Clear (blue button)
- Pickup Request (blue button)
- Reset (blue button)
- Ship (blue button)

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 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***

Contacts

Indiana University

General Questions/Shipment Notifications:

biosend@iu.edu

317-278-6158

Request kits:

<https://redcap.link/CRANEKits>