

Biospecimen Exchange for Neurological Disorders

The Late Effects of TBI (LETBI) – IU Site

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

Visit & Sample Type	V0	V1	V2	V3	V4
10ml EDTA	2	2	2	2	2

*Tubes will be sent to IUGB lab and processed into plasma and buffy coat aliquots

Kit Contents and Ordering – REDCap Survey

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

Order kits online through the Kit Request Module for:

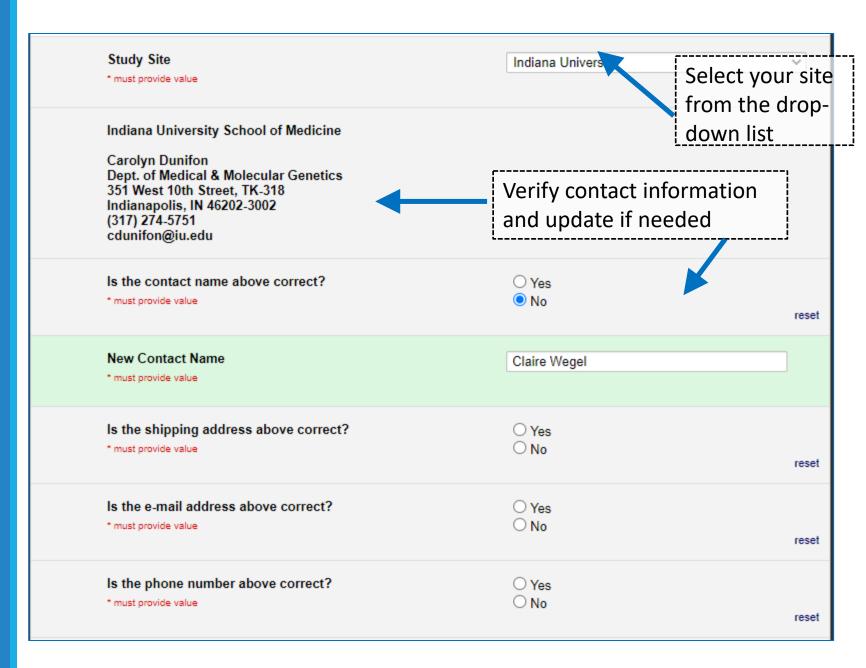
- Blood kits
- Supplemental Kit
- Extra Supplies

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

BioS	END	AAA t
Biospecimen Exchange f	or Neurological Disorders	
NINDS Biosend LETBI Kit F	Request System	
Study Site		~
* must provide value		
	Submit	

Kit Contents and Ordering: Confirm Site Info

LETBI Kit Request Module



Kit Contents and Ordering: Kit Types

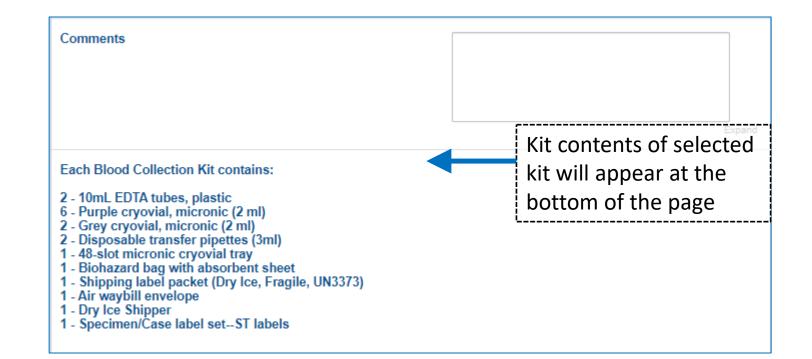
LETBI Kit Request Module

 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	Blood Collection Kit Supplemental Kit Extra Supplies		
	Please specify in comments if you need kits before the standard two week shipment time.		
Blood Collection Kit Quantity * must provide value			
Comments	Expand		

Kit Contents and Ordering: Kit Breakdown

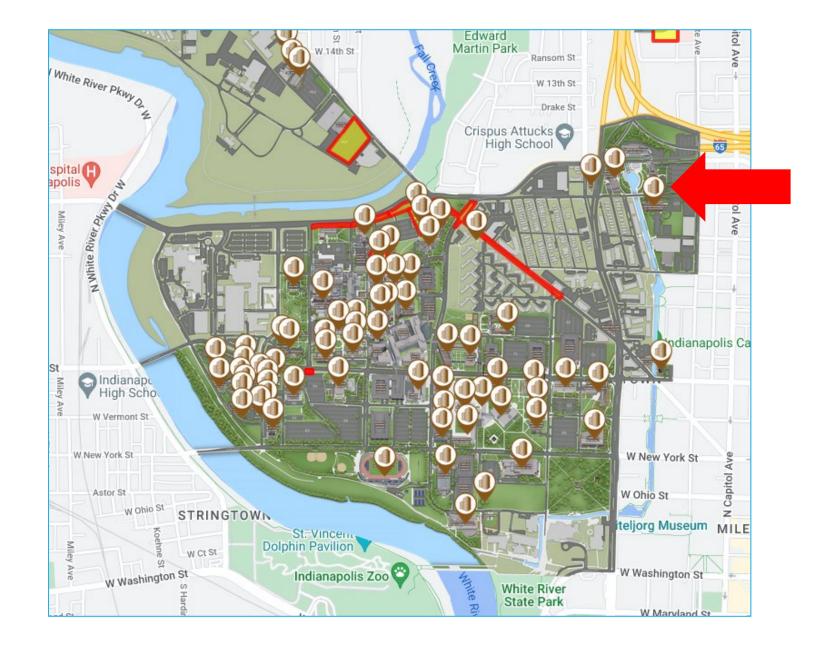
LETBI Kit Request Module



Kit Pick-Up

- BioSEND staff will offer dates/times the kits will be ready
- Kits can be picked up at:

IU Innovation Center (TK) 351 West 10th Street Indianapolis, IN 46202-3002



Collection Volumes

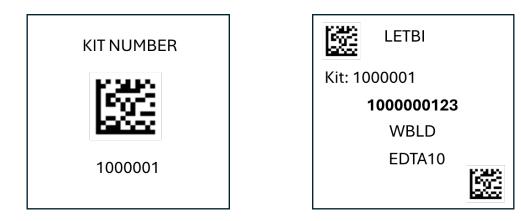
Total blood volumes

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

Sample Labelling: Example Labels

Labels are provided by Indiana University

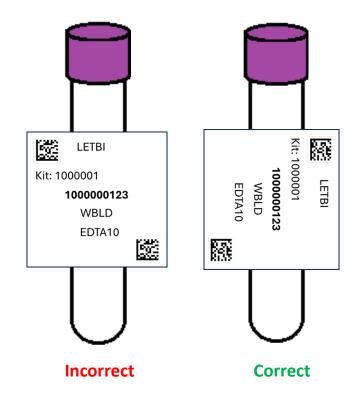
- Please check that all samples are properly labelled to ensure correct identification by IU
- If do not have enough labels to complete a visit, please contact IU *immediately*
- Labelling the tubes during processing prevents sample mix-ups



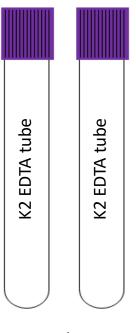
Sample Labelling: Label Placement

Please...

- Label all collection tubes before collecting 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

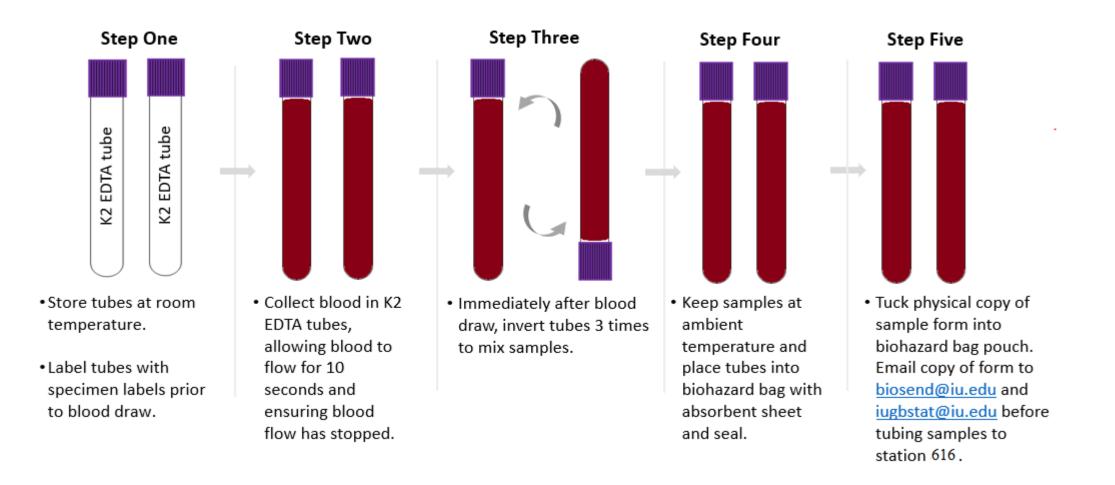


Sample Collection and Processing



2 x 10ml EDTA (plastic) collection tubes

Sample Collection and 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.

Shipping Samples: Sample Form

- Email a copy of the form to biosend@iu.edu and iugbstat@iu.edu in advance of tubing the samples. Please include "RI Lab" in the subject line
- 2. Tube samples to Station #616; Monday-Friday from 8:30am-4pm only

Study:						
Site Name:				Principal Investigator:		
Coordinator:			Telepho	ne:	Email:	
	Please list on	ly ONE subject p	er Sample Reco	rd Summary and Shipmer	nt Notifica	tion Form
						[
GUID:				KIT NU	imber	
Sex:				14	sit Type:	
					ы туре.	
4:00 PM. Th	is form must be edu prior to tubi	completed for shi	pment of all resea ysical copy shoul	nples should be sent Mor arch samples. Please email d also be included with the	iday-Frida a copy to a samples.	
4:00 PM. Th lugbstat@lu.	lis form must be edu prior to tubi	completed for shi	pment of all rese; ysical copy shoul	npies should be sent Mor arch samples. Please email	iday-Frida a copy to a samples.	at biosend@lu.edu and

Non-Conformance Reporting

Most common non-conformance issues:

- Shipment notification not sent
- Sample form incomplete/inaccurate
- Low volume
- Unlabeled or mislabeled tube(s)



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 🛓

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 \rightarrow Check holiday closures \rightarrow What do I do for Friday blood draws \rightarrow

TRAINING SLIDES

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

Training Slides 🛃

Contacts

Indiana University

General Questions/Shipment Notifications:

<u>biosend@iu.edu</u>

317-278-6158

Request kits:

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