

Parkinson's Spectrum Disorders Center

UCSF Weill Institute for
Neurosciences

**PSDC New Coordinator Training:
10.2018**



NCRAD

Training Overview:

PSDC

- Study Overview
- Kit Review
- Sample Collection and Processing
- Sample Shipping
- Sample Form
- NCRAD Website
- Common Nonconformance Issues
- Questions?

PSDC Study Specimens

	PSDC Visit 1
DNA (Buffy Coat)	X
Plasma	X
PBMC	X
Serum	X
RNA	X
CSF	X*

*CSF in select population

Kit Request Module

kits.iu.edu/psdc

Please allow 2 weeks for your kit request to be processed and shipped.



NCRAD Kit Request Module

PSDC Kit Request System

USA: University of California San Francisco	
Attn: Vy Nguyen University of California, San Francisco 675 Nelson Rising Lane, Suite 190 San Francisco, CA 94158	
Parkinson's Spectrum Disorder Center	
Is the contact name above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No reset
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
<input type="submit" value="Submit"/>	

- The coordinator name and contact information will appear.
- Verify that this information is accurate, or correct it if necessary.
- Once you confirm the info is correct, the kit supplies will drop down.

Study Visit Kits

PSDC Blood Kit Qty	<input type="text" value="1"/>
Optional NCRAD Kit (CSF) Qty	<input type="text"/>
Frozen Shipping Supply Kit Qty	<input type="text"/>
Green Top-Sodium Heparin Tube Redraw/Take Home Kit Qty	<input type="text"/>
Lavender Top-EDTA Tube Redraw/Take Home Kit Qty	<input type="text"/>
PSDC Supplemental Supply Kit Qty	<input type="text"/>
Do you need Extra Supplies? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No
Comments	<input type="text"/> <small>Expand</small>

Each PSDC Blood Kit Contains:

- 3: EDTA (Lavender-Top) Blood Collection Tube (10 ml)
- 2: Sodium Heparin (Green-Top) Blood Collection Tube (10 ml)
- 1: Serum Determination (Red-Top) Blood Collection Tube (10 ml)
- 3: PAXgene™ Blood Collection Tube (2.5 ml)
- 10: Cryovial tube (2 ml) with lavender cap
- 3: Cryovial tube (2 ml) with red cap
- 3: Cryovial tube (2 ml) with clear cap
- 2: Cryovial tube (2 ml) with blue cap
- 27: Pre-printed labels for blood collection and aliquot tubes
- 5: Pre-printed labels with kit number
- 10: Labels for handwritten Site and PIDN
- 1: Cryovial tube box (holds up to 25 cryovials)

1: Shipping Supplies for ambient shipment of PBMCs:
Plastic biohazard bag with absorbent sheet
Small IATA shipping box with insulated cooler
Small refrigerant pack
Aqui-Pak 6 tube absorbent pouch
UN3373 Biological Substance Category B label
List of contents card
FedEx return airbill and pouch
FedEx Clinic Pak



- Indicate the quantity needed of each kit
- Once selected, kit components of the chosen kit will appear at the bottom of the screen (Pictured)
- Click “Submit” to turn in your request.
- The IU staff will notify you that your request has been received and address any issues.
- **Note: You can order more than one type of kit in a single kit request**

PSDC Blood Kit

Quantity	PSDC Blood Kit Components
3	EDTA (Lavender-Top) Blood Collection Tube (10 ml)
2	Sodium Heparin (Green-Top) Blood Collection Tube (10 ml)
1	Serum Determination (Red-Top) Blood Collection Tube (10 ml)
3	PAXgene™ Blood Collection Tube (2.5 ml)
1	15ml orange cap conical tube
10	Cryovial tube (2 ml) with lavender cap
3	Cryovial tube (2 ml) with red cap
3	Cryovial tube (2 ml) with clear cap
2	Cryovial tube (2 ml) with blue cap
27	Pre-printed labels for blood collection and aliquot tubes
5	Pre-printed labels with kit number
10	Labels for handwritten Site and PIDN
1	Cryovial tube box (holds up to 25 cryovials)
1	Shipping Supplies for ambient shipment of PBMCs: <ul style="list-style-type: none"> Plastic biohazard bag with absorbent sheet Small IATA shipping box with insulated cooler Small refrigerant pack Aqui-Pak 6 tube absorbent pouch UN3373 Biological Substance Category B label List of contents card FedEx return airbill and pouch FedEx Clinic Pak



PSDC CSF Kit

Quantity	NCRAD CSF Kit Components
16	Cryovial tube (2 ml) with orange cap
1	Cryovial tube (2 ml) with blue cap
1	Cryovial tube (2 ml) with yellow cap
1	Lumbar Puncture tray (24G)
2	Individually Packaged Sterile 50ml Conical Tube
1	Cryovial tube box (holds up to 25 cryovials)
17	Pre-printed labels for blood collection and aliquot tube
5	Pre-printed labels with kit number



Frozen Shipping Kit

Quantity	Frozen Shipping Kit Components
4	Plastic Biohazard bag with 250 mL absorbent sheets
1	FedEx return airbill and pouch
1	Shipping box/Styrofoam container
1	Warning label packet with dry ice sticker
12	Bubble wrap pouch



Redraw/Take Home Kits

- Redraw may include:
 - EDTA tube, or
 - Sodium Heparin tubes
- Sample redraw may occur in one of two ways:
 - Subject travels to site
 - Site staff sends participant kit
 - Drawn with local physician
 - Cost of draw should be covered by PSDC site by direct payment to physician OR reimbursement to participant

Redraw/Take Home Kit



DNA Redraw/Take Home Kit

- 1 EDTA tube



PBMC Redraw/Take Home Kit

- 2 PBMC tubes

Specimen Labels



Three Label Types


Kit Number

250001


Kit Number


Site ID: _____
PIDN:


Site and PIDN

0004087175
 PSDC
PLASMA
Kit #: 250001

0004133813
 PSDC
BUFFY COAT
Kit #: 250001

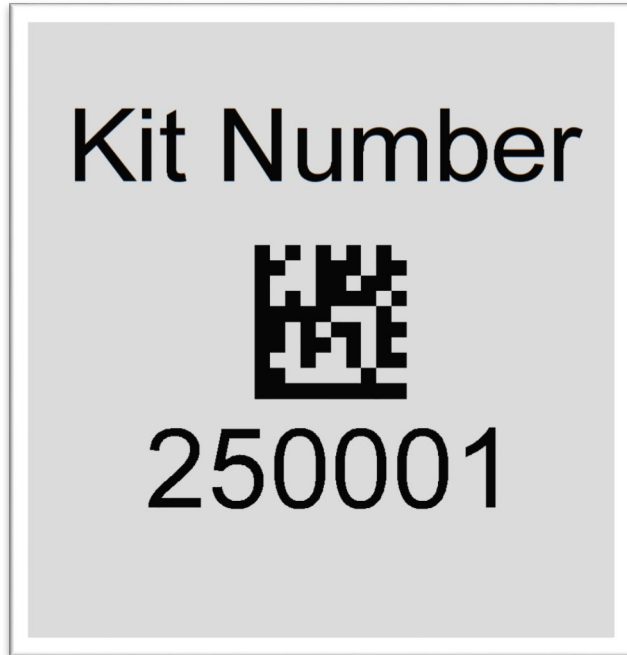
0004134017
 PSDC
PBMC
Kit #: 250001

0004133873
 PSDC
SERUM
Kit #: 250001

0004133825
 PSDC
RNA
Kit #: 250001

Collection and Aliquot Tube

Kit Number Labels



Provided by NCRAD in the kits

- Used to track patient samples and provide quality assurance – Will be placed on the following locations :
 1. Biological Sample and Shipment Notification Form
 2. CSF Sample and Shipment Notification Form (IF COLLECTED)
 3. Cryobox that houses aliquots during shipping
 4. Outside of the biohazard bag that houses PAXgene™ tubes and aliquot tubes during shipping process
- CSF samples will have a different kit number label than the blood collection specimens

Site and PIDN Label

Site ID: _____


PIDN:

- Subjects will be identified by their site ID and PIDN
- The PIDN is generated at UCSF
- Coordinator will be responsible for handwriting this onto the provided labels
 - Must use Fine Point Sharpie Marker
 - Each site will receive 3 markers in initial kit supply


Collection Tubes - BLOOD

Label 1: collection tube label


Label 2

0004087175
 PSDC
PLASMA
Kit #: 250001


EDTA Tube

0004134017
 PSDC
PBMC
Kit #: 250001

Sodium Heparin Tube

0004133873
 PSDC
SERUM
Kit #: 250001

Serum Tube

0004133825
 PSDC
RNA
Kit #: 250001

PAXgene™ Tube

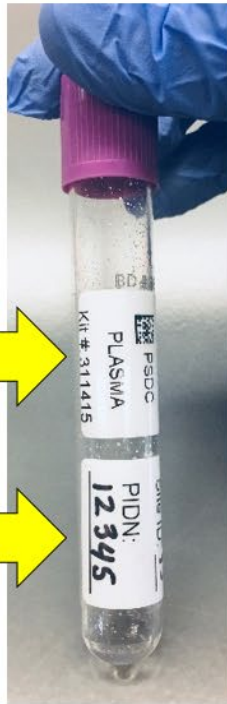
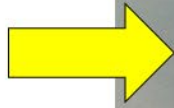
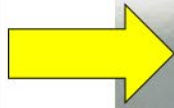
Site ID: _____
PIDN:

- All collection tubes will have two labels
 - The collection tube labels
 - The handwritten Site and PIDN label

Collection Tubes - BLOOD

Collection
and Cryovial
Tube Label

Site and
PIDN ID
Label



EDTA
Tube



Sodium Heparin
Tube

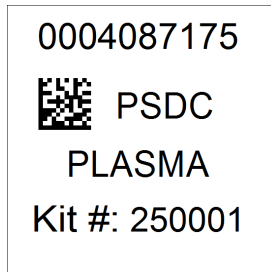


Serum Determination
Tube



PAXgeneTM
Tube

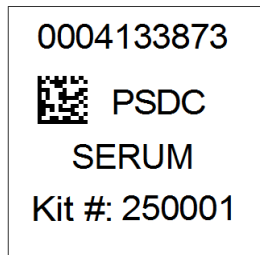
Aliquot Tube Labels – Plasma, Buffy Coat, Serum, and CSF



EDTA Tube



EDTA Tube



Serum Tube



Lumbar Puncture

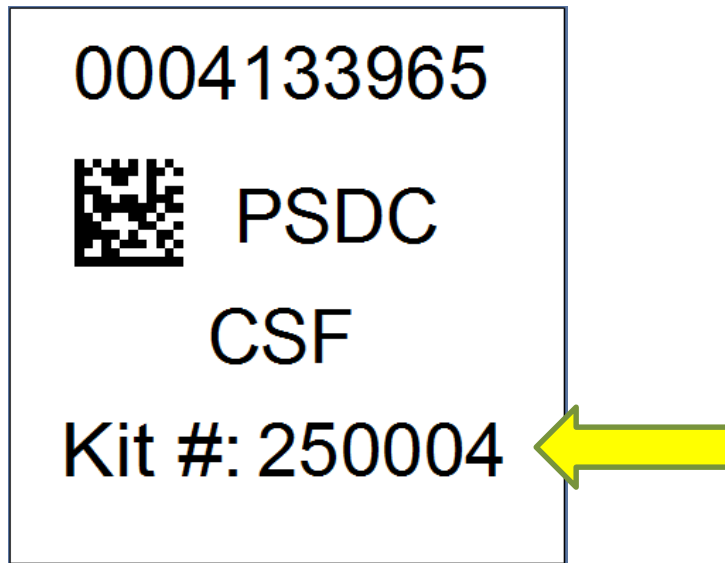
- Only one label to be placed on ALL aliquot tubes
- **Plasma**
 - From EDTA tube
- **Buffy Coat**
 - From EDTA tube
- **Serum**
 - Serum Tube
- **CSF**
 - Sterile Container

Aliquot Tube Labels – Plasma, Buffy Coat, Serum, and CSF



- Collection and Aliquot tube label only
- Please place barcode near cap

Collection and Aliquot Tube Labels - CSF

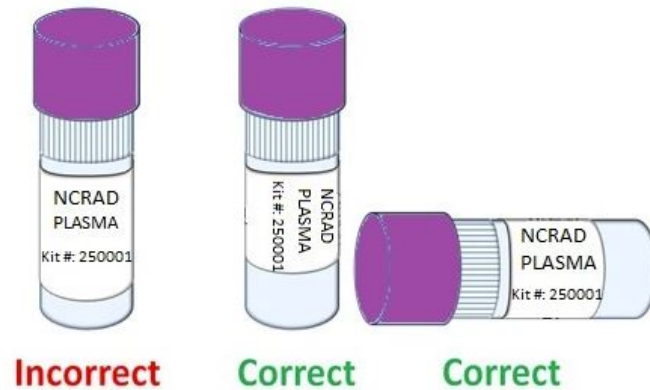


- Separate Kit Number for CSF collection
 - Kit number will differ from kit number used for the blood samples for the same subject at the same visit
- CSF label
 - Collection tubes
 - CSF aliquots

Labeling Biologic Samples

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









Handling/Processing Study Specimens



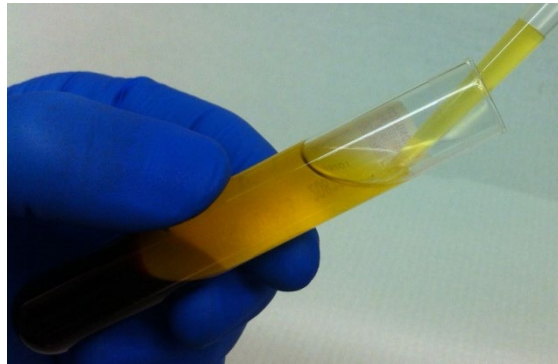
Blood Draw Order

Tube Type	Number of Tubes Drawn	Tube Image
1. EDTA (Lavender-Top) Tube (10 ml)	x3	
2. Sodium Heparin (Green-Top) Tube (10 ml)	x2	
3. Serum Determination (Red-Top) Tube (10 ml)	x1	
4. PAXgene™ Tube (2.5 ml)	x3	

Cryovial Cap Colors

Cap Color	Sample Type	Cap Image
Lavender	Plasma	
Clear	Buffy Coat	
Red	Serum	
Orange	CSF Aliquot (1.5 ml)	
Yellow	CSF Aliquot to local lab	
Blue	Residual Aliquot (Plasma, Serum, or CSF)	

Plasma Collection



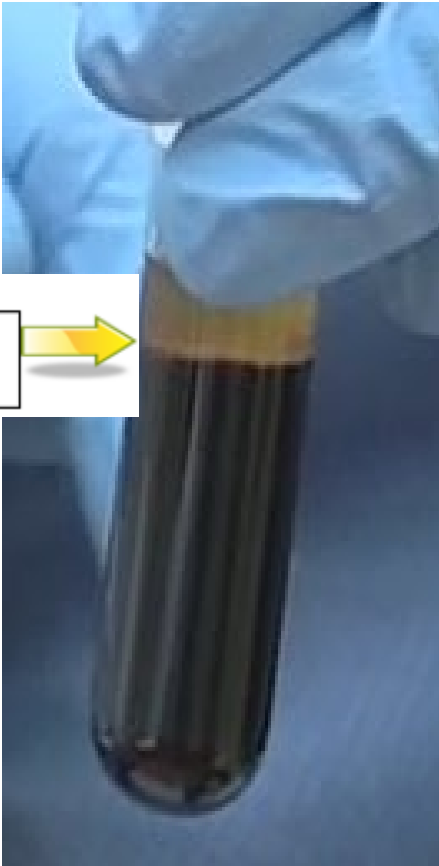
Residual Aliquot
with Blue Cap

Create up to 10 aliquots

Buffy Coat Collection



Buffy Coat layer
(mixed with RBCs)



NCRAD Tutorials: <http://kits.iu.edu/psdc/videos>

Plasma and Buffy Coat Preparation (10ml Purple Top Tube x 3)

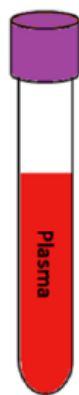


Step One



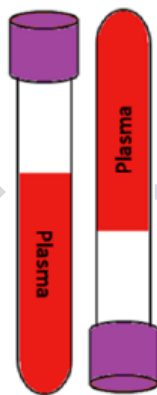
- Store tubes at room temperature
- Label tubes with pre-printed labels prior to blood draw.

Step Two



- Collect blood in EDTA 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

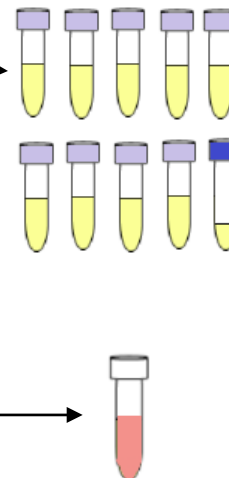


- Centrifuge samples at 1500 x g for 15 minutes at 4°C.
- EDTA tubes need to be spun, aliquoted, and in the freezer within 2 hours from the time of collection.

Step Five



- Pool all plasma from the 3 EDTA tubes into a 15ml conical tube.

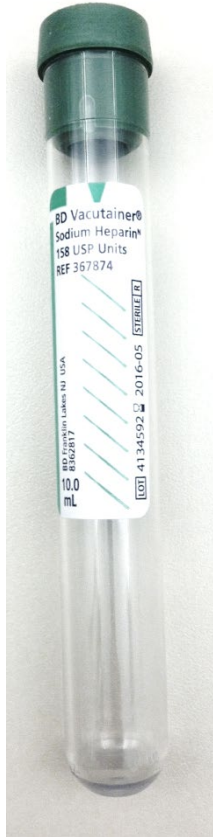


Step Six

- Label cryovial tubes with preprinted labels.
- Aliquot 1.5 ml into each cryovial tube.
- If residual aliquot is created, use blue cap to indicate volume difference and document Specimen Number on 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.

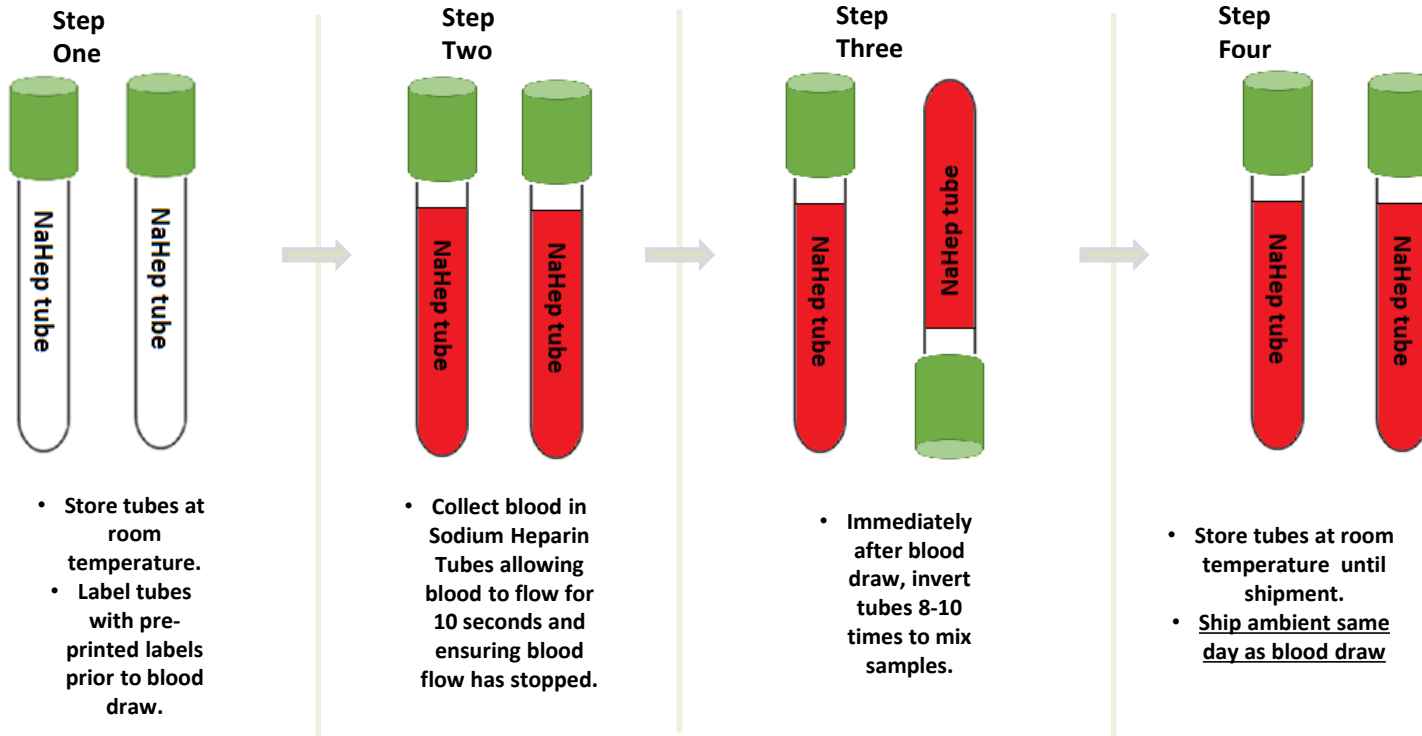
- Please allow at least 30 minutes for the centrifuge to cool down and reach 4°C.
- Samples must be stored in -80°C for at least 8 hours before shipment.

PBMC Collection



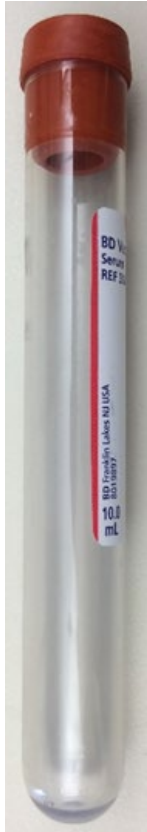
- Sodium heparin (green top) BD Vacutainer® (10 ml)
 - Not processed at site
 - *NOTE*: Must be shipped **AMBIENT** to NCRAD the day sample is drawn. No Friday Draws.

PBMC Preparation (10ml Sodium Heparin Tube x 2)



No Friday Draws

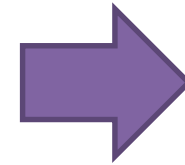
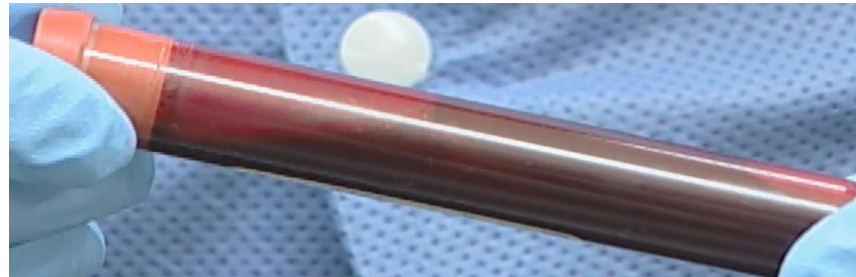
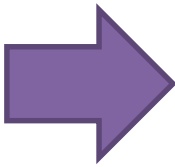
Serum Determination Tube



Serum Determination Tube (unfilled)

Serum Determination Tube
(Immediately after blood draw – pictured below)

** Please note: After standing at room temperature for 30 minutes, blood will be clotted and immobile**

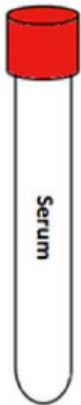


Serum Determination Tube (after centrifuge)

Serum Preparation (10ml Red Top Tube)



Step One



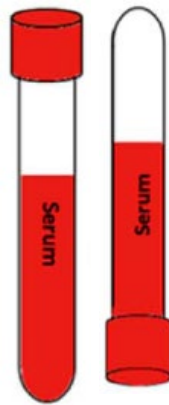
- Store tubes at room temperature.
- Label tubes with pre-printed labels prior to blood draw.

Step Two



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

Step Three



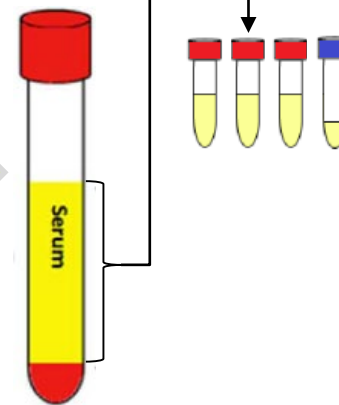
- Immediately after blood draw, invert tubes 5 times to mix samples.

Step Four



- Allow blood to clot for 30 minutes.
- Centrifuge samples at 1500 x g for 15 minutes at 4°C.
- Serum samples need to be spun, aliquoted, and in the freezer within 2 hours from the time of collection.

Step Five



- Label cryovial tubes with preprinted labels.
- Aliquot 1.5 ml into each cryovial tube.
- If residual aliquot is created, use blue cap to indicate volume difference and document Specimen Number on Biological Sample and Shipment Notification Form.
- Store serum aliquots at -80°C until shipment.

- Serum tube must be drawn before the PAXgene tube.
- Samples must be stored in -80°C for at least 8 hours before shipment.
- Please allow at least 30 minutes for the centrifuge to cool down and reach 4°C.

RNA PAXgene™ Tubes for RNA



- <http://www.preanalytix.com/videos/rna-tube-collection-video/>

Documented within MOP for site staff review

Released by PreAnalytiX

RNA Preparation (2.5ml PAXgene™ Tube)

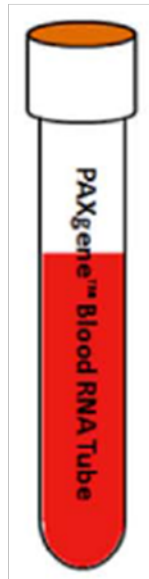


Step One



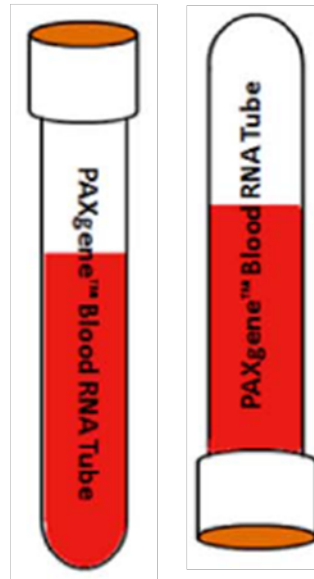
- Store tubes at room temperature.
- Label tubes with pre-printed Collection/Aliquot tube and Site/RAVE ID labels prior to blood draw.

Step Two



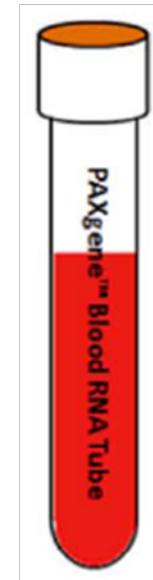
- Collect blood in PAXgene™ tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



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

Step Four



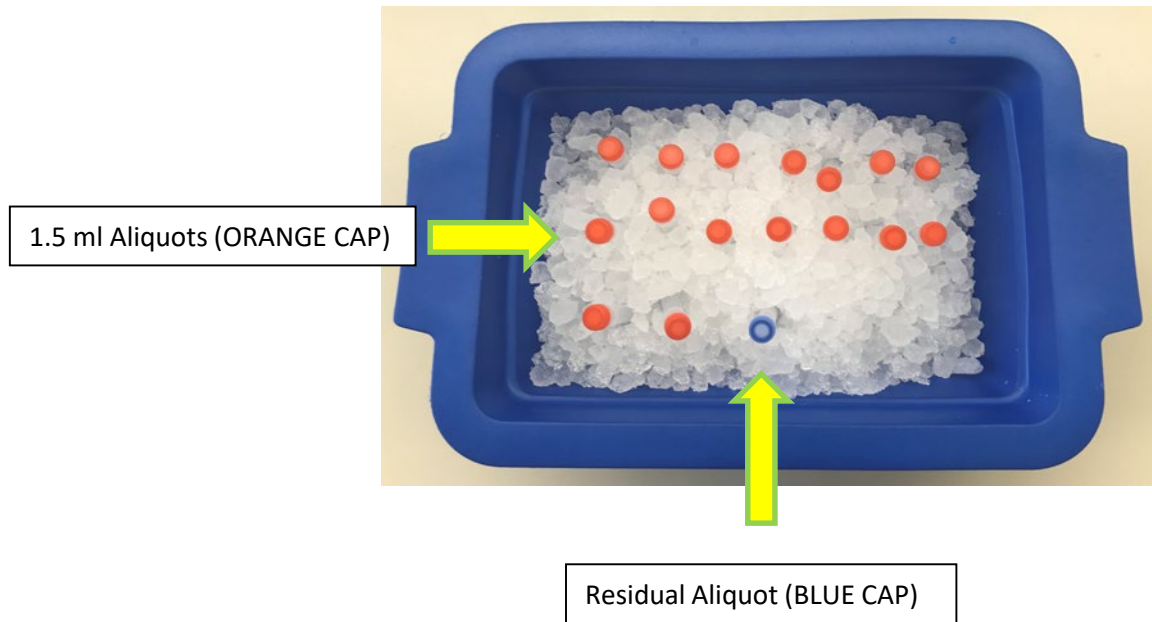
- Store tubes at -80°C in a wire rack until shipment.



CSF Collection and Processing

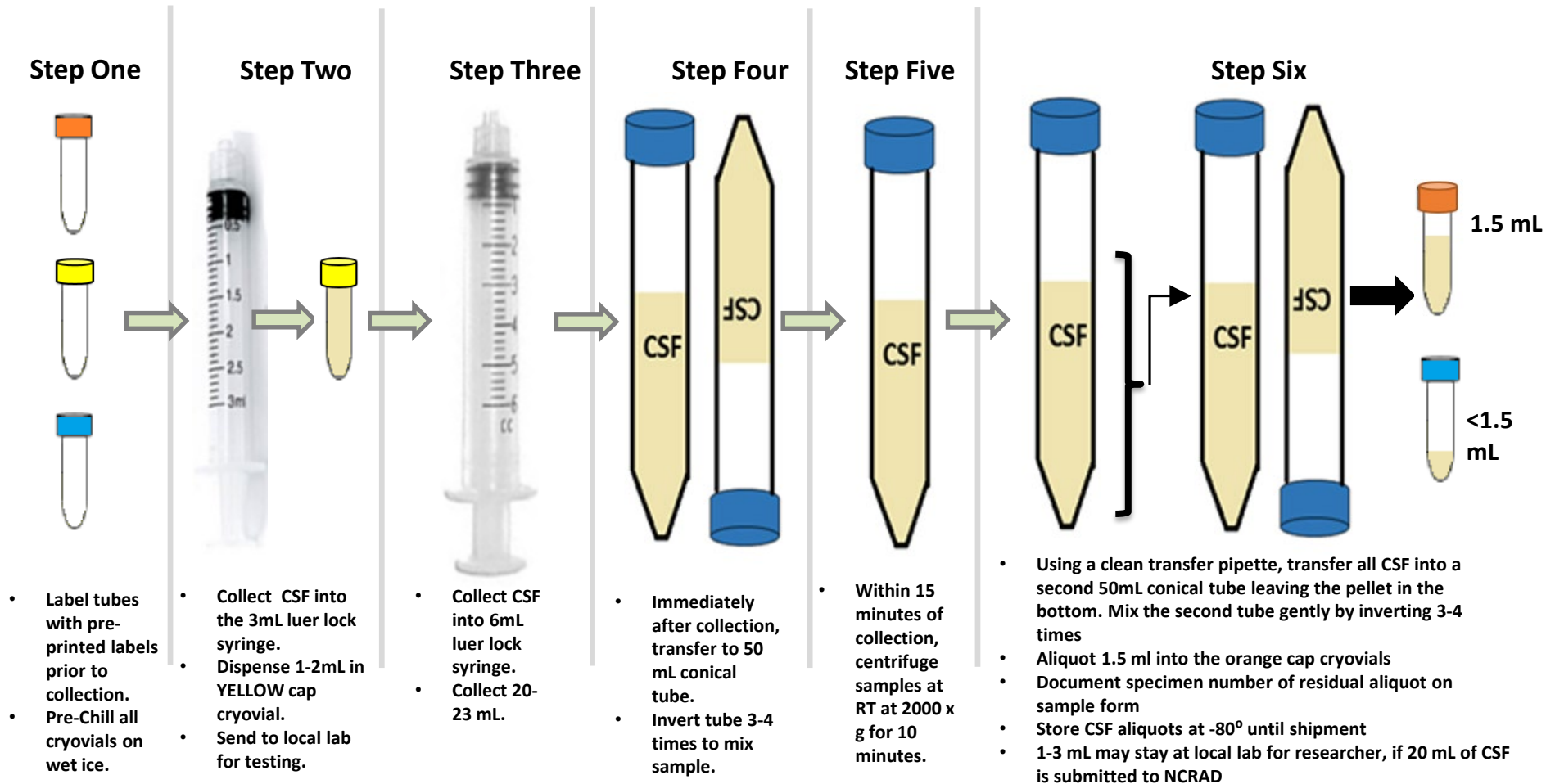


Pre-Ice CSF Cryovials



- Pre-label prior to adding cryovials in wet ice
- Pre-ice all cryovials included in kit

CSF Preparation (20-25 mL in Syringes)



- Samples must be stored in -80°C for at least 8 hours before shipment.

Sample Shipments



Sample Shipment Summary

Sample Type	Processing/ Aliquoting	Tubes to NCRAD	Ship
Whole blood (Lavender-Top EDTA) for isolation of plasma & buffy coat (for DNA extraction)	1.5 ml plasma aliquots per 2 ml cryovials	8-10	Frozen
	1 ml buffy coat aliquot per 2 ml cryovial	3	Frozen
Whole blood (Green-Top Sodium Heparin) for isolation of PBMCs	N/A	2	Ambient
Whole blood (Red-Top Serum) for isolation of serum	1.5 ml serum aliquots per 2 ml cryovials	4	Frozen
Whole blood (PAXgene™) for RNA extraction	N/A	3	Frozen
CSF	1.5 ml CSF aliquots per 2 ml cryovials	16	Frozen

Ambient Sample

- **Sodium Heparin/PBMC**
- **Only Monday-Thursday collection and same day shipping. Plan ahead to schedule FedEx.**
- **Samples must be received at IU one day after collection.**
- **Do NOT draw or ship ambient samples on Friday**
- **Include copy of Biological Sample Shipment and Notification Form**

Ambient Shipment Packaging



- Place the ambient PBMC tubes in the absorbent slots and biohazard bag.
- Place the kit number label on the outside of the biohazard bag.
- Place the bag inside the small shipping box, and then set the refrigerant pack on top of it.
- Place small shipping box within a provided FedEx Clinical Pak, seal, and place FedEx label on outside of package.

*Gel packs must be put in a freezer at minimum the night before shipping.

Frozen Samples

- **All other samples**
 - Plasma, Buffy Coat, Serum, PAXgene™, and CSF
 - **Ship Monday-Wednesday Only**
- Store samples for at least 8 hours in a -80°C freezer. Keep the samples in the freezer until they are ready for pickup.
- Include copy of Biological Sample Shipment and Notification Form
- Batch samples together
 - 4 participant samples (Plasma, Buffy, Serum, RNA, CSF)
 - **Batch shipping should be performed every three months or as a full shipment of specimens accumulates, whichever is sooner.**

Shipping Frozen Samples



Place kit number label on cryobox



Place kit number label on cryobox.
The CSF kit number will differ from the blood kit number.

Frozen Shipping Packaging

- Use the large biohazard bag to accommodate the 2, 25-Slot Cryobox and PAXgene™ tubes.
- Insert PAXgene™ tubes into the bubble slots and place within the large biohazard bag.
- Place kit number on outside of biohazard bag.



Frozen Shipping Packaging



- Place 2-3 inches of dry ice in the bottom of the Styrofoam shipping container, then insert the cryoboxes laying upright.
- Fully cover the cryoboxes with about 2 inches of dry ice in the provided shipper.
- Each Styrofoam shipper must contain about 45 lbs (20 kg) of dry ice.

Frozen Shipments

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. = 1 kg.

Airwaybills/Airbills must have the following:
1. "Dangerous Goods - Shipper's Declaration not required".
2. Dry Ice: 9; UN1845;
3. _____ x _____ Kg III
(Number pgs.) (wt.)

DRY ICE
kg.

9

UN1845

Shipper's Name and Address

Consignee Name and Address

© 2011 ULINE 1-800-395-5510

Number of packages in shipment and dry ice in kg

Net weight of dry ice in kg

Your name & address

Repository name & address

FedEx Airbill

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

FedEx Account Number

Your name, address & phone

FedEx Priority Overnight must be selected

Dangerous goods info (for dry ice shipments only)

Net weight of dry ice in kg

fedex.com 1.800.GoFedEx 1.800.463.3339

FedEx Express Package US Airbill

Form No. 0200

1 **From** Please print and press hard. Sender's FedEx Account Number: 8132 0902 9416

2 **Your Internal Billing Reference** OPTIONAL

3 **To** Recipient's Name: NCRAD Phone: (800) 526-2839
Company: Indiana Univ school of Med.
Address: 351 West 10th street
City: Indianapolis State: IN ZIP: 46202

4 **Service Selection**

<input type="checkbox"/> FedEx First Overnight	<input type="checkbox"/> FedEx 2Day A.M.
<input checked="" type="checkbox"/> FedEx Priority Overnight	<input type="checkbox"/> FedEx 2Day
<input type="checkbox"/> FedEx Standard Overnight	<input type="checkbox"/> FedEx Express Saver

5 **Packaging** *Declared value limit \$500.

6 **Special Handling and Delivery Signature Options** Fees may apply. See the FedEx Service Guide.

7 **Payment** Bill to: Sender's Acct. No. in Section 1 will be billed. Recipient Third Party Credit Card

Does this shipment contain dangerous goods?

No Yes As per attached Shipper's Declaration Yes Shipper's Declaration not required Dry Ice Dry Ice & UN 1845 20 kg

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

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 and ambient samples.
- Email: alzstudy@iu.edu
- Fax: 317-278-1100



NCRAD

Biological Sample and Shipment Notification Form

Appendix B

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: 317-278-1100 Phone: 1-800-526-2839			
General information:		FedEx tracking #: _____	
From: _____	Date: _____		
Phone: _____	Email: _____		
Study: PSDC PIDN: _____	Kit #: _____		<div style="border: 1px solid black; width: 100%; height: 100%; display: flex; align-items: center; justify-content: center;"> KIT BARCODE </div>
Sex: <input type="checkbox"/> M <input type="checkbox"/> F Year of Birth: _____			
CSF Collected? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Blood Collection:			
1. Date Drawn: _____ [YYYYMMDD]		2. Time of Draw (24 hour clock): _____ [HHMM]	
3. Last date subject ate: _____ [YYYYMMDD]		4. Last time subject ate (24 hour clock): _____ [HHMM]	
5. Sodium Heparin (PBMC) drawn 2 x 10 ml: <input type="checkbox"/> Yes <input type="checkbox"/> No Original volume drawn: _____ ml			
6. Total volume of blood drawn into 3 x 2.5 ml PAXgene RNA tubes: _____ ml - Were the PAXgene tubes the last tubes drawn? Yes <input type="checkbox"/> No <input type="checkbox"/> - Time PAXgene RNA tubes placed in freezer: 24 hour clock: _____ [HHMM]			
Blood Processing:			
Plasma (EDTA/Lavender Top Tube)		Serum (Serum Separator/Red Top Tube)	
• Time spin started (24 hour clock): _____ [HHMM]	• Duration of centrifuge: _____ [minutes]	• Time spin started (24 hour clock) (30 minutes after draw time): _____ [HHMM]	• Duration of centrifuge: _____ [minutes]
• Temp of centrifuge: _____ °C • Rate of centrifuge: _____ x g		• Temp of centrifuge: _____ °C • Rate of centrifuge: _____ x g	
Original volume drawn (3x10 ml EDTA tube): _____ ml	Original volume drawn (1x10 ml Serum tube): _____ ml		
• Time aliquoted: _____ [HHMM]	• Time aliquoted: _____ [HHMM]		
Number of 1.5 ml plasma aliquots created (8-10 total) (lavender cap cryovial): _____ x 1.5 ml	Number of 1.5 ml serum aliquots created (2-4 total) (red cap cryovial): _____ x 1.5 ml		
• If applicable, volume of residual plasma aliquot (less than 1.5 ml) (blue cap cryovial): _____ ml	• If applicable, volume of residual serum aliquot (less than 1.5 ml) (blue cap cryovial): _____ ml		
If applicable, specimen number of residual aliquot (Last four digits): _____	If applicable, specimen number of residual aliquot (Last four digits): _____		
• Time aliquots placed in freezer (24 hour clock): _____ [HHMM]	• Time aliquots placed in freezer (24 hour clock): _____ [HHMM]		
• Storage temperature of freezer: _____ °C	• Storage temperature of freezer: _____ °C		
Buffy coat aliquot created (one per EDTA tube) (Blue cap cryovial): _____ ml			
Notes: _____			

- ❖ Includes expanded blood processing section for both Plasma and Serum
- ❖ Participants should have all aspects of form completed prior to shipping

Biological Sample Notification Form - CSF

Appendix C

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: 317-278-1100 Phone: 1-800-526-2839	
General Information:	
From: _____	Date: _____
Phone: _____	Email: _____
Study: PSDC PIDN: _____	KIT BARCODE
Sex: <input type="checkbox"/> M <input type="checkbox"/> F Year of Birth: _____	
FedEx tracking #: _____	
CSF Collection:	
1. Date of Collection: _____	2. Time of Collection: 24 hour clock: _____ [HHMM]
3. Last date subject ate: _____	4. Last time subject ate: 24 hour clock: _____ [HHMM]
5. Collection process: <input type="checkbox"/> Gravity Method OR <input type="checkbox"/> Aspiration	
CSF Processing:	
Time spin started: 24 hour clock: _____	_____ [HHMM]
Duration of centrifuge: _____	_____ minutes
Temp of centrifuge: _____ °C	Rate of centrifuge: _____ x g
Total amount of CSF collected (ml): _____	_____ ml
Time aliquoted: _____	_____ [HHMM]
Number of 1.5 ml aliquots created (up to 16 total): (Orange cap cryovials): _____	_____ x 1.5 ml
If applicable, volume of CSF residual aliquot (less than 1.5 ml): (Blue cap cryovial): _____	_____ ml
If applicable, specimen number of residual aliquot tube: (Last four digits): _____	_____
Time frozen: _____	_____ [HHMM]
Storage temperature of freezer: _____	_____ °C
Notes: _____	

Redraw/Take Home Sample Form - PBMC

Appendix E

Green Top-Sodium Heparin Redraw/Take Home Sample Form

TO BLOOD DRAWING PERSONNEL

This blood sample is for a study sponsored by the National Institute of Health (NIH). Samples are housed at Indiana University School of Medicine. It will need to be shipped to the address below. Please use the enclosed pre-addressed FedEx Clinical Pak.

**PSDC at NCRAD
Indiana University School of Medicine
351 W. 10th St. TK-342
Indianapolis, IN 46202
Phone: 1-800-526-2839**

The kit provided contains vacutainer tubes with which to obtain blood from the individual for research purposes. Each kit contains 2 green-topped tubes and all necessary shipping supplies.

**DO NOT REFRIGERATE; STORE AT ROOM TEMPERATURE.
DO NOT DRAW OR SHIP ON FRIDAY OR SATURDAY.
PLEASE SHIP SAME DAY AS BLOOD IS DRAWN.**

Instructions for drawing and shipping blood samples:

1. Fill **GREEN TUBES** completely, if possible.
2. Invert (do not shake) tubes eight to ten times after drawing blood to thoroughly mix additive with sample.
3. **Enclose this form in shipment with sample.**
4. Ship samples by **Federal Express** immediately after drawing. Use the enclosed, pre-paid Federal Express mailer. There will be no cost to you or the patient for the shipping. Consult the enclosed information sheet for packing instructions.

KIT NUMBER (RECORDED ON LABEL): _____

PIDN (RECORDED ON LABEL): _____

STUDY SITE ID (RECORDED ON LABEL): _____

DATE BLOOD WAS DRAWN: _____

DONOR YEAR OF BIRTH: _____ **DONOR SEX:** _____

Redraw/Take Home Sample Form - EDTA

Appendix F

Lavender Top-EDTA Redraw/Take Home Sample Form

TO BLOOD DRAWING PERSONNEL

This blood sample is for a study sponsored by the National Institute of Health (NIH). Samples are housed at Indiana University School of Medicine. It will need to be shipped to the address below. Please use the enclosed pre-addressed FedEx Clinical Pak.

**PSDC at NCRAD
Indiana University School of Medicine
351 W. 10th St. TK-342
Indianapolis, IN 46202
Phone: 1-800-526-2839**

The kit provided contains a vacutainer tube with which to obtain blood from the individual for research purposes. Each kit contains 1 lavender-tube and all necessary shipping supplies.

**DO NOT REFRIGERATE; STORE AT ROOM TEMPERATURE.
DO NOT DRAW OR SHIP ON FRIDAY OR SATURDAY.
PLEASE SHIP SAME DAY AS BLOOD IS DRAWN.**

Instructions for drawing and shipping blood samples:

1. Fill **LAVENDER TUBE** completely, if possible.
2. Invert (do not shake) tube eight to ten times after drawing blood to thoroughly mix additive with sample.
3. **Enclose this form in shipment with sample.**
4. Ship samples by **Federal Express** immediately after drawing. Use the enclosed, pre-paid Federal Express mailer. There will be no cost to you or the patient for the shipping. Consult the enclosed information sheet for packing instructions.

KIT NUMBER (RECORDED ON LABEL): _____

PIDN (RECORDED ON LABEL): _____

STUDY SITE ID (RECORDED ON LABEL): _____

DATE BLOOD WAS DRAWN: _____

DONOR YEAR OF BIRTH: _____

DONOR SEX: _____

NCRAD Website

PSDC Study Specific Webpage

https://ncrad.org/resource_psd.html



NCRAD Website

Helpful Pages

- https://ncrad.org/holiday_closures.html
- https://ncrad.org/friday_blood_draws.html



What to do for Friday Blood Draws

NCRAD is not open for business on Saturday or Sunday; therefore, we ask that no samples be shipped on a Friday. We cannot guarantee the conditions in which the samples will be held by the shipping courier over the weekend. It is important to have plans in place for each type of sample to be held over the weekend prior to shipping. Please refer to the table below for how to handle samples drawn on a Friday.

When possible, please only ship frozen samples on Monday-Wednesday. There is always the potential for an unexpected shipping courier delay and by shipping Monday through Wednesday there should be enough time to receive the samples before the weekend.

Sample Type	Tube Type	Product	Shipment Method	Friday Draw Instructions
Whole Blood	Sodium Heparin	PBMC	Ambient	DO NOT DRAW ON FRIDAY. Must be drawn on Monday - Thursday.
Whole Blood	EDTA Tube	DNA Only	Ambient	Do NOT refrigerate. Please keep sample at room temperature until the specimen can be shipped via next day delivery methods the following Monday.



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

Nonconformance Issues

- Sample aliquots and collection tubes frozen at an angle/inverted

Recommendation:
Place aliquots in Argos boxes/tube rack in freezer *upright* until shipment. Store samples for at least 8 hours in freezer.

- Fields left blank on Sample and Shipment Notification Forms
 - Last time subject ate often left blank/unknown
- Incorrect data reported on Sample and Shipment Notification Forms

Recommendation:
Complete Sample Notification forms during the participant study visit as samples are processed.

- Multiple low volume plasma/CSF aliquots

Recommendation:
Lay out cryovials in a row and aliquot in order until plasma/CSF is depleted

Nonconformance Cont.

- All frozen samples for a participant not sent within one shipment box (Paxgene tube, plasma, buffy coat, and serum aliquots should be kept together)
- Aliquots arriving to NCRAD without labels
- Sample forms not faxed or scanned to NCRAD the day before shipment



Recommendation:

Ship Samples to NCRAD utilizing the Notification Form, by RAVE ID. Do not throw away labels until samples are packed and shipped.

- PBMC sample not shipped the day of blood draw



Recommendation:

No samples should be held ambient for any period of time at the site. Ensure all samples are frozen or shipped by end of the day.

Contact Information

- Questions?

Please contact Madeline Potter:

- Phone: 1-317-278-9546
- E-mail: mkpotter@iu.edu

Or

- Study Phone: 1-800-526-2839
- Study E-mail: alzstudy@iu.edu
- Website: www.ncrad.org