

ALLFTD NEW COORDINATOR TRAINING



Training Overview

- Collection Overview
- Kit Requests
- Specimen Labels
- Sample Forms
- Sample Collection and Processing
- Sample Shipping
- NCRAD Website
- Questions?



ALLFTD Study Specimens

	RAVE CYCLE (ALL)
DNA (BUFFY COAT)	X
PLASMA	X
PBMC	X
SERUM	X
RNA	X
CSF*	X

*Select subjects to donate CSF



ALLFTD Kit Request Module

http://kits.iu.edu/allftd

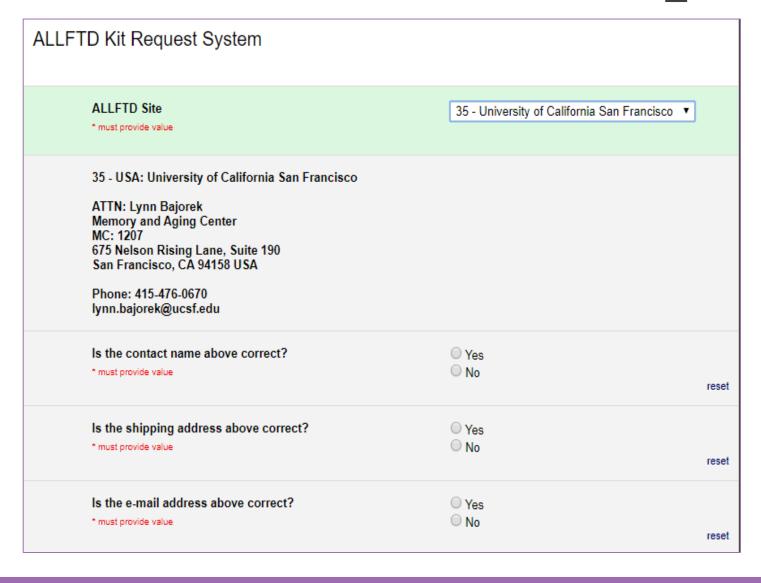


When to Order Kits

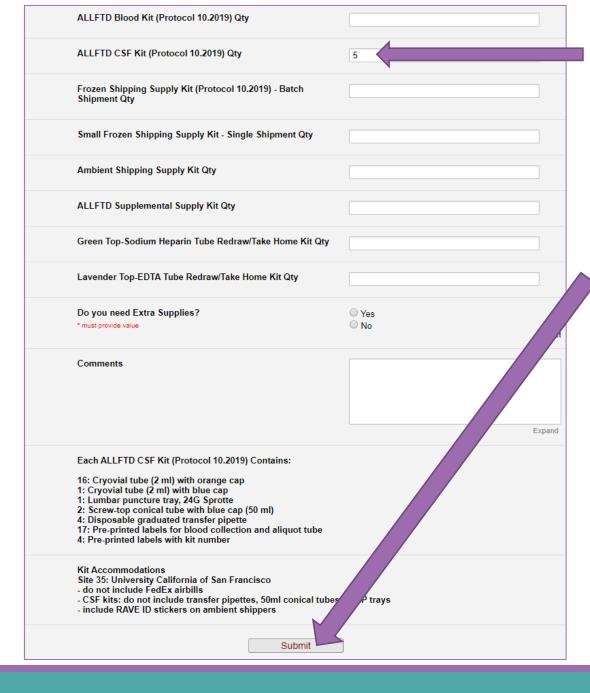
- Each site will be responsible for ordering kits (labels included) and maintaining a supply on site for scheduled participants
- Allow a minimum of 2 weeks for your order to be processed and delivered.



ALLFTD Kit Request Module



- Choose your site from the drop-down list.
- The coordinator name and contact information will appear.
- Verify that this information is accurate, or correct it if necessary.



- 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**

Redraw/Take-Home Kits

Redraw may include:

- EDTA tube, or
- 2 x 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 ALLFTD site by direct payment to physician OR reimbursement to participant



Redraw/Take-Home Kits

DNA REDRAW/TAKE-HOME KIT

(1 EDTA TUBE)



PBMC REDRAW/TAKE-HOME KIT

(2 PBMC TUBES)





Specimen Labels

TYPES OF LABELS
HOW TO LABEL TUBES



Three Label Types

Kit Number

Kit Number



302326

Site and RAVE ID

Site ID: ____

RAVE #:

Collection and Aliquot Tube

0003591409



ALLFTD

PLASMA

Kit #: 302326

0003591410



ALLFTD

BUFFY COAT

Kit #: 302326

0003591415



ALLFTD

PBMC

Kit #: 302326

0003591425



ALLFTD

SERUM

Kit #: 302326

0003591433



RNA

Kit #: 302326



Kit Number Labels

Kit Number



302326

Used to track patient samples and provide quality assurance – Will be placed on the following locations :

- Biological Sample and Shipment Notification Form
- (IF COLLECTED) CSF Sample and Shipment Notification Form*
- Outside of the biohazard bag that houses the PBMC
- Cryobox that houses aliquots during shipping
- 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 RAVE ID Label

Site ID:	
RAVE #:	

- Subjects will be identified by their site ID and RAVE #
- The RAVE # may only be available shortly before the visit
- Sites will be responsible for handwriting this onto the provided labels
 - Must use a fine point marker
 - Write information on label prior to adhering to tube
 - Will be placed on all collection tubes



Collection Tubes - Blood

Label 1: Collection Tube Label

0003591409

ALLFTD

PLASMA

Kit #: 302326

EDTA Tube

0003591425

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SERUM

Kit #: 302326

Serum Tube

0003591415

ALLFTD

PBMC

Kit #: 302326

Sodium Heparin Tube

0003591433

ALLFTD

RNA

Kit #: 302326

PAXgene™ Tube

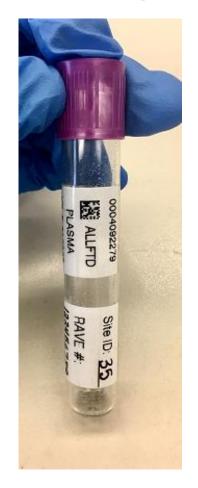
Label 2: Site and RAVE ID Label

Site ID:

RAVE #:



Collection Tubes - Blood



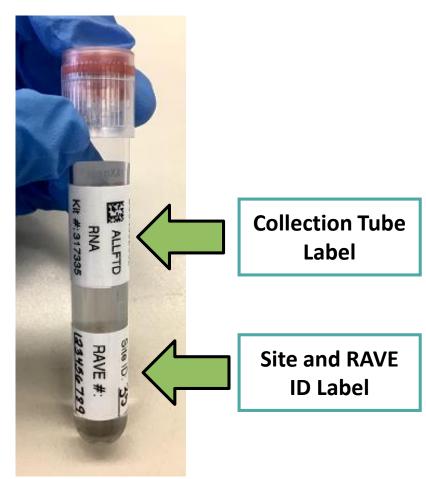




Sodium Heparin Tube



Serum Determination Tube



PAXgene™ Tube



Aliquot Tube Labels

0003591409



ALLFTD

PLASMA

Kit #: 302326

0003591410



ALLFTD

BUFFY COAT

Kit #: 302326

0003591425



ALLFTD

SERUM

Kit #: 302326

0004811357



🗯 ALLFTD

CSF

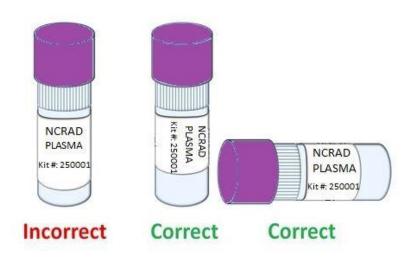
Kit #: 302327

- Only one label to be placed on ALL aliquot tubes
- Plasma
 - From EDTA tube
- Buffy Coat
 - From EDTA tube
- Serum
 - Serum Tube
- CSF
 - (Select Patient Population)
 - Different kit number than blood collection for the same subject at the same visit



Labeling Biologic Samples

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





Aliquot Tube Labels



- Aliquot tube label only
- Please place barcode near cap
- One label per tube



Biological Sample and Shipment Notification Forms

"SAMPLE FORMS"



Appendix B: Blood Sample and Shipment Notification Form

Please email or fax the form on or prior to the date of shipment

To: Kelley Faber Em	To: Kelley Faber Email: alzstudy@iu.edu FAX: 317-321-2003		Ph	one: 1-800-526-2839		
From:	UF	PS tracki	ng #:_			_
Phone:	Email:				Site #:	
Study: ALLFTD Longitudinal Arm	ALLFTD Biofluid-Fo	ocused A	rm 🔲]		
RAVE ID: RAVE Cycle:					KIT BAR	CODE
Sex: MF Year of Birth:			K	(it #:		
Blood Collection:	(All Times Recorded	dusing 2	4 hou	ır clock: HHMM)		
Date of Draw:	, I			[H	ним)	
Date participant last at	e:		Time	e participant last ate:		_
[MMDDYY]			[HH]	MM]		
PBMC (<u>NaHep</u> Tu	bes) 🔲 N/A			RNA (PAX	gene''' Tu	ibes) 🔲 N/A
#1 Specimen No.	Original			Original volum		
(Last four digits):	volume drawn:		ml	(2 x 2.5 ml PAXgene*		ml
#2 Specimen No. (Last four digits):	Original volume drawn:	1	ml	0000040000	tubes e frozen:	[HHMM]
	Storage tempera	ture of f	reeze			
Blood Processing:						
	Plasma & Buffy Coa	t (Laven	der-T	op) Tube (10 mL)		
Time spin started:						_[HHMM]
Duration of centrifugation:				_ Minutes		
Temp of centrifuge: °C Rate Time aliquoted:	of centrifuge:	x g			Т	[HHMM]
Number of 1.5 mL plasma aliquots cre	eated (lavender cap. u	p to 91:			+	_ [111141141]
If applicable, volume of residual plasn			blue o	cap):		mL
If applicable, specimen number of res		last four	digits	5):		
Buffy coat #1 last four digits of specin						
Buffy coat #1 volume: Buffy coat #2 last four digits of specin		Original	blood	d volume drawn:	m	L
		Original	blood	d volume drawn:	m	L
Buffy coat #3 last four digits of specin						
Buffy coat #3 volume:		Original	blood	d volume drawn:	m	L
Time plasma and buffy coat aliquots frozen: [HHMM]						
Time spin started	Serum (Red-	·lop) lui	be (10) mL)	Т	THUMMI
Duration of centrifugation:					 	[HHMM] Minutes
	of centrifuge:	хg				THINGS.
Time aliquoted;						_[HHMM]
Number of 1.5 mL serum aliquots created (red cap, up to 3):				_		
If applicable, volume of residual serur	<u> </u>				 	_
If applicable, specimen number of res	idual serum aliquot (la	ast four (digits)):	 	_ mL
Time serum aliquots frozen: NOTES:					L	_ [HHMM]

Biological Sample and Shipment Notification Form (Blood)

- Includes expanded blood processing section for both plasma and serum
- All aspects of this form must be completed by the study site prior to the samples and sample form being shipped to NCRAD



Appendix C: CSF Sample and Shipment Notification Form

Please email or fax the form on or prior to the date of shipmen

To: Kelley Faber	Email: alzstudy@iu.edu	FAX: 317-		Phone: 1-800-526-2839
From:	UP	S tracking #:		
Phone:	Em	nail:		
Site #:				
Study: ALLFTD Longitudinal A	Arm ALLFTD <u>Biofluid</u> -Foo	used Arm 🔲 📑		
		Kit #:	KIT BAF	RCODE
RAVE ID: RAVE	Cycle:	<u>i</u>		
Sex: MF Year	of Birth:			
CSF Collection:	(All Times Recorde	d using 24 hour cloc	k: HHMM)	
1. Date of Draw:	[MMDDYY]	2. Time of Di	aw:	[HHMM]
3. Date participant last ate:	[MMDDYY]	4. Time parti	cipant last ate:	[HHMM]
Collection Process: Gravi	tational OR Pull			
CSF Processing:				
Time spin started:			[НН	IMM]
Duration of centrifuge:			mir	nutes
Temp of centrifuge: °C	Rate of centrifuge:	x g	1	
Total amount of CSF collect	ed (mL):		mL	
Time aliquoted:			[Н	нмм]
Number of 1.5 mL CSF aliqu (Orange cap cryovials):	ots created (up to 15 total):			
If applicable, volume of resi (Blue cap cryovials):	dual CSF aliquot (less than 1.5 m	L):	mL	
000000000	ber of residual CSF aliquot tube:	:		
Time frozen:			[нн	IMM]
Storage temperature of free	ezer:		°C	
NOTES:				

Biological Sample and Shipment Notification Form (CSF)

- Includes expanded CSF processing section
- All aspects of this form must be completed by the study site prior to the samples and sample form being shipped to NCRAD



Appendix D: 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 UPS Clinical Pak.

ALLFTD at NCRAD Indiana University School of Medicine 351 W. 10° St. TK-217 Indianapolis, IN 46202 Phone: 1-800-526-2839

The kit provided contains collection 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:

- Place refrigerant pack in freezer 24 hours prior to shipment.
- 2. Fill GREEN TUBES completely, if possible.
- 3. Invert (do not shake) tube eight to ten times after drawing blood to thoroughly mix additive with sample.
- Enclose this form in shipment with samples. Place green tubes in biohazard bag and seal, then place bag and gel pack in the Styrofoam container and close.
- Ship samples by UPS immediately after drawing. Use the enclosed, pre-paid UPS mailer. There will be no cost to you or the patient for the shipping.

KIT NUMBER (RECORDED ON LABEL):			
RAVE IDENTIFICATION NUMBER (RECORDED ON LABEL):			
RAVE CYCLE NUMBER:			
STUDY SITE ID (RECORDED ON LABEL):			
DATE BLOOD WAS DRAWN:			
DONOR YEAR OF BIRTH:			
DONOR SEX:			

Redraw/Take-Home Sample Form (PBMC)

- Includes collection and shipping directions for local physician
- All aspects of this form must be completed by the study site prior to the samples and sample form being shipped to NCRAD

Appendix E: 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 UPS Clinical Pak.

ALLFTD at NCRAD Indiana University School of Medicine 351 W. 10th St. TK-217 Indianapolis, IN 46202 Phone: 1-800-526-2839

The kit provided contains a collection 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:

- Place refrigerant pack in freezer 24 hours prior to shipment.
- 2. Fill LAVENDER TUBES completely, if possible.
- 3. Invert (do not shake) tube eight to ten times after drawing blood to thoroughly mix additive with sample.
- Enclose this form in shipment with samples. Place lavender tubes in biohazard bag and seal, then
 place bag and gel pack in the Styrofoam container and close.
- Ship samples by UPS immediately after drawing. Use the enclosed, pre-paid UPS mailer. There will be no cost to you or the patient for the shipping.

KIT NUMBER (RECORDED ON LABEL):		
RAVE IDENTIFICATION NUMBER (RECORDED ON LABEL):		
RAVE CYCLE NUMBER:		
STUDY SITE ID (RECORDED ON LABEL):		
DATE BLOOD WAS DRAWN:		
DONOR YEAR OF BIRTH:		
DONOR SEX:		

Redraw/Take-Home Sample Form (DNA)

- Includes collection and shipping directions for local physician
- All aspects of this form must be completed by the study site prior to the samples and sample form being shipped to NCRAD

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



Handling/Processing Study Specimens

DRAW ORDER
COLLECTION AND ALIQUOTING



Blood Draw Order

	Tube Type	Number of Tubes Drawn	Tube Image
1.	EDTA (Lavender-Top) Tube (10 ml)	х3	to Supple of State of
2.	Sodium Heparin (Green-Top) Tube (10 ml)	x2	CETABOLIS 20-010C E CQ24C A GETA
3.	Serum Determination (Red-Top) Tube (10 ml)	x1	SE SE PROPERTY OF THE PARTY OF
4.	PAXgene™ Tube (2.5 ml)	x2	CONTRACTOR OF THE PROPERTY OF

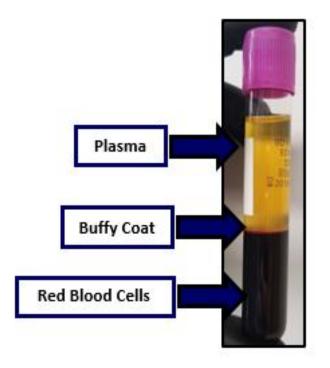


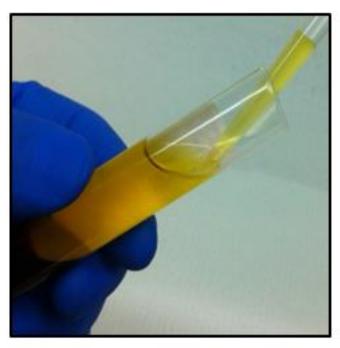
Cryovial Cap Colors

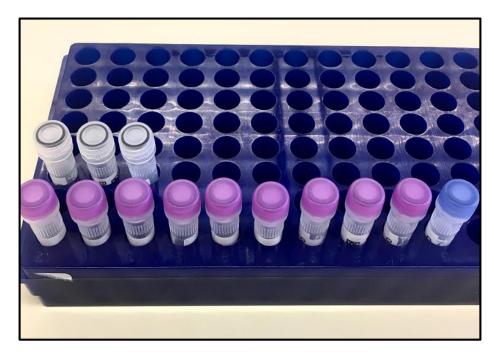
Cap Color	Sample Type	Cap Image
Lavender	Plasma	
Clear	Buffy Coat	
Red	Serum	
Orange	CSF	
Blue	Residual Aliquot (Plasma, Serum, or CSF)	



Plasma Collection



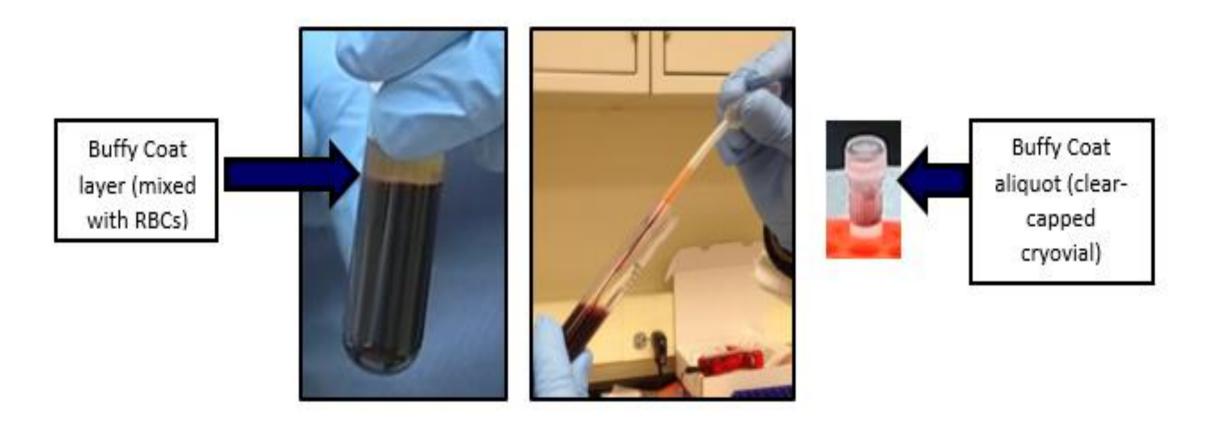




3 EDTA tubes will yield approximately 10 plasma aliquots (with 1 residual in blue cap) and 3 buffy coats



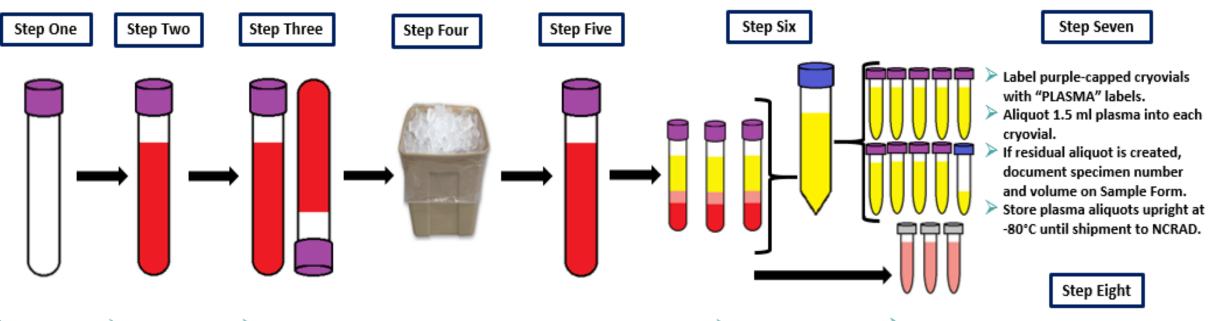
Buffy Coat Collection



Please see the NCRAD tutorial: https://ncrad.org/resource_allftd.html



Plasma and Buffy Coat Preparation



- Store tubes at room temp.
- Each tube should be labeled with Collection Tube and Site and RAVE ID Labels.
- Collect blood Immediately after blood EDTA Tube, draw, invert tubes 8-10 times to mix flow for 10 samples.

into each

allowing

blood to

ensuring

blood flow

has stopped.

seconds and

- Place thoroughly mixed tube on wet ice until centrifugation begins.
- Centrifuge samples at 1500 x g for 15 minutes at 4°C.

- Pool all plasma from the 3 EDTA tubes into a 50 ml conical tube and invert gently 3 times to mix the plasma.
- Label clear-capped cryovials with "BUFFY COAT" labels.
- Using a clean transfer pipette, collect the buffy coat (may have residual plasma and some RBCs included).
- Transfer the buffy coat from each EDTA tube into its own cryovial.
- Store buffy coat aliquots upright at -80°C until shipment to NCRAD.
- Spin, aliquot, and freeze all plasma and buffy coat aliquots within 2 hours of collection.

PBMC Collection

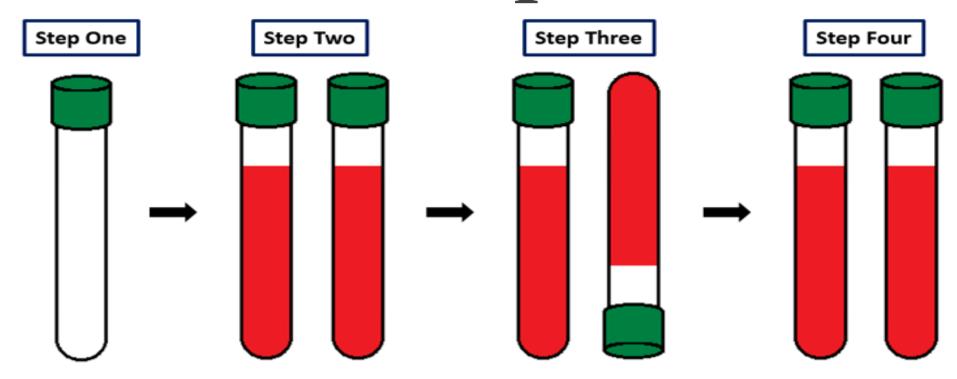


2 x Sodium heparin (green top) BD Vacutainer® (10 ml)

- Not processed at site
- *NOTE*: Must be shipped
 AMBIENT to NCRAD the day
 sample is drawn.
- Only draw and ship Monday through Thursday
- No Friday Draws.



PBMC Preparation



- Store tubes at room temp.
- Label tubes with pre-printed Site and RAVE ID and collection tube labels prior to blood draw.
- Collect blood in Sodium Heparin tubes allowing blood to flow for 10 seconds, and ensuring blood flow has stopped.

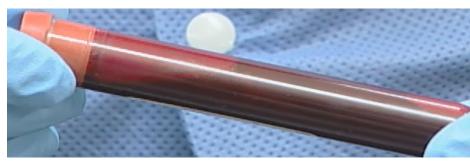
Immediately after blood draw, invert tubes 8-10 times to mix sample.

- Store tubes at room temp. until shipment.
- Ship ambient same day as blood draw.



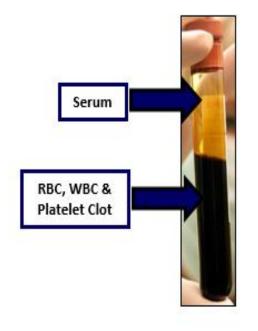
Serum Collection

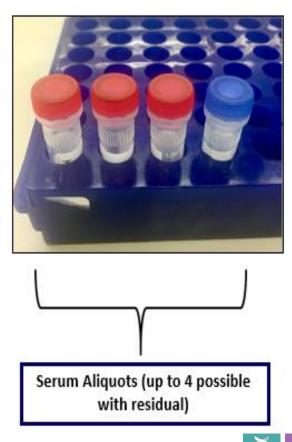




(Immediately after blood draw – pictured above)

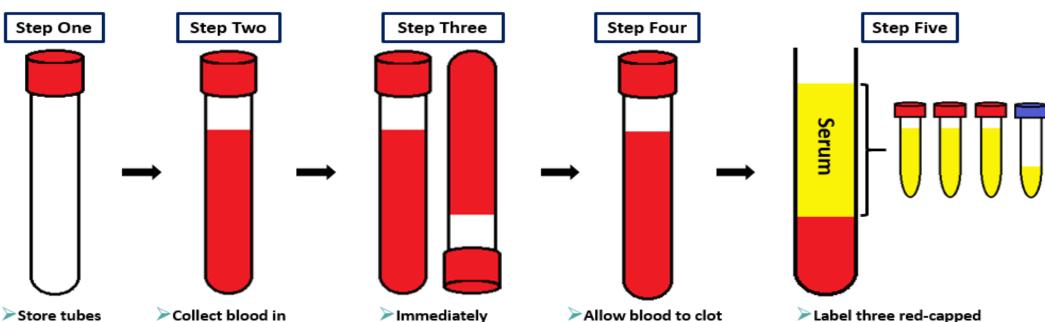
*Please note: After standing at room temperature for 30 minutes, blood will be clotted and immobile**







Serum Preparation



- Store tubes at room temp.
- Each tube should be labeled with Collection Tube and Site and RAVE ID Labels.
- Collect blood in Serum Tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

- Immediately after blood draw, invert tube 8-10 times to mix sample.
- FAllow blood to clot for 30 minutes.
 Within 45 minutes
- of blood draw, centrifuge samples at 1500 x g for 15 minutes at 4°C.

- Label three red-capped cryovials and one blue-capped cryovial with "SERUM" labels.
- Aliquot 1.5 ml into each cryovial. If residual aliquot is created, document specimen number and volume on Sample Form.
- Store serum aliquots upright at -80°C until shipment.
- Spin, aliquot, and freeze aliquots within 2 hours of collection.

RNA Collection

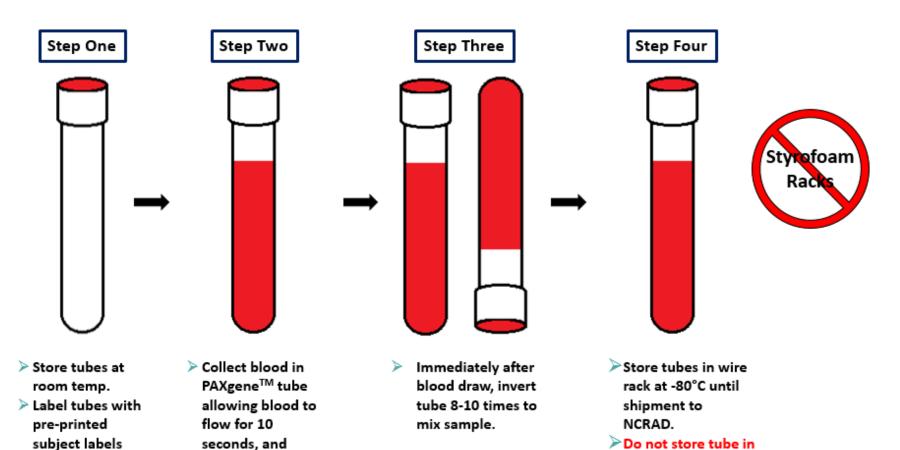
https://www.youtube.com/watch?v=Ir3dFl6oz3U&feature=youtu.be

- Documented within ALLFTD MOP for site staff review
- Released by PreAnalytix





RNA Preparation



Styrofoam racks.

prior to blood

draw.

ensuring blood

flow has stopped.



CSF Collection and Processing

SELECT SUBJECTS ONLY



Pre-Ice CSF Cryovials

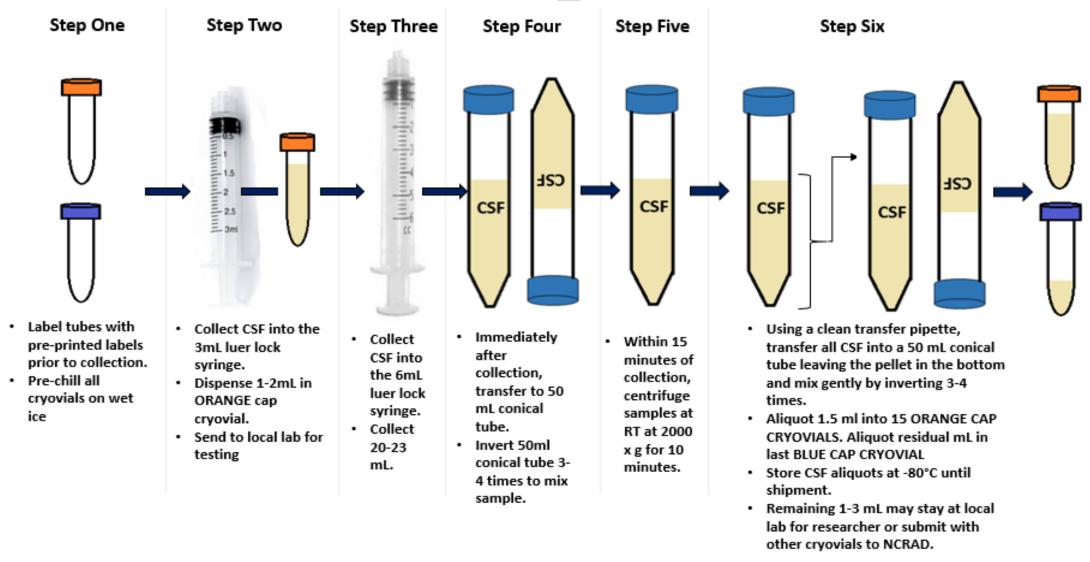


Helpful Tips:

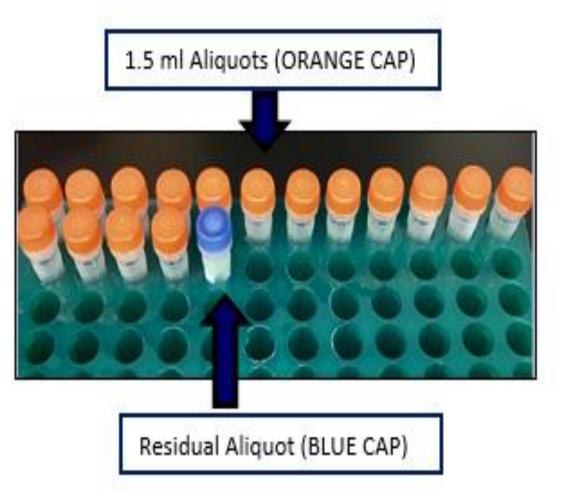
- Keep as organized as possible
- Pre-label prior to adding cryovials in wet ice
- Pre-ice all cryovials included in kit



CSF Preparation



CSF Aliquots



- •Can collect up to 17 aliquots (including the blue-cap residual)
- •Freeze vertically in a cryovial rack or 25-cell cryobox
- •1 extra orange-cap cryovial will be provided without a label. This aliquot will be for local labs
- •Tutorial:

https://ncrad.org/resource_allft d.html



Sample Shipments

HOW TO SHIP SAMPLES BACK TO NCRAD



Ambient Sample Shipment

- Sodium Heparin/PBMC
- Only Monday-Thursday collection and same day shipping. Plan ahead to schedule UPS
- Samples must be received at NCRAD 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

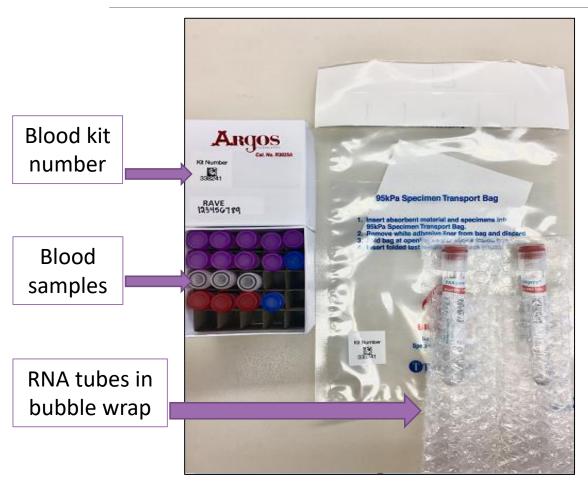


- 1. Place the ambient PBMC tubes in the absorbent slots and biohazard bag.
- 2. Place the kit number label on the outside of the biohazard bag.
- 3. Place the bag inside the small shipping box, and then set the refrigerant pack on top of it.
- 4. Place small shipping box within a provided UPS Clinical Pak, seal, and follow instructions on XXX to create UPS airbill
- 5. Note: Gel packs must be put in freezer at minimum the night before shipping



- All other samples
 - > Plasma, Buffy Coat, Serum, RNA, and CSF
 - ➤ Ship Monday-Wednesday Only
- •Hold packaged samples in a -80°C freezer until pickup.
- Include copy of Biological Sample Shipment and Notification Form







- •Batch shipping should be performed quarterly or when 8 cryoboxes of samples have been collected
 - Example #1: 4 subjects with blood AND CSF collected (8 total cryoboxes for 4 subjects)
 - Example #2: 8 subjects with ONLY blood collected (8 total cryoboxes for 8 subjects)
 - Example #3: 2 subjects with blood AND CSF collected (4 total cryoboxes for 2 subjects) and 4 subjects with ONLY blood collected (4 total cryoboxes for 4 subjects)

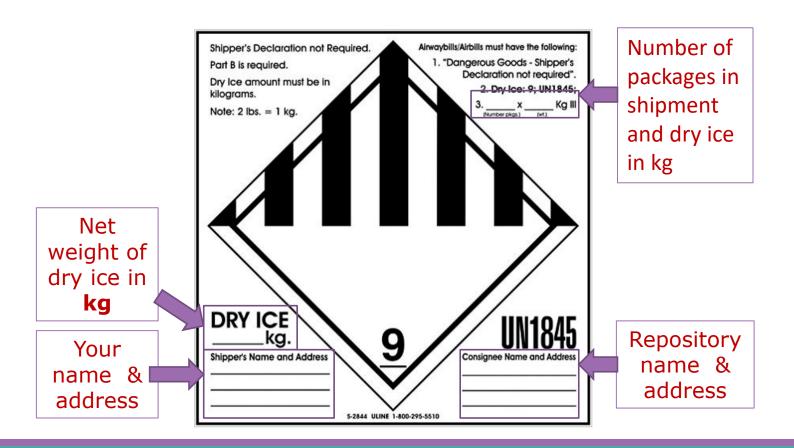
No more than 8 cryoboxes per batch frozen shipment





- •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.

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!





UPS System

- 1. Log into the ShipExec Thin Client at kits.iu.edu/UPS
 - If a new user or contact needs access, please reach out to your study contact for access
- 2. Follow instructions on section 8.3 of ALLFTD Manual of Procedures to create your return airbill and schedule a UPS pickup



NCRAD Website – ALLFTD Page

- Specimen collection overview
- Link to kit request module
- Sample forms
- MOP
- Training Slides

https://ncrad.iu.edu/resource_allftd.html



NCRAD Website – Helpful Pages



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.



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

https://ncrad.org/holiday_closures.html https://ncrad.org/friday blood draws.html



ALLFTD Contact Information

General Information

• Phone: 1-800-526-2839

• E-mail: <u>alzstudy@iu.edu</u>



Justin Delay – ALLFTD Study Coordinator

E-mail: jndelay@iu.edu

<u>Ariel Quickery – Specialist (Kits)</u>

E-mail: <u>aquicker@iu.edu</u>

Erica Lindsey – Specialist (Data)

E-mail: <u>lindsey2@iu.edu</u>

