



Clinical Trial Readiness for MSA (CTR-MSA)

BIOSPECIMEN COLLECTION & PROCESSING

Specimen Uniformity and Quality

GENERAL REMINDERS



Specimen Uniformity and Quality

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

- Standardization of processing across sites is key
- Reference the *BioSEND 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 Equipment

Sites will need to supply the following items:

Phlebotomy

- Gloves
- Alcohol wipes
- Butterfly needles
- Tourniquet
- Gauze pads
- Bandages
- Sharps bin and lid



Site Equipment

Sites will need to supply the following items:

Processing

- Crushed ice
- Microcentrifuge tube rack
- Calibrated pipettes and pipette tips
- Centrifuge capable of maintaining 4°C
- -80°C Freezer
- Dry ice



Collection Protocol

Sample Type & Volume	BL	6M	12M
Plasma aliquots, 1.5ml	6	6	6
Serum aliquots, 1.5ml	6	6	6
Buffy Coat	2	2	2
Whole Blood, 3ml	2	2	2
CSF aliquots, 1.5ml	10	10	10
Skin Biopsy	2	2	2

Kit Ordering – Biosend.org

The screenshot shows the Biosend.org website navigation menu. The 'Active Studies' link is circled in red. Below the navigation menu is a grid of three images with captions: 'About BioSEND' (a building with trees), 'Banking Samples' (a large metal container), and 'Biospecimens' (a dark container with a label). The 'Biospecimens' image includes a partial view of a label with the text 'and other neuropsychiatr to researchers'.

NINDS BioSEND Accessing Biospecimens Banking Samples **Active Studies** About BioSEND

AJPD Study Resources	MBPS Study Resources	SPARX3 Study Resources
CHANGE-HD Study Resources	PBS Study Resources	Udall Study Resources
DLB Study Resources	PHD3 Study Resources	Holiday Closures
DVRP Study Resources	PSP Study Resources	Shipping Information
EpiBioS4Rx Study Resources	SBPD Study Resources	Sample Shipment Form
LBD Study Resources	CRC-SCA Study Resources	
LETBI Study Resources	READISCA Study Resources	

About BioSEND **Banking Samples** **Biospecimens**


and other neuropsychiatr
to researchers

Kit Ordering – Study Resource Page

Study-specific resource page available. Will include:

- Link to Kit Request Module
- Link to Sample Collection & Processing Form
- Manual of Procedures
- Training Slides

BIOSEND NINDS Accessing Biospecimens Banking Samples Active Studies About BioSEND



Welcome CRC-SCA Study staff, coordinators, and PIs. This section encompasses study specific tools and resources for your reference. If you have any questions, comments, or new ideas please contact biosend@iu.edu or by phone directly at (317)278-0594.

Specimen Table

Cohort	Population	Plasma	Genomic DNA	Serum	CSF
		✓	✓	✓	✓

Study Resources

Kit Request Module

Please follow the below link to access the CRC-SCA 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 compiled and delivered to your site.

[Kit Request System](#)

Downloads

- Sample Shipment Form (pdf)
- Manual of Procedures
- New Coordinator Training Slides

Additional Resources

- Online Sample Form
- Kit Request System

Contact Us

biosend@iu.edu
317-278-0594

Confirm/Update Shipping Information

Select your Study Site from the drop down box to populate the most current information we have for your site. Please confirm or update your site's information as needed.

Study Site <small>* must provide value</small>	Indiana University
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 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

Note: Annotations in the original image include arrows pointing to the 'Study Site' dropdown, the contact information text, and the 'New Contact Name' input field, along with dashed boxes around the dropdown and the 'New Contact Name' field with the text 'Verify contact information and update if needed'.

Kit Ordering – Kit Options

Selecting a kit option will populate contents for that kit

Kit Type
****Please allow two weeks for shipment****

* must provide value

- Blood Collection Kit
- CSF Processing Kit
- Supplemental Kit
- Skin Biopsy Kit
- Extra Supplies

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

Blood Collection Kit contains:

- 6 - Cryovial (Sarstedt®) with purple cap, 2ml
 - 2 - Cryovial (Sarstedt®) with clear cap, 2ml
 - 6 - Cryovial (Sarstedt®) with red cap, 2ml
 - 2 - EDTA (glass) tube, 10ml
 - 2 - Serum (glass) tube, 10ml
 - 2 - EDTA (plastic) tube, 3ml
 - 6 - Bubble-tube sleeve
 - 3 - Disposable pipet, 3ml
 - 1 - Cryobox, 25 cell
 - 1 - Label set (kit & specimen labels)
-
- 2 - Plastic Biohazard bag with absorbent sheet (small)
 - 1 - UPS Airbill Sleeve
 - 1 - Shipping box/Styrofoam container
 - 1 - UN3373 label
 - 1 - Fragile label
 - 1 - Dry ice label

Kit Ordering – Blood Kits

Kit Type

****Please allow two weeks for shipment****

* must provide value

- Blood Collection Kit
- CSF Processing Kit
- Supplemental Kit
- Skin Biopsy Kit
- Extra Supplies

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

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 Kits

Kit Type
****Please allow two weeks for shipment****
* must provide value

Blood Collection Kit
 CSF Processing Kit
 Supplemental Kit
 Skin Biopsy 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

2

CSF Processing Kit Quantity
* must provide value

2

- 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

Extra Supplies

This option allows you to order individual kit components. For ex, if you have a kit with blood tubes that have expired, you may order new collection tubes to replace them.

Kit Type **Please allow two weeks for shipment** <small>* must provide value</small>	<input type="checkbox"/> Blood Collection Kit <input type="checkbox"/> CSF Processing Kit <input type="checkbox"/> Supplemental Kit <input type="checkbox"/> Skin Biopsy Kit <input checked="" type="checkbox"/> Extra Supplies
<small>Please specify in comments if you need kits before the standard two week shipment time.</small>	
Bubble tube sleeve	<input type="radio"/> 2 <input type="radio"/> 4
Cryobox, 25 cell	<input type="radio"/> 2 <input type="radio"/> 4
Cryovial (Sarstedt®) with purple cap, 2ml	<input type="radio"/> 10 <input type="radio"/> 20
Cryovial (Sarstedt®) with clear cap, 2ml	<input type="radio"/> 10 <input type="radio"/> 20
Cryovial (Sarstedt®) with red cap, 2ml	<input type="radio"/> 10 <input type="radio"/> 20
Air waybill envelope	<input type="radio"/> 2 <input type="radio"/> 4 <small>Plastic envelope to affix air waybill to package</small>
Shipping Container for Dry Ice Shipments	<input type="radio"/> 2 <input type="radio"/> 4
Biohazard bag with absorbent sheet	<input type="radio"/> 2 <input type="radio"/> 4
Conical tube (individually wrapped), 15ml	<input type="radio"/> 2 <input type="radio"/> 4

Submit Request

- 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 requests, but will do our best to accommodate.

NINDS
BIOSEND

NINDS Biosend CTR-MSA Kit Request System

Study Site * must provide value

NYU

Contact Name
Shipment Address
Email
Phone

Is the contact name above correct? Yes No * must provide value [reset](#)

Is the shipping address above correct? Yes No * must provide value [reset](#)

Is the e-mail address above correct? Yes No * must provide value [reset](#)

Is the phone number above correct? Yes No * must provide value [reset](#)

Kit Type **Please allow two weeks for shipment** * must provide value

Blood Collection Kit
 CSF Processing Kit
 Supplemental Kit
 Skin Biopsy Kit
 Extra Supplies

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

Comments

[Expand](#)

Submit

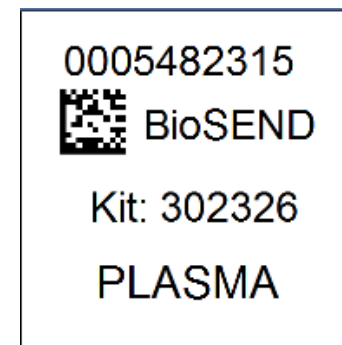
Sample Labelling

Labels are provided by Indiana University for BioSEND samples only

- Please check that all samples are properly labelled with correct specimen type



Kit Labels

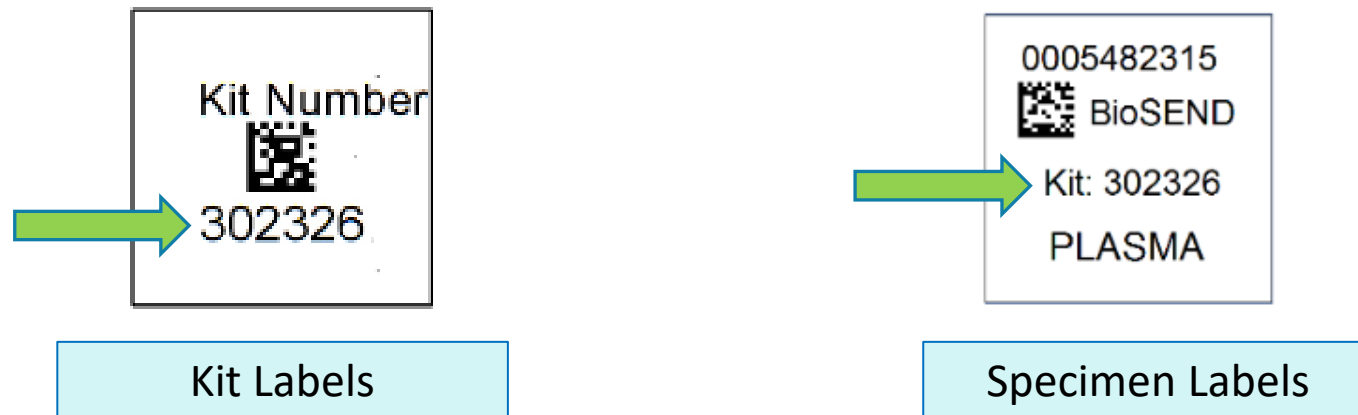


Specimen Labels

Sample Labelling – Kit Number

Kit Number

- Each Blood Collection Kit will have a unique “Kit Number” used to track participant samples and provide quality assurance
- Any kit number can be used for any subject or visit—which is why it is very important to document which kit number was used for which subject and visit



Sample Labelling – Kit Labels

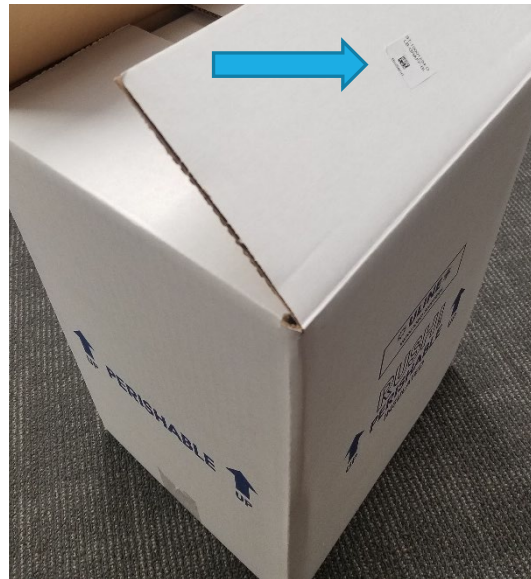
Kit Number



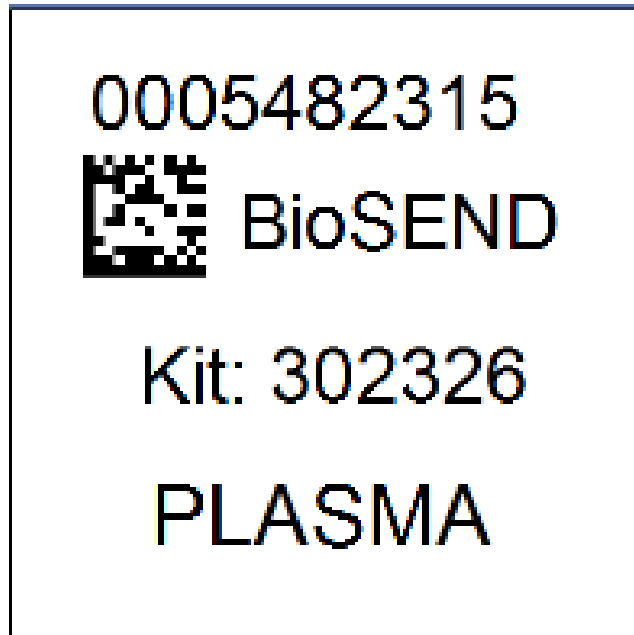
302326

Kit labels are placed:

- On the biohazard bags
- On the lid of frozen shippers



Sample Labelling – Specimen Labels



Unique Barcode



Biorepository Name



Kit Number

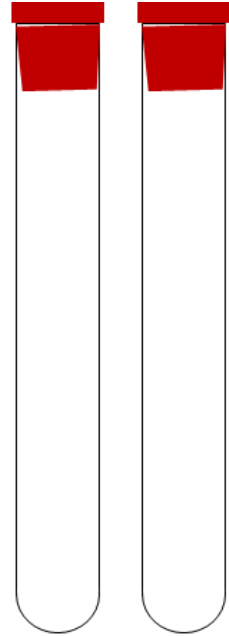


Sample Type

Sample Collection and Processing

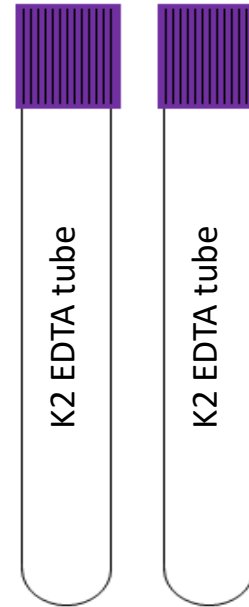
Blood Tube Draw Order

2 x 10ml Serum tubes



1

2 x 10ml EDTA tubes



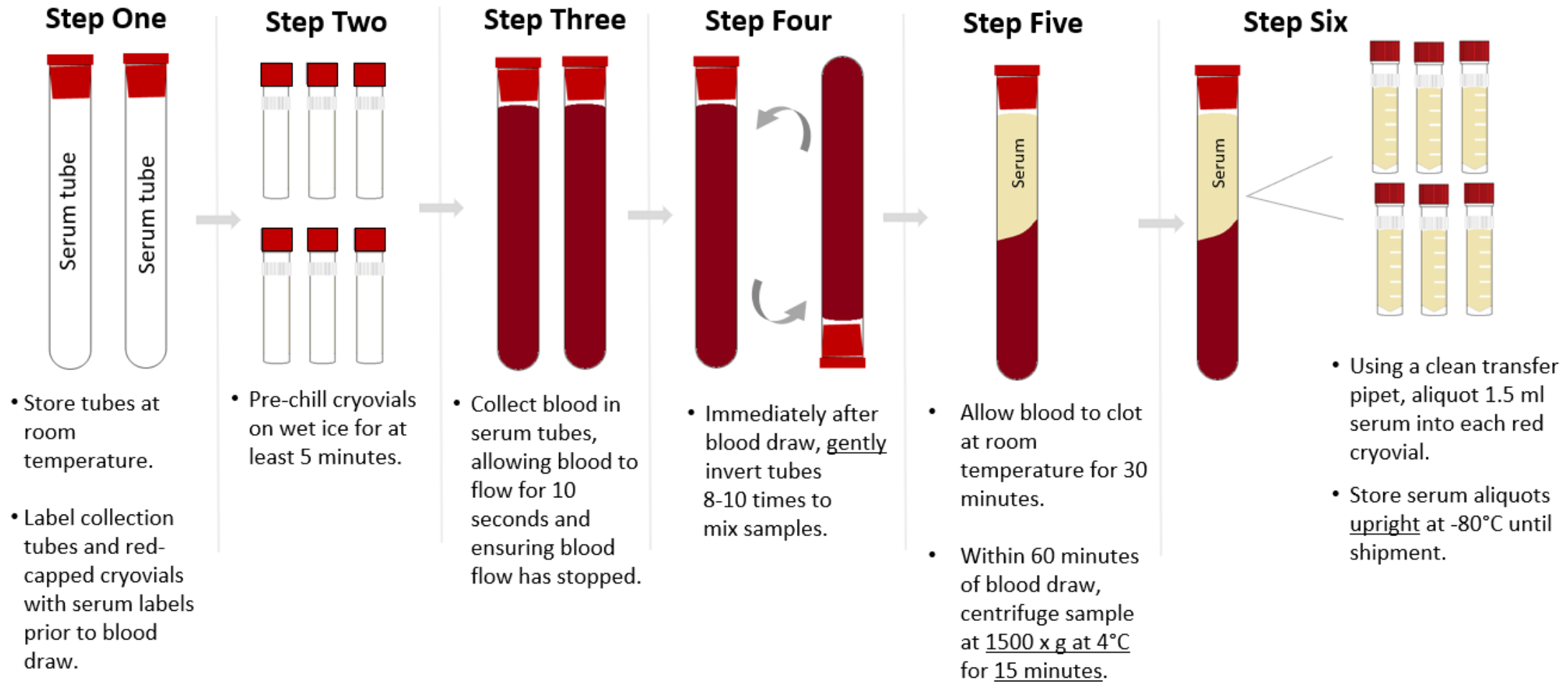
2

2 x 3ml EDTA tube

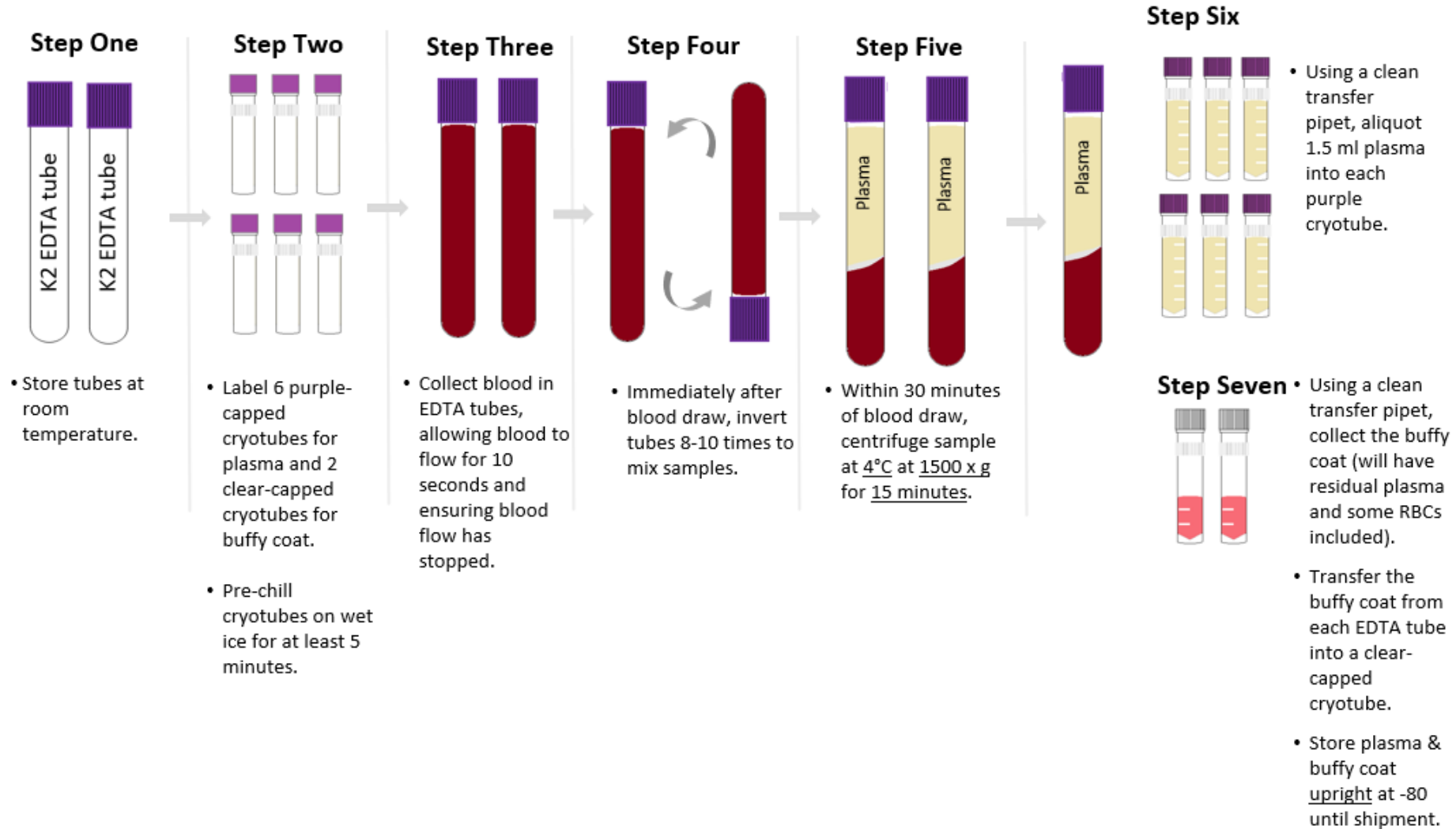


3

Sample Collection and Processing: Serum



Sample Collection and Processing: Plasma & Buffy Coat



Sample Collection and Processing: Whole Blood

Step One



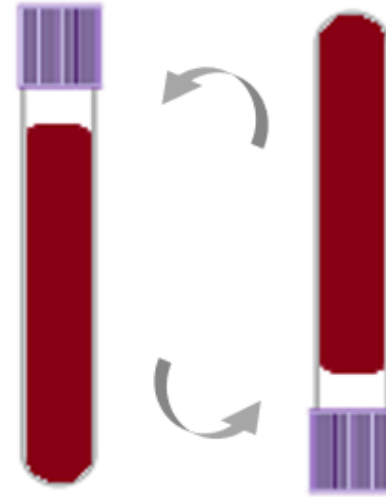
- Store tube at room temperature.
- Label tube with preprinted WBLD label prior to blood draw.

Step Two



- Collect blood into 3ml EDTA tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



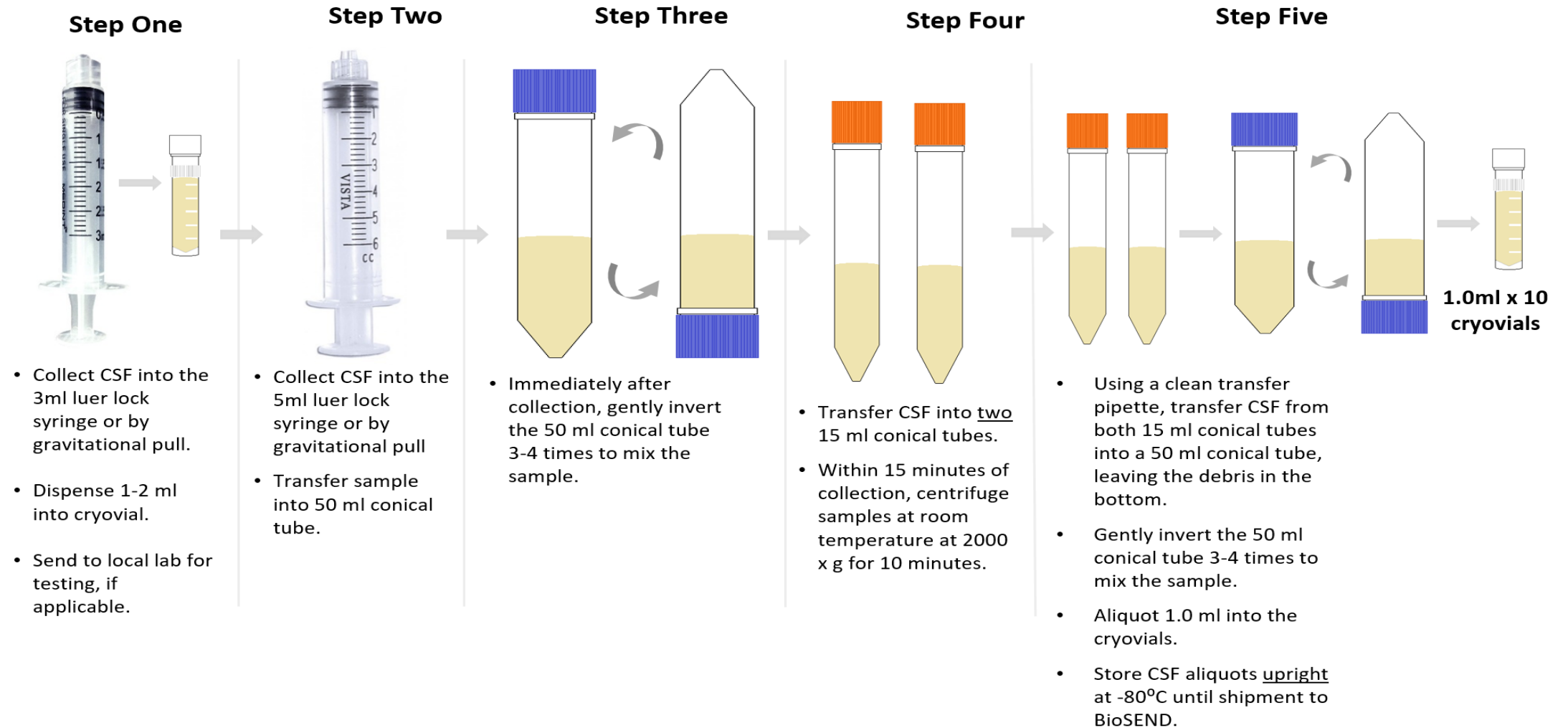
- Immediately after blood draw, invert tube 8-10 times to mix sample.

Step Four



- Transfer to -80°C . Store upright and keep frozen until shipment to BioSEND.

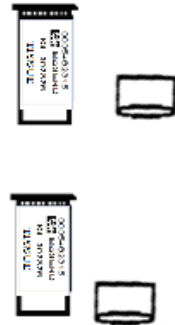
Sample Collection and Processing: CSF



Sample Collection and Processing: Skin Biopsy

COLLECTION SCHEMATIC: DOUBLE PUNCH BIOPSY COLLECTION AND PREPARATION

Step One



- Label 2ml cryovials with pre-printed "TISSUE" label.
- Remove lids from 2mL cryovials. Set aside in a sterile location.

Step Two



- Using standard punch biopsy procedures, collect two biopsy from the paravertebral C8 region approximately 3mm in diameter and 3mm deep.
- Record time of biopsy collection.

Step Three



- Place the biopsy into the 2mL cryovial.
- Close the 2mL cryovial securely.

Step Four



- As soon as possible after collection, store samples upright in the provided cryobox, at -80°C.
- Record time sample was placed in freezer on sample form.
- Ship samples to BioSEND per Appendix K

Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- Please ship samples as they are collected (within two weeks of collection)
- All samples ship frozen on dry ice
- Frozen samples should be shipped **Monday through Wednesday only**



Shipping Samples: Frozen

Packing and Shipping Frozen Samples

- Fill shippers with a minimum of 10lbs of dry ice
- Place cryobox and whole blood in separate biohazard bags
- Place layer of dry ice in between biohazard bags
- 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 correctly, or courier will reject/return your package!

Shipping Samples

Labeling frozen shippers

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. $\frac{\text{Number}}{\text{(Number pkgs)}} \times \frac{\text{wt}}{\text{(wt)}} \text{ Kg}$

Dry Ice kg.

9

UN 1845

Shipper's Name and Address

Consignee Name and Address

06426 1/01 RRD

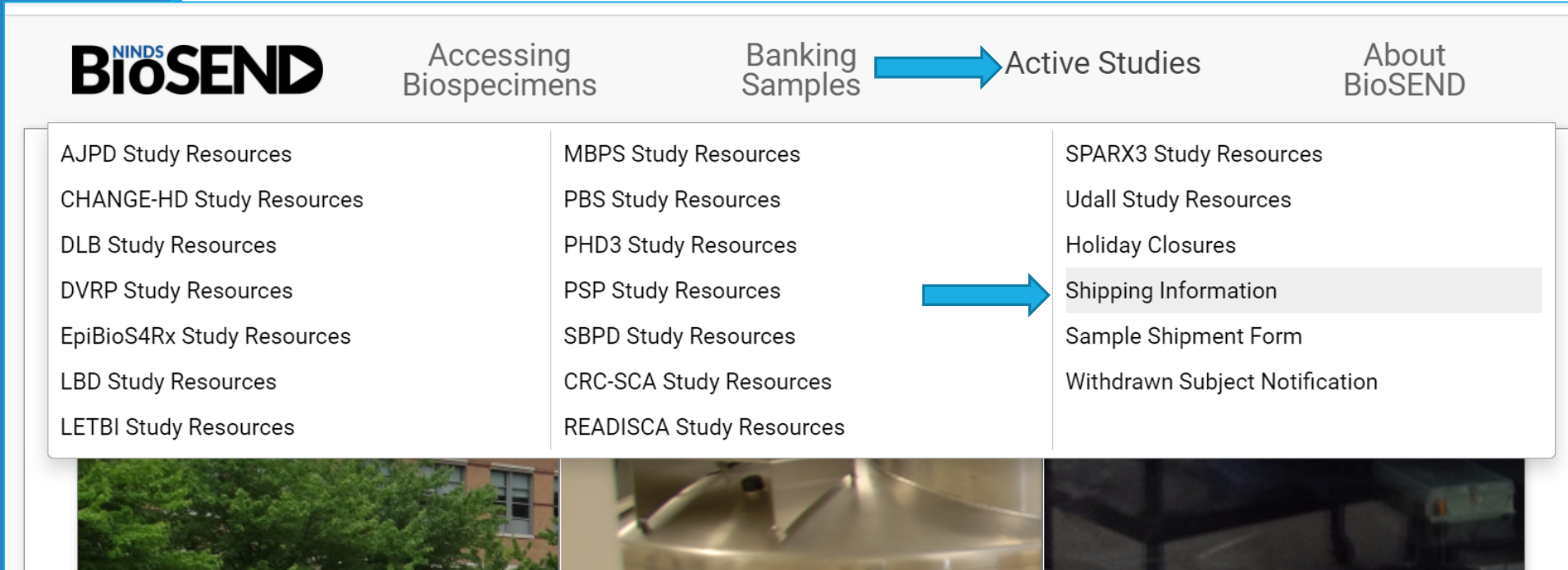
Net weight of dry ice in kg

Your name & address

IU information and address

Shipping Samples

UPS resources available on BioSEND website on the “Shipping Information” page



The screenshot shows the BioSEND website navigation menu. The logo is 'NINDS BioSEND'. The main navigation items are 'Accessing Biospecimens', 'Banking Samples', 'Active Studies', and 'About BioSEND'. A blue arrow points from 'Banking Samples' to 'Active Studies'. Below 'Active Studies' is a dropdown menu with the following items: 'SPARX3 Study Resources', 'Udall Study Resources', 'Holiday Closures', 'Shipping Information' (highlighted with a blue arrow), 'Sample Shipment Form', and 'Withdrawn Subject Notification'. Below the menu are three small images: a building with green trees, a close-up of a metal container, and a dark interior space.

NINDS BioSEND

Accessing Biospecimens Banking Samples → Active Studies About BioSEND

- AJPD Study Resources
- CHANGE-HD Study Resources
- DLB Study Resources
- DVRP Study Resources
- EpiBioS4Rx Study Resources
- LBD Study Resources
- LETBI Study Resources
- MBPS Study Resources
- PBS Study Resources
- PHD3 Study Resources
- PSP Study Resources
- SBPD Study Resources
- CRC-SCA Study Resources
- READISCA Study Resources
- SPARX3 Study Resources
- Udall Study Resources
- Holiday Closures
- Shipping Information**
- Sample Shipment Form
- Withdrawn Subject Notification

Shipping Information Page

Links on this page to:

1. Generate airwaybills & schedule pickups
2. View printed guide on how to use ShipExec™
3. Request user account and update site address in system
4. View video tutorial for using UPS ShipExec™

UPS Shipping Resources

1

To generate air waybills and schedule UPS pickups for shipments to BioSEND, please visit the UPS ShipExec™ Thin Client [website](#).

2

For instructions on how to use the UPS ShipExec™ Thin Client website, please refer to the [BioSEND UPS ShipExec™ Thin Client Guide](#)

3

To request a new user account for UPS ShipExec™ Thin Client or to request an update to your site's address in the system, please [use this form](#) to submit your request.

Navigating UPS ShipExec™

4

The screenshot shows the UPS ShipExec™ Thin Client Home Page. At the top, there is a navigation bar with the ShipExec™ logo and links for Home, My Account, and My Site. Below the navigation bar, the page title reads "Welcome to the ShipExec™ Thin Client Home Page". The main content area is divided into two columns: "System Notifications" and "Company Notifications". Under "System Notifications", there are two links: "ShipExec Documentation" and "Importing Your Personal Address Book". Under "Company Notifications", there is a message: "No Company Notifications to display". A large video player overlay is centered on the page, showing a play button and a progress bar at the bottom. The video player controls include a play button, a volume icon, a progress bar showing 0:58 / 9:18, a CC icon, a 1x magnification icon, a settings gear icon, and a close icon.

Shipping Samples – UPS ShipExec™

If you will be assisting in shipping samples, please request a user account and familiarize yourself with the system well in advance of your first sample shipment

Shipping Samples: Frozen

Please notify BioSEND ahead of shipment

- Please complete the Sample Collection and Processing Form in REDCap ahead of shipment (can be completed day of shipment).
 - A completed copy of this form should be included in the sample shipper
- If you are having trouble with REDCap, please notify BioSEND directly of shipment at biosend@iu.edu

Sample Collection and Processing Form

First page captures basic subject and visit information

Please complete the Specimen Collection and Processing Form, below.

Study

CTR-MSA ▾

Study Site

New York University ▾

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

Next Page >>

Save & Return Later

Sample Collection and Processing Form

Second page captures processing
information

Blood Collection and Processing	
Date of venipuncture blood collection	<input type="text"/>  Today M-D-Y
Time of venipuncture blood collection	<input type="text"/>  Now H:M Use 24 Hour clock
1. SERUM (red-top tubes, 10 mL)	
Was blood collected and processed for SERUM?	<input checked="" type="button" value="Yes"/> <input type="button" value="No"/> reset
Time of SERUM tube centrifugation	<input type="text"/>  Now H:M Use 24 Hour clock
Duration of SERUM tube centrifugation	<input type="text" value="15"/> minutes
Rate of SERUM tube centrifugation	<input type="text" value="1500"/> x g
Temperature of SERUM tube centrifugation	<input type="text" value="4"/> degrees Celsius
Total volume of SERUM collected	<input type="text"/> mL
Number of SERUM aliquots created for BioSEND	<input type="text"/> Each aliquot should be 1.5 mL
Time SERUM aliquots were placed in freezer	<input type="text"/>  Now H:M Use 24 Hour clock

Sample Collection and Processing Form

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

CTR-MSA Frozen Shipping Manifest

Page 5

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 CAPCOG-TBI

Study Site: Mind Research Network

GUID: _____

Visit: BL
 3M
 6M
 12M

IU Kit Number: _____

Date of blood collection: _____

Date of CSF collection: _____

SERUM

Number of SERUM aliquots shipped: _____

PLASMA EDTA

Number of PLASMA EDTA aliquots shipped: _____

Number of BUFFY COAT aliquots shipped: _____

WHOLE BLOOD EDTA

Number of WHOLE BLOOD tubes shipped: _____

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

Non-Conformance

Most common non-conformance issues:

- Samples shipped for weekend/holiday delivery
- Sample form incomplete/inaccurate
- Unlabeled or mislabeled tube(s)
- Sample hemolysis



Non-Conformance

- BioSEND will notify sites directly of any issues upon receipt
- Non-conformance is reported on a weekly basis to NINDS Continued non-conformance may result in required re-training and notification to site PI
- ***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

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Biorepository Clinical Research Coordinator:

Carolyn Dunifon

cdunifon@iu.edu

Tel: 317.274.5751