



A Phase 2 Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of BHV-4157 in Patients with Mild to Moderate Alzheimer's Disease

(T2 PROTECT AD)

&

The National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD)

Biofluids Collection Training Slides

Training Overview

- GUIDs
- Specimen Collection Schedule
- Kit Request Module
- Specimen Labels
- Handling/Processing Study Specimens
- Sample Shipping
- NCRAD Website
- Questions

Contact Information

- Questions?

Please contact NCRAD Coordinators at:

- Phone: 317-278-1228 or 1-800-526-2839
- E-mail: mipetkov@iu.edu or alzstudy@iu.edu
- Website: www.ncrad.org



Globally Unique Identifier (GUID)

- The GUID is a subject ID that allows researchers to share data specific to a study participant, without exposing personally identifiable information
- A GUID is made up of random alpha-numeric characters and does not include any PHI in the identifier

Globally Unique Identifier (GUID)

1. Create an account: <https://bricsguid.nia.nih.gov/portal/jsp/login.jsp>
2. Once you have an account, go to the GUID Tool – Create GUID
3. To open the ‘Launch GUID Tool’ you will need to have Java installed on your device
4. When the GUID Tool is open, you will need all of the following information
 - Complete legal given (first)name of participant at **birth**
 - The participant’s middle name, if applicable
 - Complete legal family (last) name of subject at **birth**
 - Day of birth
 - Month of birth
 - Year of birth
 - Name of city/municipality in which subject was born
 - Country of birth

Specimen Collection Schedule

Visit	Collection Container	Specimen Type	Container Received
Screening	15 ml Sterile Conical tube(s)	CSF	2.0 ml Cryovials
Baseline	6 ml Serum (Red-Top) Blood Collection Tube	Serum	2.0 ml Cryovials
	6 ml EDTA (Lavender-Top) Blood Collection Tube	Plasma-PK	2.0 ml Cryovials
	10 ml EDTA (Lavender-Top) Blood Collection Tube	Plasma	2.0 ml Cryovials
		Buffy Coat	2.0 ml Cryovials
Weeks 4, 8, & 12	6 ml EDTA (Lavender-Top) Blood Collection Tube	Plasma-PK	2.0 ml Cryovials
Week 24	6 ml Serum (Red-Top) Blood Collection Tube	Serum	2.0 ml Cryovials
	6 ml EDTA (Lavender-Top) Blood Collection Tube	Plasma-PK	2.0 ml Cryovials
	Sterile Containers	CSF	2.0ml Cryovials

Specimen Collection Schedule, cont'd

Visit	Collection Container	Specimen Type	Container Received
Week 48	6 ml Serum (Red-Top) Blood Collection Tube	Serum	2.0 ml Cryovials
	6 ml EDTA (Lavender-Top)Blood Collection Tube	Plasma-PK	2.0 ml Cryovials
	10 ml EDTA (Lavender-Top) Blood Collection Tube	Plasma	2.0 ml Cryovials
		Buffy Coat	2.0 ml Cryovials
	15 ml Sterile Conical Tubes	CSF	2.0 ml Cryovials

Kit Request Module

<http://kits.iu.edu/t2>



Kit Request Module

- An initial stock of kits will be delivered prior to the designated site specific start date.
- Kits and individual supplies available to order:
 - Blood Collection Kits:
 - Baseline, Week 4, Week 8, Week 12, Week 24, Week 48
 - CSF Kit
 - LP 22 Gauge Kit
 - LP 24 Gauge Kit
 - Blood Supplemental Kit
 - CSF Supplemental Kit
 - Frozen Shipping Kit
 - Individual Supplies

Kit Request Module

1. Choose your site from the drop down list.
2. The coordinator name and contact information will populate.
3. Verify that this information is correct.

Study Site <small>* must provide value</small>	<div><div>H</div><div>2 - Oregon Health and Science University ▼</div></div>
Oregon Health and Science University Kate Mincks 3181 SW Sam Jackson Park Road, CR-131 Portland, OR 97239 503-494-6601 mincks@ohsu.edu	
Is the contact name above correct? <small>* must provide value</small>	<div><div>H</div><div><input type="radio"/> Yes <input type="radio"/> No</div></div>
Is the shipping address above correct? <small>* must provide value</small>	<div><div>H</div><div><input type="radio"/> Yes <input type="radio"/> No</div></div>
Is the e-mail address above correct? <small>* must provide value</small>	<div><div>H</div><div><input type="radio"/> Yes <input type="radio"/> No</div></div>

Kit Request Module: Kit Selection

- Indicate the quantity needed of each kit.
- Once selected, kit components of the chosen kit will appear at the bottom of the screen (Pictured)
- **Note: You can order more than one type of kit in a single kit request**

Total Number of Baseline Blood Collection Kits Requested	<input type="text"/>
Total Number of Week 4 Blood Collection Kits Requested	<input type="text"/>
Total Number of Week 8 Blood Collection Kits Requested	<input type="text"/>
Total Number of Week 12 Blood Collection Kits Requested	<input type="text"/>
Total Number of Week 24 Blood Collection Kits Requested	<input type="text"/>
Total Number of Week 48 Blood Collection Kits Requested	<input type="text"/>
Total Number of 22 Gauge LP Kits Requested	<input type="text"/>
Total Number of 24 Gauge LP Kits Requested	<input type="text"/>
Total Number of CSF Kits Requested	<input type="text" value="3"/>
Total Number of Blood Supplemental Kits Requested	<input type="text"/>
Total Number of Supplemental CSF Kits Requested	<input type="text"/>
Total Number of Frozen Shipping Kits Requested	<input type="text" value="1"/>
Do you require any individual supplies?	<input type="radio"/> Yes <input type="radio"/> No
reset	
Each CSF Kit Contains:	
2: 15-ml conical polypropylene tube-individually wrapped 30: Cryovial tube (2.0 ml) with orange cap 1: Cryovial tube (2.0 ml) with blue cap 1: Cryovial tube (2.0 ml) with yellow cap	
Each Frozen Shipping Kit Includes:	
5: Plastic Biohazard bag with absorbent sheet (small) 1: FedEx return airbill and pouch 1: Shipping box/Styrofoam container 1: Warning label packet with dry ice sticker	

Kit Request Module: Kit Selection

- For individual supplies, select the ones needed and specify quantities below.
- Click “Submit” to turn in your request.
- The IU staff will notify you that your request has been received and address any issues.

Do you require any individual supplies? ☒ Yes ☐ No [reset](#)

Individual Supplies

- ☒ Cryobox (25-slot)
- ☒ Cryovial tube (2.0 ml) with lavender cap
- ☐ Cryovial tube (2.0 ml) with red cap
- ☐ Cryovial tube (2.0 ml) with orange cap
- ☐ Cryovial tube (2.0 ml) with yellow cap
- ☐ Cryovial tube (2.0 ml) with blue cap
- ☐ Cryovial tube (2.0 ml) with clear cap
- ☐ 15-ml conical polypropylene tube
- ☐ FedEx return airbill
- ☐ Shipping container for dry ice shipment
- ☐ Plastic biohazard bag with absorbent sheet
- ☐ Disposable graduated transfer pipette
- ☐ Serum (Red-Top) Blood Collection Tube (6 ml)
- ☐ EDTA (Lavender-Top) Blood Collection Tube (6 ml)
- ☐ EDTA (Lavender-Top) Blood Collection Tube (10 ml)
- ☐ Warning label packet
- ☐ UN3373 label
- ☐ Biohazard label
- ☐ Dry ice shipping label
- ☐ Fine Point Sharpies
- ☐ Site and Individual ID Labels

Please enter individual supplies and quantities requested

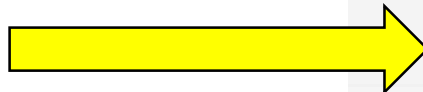
Cryobox (25-slot): 2
Cryovial tube (2.0 ml) with lavender cap: 15

[Expand](#)

Comments

[Expand](#)

[Submit](#)



Kit Request Module

- Each site is responsible for ordering kits and maintaining supplies on site for their scheduled participants.
- To order kits, sites will use the Indiana University online kit ordering module: <http://www.kits.iu.edu/t2>
- Allow around **2 weeks** for your order to be processed and delivered.

Specimen Labels



Specimen Labels

- Label type summary:
 - Kit Number Labels
 - Site and ADCS ID Labels
 - Collection and Aliquot Tube Labels
 - Differ by specimen type
- All labels are provided in the kits

Specimen Labels: Kit Number Labels

- Used to track patient samples and provide quality assurance
- Will be placed on:
 - Biological Sample and Shipment Notification Form
 - CSF Sample and Shipment Notification Form
 - CSF samples will have a different kit number than blood samples
 - Outside of cryobox(es) that houses aliquot tubes during storage and shipment



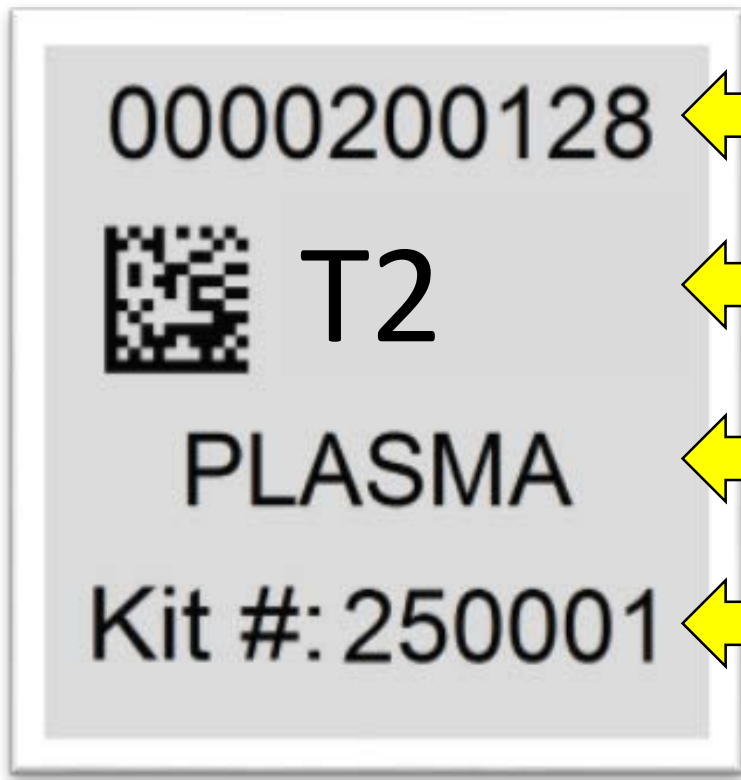
Specimen Labels: Site and ADCS ID Labels

- Subjects will be identified by their site ID and ADCS ID
- Sites will be responsible for handwriting the IDs on the provided labels
 - Fill in labels prior to adhering to tubes
 - Must use fine-point marker
 - Each site will receive a 4-pack of markers in initial kit supply
- Labels will be placed on all collection tubes:
 - Serum Red Top Tube (6 ml)
 - EDTA Lavender Top Tube (6 ml)
 - EDTA Lavender Top Tube (10 ml)

Site: _____

ADCS ID:

Specimen Labels: Collection & Aliquot Tube Labels



0000200128

← Specimen Number (Assigned by NCRAD)



T2

← Study Name

PLASMA

← Sample Type (Plasma, Buffy Coat, Serum, Plasma-PK or CSF)

Kit #: 250001

← Kit # (Assigned by NCRAD and unique to the subject and visit)

Specimen Labels: Blood Collection Tubes

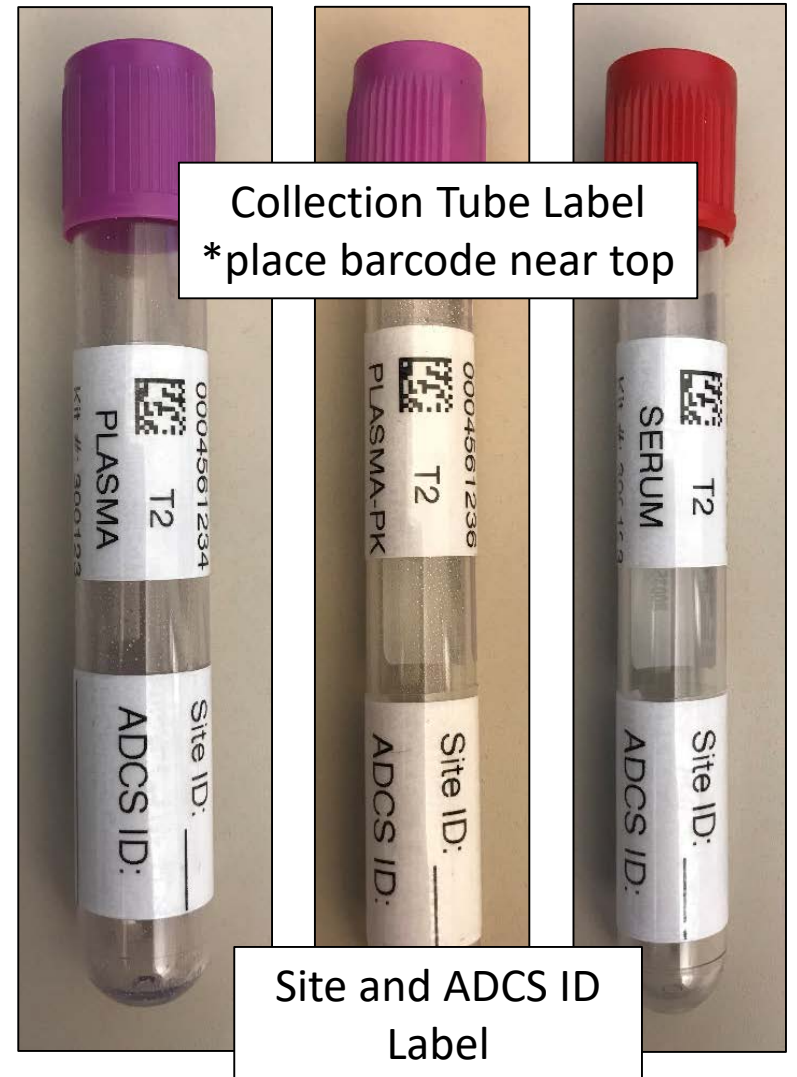
- All collection tubes will have two labels:
 - Aliquot and Collection Tube Label
 - Site and ADCS ID Label

Label 1:

0004561236 [Barcode] T2 PLASMA Kit #: 250001	0004561473 [Barcode] T2 PLASMA-PK Kit #: 250001	0004561912 [Barcode] T2 SERUM Kit #: 250001
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Label 2:

Site: _____
ADCS ID: _____



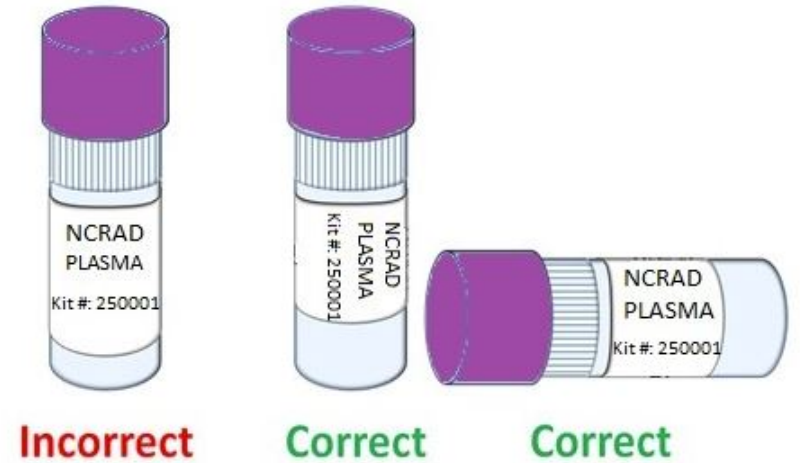
Specimen Labels: Aliquot Tube Labels (Plasma, Buffy Coat, Serum, Plasma-PK, and CSF)



- Use only the Collection and Aliquot Tube label
- Place barcode near the cap

Specimen Labels: Labeling Biologic Samples

- 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.



Handling/Processing Study Specimens



Site Required Equipment


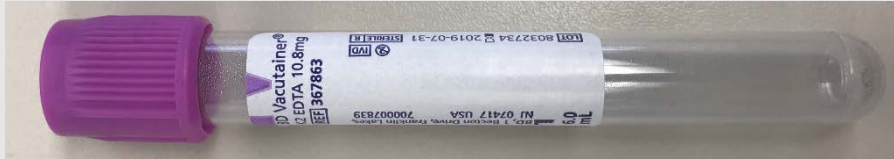

- Blood Collection/Safety Equipment:

1. Personal Protective Equipment (PPE)
 - Lab Coat, Safety Glasses
2. Tourniquet
3. Alcohol Prep Pad
4. Gauze Pad
5. Butterfly Needles
6. Bandage
7. Sharps Bin and Lid

- Processing/Storage Equipment:

1. Centrifuge capable of ≥ 2000 rcf with refrigeration to 4°C
2. -80°C Freezer
3. Wet Ice Bucket

Blood Collection & Processing: Sample Collection Tube

Tube Type	Number of Tubes Drawn (per visit)	Tube Image
Serum (Red-Top) Tube (6 ml)	1	
EDTA (Lavender-Top) Tube (6 ml)	1	
EDTA (Lavender-Top) Tube (10 ml)	1	

Blood Collection & Processing: Draw Order

*****Important Note*****

In order to ensure the highest quality samples are collected, processed, and stored, it is essential to follow the specific collection, processing, and shipment procedures detailed in the following pages. Please read the following instructions first before collecting any specimens. Have all your supplies and equipment out and prepared prior to drawing blood.

Please note that the centrifuge may take 30 minutes to cool, so please plan accordingly.

Draw blood in the following order:

1. Plain Red Top Serum Blood Collection Tube (6 ml)
2. EDTA (Lavender-Top) Blood Collection Tube (6 ml) for PK Analysis
3. EDTA (Lavender-Top) Blood Collection Tube (10 ml) for Buffy Coat and Plasma

Blood Collection & Processing: Aliquot Cryovials & Cap Colors

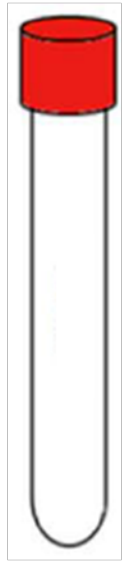
Cap Color	Sample Type
Lavender Cap	Plasma
Red Cap	Serum
Orange Cap	CSF
Yellow Cap	CSF to Local Lab
Blue Cap	Residual
Clear Cap	Buffy Coat



Serum Preparation (6ml Red Top Tube)

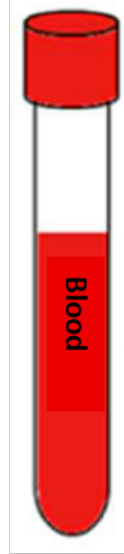


Step One



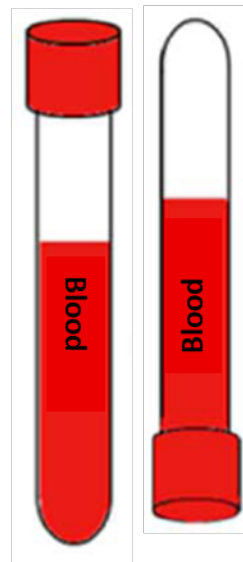
- Store tubes at room temperature.
- Label tubes with pre-printed subject labels prior to blood draw.

Step Two



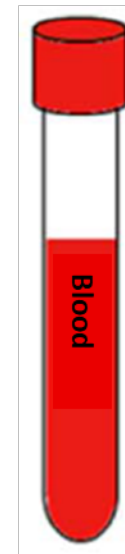
- Collect blood in Serum Tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



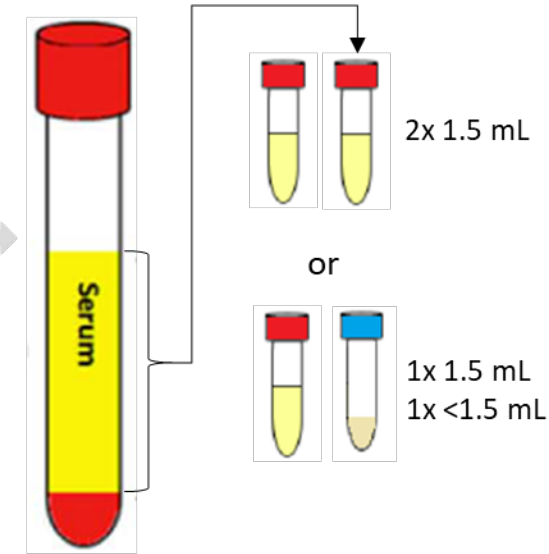
- Immediately after blood draw, invert tubes 5 times to mix samples.

Step Four



- Allow blood to clot for 30 minutes.
- Within 60 minutes of blood draw, centrifuge samples at 2000 x g for 10 minutes at 4°C

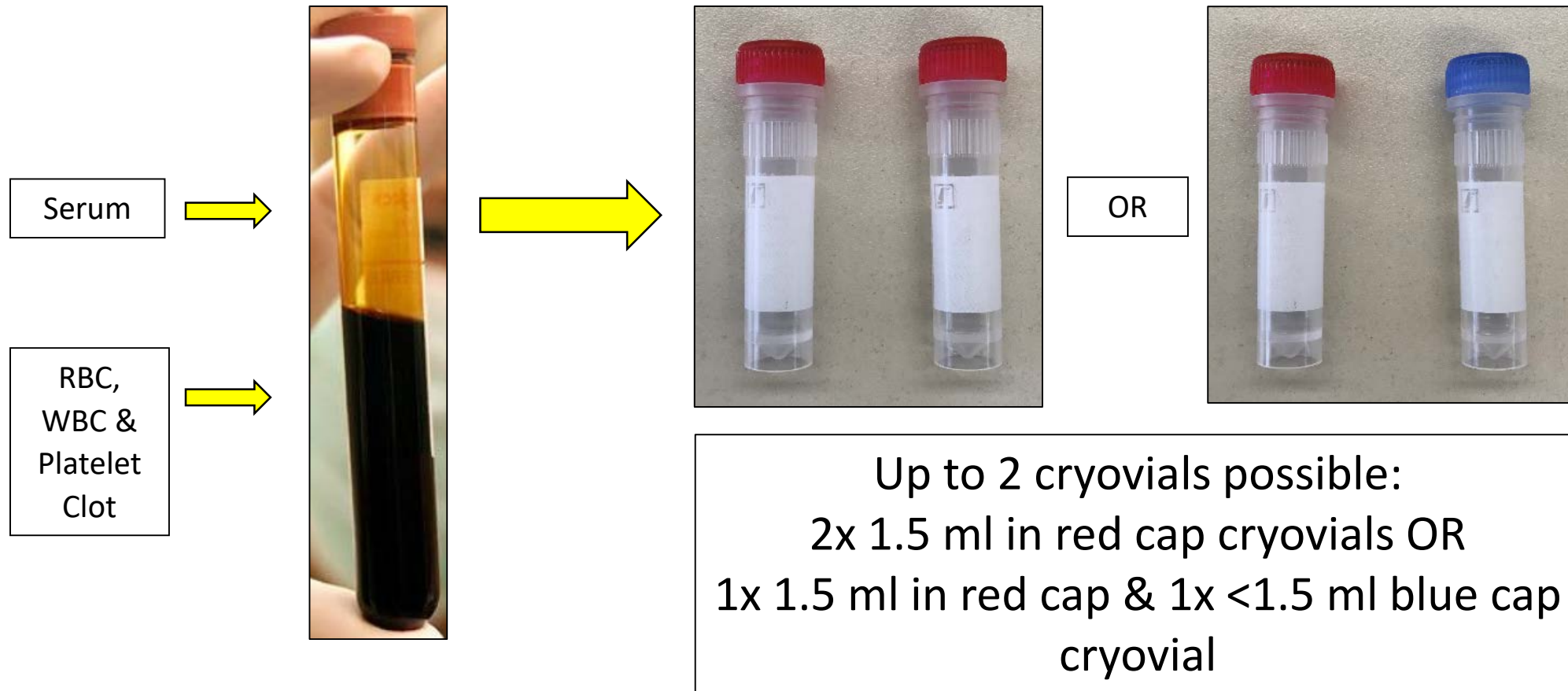
Step Five



- Label cryovial tubes with preprinted labels.
- Aliquot 1.5 ml into each red-cap cryovial tube.
- If any residual remains, aliquot into a blue-cap cryovial and note the residual on the Biological Sample and Shipment Notification Form.
- Samples need to be spun, aliquoted, and frozen within 2 hours from time of collection.
- Store serum aliquots at -80°C until shipment.

Aliquot serum to 1.5 ml

Serum Tube - Serum Collection



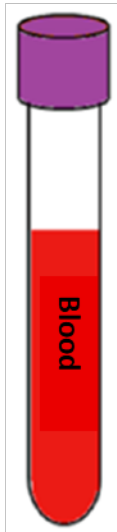
Plasma-PK (6ml Lavender Top Tube)

Step One



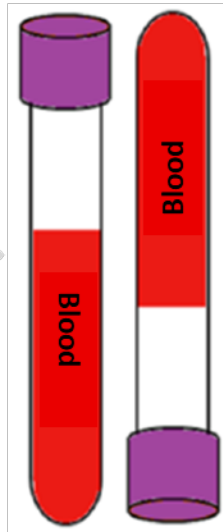
- Store tubes at room temperature.
- Label tubes and cryovials with pre-printed subject labels prior to blood draw.

Step Two



- Collect blood in Lavender Top Tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



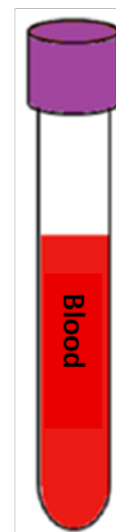
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

Step Four



- Place thoroughly mixed tube on wet ice until centrifugation begins.

Step Five

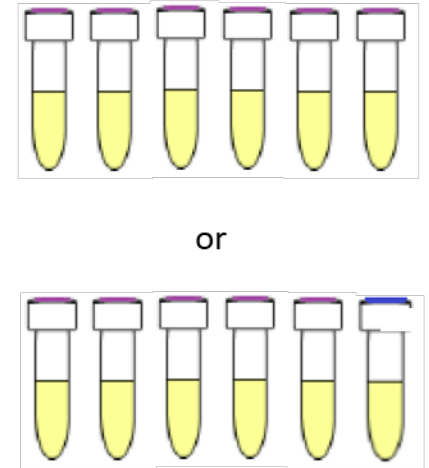


- Centrifuge samples at 2000 x g for 10 minutes, at 4°C.



- Must be spun, aliquoted, and stored in -80°C freezer within 2 hours of collection.

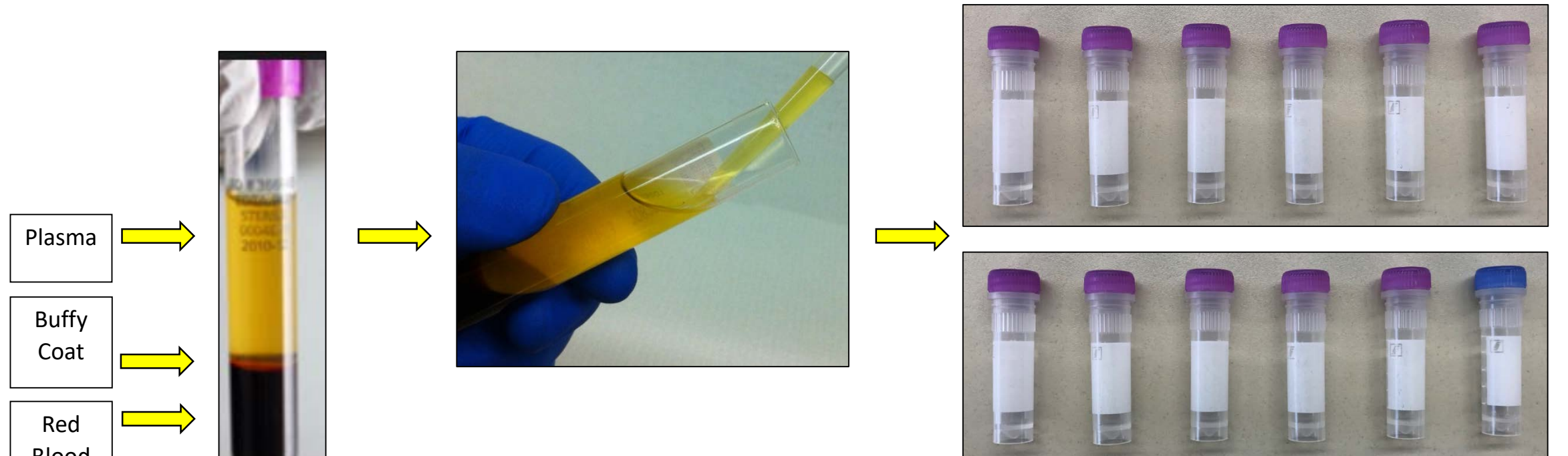
Step Six



- Aliquot 0.50 ml into each 2.0 ml cryovial tube with lavender cap.
- Store plasma aliquots at -80°C until shipment.
- If a residual aliquot (<.50 mL) is created place in clear cap with blue sticker and document sample number and volume on the sample form.

Aliquot plasma-pk to 0.5 ml

EDTA Tube (6 ml) - Plasma PK Collection

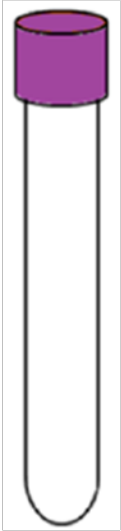


Up to 6 cryovials possible:
6x 0.5 ml Lavender Top OR
5x 0.5 ml Lavender Top and 1x <0.5 ml Blue Top

Plasma and Buffy Coat Preparation (10ml Lavender-Top Tube)

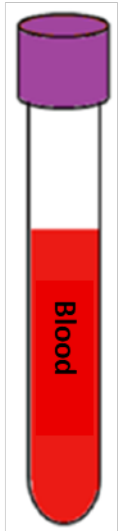


Step One



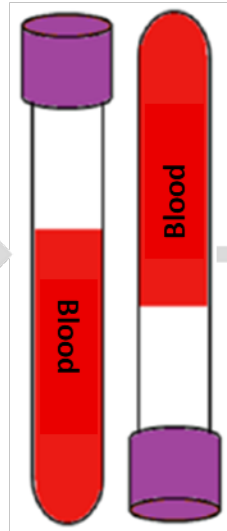
- Store tubes at room temperature.
- Label tubes with pre-printed subject labels prior to blood draw.

Step Two



- Collect blood in Plasma Tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



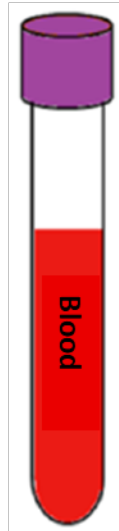
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

Step Four



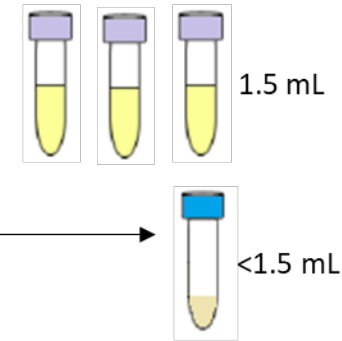
- Place thoroughly mixed tube on wet ice until centrifugation begins.

Step Five



- Within 30 minutes of blood draw, centrifuge samples at 2000 xg for 10 minutes at 4°C.
- Samples need to be spun, aliquoted, and frozen within 2 hours from time of collection.

Step Six



Step Seven

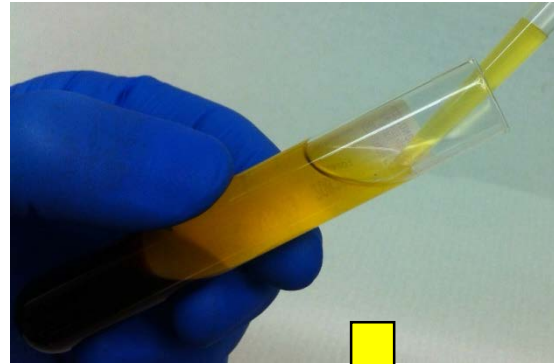
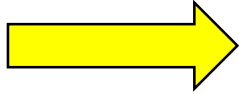
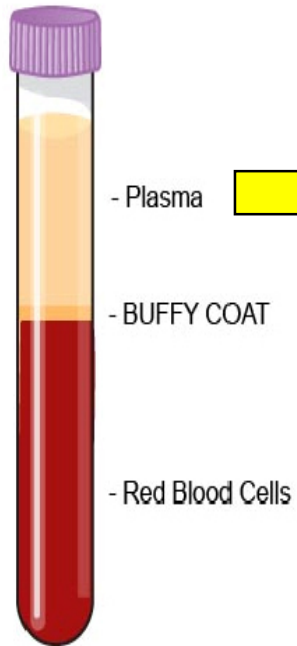


- Label cryovial tubes with preprinted labels
- Aliquot 1.5 ml into each purple-cap cryovial tube.
- If residual remains, aliquot to a blue-cap cryovial and note the residual on the Biological Sample and Shipment Notification Form
- Store plasma aliquots at -80°C until shipment.

- Label cryovial tube with preprinted label.
- Using a clean transfer pipette, collect the buffy coat (may have residual plasma and some RBCs included).
- Transfer the buffy coat into the cryovial tube.
- Store buffy coat aliquot at -80°C until shipment.

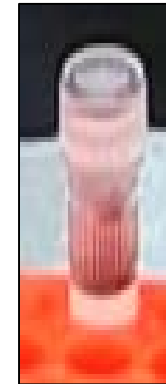
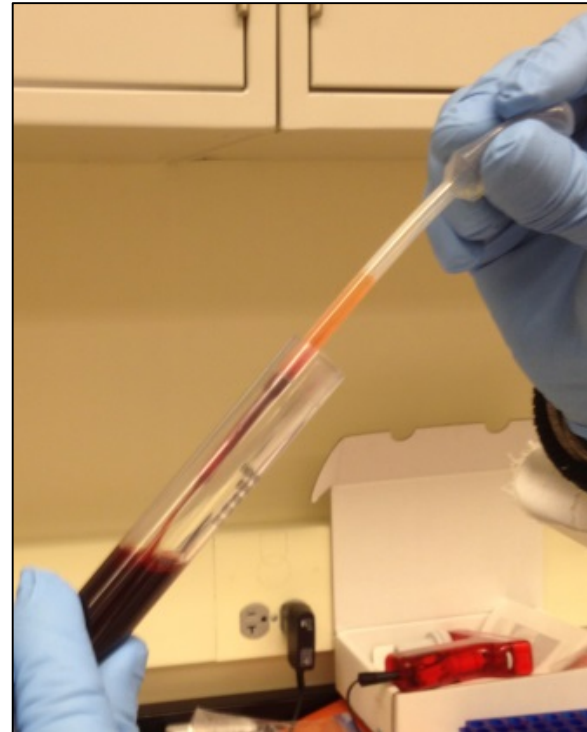
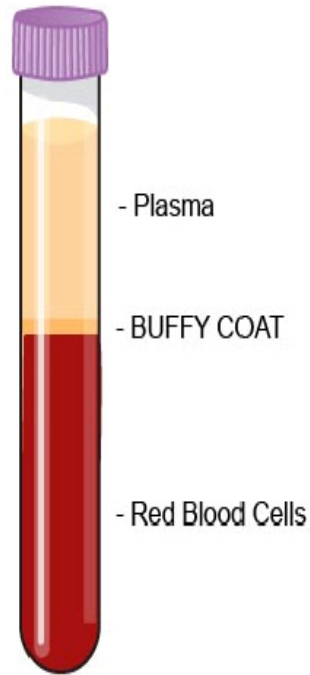
Aliquot plasma to 1.5 ml

EDTA Tube (10 ml) – Plasma Collection



Up to 4 cryovials possible:
3x 1.5 ml in lavender cap cryovials
1x <1.5 ml blue cap cryovial

EDTA Tube (10 ml) – Buffy Coat Collection



Buffy Coat
Aliquot
(Please use
CLEAR CAP
cryovial)

CSF Collection and Processing

Important Note

Fasting prior to the lumbar puncture is at the discretion of the site's PI. However, efforts should be made to keep the conditions under which an LP is performed (fasting, time of day, etc.) consistent for each LP performed on a participant.



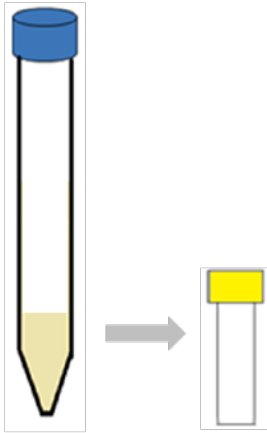
CSF Preparation

Step One



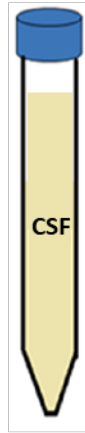
- Label tubes with pre-printed subject labels prior to collection.
- Pre-chill all cryovials on wet ice.

Step Two



- Collect initial 1-2 ml (if bloody, collect CSF until cleared of blood) into 15 ml conical tube.
- If not bloody, transfer 1-2 ml into the yellow-cap cryovial.
- Send to local lab for testing.

Step Three



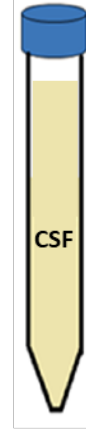
- Collect another 15 ml CSF into a new 15 ml sterile conical tube.

Step Four



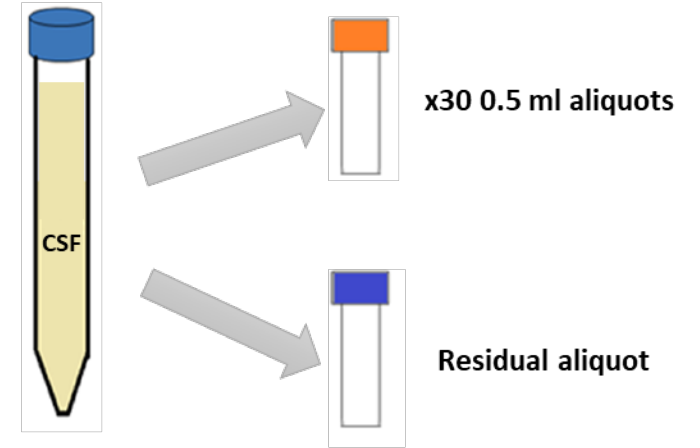
- Place sample upright on wet ice until centrifugation begins.

Step Five



- Within 15 minutes of collection, centrifuge sample at 4°C for 10 minutes (no brake).

Step Six



- Using a clean transfer pipette, aliquot 0.5 ml into the orange-cap cryovials, leaving debris at the bottom of the conical tube.
- If a residual aliquot is created, aliquot into blue-cap cryovial. Document specimen number and volume on CSF Sample Notification Form.
- Store CSF aliquots at -80°C until shipment.

Aliquot CSF to 0.5 ml

Sample Shipping



Frozen Shipping: Guidelines

- **Ship Monday-Wednesday Only**

- Hold packaged samples in a -80°C freezer until pickup.
- Batch Samples together
 - 5 Cryoboxes
 - **Batch shipping should be performed every 3 months or as a full shipment of specimens accumulates, whichever is sooner.**

Sample Shipment Summary

Sample Type	Processing/Aliquoting	Tubes to NCRAD	Ship
Whole blood (Red-Top Serum Tube) for Serum Isolation	1.5 ml aliquots per 2.0 ml cryovials	Up to 2	Frozen (Monday-Wednesday)
Whole blood (Lavender-Top EDTA 6 ml Tube) for Plasma-PK Analysis	0.5 ml aliquots per 2.0 ml cryovials	Up to 6	Frozen (Monday-Wednesday)
Whole blood (Lavender-Top EDTA tube) for isolation of plasma and buffy coat	Plasma: 1.5 ml plasma aliquots per 2.0 ml cryovials	Up to 4	Frozen (Monday-Wednesday)
	Buffy Coat: 0.75 ml buffy coat aliquot per 2.0 ml cryovial	1	Frozen (Monday-Wednesday)
CSF	0.5 ml CSF aliquots per 2.0 ml cryovials	Up to 30	Frozen (Monday-Wednesday)

Frozen Shipping: Cryoboxes

Visits: Screening CSF, Baseline Blood



Labels:
1: SC CSF
2: BL Serum,
Plasma, BC, &
Plasma-PK



CSF Aliquot tube for local lab
(label not provided)
**not shipped to NCRAD*

Include only one subject per box.

Frozen Shipping: Cryoboxes

Visits: Week 4 Blood, Week 8 Blood, Week 12 Blood

Labels:

- 1: Week 4
Plasma- PK
- 2: Week 8
Plasma-PK
- 3: Week 12
Plasma-PK



Include only one subject per box.

Frozen Shipping: Cryoboxes

Visits: Week 24 CSF & Blood



Labels:
1: W24 CSF
2: W24 Serum
& Plasma-PK

Include only one subject per box.



CSF Aliquot tube for local lab
(label not provided)
**not shipped to NCRAD*

Frozen Shipping: Cryoboxes

Visit: Week 48 CSF & Blood



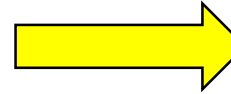
Labels:
1: W48 CSF
2: W48 Plasma,
BC, Serum,
Plasma-PK

Include only one subject per box.



CSF Aliquot tube for local lab
(label not provided)
**not shipped to NCRAD*

Frozen Shipping: Cryoboxes



CSF, serum, plasma-pk, plasma, and buffy coat aliquots can be combined in one box. Be sure to adhere the necessary Kit Labels on the lid of the cryobox.

Place cryobox in one Biohazard Bag.

Frozen Shipping: Dry Ice Requirements

- Fully cover the cryoboxes with about 2 inches of dry ice in the provided shipper.
- Each Styrofoam shipper can hold up to 5 cryoboxes
- Each Styrofoam shipper must be completely filled and will contain about 45 lbs (20 kg) of dry ice.



Frozen Shipping: Dry Ice Requirements

Class 9 Dry Ice label should not be covered with other stickers and must be completed or the shipping carrier will reject/return your package!

Shipper's Declaration not Required.
Part B is required
Dry Ice amount must be in kilograms.
Note: 2 lbs. = 1kg.

Airway/bills/airbills must have the following:
1. "Dangerous Goods – Shipper's Declaration not required".
2. Dry Ice; 9; UN1845;
3. $\frac{\text{Number}}{\text{(pgt)}} \times \frac{\text{Kg}}{\text{(wt.)}}$ Kg III

Net weight of dry ice in kg

Repository name & address:

NCRAD
IU School of Medicine
351 W. 10th St
TK-342
Indianapolis, IN 46202

DRY ICE,
____ kg.

Shipper's name and Address

Consignee Name and Address

UN1845

9

Your name & address

Shipping Frozen Samples

- Schedule FedEx
- *Send Biological Sample and Shipment Notification Form to IU ahead of shipment*
 - *Email: alzstudy@iu.edu or*
 - *Fax: 317-321-2003*

Shipping Regulations and Training

PLEASE NOTE:

- All study personnel responsible for shipping should be certified in biospecimen shipping.
- It is the responsibility of each site to ensure that the appropriate training has been provided and conducted in regards to IATA shipping.

Please see following slides for resources.

Federal Regulations/Training

- Sites are responsible for ensuring proper training is obtained.
- Current federal and international regulations require anyone directly involved with the shipment of potentially infectious materials and other regulated biological materials (including biological specimens and cultures) **be properly trained on pertinent shipping requirements.**

- **International Air Transport Association (IATA) Training**

DGI Training Center 800-338-2291 DGItraining.com Provides IATA Certified Air Seminars and online courses	IATA Training Schools North America 1(514)390-6726 Europe, Africa & Middle East 41 (22) 799 2751 Asia, Australia & the Pacific 65 239 7232 www.iata.org Training schools located in 30 countries
Saf-T Pak Inc. www.saftpak.com Provides dangerous goods training via CD or on-site instruction for North America and Europe	Aiconsult Email: Airconsult@wanadoo.fr www.airconsult-bf.com
Bureau of Dangerous Goods LTD., TIANJIN Addr.: No.3 Yingshui road, Nankai district, Tianjin China Tel: 022-23495890 83326960 83326854 / Fax: 022-83326959 Email: cdmin@bdg-china.com.cn www.bdg-china.com.cn	

UN3373 Biological Substance, Category B Training

- Biological Substance, Category B are specimens being transported for “investigational purposes”
- Recommend: investigator sites document training of category B/dangerous goods
- We recommend establishing a record of your staff’s training and date of instruction
- The training records must be made available upon request by the appropriate national authority
 - Additional information from the Department of Transportation (DOT) can be found on their website <http://hazmat.dot.gov>

Frozen Shipping: FedEx Airbill

- Airbill must be completed or the shipping carrier will reject/return your package!

Your name,
address, and
phone

FedEx Express Package US Airbill FedEx Tracking Number **8132 0902 9840** Form ID No. **0200** Sender's Copy

1 From Please print and press hard.
Date _____ Sender's FedEx Account Number _____
Sender's Name _____ Phone (____) _____
Company _____
Address _____ Dept./Floor/Suite/Room _____
City _____ State _____ ZIP _____

2 Your Internal Billing Reference
First 24 characters will appear on invoice. OPTIONAL _____

3 To
Recipient's Name **NCRAD** Phone (____) **800.526.2939**
Company **IV School of Medicine**
Address **351 W. 10th St. TK. 342** Dept./Floor/Suite/Room _____
Address _____
City **Indianapolis** State **IN** ZIP **46202**

4 Express Package Service *To most locations. Packages up to 150 lbs. For packages over 150 lbs., use the FedEx Express Freight US Airbill.

Next Business Day
☐ FedEx First Overnight
Earliest next business morning delivery to select locations. Friday shipments will be delivered on Monday unless Saturday Delivery is selected.
☒ **FedEx Priority Overnight**
Next business morning.* Friday shipments will be delivered on Monday unless Saturday Delivery is selected.
☐ FedEx Standard Overnight
Next business afternoon.* Saturday Delivery NOT available.

2 or 3 Business Days
☐ FedEx 2Day A.M.
Second business morning.* Saturday Delivery NOT available.
☐ FedEx 2Day
Second business afternoon.* Thursday shipments will be delivered on Monday unless Saturday Delivery is selected.
☐ FedEx Express Saver
Third business day.* Saturday Delivery NOT available.

5 Packaging *Declared value limit \$500.
☐ FedEx Envelope* ☐ FedEx Pak* ☐ FedEx Box ☐ FedEx Tube ☐ Other

6 Special Handling and Delivery Signature Options Fees may apply. See the FedEx Service Guide.
☐ Saturday Delivery
NOT available for FedEx Standard Overnight, FedEx 2Day A.M., or FedEx Express Saver.
☐ No Signature Required
Package may be left without obtaining a signature for delivery.
☐ Direct Signature
Someone at recipient's address may sign for delivery.
☐ Indirect Signature
If no one is available at recipient's address, someone at a neighboring address may sign for delivery. For residential deliveries only.

Does this shipment contain dangerous goods?
☐ No ☒ **Yes** As per attached Shipper's Declaration. ☐ Yes Shipper's Declaration not required. ☒ **Dry Ice** **1** x _____ kg
Restrictions apply for dangerous goods — see the current FedEx Service Guide. ☐ Cargo Aircraft Only

7 Payment Bill to:
Enter FedEx Acct. No. or Credit Card No. below.
☐ Sender Acct. No. in Section 1 will be billed. ☐ Recipient ☒ **Third Party** ☐ Credit Card ☐ Cash/Check
FedEx Acct. No. _____ Exp. Date _____

Total Packages _____ Total Weight _____ lbs. \$ _____
Total Declared Value[†] _____

Ship it. Track it. Pay for it. All online.
Go to fedex.com

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†Our liability is limited to US\$100 unless you declare a higher value. See back for details. By using this airbill you agree to the service conditions on the back of this airbill and in the current FedEx Service Guide, including terms that limit our liability.
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Dangerous
goods info
for dry ice
shipments

Net weight of
dry ice in kg

FedEx Account
Number (will
be prefilled)

Sample shipment to NCRAD will be paid for by the T2 grant at UCSD.

Biological Sample and Shipment Notification Forms

- A copy of the sample form *must* be emailed or faxed to NCRAD prior to the date of sample arrival.
- Please include sample forms in all shipments of frozen samples.
- Email: alzstudy@iu.edu
- Fax: 317-321-2003



Biological Sample and Shipment Notification Form: Blood

- Blood Collection for:
 - Serum
 - Plasma-PK
 - Plasma
 - Buffy Coat
- Send by E-mail or fax prior to shipment, and include a copy in each shipment

Biological Sample and Shipment Notification Form
Please email or fax the form on or prior to the date of shipment.

To: Kelley Faber Email: alzstudy@iu.edu FAX: 317-321-2003 Phone: 1-800-526-2839

General Information: FedEx tracking #: _____

From: _____ Date: _____

Phone: _____ Email: _____

Study: T2 PROTECT AD **GUID:** _____ **Kit #:** _____

Visit: Baseline **Week:** 4 8 12 24 48

Site ID: _____ **ADCS IND #:** _____

Sex: M F **Year of Birth:** _____ **CSF Collected?** Yes No

KIT BARCODE

Blood Collection:

1. Date Drawn: _____ [MMDDYY]	2. Time of Draw: _____ [HHMM]
3. Last time subject ate: _____ [MMDDYY]	4. Last time subject ate: _____ [HHMM]

Blood Processing:

Serum (Red-top) Tube (6 mL)		Plasma & Buffy Coat (Lavender-top) Tube (10 mL)	
Time spin started: _____ [HHMM]	_____ [HHMM]	Time spin started: _____ [HHMM]	_____ [HHMM]
Duration of centrifuge: _____ Minutes	_____ Minutes	Duration of centrifuge: _____ Minutes	_____ Minutes
Temp of Centrifuge: _____ °C	Rate of centrifuge: _____ x g	Temp of Centrifuge: _____ °C	Rate of centrifuge: _____ x g
Original volume drawn (1 x 6 mL tube): _____ mL	_____ mL	Original volume drawn (1 x 10 mL tube): _____ mL	_____ mL
Time aliquoted: _____ [HHMM]	_____ [HHMM]	Time aliquoted: _____ [HHMM]	_____ [HHMM]
Number of 1.5 mL serum aliquots created (red cap): _____	_____	Number of 1.5 mL plasma aliquots created (lavender cap): _____	_____
If applicable, volume of residual serum aliquot (less than 1.5 mL in blue cap): _____ mL	_____ mL	If applicable, volume of residual plasma aliquot (less than 1.5 mL in blue cap): _____ mL	_____ mL
If applicable, specimen number of residual serum aliquot (last four digits): _____	_____	If applicable, specimen number of residual plasma aliquot (last four digits): _____	_____
Time aliquots placed in freezer: _____ [HHMM]	_____ [HHMM]	Time aliquots placed in freezer: _____ [HHMM]	_____ [HHMM]
Storage temperature in freezer: _____ °C	_____ °C	Storage temperature in freezer: _____ °C	_____ °C
		Buffy coat aliquot created (clear cap, one per 10 mL EDTA tube) _____ mL	

Plasma-PK (Lavender-top) Tube (6 mL)	
Time spin started: _____ [HHMM]	Original volume drawn (1 x 6 mL tube): _____ mL
Duration of centrifuge: _____ Minutes	Number of 0.5 mL plasma-pk aliquots: _____
Temp of Centrifuge: _____ °C	Rate of centrifuge: _____ x g
If applicable, volume of residual plasma-pk aliquot (blue cap) & last 4 digits: _____	_____ mL
Time aliquoted: _____ [HHMM]	Time aliquots placed in freezer: _____ [HHMM]
	Storage temperature in freezer: _____ °C

Notes: _____

Biological Sample and Shipment Notification Form: CSF

**Send by E-mail
or Fax prior to
shipment, and
include a copy
in each
shipment**

CSF Sample and Shipment Notification Form			
Please email or fax the form on or prior to the date of shipment.			
To: Kelley Faber Email: alzstudy@iu.edu FAX: 317-321-2003 Phone: 1-800-526-2839			
General Information:		FedEx tracking #: _____	
From: _____	Date: _____		
Phone: _____	Email: _____		
Study: T2 PROTECT AD	GUID: _____	Kit #: _____	KIT BARCODE
Visit: Screening	Week 24	Week 48	
Site ID: _____	ADCS IND #: _____	Gauge needle used for LP: 22G 24G	
Sex: M F	Year of Birth: _____	CSF Collected? Yes No	
CSF Collection:			
5. Date of collection: [MMDDYY]		6. Time of collection: [HHMM]	
7. Last time subject ate: [MMDDYY]		8. Last time subject ate: [HHMM]	
9. Collection process: Gravity Method		Aspiration	
CSF Processing:			
Time spin started: _____		[HHMM]	
Duration of centrifuge: _____		Minutes	
Temp of Centrifuge: _____ °C		Rate of centrifuge: _____ x g	
Total amount of CSF collected: _____		mL	
Time aliquoted: _____		[HHMM]	
Number of 0.5 mL CSF aliquots created (orange cap): _____		x 0.5 mL	
If applicable, volume of residual CSF aliquot (less than 0.5 mL in blue cap): _____		mL	
If applicable, specimen number of residual serum aliquot (last four digits): _____			
Time frozen: _____		[HHMM]	
Storage temperature in freezer: _____		°C	
Notes:			

NCRAD Website

- Helpful Pages:
 - https://ncrad.org/holiday_closures.html

 Holiday 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
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

NCRAD Website: T2 Protect AD Active Study Page

T2 Active Study Page



Welcome T2 Study staff, coordinators, and PI's.

This section encompasses study specific tools and videos for your reference. If you have any questions, comments, or new ideas, please contact NCRAD by email or phone 800-526-2839 or 317-278-1228.

https://ncrad.org/resource_t2protect.html

*Training videos, manual of procedures, and sample forms are available for reference on the T2 Protect AD Active Study Page.

T2 Specimen Collection Overview

	Screening	Baseline	Week 4	Week 8	Week 12	Week 24	Week 48
Serum		✓				✓	✓
Plasma		✓					✓
Buffy Coat		✓					✓
Plasma-PK		✓	✓	✓	✓	✓	✓
CSF	✓					✓	✓

Study Resources

Kit Request Module

Study Specific Sample Notification Forms

T2 Manual of Procedures

Study Related Video Tutorials

T2 Training Slides

Contact Information

- Questions?

Please contact NCRAD Coordinators at:

- Phone: 1-800-526-2839 or 317-278-1228
- E-mail: alzstudy@iu.edu or mipetkov@iu.edu
- Website: www.ncrad.org

