

NINDS Udall Centers of Excellence for Parkinson's Disease Research: UAB

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
- Specimens must be processed within 2 hours of collection
- 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
- Microcentrifuge tube rack
- Sharps bin and lid

- Crushed ice
- Pipettes and pipette tips
- Centrifuge capable of maintaining 4°C
- -80°C Freezer
- Dry ice

Procedures

MAINTAINING SPECIMEN UNIFORMITY AND QUALITY

Biospecimen Collection Protocol

	BL	12M	24M	36M	48M	60M	72M	84M
Buffy coat (2 aliquots)	X	X	X	X	X	X	X	X
Plasma (6 x 1ml)	X	X	X	X	X	X	X	X
CSF (10 x 1ml)	X							

Kit Contents and Ordering

- All sites will be sent a Supplemental Kit with their first kit shipment
 - Contains extra blood collection tubes, processing supplies, and LP needles
 - 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

http://kits.iu.edu/biosend/udall

Order kits online through the Kit Request Module for:

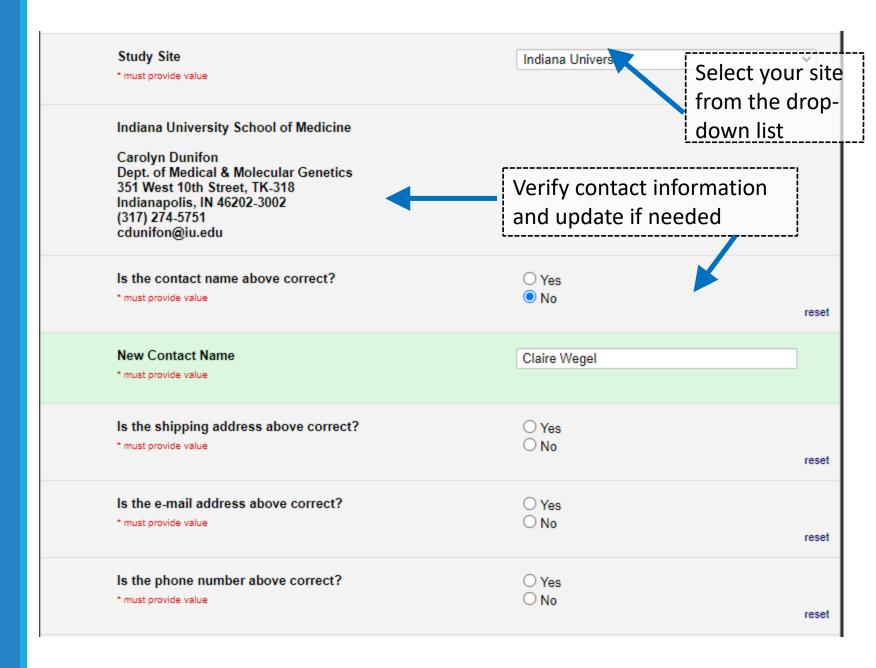
- Blood & CSF Kits
- Extra Supplies

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



Kit Contents and Ordering: Confirm Site Info

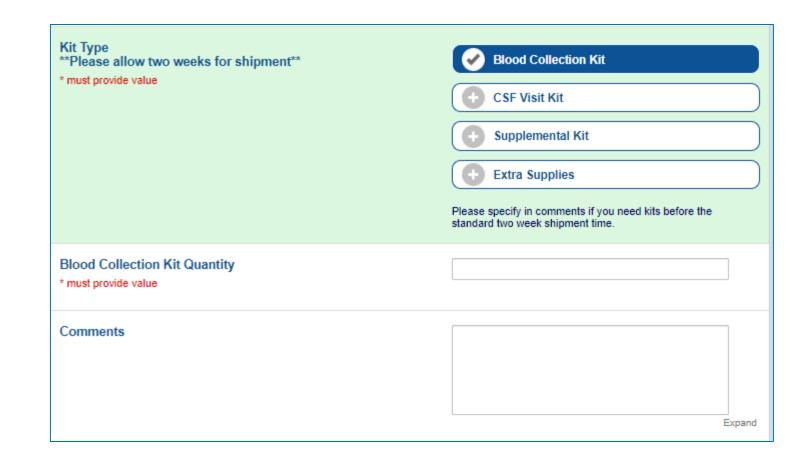
UDALL Kit Request Module



Kit Contents and Ordering: Kit Types

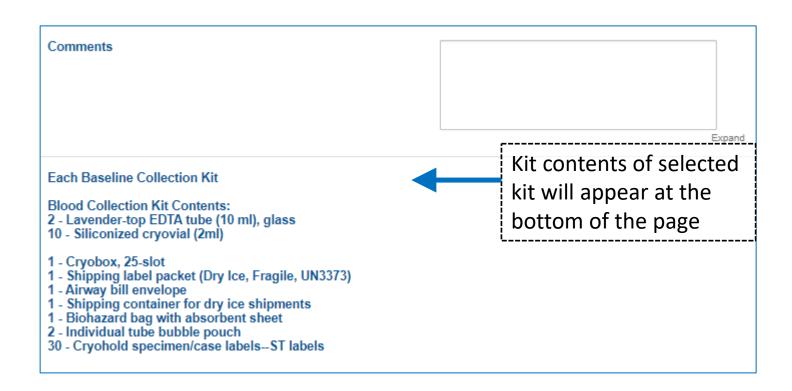
UDALL Kit Request Module

- 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.
- CSF processing kits are ordered independently of blood kits, as
 CSF is not required
- All specimen labels (including CSF) will be included in the Blood Collection Kit. If CSF is not collected at a visit, you may discard these extra labels



Kit Contents and Ordering: Kit Breakdown

UDALL Kit Request Module



Kit Contents and Ordering: Blood Kit



Kit Contents and Ordering: CSF Kits

CSF: LP Tray:





Collection Volumes

Total blood and CSF volumes

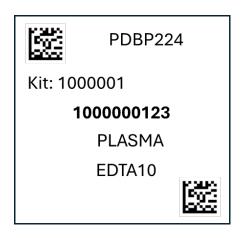
Sample Type	Amount
Whole Blood for Plasma and Buffy Coat	20 ml
Cerebrospinal Fluid	10 ml

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 and aliquot tubes before cooling, collecting, processing, 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



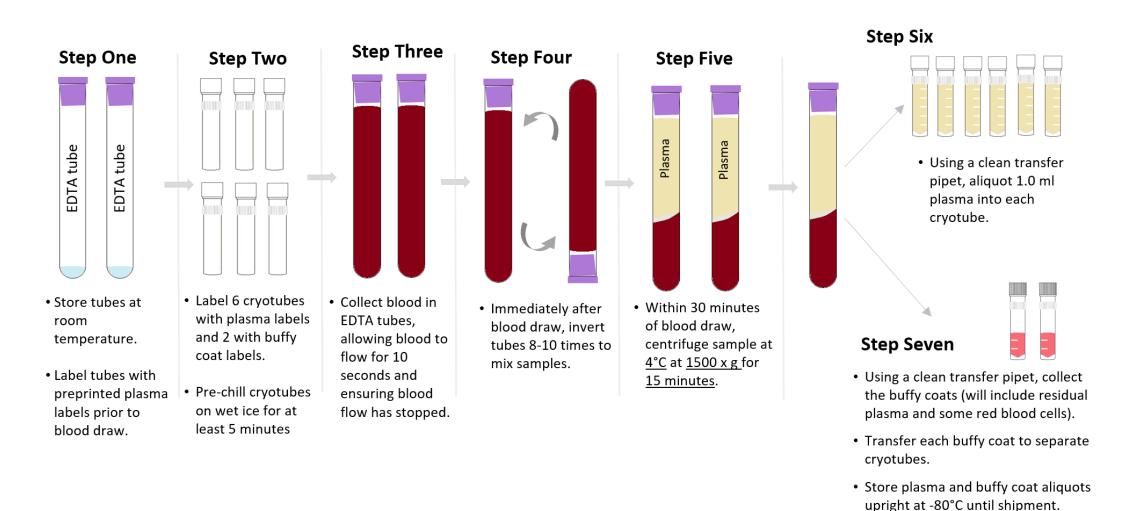


Sample Collection and Processing

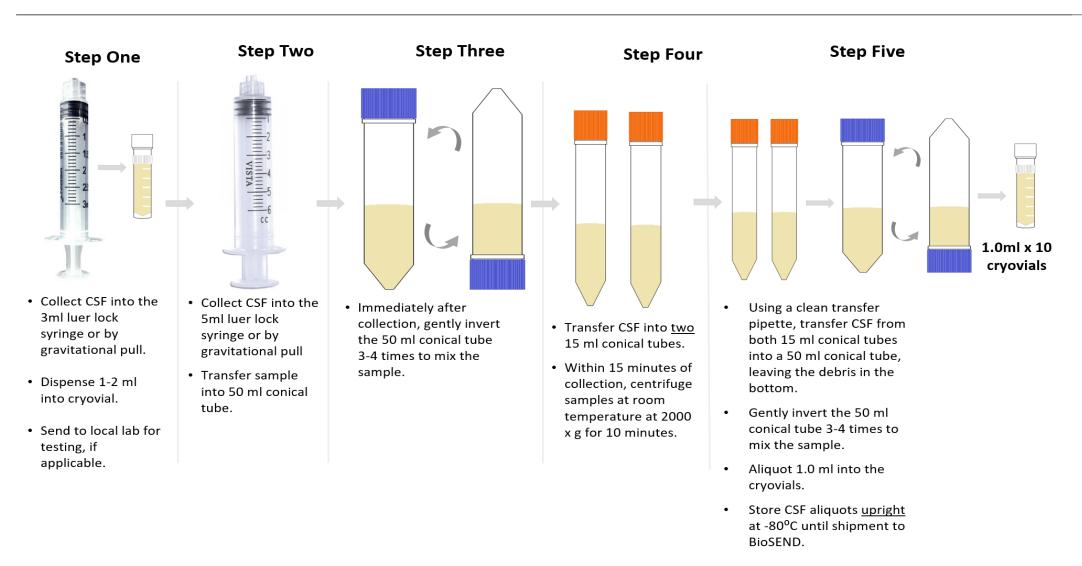
EDTA for plasma and buffy coat



Sample Collection and Processing: Plasma & Buffy Coat



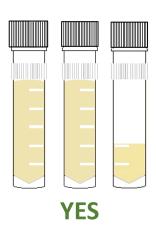
Sample Collection and Processing: CSF

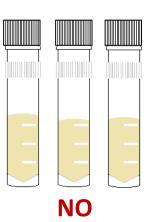


Sample Collection and Processing: Aliquots

Filling biomarker plasma and CSF aliquots:

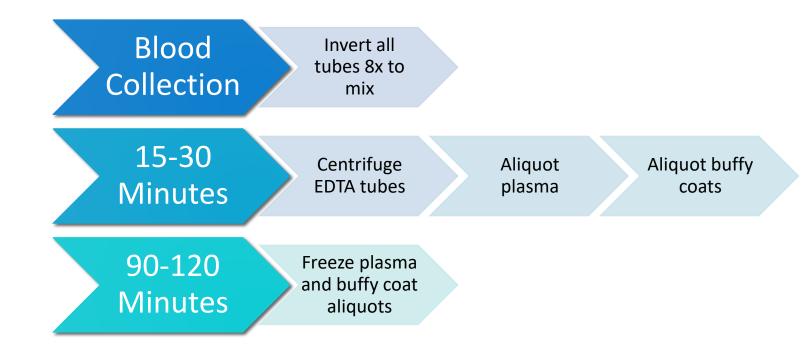
- Fill as many cryovials as possible to 1.0 ml (plasma& CSF)
- Over-filled vials may burst in freezer!
- Ship ALL material to IU, even if final vial is less than standard volume





Sample Collection and Processing: Timeline

Timeline for blood processing



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: Issue #2

Troubleshooting Blood Collection

Issue #2: Hemolyzed serum and/or plasma caused by incorrect collection

Cause: Blood Collection Methods	Corrective Action	
Improper venipuncture site	Draw from median cubital, basalic, and cephalic veins from antecubital region of arm	
Prolonged tourniquet use	Tourniquet should be released after no more than 1 min, excessive fist clenching should be avoided	
Not allowing alcohol to dry on skin before venipuncture	Without touching, allow the venipuncture site to air dry	
Use of too large/small bore needle resulting in excess force applied to blood	Avoid using too small/large needle. Needle size dependent on the subject's physical characteristics & amount of blood to be drawn. Most commonly used sizes are 19 – 23.	
Pulling/pushing plunger too fast while drawing/transferring blood	Avoid drawing the syringe plunger too forcefully when collecting blood	
Ensure all blood collection assemblies are fitted securely, to avoid frothing		

For more information, visit: http://www.bd.com/vacutainer/pdfs/techtalk/TechTalk_Jan2004_VS7167.pdf

Sample Collection and Processing: Issue #2 continued

Troubleshooting Blood Collection

Issue #2: Hemolyzed serum and/or plasma caused by incorrect processing

Cause: Sample Processing Methods	Corrective Actions
Vigorous mixing/shaking	Gently invert blood collection tube when mixing additive with specimen, follow guidelines in Biologics Manual regarding number of times to invert each type of tube
Not allowing serum to clot for recommended time	Serum tubes without clot activator should be allowed to clot for 60 min in a vertical position
Exposure to excessive heat or cold	Keep samples at ambient temperature until processing
Prolonged contact of serum/plasma with cells	Do not store uncentrifuged samples beyond recommended time

For more information, visit: http://www.bd.com/vacutainer/pdfs/techtalk/TechTalk_Jan2004_VS7167.pdf

Sample Collection and Processing Form

Direct link:

https://redcap.link/UDALLUABS ampleForm

First part captures basic subject and visit information

BioSEND

C Returning?

AAA

+ -

Biospecimen Exchange for Neurological Disorders

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the Sample Record and Shipment Notification Form will be emailed to you.

Please print a copy of that document and include it in the shipping container.

BioSEND UDALL UAB 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.	
GUID:	
Sex (used for DNA quality control)	•
Visit	•
IU Kit Number	
	6 characters remaining

Sample Collection and Processing Form

Direct link:
https://redcap.link/UDALLUABS
ampleForm

Second part captures collection information

Date of venipuncture blood collection	Today M-D-Y	
Time of venipuncture blood collection	Use 24 Hour clock	
Date participant last ate	Today M-D-Y	
Time participant last ate	Now H:M	
PLASMA EDTA		
Number of PLASMA EDTA aliquots shipped:	Each aliquot should be 1.0 mL	
Number of BUFFY COAT aliquots shipped:		
CSF		
Was CSF collected?		
	Yes	
	Yes No	reset
Date of CSF collection		reset
	No	reset
Date of CSF collection	No Today M-D-Y Now H:M	reset
Date of CSF collection Time of CSF collection	No Today M-D-Y Now H:M	reset

Page 1

Sample Collection and Processing Form

Direct link: https://redcap.link/UDALLUABSampleForm

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

UDALL UAB 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 Site:	O University of Alabama
GUID:	
Visit:	○ BL ○ 12M ○ 24M ○ 36M ○ 48M ○ 60M ○ 72M ○ 84M
IU Kit Number:	
Date of blood collection:	
Date of CSF collection:	
PLASMA EDTA	
Number of PLASMA EDTA aliquots shipped:	
Number of BUFFY COAT aliquots shipped:	
CSF	
Number of CSF aliquots shipped:	
Shipping Information - Please complete.	
Frozen shipments should be sent Monday-Wednesday only. Pl Contact us at biosend@iu.edu if you are unsure whether or no	lease check for holiday closures prior to shipping. bt it is safe to ship.

Shipping Frozen Samples: Tips

Packing and Shipping Frozen Samples

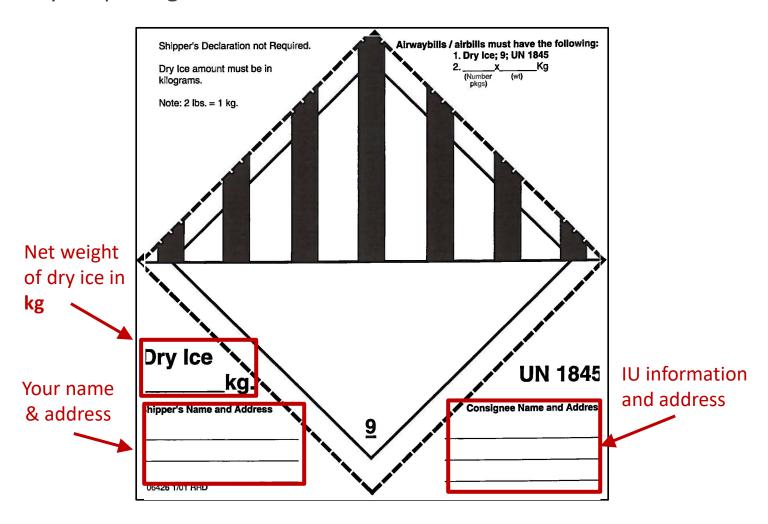
- Plasma, buffy coats and CSF all ship frozen
- Ship frozen samples on dry ice
- Frozen samples should be shipped only Monday through Wednesday
- Always fill carton to top with dry ice
- Do not pack shipment until the day of pickup



Shipping Samples

Packing and Shipping Frozen Samples

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



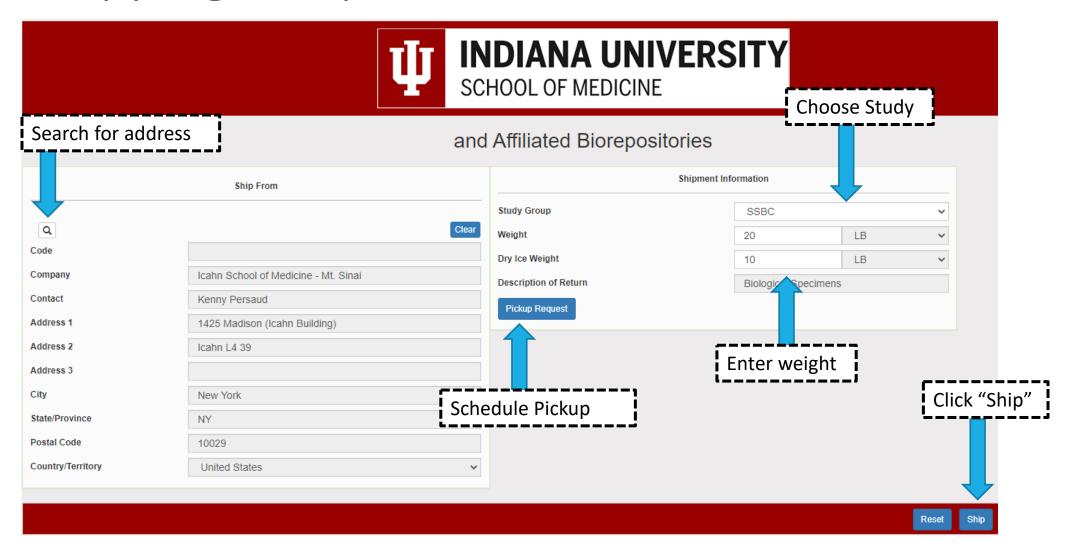
Shipping Samples: Frozen

Packing and Shipping Frozen Samples





Shipping Samples – UPS: https://kits.iu.edu/UPS



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

TRACKING #: 1Z 976 R8W 84 3985 8595

1



BILLING:

DESC: Biological Specimens RETURN SERVICE

Reference No.1: 4087277

OL 20.03.09 NV45 83.0A 12/



Non-Conformance

Non-conformance to standard procedures may reduce the utility of the biospecimens:

- Not processing plasma within 2 hours of collection allows for breakdown of certain proteins and small molecules
- Over/under centrifuging changes plasma, CSF composition



Non-Conformance Reporting con't

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)
- Sample hemolysis



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:

http://kits.iu.edu/biosend/UDALL