

BioSEND

Biospecimen Exchange for Neurological Disorders

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

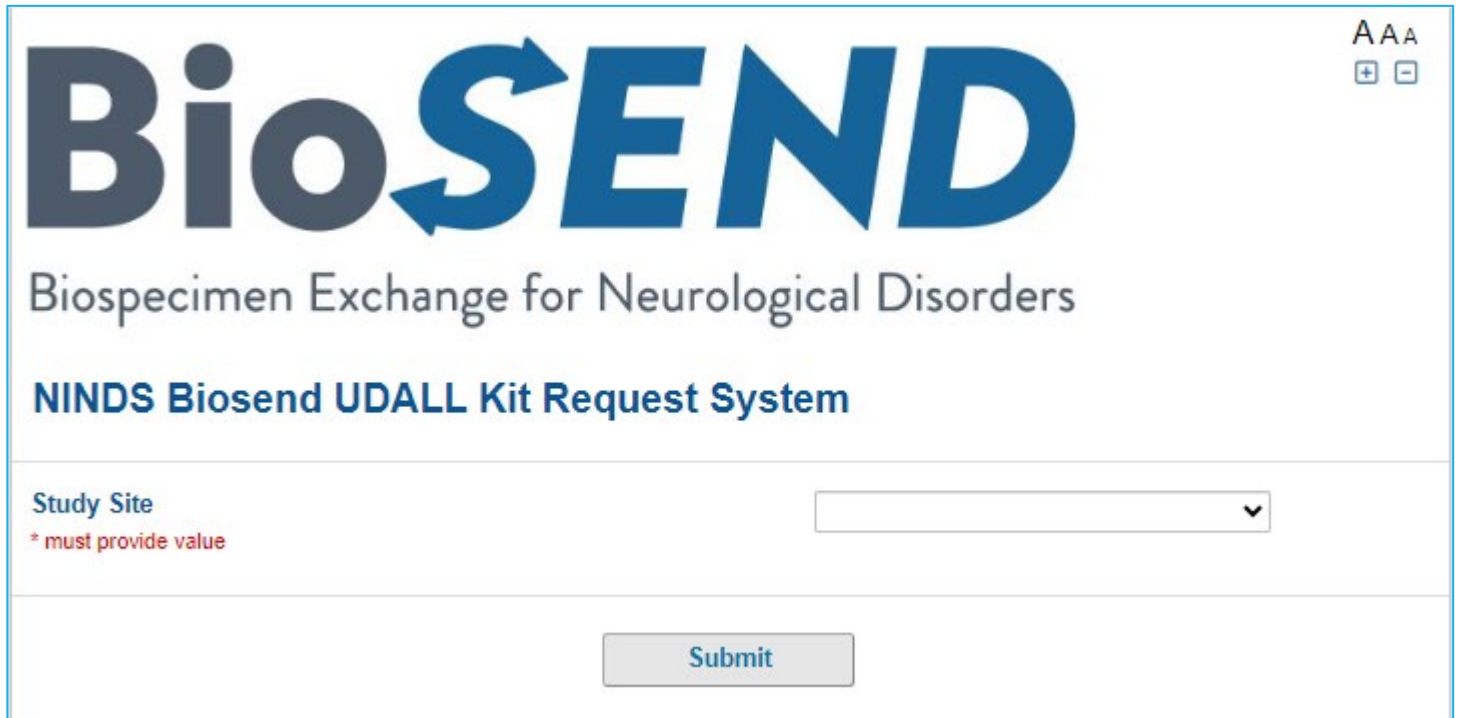
Kit Contents and Ordering – REDCap Survey

<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.



The screenshot displays the Biosend website interface. At the top, the logo "BioSEND" is prominently featured in blue, with the "S" containing a circular arrow. Below the logo, the text "Biospecimen Exchange for Neurological Disorders" is displayed. Underneath, the title "NINDS Biosend UDALL Kit Request System" is shown in a smaller blue font. In the top right corner, there are accessibility icons for font size (AAA) and zoom in/out (+/-). The main form area contains a "Study Site" label, a red asterisk indicating a required field, and a dropdown menu. A "Submit" button is located at the bottom center of the form.

Kit Contents and Ordering: Confirm Site Info

UDALL 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

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 Type
Please allow two weeks for shipment
* must provide value

Blood Collection Kit

CSF Visit 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

UDALL Kit Request Module

<p>Comments</p>	<input type="text"/>
<hr/>	
<p>Each Baseline Collection Kit</p> <p>Blood Collection Kit Contents:</p> <ul style="list-style-type: none">2 - Lavender-top EDTA tube (10 ml), glass10 - Siliconized cryovial (2ml) <p>1 - Cryobox, 25-slot</p> <p>1 - Shipping label packet (Dry Ice, Fragile, UN3373)</p> <p>1 - Airway bill envelope</p> <p>1 - Shipping container for dry ice shipments</p> <p>1 - Biohazard bag with absorbent sheet</p> <p>2 - Individual tube bubble pouch</p> <p>30 - Cryohold specimen/case labels--ST labels</p>	<p>Expand</p> <p>Kit contents of selected kit will appear at the bottom of the page</p>

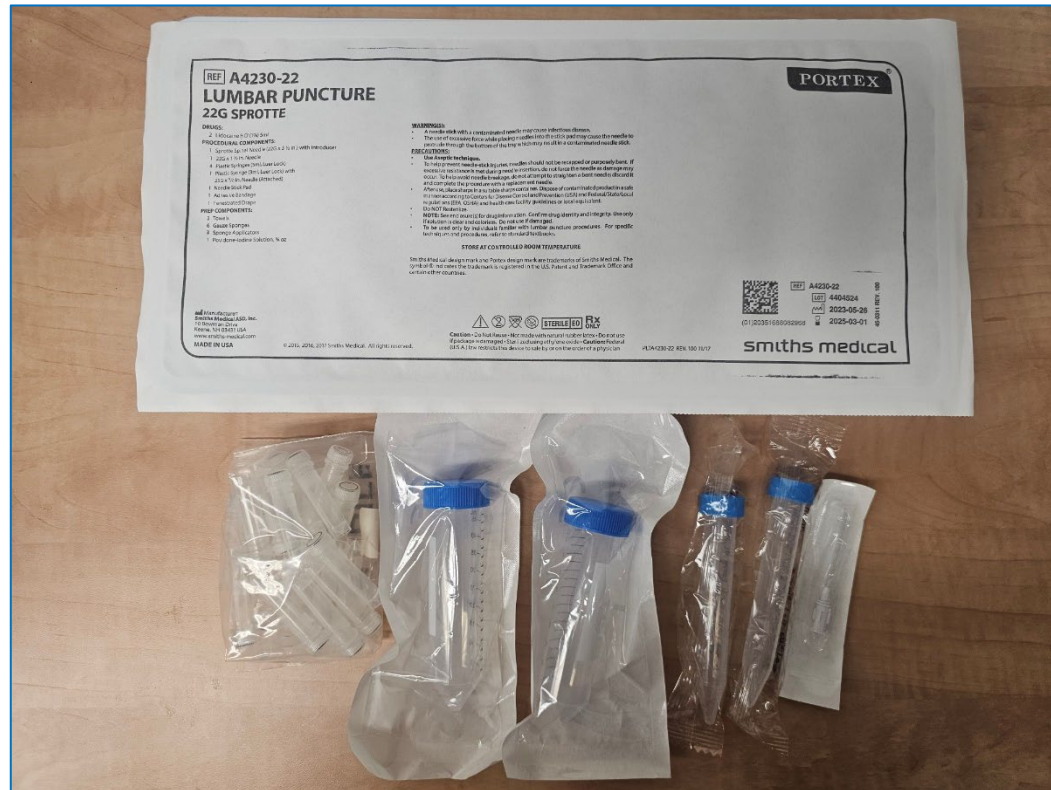
Kit Contents and Ordering: Blood Kit



Kit Contents and Ordering: CSF Kits

CSF:

LP Tray:



Collection Volumes

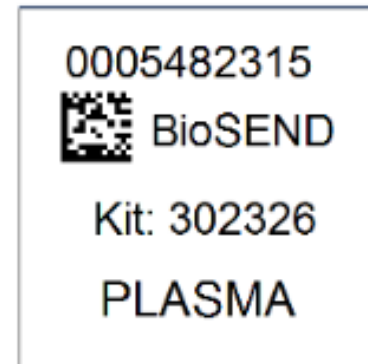
Total blood and CSF volumes

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

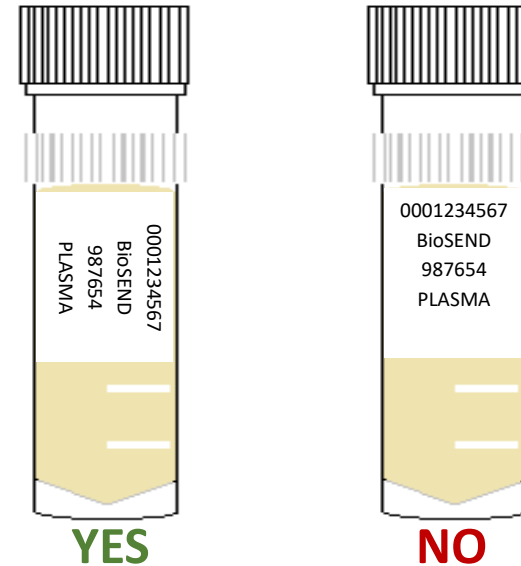
- Please check that all samples are properly labelled to ensure correct identification by IU
- If do not have enough labels to complete a visit, please contact IU *immediately*
- Labelling the tubes during processing prevents sample mix-ups



Sample Labelling: Label Placement

Please...

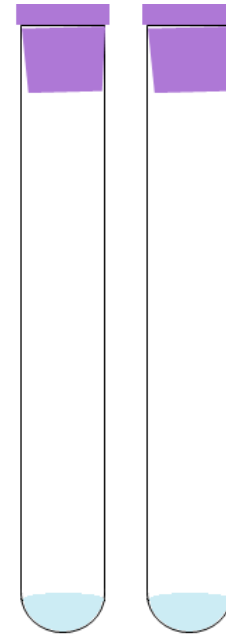
- Label all collection and aliquot tubes before cooling, collecting, processing, or freezing samples
- Label only 1 subject's tubes at a time to avoid mix-ups
- Wrap the label around the tube horizontally - label position is important for all tube types
- Make sure the label is completely adhered by rolling between your fingers



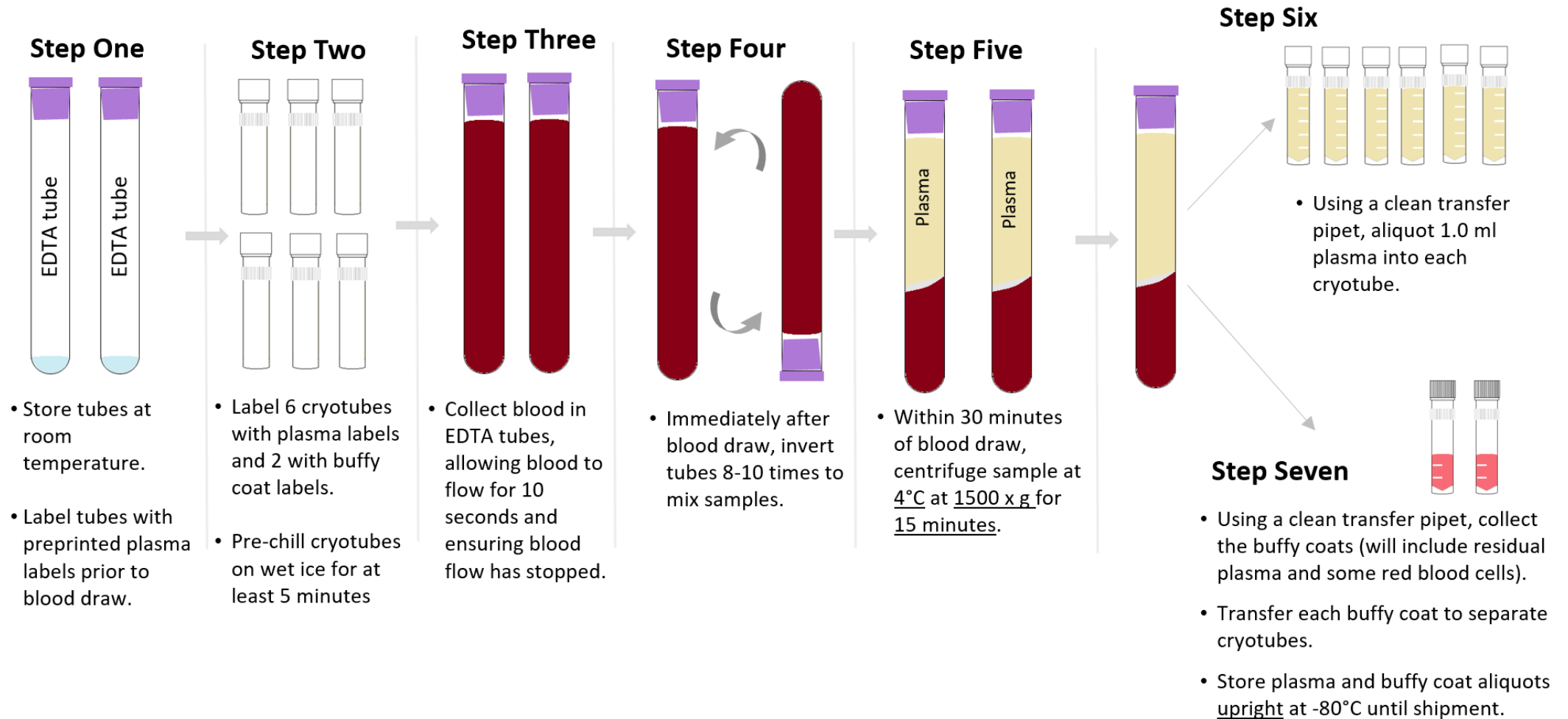
Sample Collection and Processing

EDTA for plasma and buffy coat

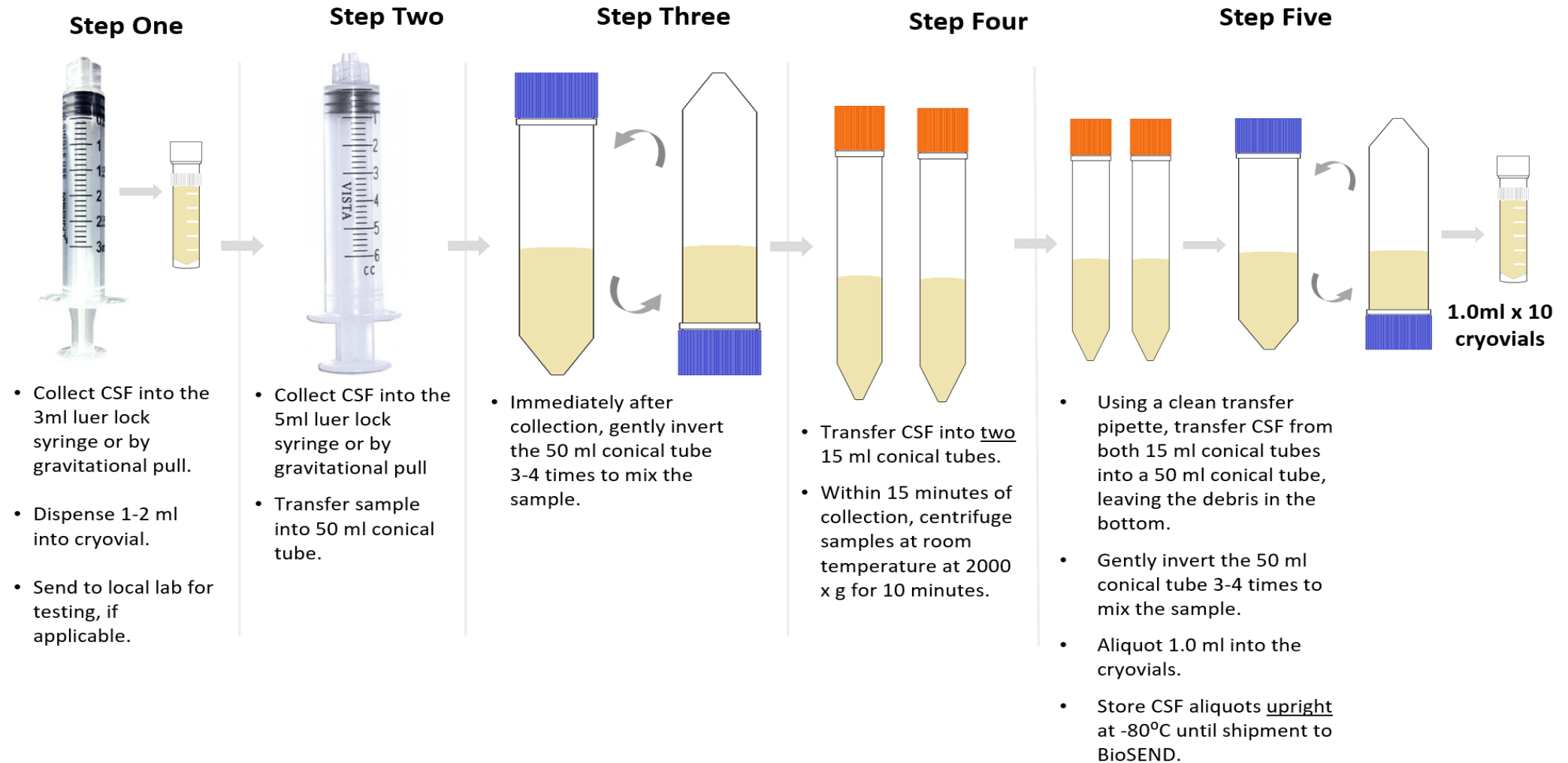
10ml EDTA



Sample Collection and Processing: Plasma & Buffy Coat



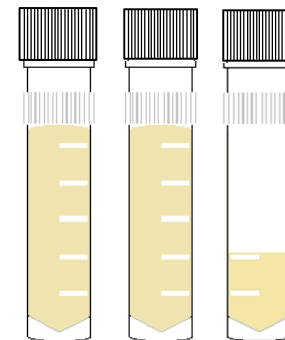
Sample Collection and Processing: CSF



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



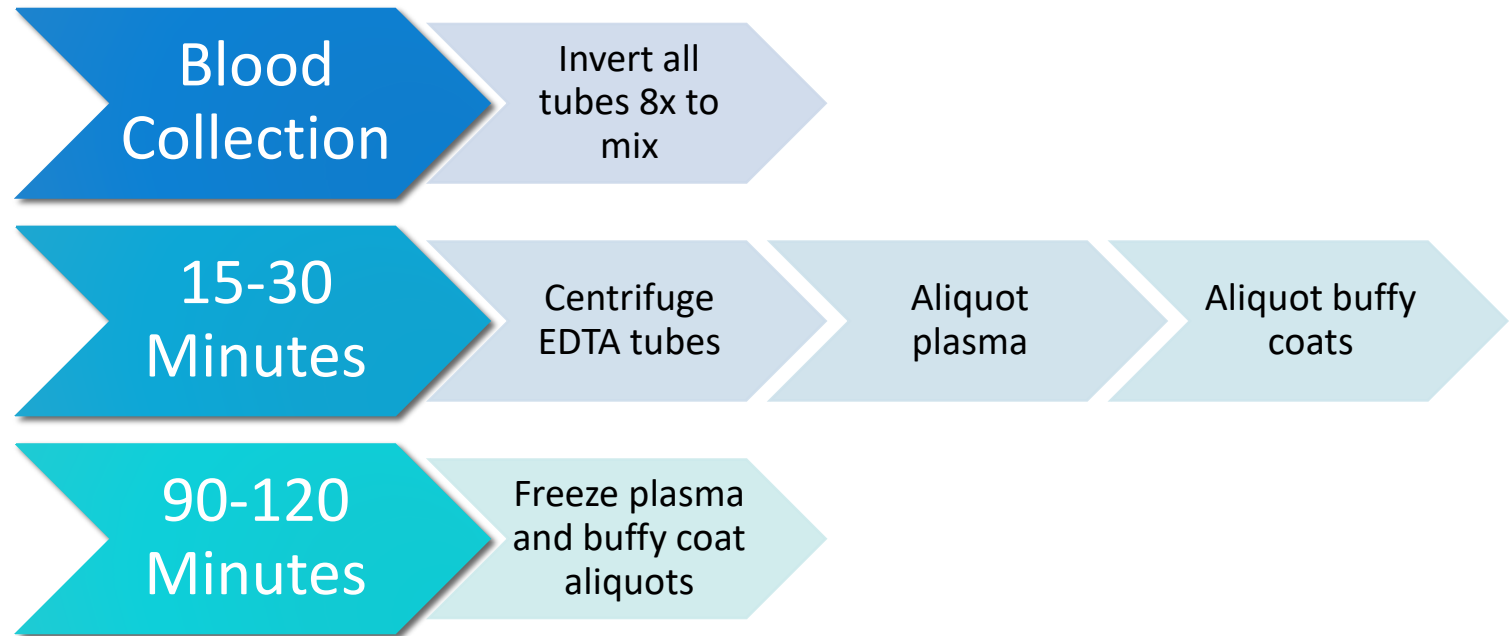
YES



NO

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

BioSEND

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/UDALLUABSsampleForm>

First part captures basic subject and visit information

Sample Collection and Processing Form

Direct link:

<https://redcap.link/UDALLUABSsampleForm>

Second part captures collection information

Date of venipuncture blood collection  Today M-D-Y

Time of venipuncture blood collection  Now H:M
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?

reset

Date of CSF collection  Today M-D-Y

Time of CSF collection  Now H:M
Use 24 Hour clock

Number of CSF aliquots shipped:

NOTES

Please record any issues with collection/processing:

Expand

Sample Collection and Processing Form

Direct link:

<https://redcap.link/UDALLUABSsampleForm>

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: 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. Please check for holiday closures prior to shipping. Contact us at biosend@iu.edu if you are unsure whether or not 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



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 / airbills must have the following:
1. Dry Ice; 9; UN 1845
2. $\frac{\text{Number}}{\text{(Number pkgs)}} \times \frac{\text{wt}}{\text{(wt)}} \text{ Kg}$

Net weight of dry ice in kg

Dry Ice kg.

Your name & address

Shipper's Name and Address

UN 1845

Consignee Name and Address

IU information and address

9

06426 1/01 RRD

The image shows a Class 9 Dry Ice Label template. It features a central diamond shape with a dashed border and a solid border. Inside the diamond, there are several vertical bars of varying heights. The label includes instructions for completion, such as 'Shipper's Declaration not Required' and 'Dry Ice amount must be in kilograms'. It also provides a formula for calculating the weight of dry ice in kilograms based on the number of packages and the weight of each package. The label is divided into sections for 'Shipper's Name and Address' and 'Consignee Name and Address'. Red arrows point to specific fields with labels: 'Net weight of dry ice in kg' points to the 'kg.' field; 'Your name & address' points to the 'Shipper's Name and Address' field; and 'IU information and address' points to the 'Consignee Name and Address' field. The number '9' is printed in the center of the diamond, and 'UN 1845' is printed on the right side. The code '06426 1/01 RRD' is printed at the bottom left.

Shipping Samples: Frozen

Packing and Shipping Frozen Samples



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

The screenshot shows the shipping interface for Indiana University School of Medicine. The header includes 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



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



Contacts

Indiana University

General Questions/Shipment Notifications:

biosend@iu.edu

317-278-6158

Request kits:

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