

Longitudinal Early-onset Alzheimer's Disease Study

in collaboration with

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

Biofluids Collection Training Slides



National Centralized Repository for Alzheimer's Disease and Related Dementias

Contact Information

Questions?

Please contact NCRAD Coordinators at:

• Phone: 1-800-526-2839 or 317-274-7546

• E-mail: alzstudy@iu.edu or agericks@iu.edu

Website: www.ncrad.org



Training Overview:

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



Biofluids Collection Schedule Overview

	CI Baseline	CN Baseline	CI Month 12	CN Month 12*	CI Month 24	CN Month 24	CI Month 36	CI Month 48 /Annual visit
Serum	X	X	Χ	X	X	X	X	X
Plasma	X	Χ	X	X	X	X	X	X
DNA	X	X	X	X	X	X	X	X
Whole blood for	X							
CLIA lab testing								
Whole blood for			Collect	ted only on	ce over the	e entire cou	rse of a part	cicipant's
long read	X	X	participation in the LEADS Study.					
sequencing			May be collected at longitudinal visits if not collected at Baseline				at Baseline	
RNA	X	Χ	Χ	X	X	Χ	X	X
PBMC	X	X	Χ	X	X	X	X	X
CSF	Χ	X	X		X	X	X	

^{*}CN M12 CSF may be collected if CSF was not collected at Baseline.



Biofluids Collection Schedule for CI Participants:

Sample Type	Tube Type	Number of Tubes Supplied in Kit	Aliquot Volume	Tubes to NCRAD	Ship
Whole blood for isolation of	Plain Red-Top Serum Blood Collection Tube (10 ml)	1	N/A	N/A	N/A
serum	SERUM: 2.0 ml cryovials with red cap (residual volume placed in 2.0 ml cryovial with blue cap)	4	1.5 ml serum aliquot per 2.0 ml cryovial (red cap)	Up to 4	Frozen
	EDTA (Lavender-Top) Blood Collection Tube (10 ml)	3	N/A	N/A	N/A
Whole blood for isolation of plasma & buffy coat (for DNA extraction)	PLASMA: 2.0 ml cryovials with lavender cap (residual volume placed in 2.0 ml cryovial with blue cap)	10	1.5 ml plasma aliquot per 2.0 ml cryovial (lavender cap)	Up to 10	Frozen
	BUFFY COAT: 2.0 ml cryovial	3	1 ml buffy coat aliquot per 2.0 ml cryovial (clear cap)	3	Frozen
Whole blood for testing at the CLIA laboratory (*collected at BASELINE ONLY)	EDTA (Lavender-Top) Blood Collection tube (6ml)	1	N/A	1	Frozen
Whole blood for long read sequencing (*collected only once)	EDTA (Lavender-Top) Blood Collection tube (3ml)	1	1 ml whole blood aliquot per 2.0 ml cryovial (green cap)	3	Frozen
Whole blood for RNA extraction	PAXgene [™] Blood Collection Tube (2.5 ml)	1	N/A	1	Frozen
Whole blood for PBMC	Sodium Heparin (Green-Top) Blood Collection tube (10 ml)	2	N/A	2	Ambient
CSF Collection (*not collected at 48-Month/Annual visit)	Sterile Container	Conical tubes, 15 cryovial tubes (13 orange cap, 1 blue cap, 1 yellow cap)	1.5 ml CSF aliquots per 2.0 ml cryovial (orange cap); residual volume placed in 2.0 ml cryovial with blue cap; 1-2 ml for local lab placed in 2.0 ml cryovial with vellow cap.	Up to 14	Frozen

Biofluids Collection Schedule for CN Participants:

				-	
Sample Type	Tube Type	Number of Tubes Supplied in Kit	Aliquot Volume	Tubes to NCRAD	Ship
	Plain Red-Top Serum Blood Collection Tube (10 ml)	1	N/A	N/A	N/A
Whole blood for isolation of serum	SERUM: 2.0 ml cryovials with red cap (residual volume placed in 2.0 ml cryovial with blue cap)	4	1.5 ml serum aliquot per 2.0 ml cryovial (red cap)	Up to 4	Frozen
	EDTA (Lavender-Top) Blood Collection Tube (10 ml)	3	N/A	N/A	N/A
Whole blood for isolation of plasma & buffy coat (for DNA extraction)	PLASMA: 2.0 ml cryovials with lavender cap (residual volume placed in 2.0 ml cryovial with blue cap)	10	1.5 ml plasma aliquot per 2.0 ml cryovial (lavender cap)	Up to 10	Frozen
	BUFFY COAT: 2.0 ml cryovial	3	1 ml buffy coat aliquot per 2.0 ml cryovial (clear cap)	3	Frozen
Whole blood for long read sequencing (*collected only once)	EDTA (Lavender-Top) Blood Collection tube (3ml)	1	1 ml whole blood aliquot per 2.0 ml cryovial (green cap)	3	Frozen
Whole blood for RNA extraction	PAXgene [™] Blood Collection Tube (2.5 ml)	1	N/A	1	Frozen
Whole blood for PBMC	Sodium Heparin (Green-Top) Blood Collection tube (10 ml)	2	N/A	2	Ambient
CSF Collection (*collected at BL and M24, may be collected at M12 if CSF was not collected at BL)	Sterile Containers (cryovial with yellow cap)	Conical tubes, 15 cryovial tubes (13 orange cap, 1 blue cap, 1 yellow cap)	1.5 ml CSF aliquots per 2.0 ml cryovial (orange cap); residual volume placed in 2.0 ml cryovial with blue cap; 1-2 ml for local lab placed in 2.0 ml cryovial	Up to 14	Frozen

with yellow cap.

Kit Request Module

http://kits.iu.edu/leads



National Centralized Repository for Alzheimer's Disease and Related Dementias

Kit Request Module

- An initial stock of kits will be delivered prior to the designated site-specific start date.
- Kits and individual supplies are available to order:
 - Blood Kit: CI Baseline (BL)
 - Blood Kit: Cl Month 12 Month 72
 - Blood Kit: CN Baseline Month 72
 - Blood Kit: Long Read Sequencing (LRS)
 - Blood Kit: Supplemental (rarely needed)
 - CSF Kit: CI BL M72 & CN BL M72
 - CSF Kit: Supplemental (rarely needed)
 - LP Kit: 22G
 - LP Kit: 24G
 - Shipping Kit: Frozen Shipping
 - Shipping Kit: Ambient Blood
 - Shipping Kit: CSF (rarely needed)



Blood Kit: CI Baseline (BL)

Kit comes with the supplies necessary for the collection and processing of:

- Whole blood for isolation of serum
- Whole blood for isolation of plasma and buffy coat
- Whole blood for CLIA genetic testing
- Whole blood for isolation of RNA
- Whole blood for isolation of PBMC



Blood Kit: CI M12 - M70 & CN BL - M70

Kit comes with the supplies necessary for the collection and processing of:

- Whole blood for isolation of serum
- Whole blood for isolation of plasma and buffy coat
- Whole blood for isolation of RNA
- Whole blood for isolation of PBMC



Blood Kit: Long Read Sequencing (LRS)

Kit comes with the supplies necessary for the collection and processing of:

Whole blood for Long Read Sequencing



CSF Kit: CI BL – M70 & CN BL – M70

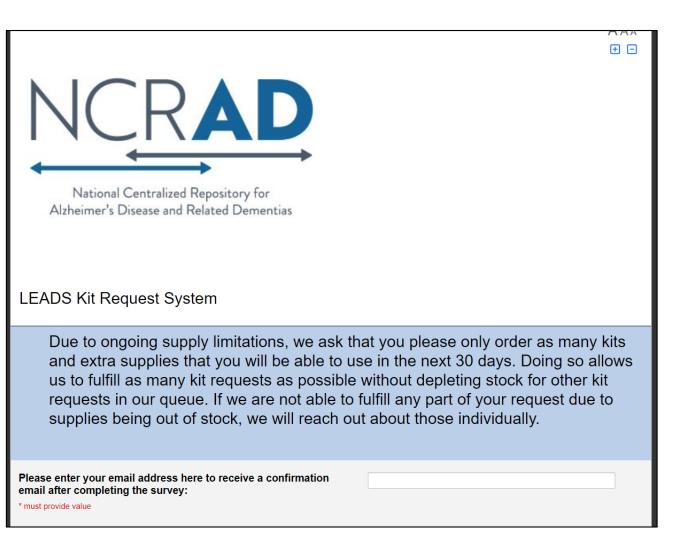
Kit comes with the supplies necessary for the collection and processing of:

Cerebral Spinal Fluid (CSF)



NCRAD Kit Request Module

- 1. Reminder: only order kits/supplies that will be used within 30 days of receipt.
- 1. Enter your email address this is how you will receive updates about your order.





Kit Request Module

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

LEADS Site	Northwestern University	
* must provide value		
067: Northwestern University		
Cognitive Neurology and Alzheimer's Disease Center (CNADC)		
Northwestern University		
Feinberg School of Medicine		
% Kristine Lipowski 320 East Superior Street, Searle 12-541		
Chicago, IL 60611		
Phone: 312-503-2486		
k-lipowski@northwestern.edu		
Is the contact name above correct?	○ Yes	
* must provide value	O No	
	No	
Is the shipping address above correct?	O Yes	
* must provide value	○ No	
	- NO	
Is the e-mail address above correct?		
	O Yes	
* must provide value	○ No	



CI Baseline Blood-Based Kit Qty	1
CI M12 Blood-Based Kit Qty	
CI M24 Blood-Based Kit Qty	
CI M36 Blood-Based Kit Qty	
CI M48 Blood-Based Kit Qty	
CI M60 Blood-Based Kit Qty	
CN Baseline Blood-Based Kit Qty	
CN M12 Blood-Based Kit Qty	
CN M24 Blood-Based Kit Qty	
Long Read Sequencing Blood-Based Kit Qty	
LEADS Blood Supplemental Supply Kit Qty (usually need 1 at start-up)	
LEADS <u>Large</u> Frozen Blood Shipping Supply Kit Qty (will fit samples from 5 subjects)	
LEADS <u>Small</u> Frozen Blood Shipping Supply Kit Qty (will fit samples from 2 subjects)	
LEADS Ambient Shipping Supply Kit Qty (need 1 per subject)	
LEADS 22G LP Kit Qty	
LEADS 24G LP Kit Qty	
LEADS CSF Kit Qty (please provide arm and visit for each CSF kit in the "Comments" section)	
LEADS CSF Supplemental Supply Kit Qty (usually need 1 at start- up)	
LEADS CSF Shipping Supply Kit Qty (only needed when planning on shipping CSF separate from blood - rarely needed)	

Study Visit Kits

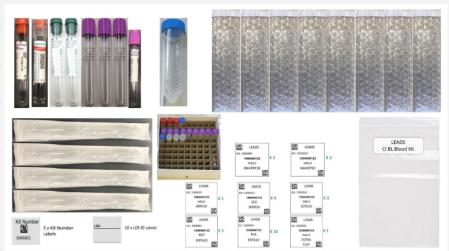
- Indicate the quantity needed of each kit
- Once selected, kit components of the chosen kit will appear at the bottom of the screen (Pictured)

Each CI (EOAD) Baseline Blood-Based Kit Contains:

Finale IU Site: 11194

Finale All Other Sites: 11188

- 1 PAXgene™ Blood Collection Tube (2.5 ml) CT004
- 1 Plain Red Top Serum (Red-Top) Blood Collection Tube (10 ml) CT006
- 2 Sodium Heparin (Green-Top) Blood Collection Tube (10 ml) CT008
- 3 EDTA (Lavender-Top) Blood Collection Tube (10 ml) CT001
- 1 EDTA (Lavender-Top) Blood Collection Tube (6 ml) CT003
- 9 Cryovial tube (2.0 ml) with LAVENDAR cap CV027
- 3 Cryovial tube (2.0 ml) with RED cap CV028
- 2 Cryovial tube (2.0 ml) with BLUE cap CV034
- 3 Cryovial tube (2.0 ml) with CLEAR cap CV014
- · 4 Disposable graduated transfer pipette (3 ml) CV015
- 1 50ml conical (Unwrapped) CV0198
- 7 Bubble wrap tube sleeve SH032 (Note to sites: Reuse 3 for frozen blood tubes for shipping)
- 1 81-cell cryobox CV021
- 1 Resealable bag ST002
- <u>Labels</u>:
 - 25 Pre-printed Collection and Aliquot Tube Label (1 x WBLD SERR10, 4 x SER SERR10, 3 x WBLD EDTA10, 3 x BUF EDTA10, 10 x PLA EDTA10, 1 x WBLD EDTA6, 1 x WBLD RNAPXT10, & 2 x WBLD NAHEP10) - LB003
 - 5 Pre-printed Kit Number Label LB003
 - 10 Labels for handwritten Site and LEADS ID LB003



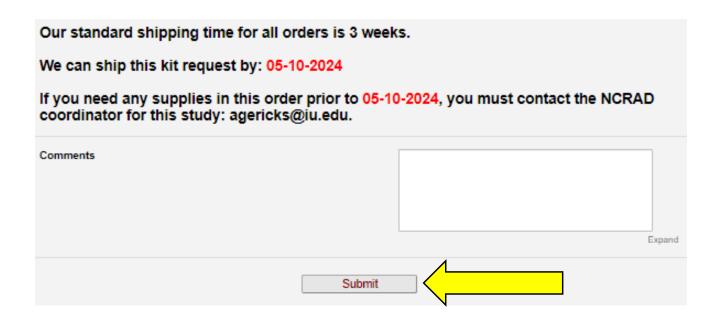
Do you need Extra Supplies? *must provide value	⊚Yes ○ No
25 cell Cryobox (CV005)	○5 ○10
81 cell Cryobox (CV021)	○ 5 ○ 10
Cryovial tubes (2.0 ml) with lavender cap (CV027)	○ 10 ○ 25
Cryovial tubes (2.0 ml) with red cap (CV028)	○ 10 ○ 25
Cryovial tubes (2.0 ml) with orange cap (CV017 & CV018)	○ 25 ○ 50
Cryovial tubes (2.0 ml) with clear cap (CV014)	○ 5 ○ 10
Cryovial tubes (2.0 ml) with yellow cap (CV037)	○ 5 ○ 10
Cryovial tubes (2.0 ml) with blue cap (CV034)	○ 10 ○ 25
UPS Laboratory Paks (SH053)	○ 5 ○ 10
UN3373 labels (LB008)	○ 5 ○ 10
Biohazard label (LB009)	05

Study Visit Kits

1. Indicate if you need extra individual supplies. Selecting "yes" will cause a list of supplies to appear, and you can select which item(s) you need.



Study Visit Kits



- 1. The module automatically calculates the date in 3 weeks. This is when you can expect your kit to ship by.
- 2. Click Submit.



Hints When Ordering Kits...

- For a visit where you will draw CSF, you will need an LP tray in addition to CSF kit.
- You will need 1 ambient shipping kit per blood kit.
- You will need 1 frozen shipping kit per every 4-5 subjects.
- Upon site start up, you should order 1 CSF Supplemental and Blood Supplemental kit.



NCRAD Kit Request Module: When It Must be Used

- Each site will be responsible for ordering kits (labels included) and maintaining supplies on site for scheduled participants.
- To order, sites will use the Indiana University online kit ordering module: https://kits.iu.edu/leads
- Allow a minimum of 3 weeks for your order to be processed and delivered.



Specimen Labels



National Centralized Repository for Alzheimer's Disease and Related Dementias

Label Type Summary

- Kit Number Labels
- 2. Site and LEADS ID Labels
- 3. Collection and Aliquot Tube Labels
 - Differ by specimen type



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. Sample and Shipment Notification Form: Blood & CSF (where applicable)
 - CSF samples will have a different kit number than the blood collection specimens
 - 2. Outside cryobox that houses aliquot tubes during storage and shipment
 - 3. Outside of the biohazard bag that houses collection tubes during ambient shipment
- Kits will include extra kit labels that should be thrown away if not used



Site and LEADS ID Label

LDS:

- Subjects will be identified by their site ID and LEADS ID
- The LEADS ID may only be available shortly before the visit
- Sites will be responsible for handwriting this onto the provided labels
 - Must use fine point permanent marker



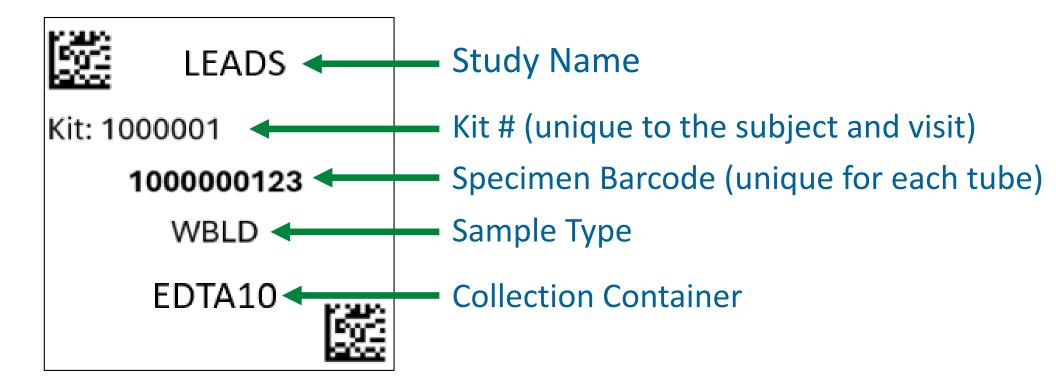
Site and LEADS ID Label Cont.

LDS:

- Write information on label prior to adhering to tube
- Label will be placed on all collection tubes:
 - PAXgene™ Blood Collection Tube (2.5ml) for RNA
 - Plain Red Top Serum Blood Collection Tube (10ml) for Serum
 - Sodium Heparin (Green-Top) Blood Collection Tube (10ml) x 2
 - EDTA (Lavender-Top) Blood Collection Tube (10ml) for DNA and Plasma x 3
 - EDTA (Lavender-Top) Blood Collection Tube (6 ml) for CLIA lab testing **Cl Baseline ONLY**
 - EDTA (Lavender-Top) Blood Collection Tube (3ml) for LRS**collected only once**
- Kits will include extra label



Collection and Aliquot Tube Labels



Labels to be placed on ALL collection and aliquot tubes



Collection and Aliquot Tube Labels

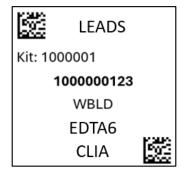


















Every combination of Sample
Type and Collection Tube that
you may encounter



Collection Tube lines to determine what tube / cryovial the label should be placed on

Specimen Type & Collection Tube Guide

SPECIMEN TYPE ABBREVIATIONS

WBLD - Whole Blood

SER - Serum

PLA - Plasma

BUF - Buffy Coat

CSF - Cerebrospinal Fluid

COLLECTION TUBE ABBREVIATIONS

SERR10 10mL Serum Red-Top Tube

EDTA10 10mL EDTA Lavender-Top Tube

EDTA6 6mL EDTA Lavender-Top Tube

EDDTA3 3mL EDTA Lavender-Top Tube

RNAPXT10 10mL RNA PAXGene[™] Tube

NAHEP10 10mL Sodium Heparin (NaHep) PBMC Tube

STERCNT Sterile Container (for CSF)



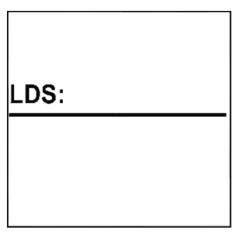
Specimen Labels: Blood Collection Tubes

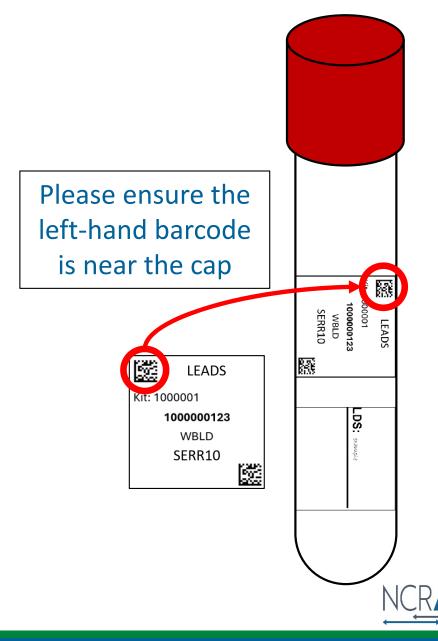
- All Serum, EDTA, and PAXGene™ collection tubes will have two labels:
 - Label 1: Collection Tube Label
 - Label 2: LEADS ID Label

Label 1:

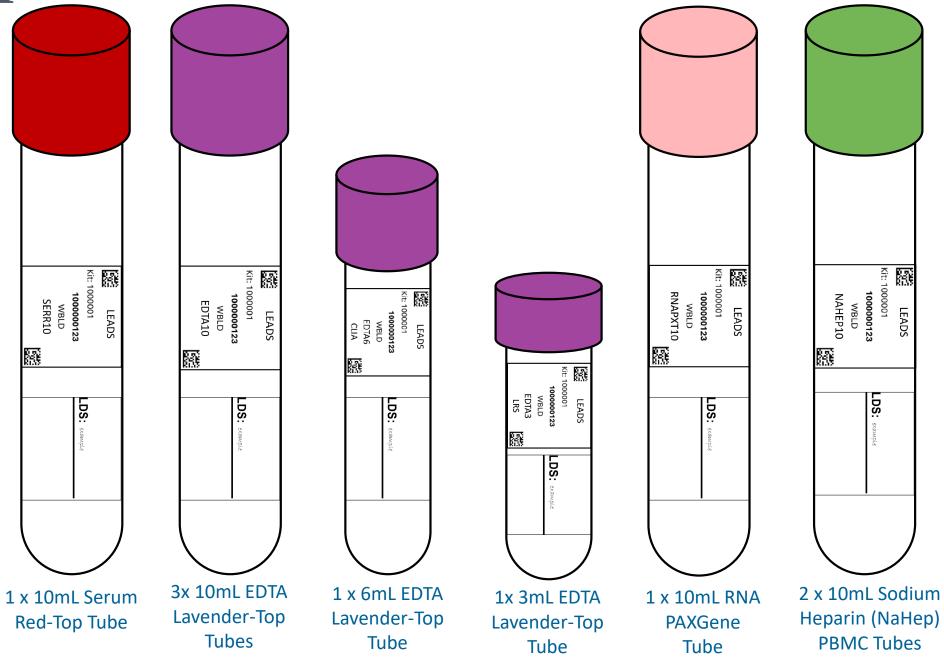


Label 2:



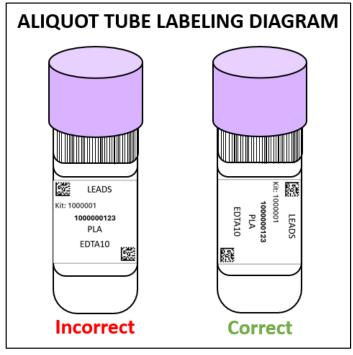


Specimen Labels: Blood Collection Tubes



Specimen Labels: Aliquot Tubes





Cap Color	Sample Type	
Red Cap	Serum	
Lavender Cap	Plasma	
Clear Cap	Buffy Coat	
Green Cap	Whole blood	
Blue Cap	Residual (plasma, serum,	
	whole blood or CSF)	
Orange Cap	CSF	
Yellow Cap	CSF for local lab	

- Aliquot Tubes: 2ml cryovials
 - Serum, Plasma, Buffy Coat, Whole Blood, and CSF
- Collection and Aliquot tube label only
- Place left-hand barcode near cap

Labeling Biologic Samples

Please...

- 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 <u>horizontally</u>. Label position is important for <u>all</u> 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

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



Blood 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. Collection of biomarkers and CSF should be collected after a minimum 6-hour fast, preferably in the morning. 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 (10 ml) for Serum
- 2. EDTA (Lavender-Top) Blood Collection Tube (10 ml) for DNA and Plasma x 3
- 3. EDTA (Lavender-Top) Blood Collection Tube (6 ml) for CLIA lab testing **CI Baseline ONLY**
- 4. EDTA (Lavender-Top) Blood Collection Tube (3 ml) for LRS **only collected once per participant**
- 5. PAXgene™ Blood Collection Tube (2.5 ml) for RNA
- 6. Sodium Heparin (Green-Top) Blood Collection Tube (10 ml) x 2

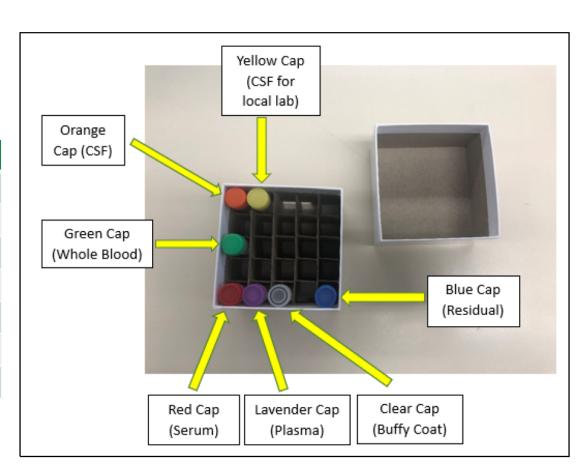


Sample Collection - Blood

Tube Type	Number of Tubes Drawn	Tube Image
1. Plain Red-Top Serum Blood Collection Tube (10 ml) for Serum	x1	THE RESIDENCE AND ADDRESS OF THE PARTY OF TH
2. EDTA (Lavender-Top) Blood Collection Tube (10 ml) for Plasma	X3	105.11 569 (.27 3768.8 (724) VI 8 19996 (1
3. EDTA (Lavender-Top) Blood Collection Tube (6ml) for CLIA lab testing **CI Baseline ONLY**	x1	ENGINEER WITH A LINE OF THE PARTY OF THE PAR
4. EDTA (Lavender-Top) Blood Collection Tube (3ml) for LRS **only collected once per participant**	X1	A COLUMN CASA CASA CASA CASA CASA CASA CASA CAS
1. PAXgene™ Blood Collection Tube (2.5 ml) for RNA	x1	
3. Sodium Heparin (Green-Top) Blood Collection Tube (10 ml) for PBMC	x2	CELLIBRITA 20-6105 © CORPETA (SECURITARIA) AND NO MORNAL WINESS OF SECURITARIA (SECURITARIA) AND NO MORNAL

Aliquot Cap Colors

Cap Color	Sample Type
Red Cap	Serum
Lavender Cap	Plasma
Clear Cap	Buffy Coat
Green Cap	Whole Blood (LRS)
Blue Cap	Residual
Orange Cap	CSF
Yellow Cap	CSF for local lab





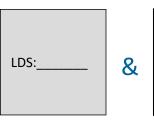
Serum Preparation (10ml Red Top Tube)

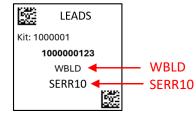
Prior to blood draw, label all tubes:

1 x 10mL Serum Tube



Label with:

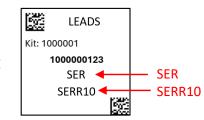




3 x 2ml Red Cap Cryovials & 1 x 2ml Blue Cap Cryovial

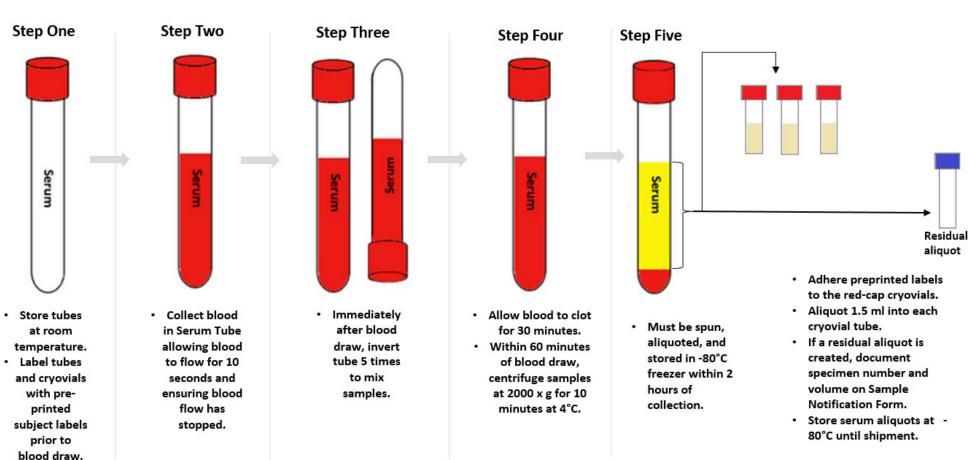


Label with:

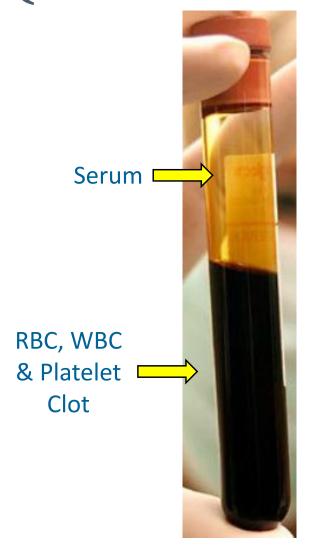


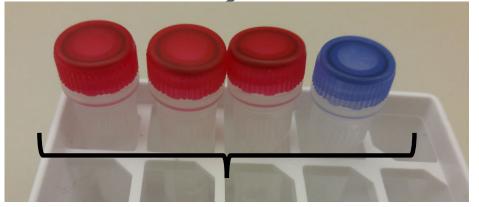
Serum Preparation (10ml Red Top Tube)





Plain Red-Top Serum Tube (Serum Collection)





Serum Aliquots (up to 4 possible)



Close up view of 2.0 ml cryovial



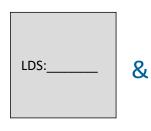
Plasma and Buffy Coat Preparation (10ml Lavender-Top Tube x 3)

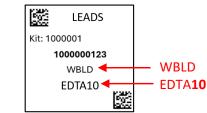
Prior to blood draw, label all tubes:

3 x 10mL EDTA Tubes



Label with:

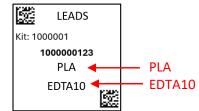




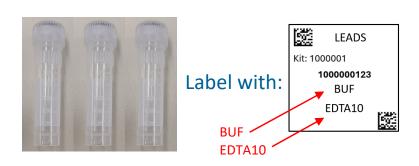
9 x 2ml Purple Cap Cryovials & 1 x 2ml Blue Cap Cryovial



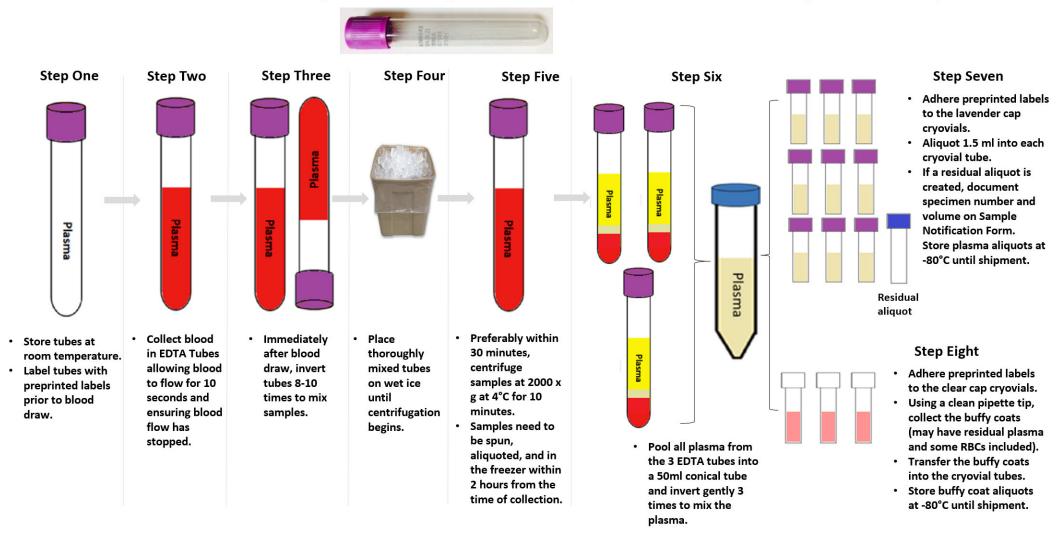
Label with:



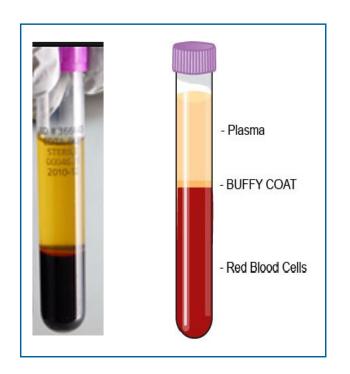
3 x 2ml Clear Cap Cryovials

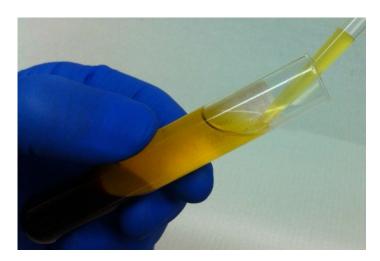


Plasma and Buffy Coat Preparation (10ml Lavender-Top Tube x 3)



EDTA Tube (Plasma Collection)







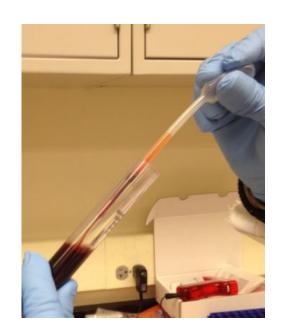
Plasma Aliquots (10 possible)





EDTA Tube (Buffy Coat Collection)







Buffy Coat Aliquot (Please use CLEAR CAP cryovial)

Important Note:

Buffy Coat aliquots will be distinguished from the plasma aliquots through a clear cap.



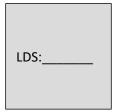
Whole Blood Preparation (6 mL Lavender-Top Tube)

Prior to blood draw, label all tubes:

1 x 6mL EDTA Tube



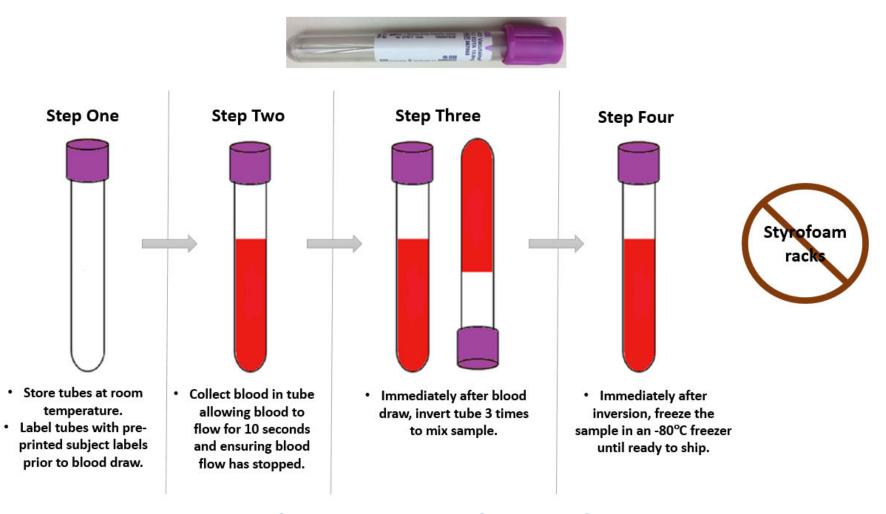
Label with:



Kit: 1000001



Whole Blood Preparation (6 mL Lavender-Top Tube)

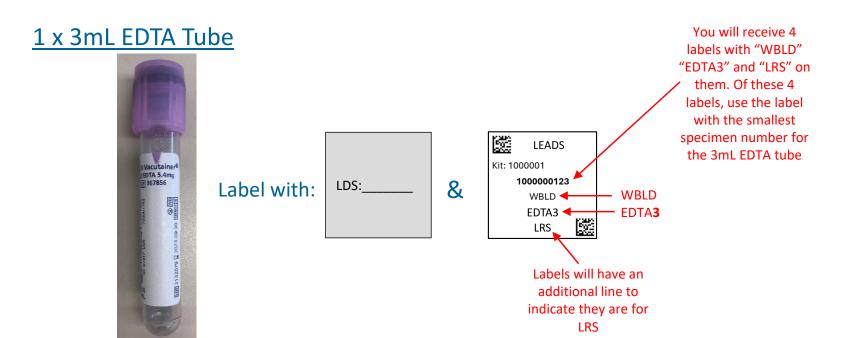


CI Subjects at Baseline Only



Whole Blood Collection (1 x 3ml EDTA Purple Top Tube)

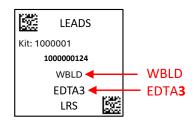
Prior to blood draw, label all tubes:



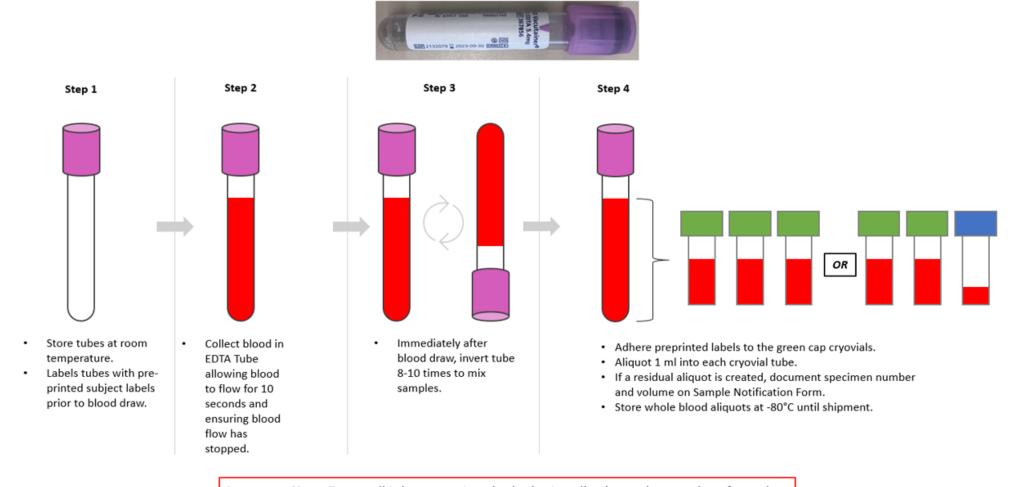
3 x 2ml Green Cap Cryovials & 1 x 2ml Blue Cap Cryovial



Label with:



Whole Blood Collection (1 x 3ml EDTA Purple Top Tube)



Important Note: Ensure all tubes are not expired prior to collection and processing of samples.



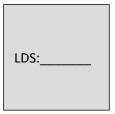
RNA Preparation (2.5ml PAXgene™ Tube)

Prior to blood draw, label all tubes:

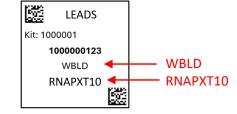
1 x RNA PAXGeneTM Tube



Label with:

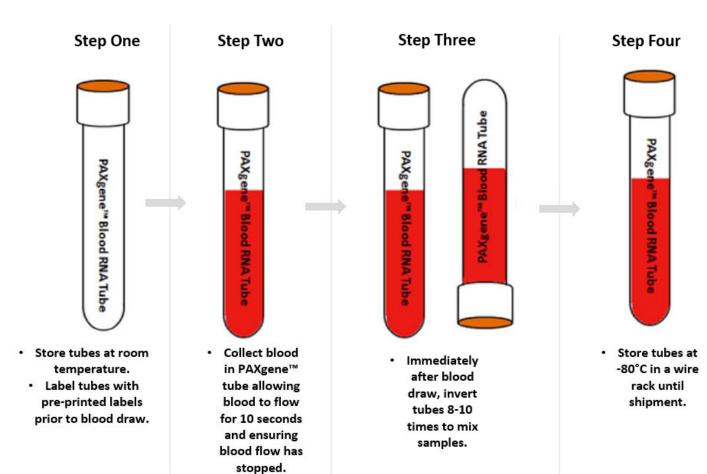


&



RNA Preparation (2.5ml PAXgene™ Tube)









PBMC Preparation (10ml Sodium Heparin Tube) x 2

Prior to blood draw, label all tubes:

2 x 10mL Sodium Heparin (NaHep) PBMC Tubes

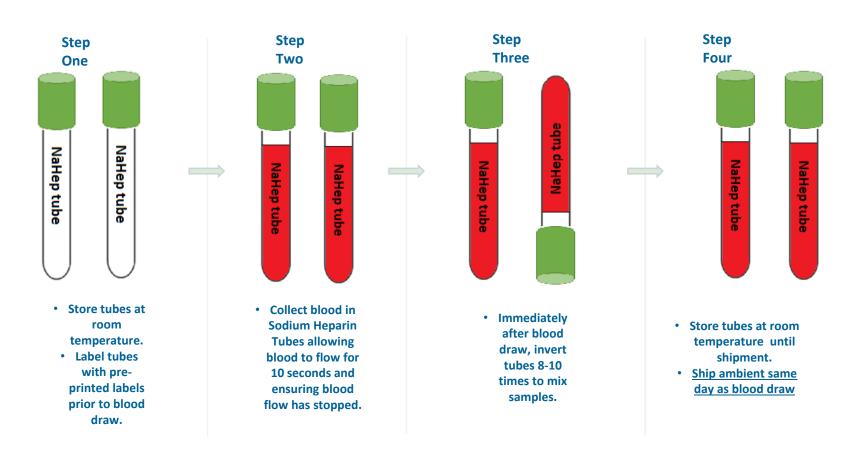


Label with:



PBMC Preparation (10ml Sodium Heparin Tube) x 2



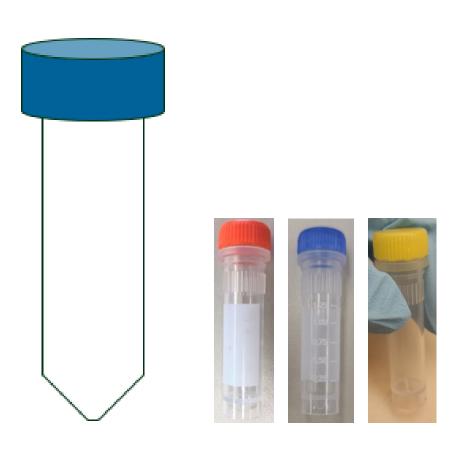


CSF Collection and Processing



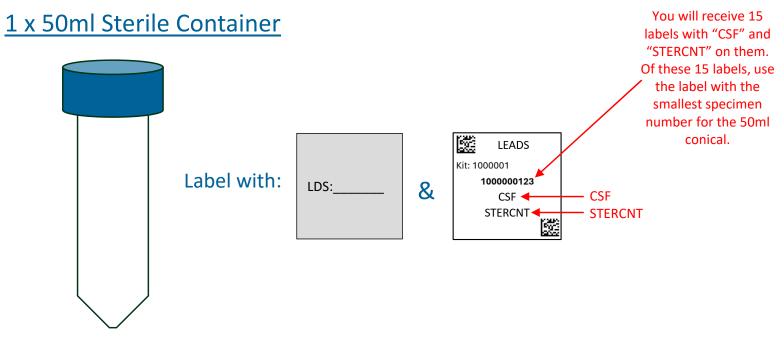
Important Note

CSF samples should be collected in the morning before breakfast and after an overnight fast. Collection of biomarker fluids and CSF should be collected after a minimum 6-hour fast. Only water is permitted until blood draws and the lumbar puncture are completed. Please remember to record "Last time eaten" on CSF Biological Sample and Shipment Notification Form.



CSF

Prior to blood draw, label all tubes:

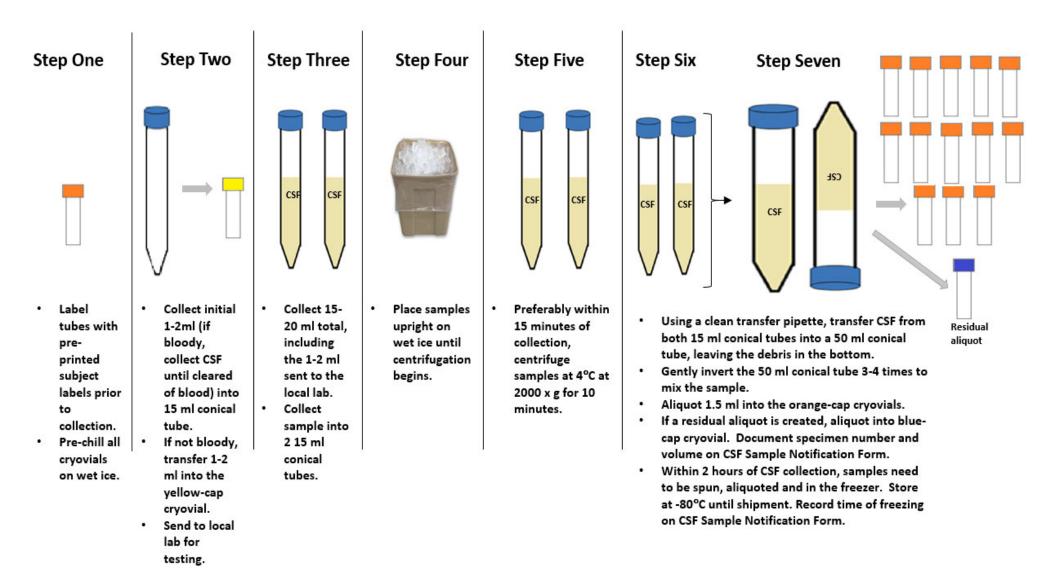


13 x 2ml Orange Cap Cryovials & 1 x 2ml Blue Cap Cryovial



*NCRAD does not provide a label for the yellow cap cryovial for CSF for your local lab.

CSF Preparation (15-20 ml total)





Sample Shipping



Sample Shipment Summary

Sample Type	Processing/ Aliquoting	Tubes to NCRAD	Ship	Days to Ship
Whole blood for RNA extraction	N/A	1	Frozen	Monday- Wednesday
Whole blood (Plain Red-Top Serum Tube) for isolation of serum	1.5 ml serum aliquots per 2.0 ml cryovial (red cap); residual volume placed in 2.0 ml cryovial with blue cap	Up to 4	Frozen	Monday- Wednesday
Whole blood for PBMC	N/A	2	Ambient/ same day	Monday - Thursday
Whole blood (Lavender-Top EDTA) for isolation of plasma	1.5 ml plasma aliquots per 2.0 ml cryovial (lavender cap); residual volume placed in 2.0 ml cryovial with blue cap	Up to 10	Frozen	Monday- Wednesday
& buffy coat (for DNA extraction)	1 ml buffy coat aliquot per 2.0 ml cryovial (clear cap)	3	Frozen	Monday- Wednesday
Whole blood (Lavender-Top EDTA) for CLIA lab testing	N/A	1	Frozen	Monday- Wednesday
CSF Collection	1.5 ml CSF aliquots per 2.0 ml cryovial (orange cap); residual volume placed in 2.0 ml cryovial with blue cap; 1-2 ml for local lab placed in 2.0 ml cryovial with yellow cap.	Up to 14	Frozen	Monday- Wednesday

Ambient Sample

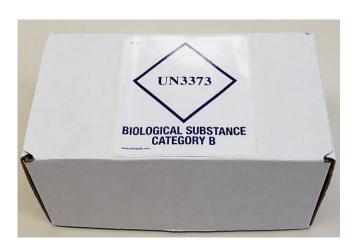
- Sodium Heparin/PBMC
- Only Monday-Thursday collection and same day shipping. Plan ahead to schedule UPS.
- Samples must be received at IU one day after collection.
- Do NOT draw or ship ambient samples on Friday
- Include copy of Biological Sample Shipment and Notification Form



Ambient Sample Shipping







- Place refrigerant pack in the freezer 24 hours prior to shipment.
- Place filled and labeled Sodium Heparin tubes within the slots in the absorbent pad and place in biohazard bag.
- Place the kit number label on biohazard bag.
- Place the refrigerant pack into the cooler on top of the filled biohazard bag. Place lid on cooler.
- Place the cooler in the small IATA Shipping Box.
- Place an extra copy of the "Biological Sample and Shipment Notification Form" within the shipping box along with a list of contents form.
- Close shipping box and ensure labeled with UN3373 label.
- Place box within a provided UPS ClinPak, seal, and place UPS label on outside of package.

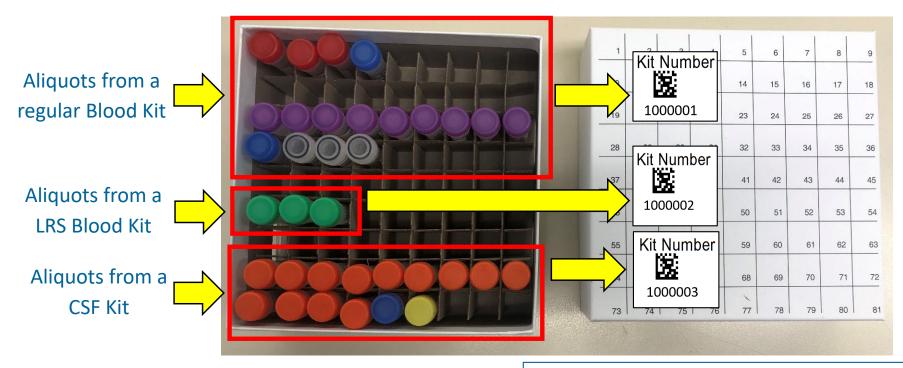
Frozen Sample Shipping

Ship Monday-Wednesday Only

- •RNA, Serum, Plasma, Buffy Coat, CSF, Whole Blood for CLIA*, and Whole Blood for LRS* (*when applicable)
- 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.



Frozen Shipping - Cryoboxes



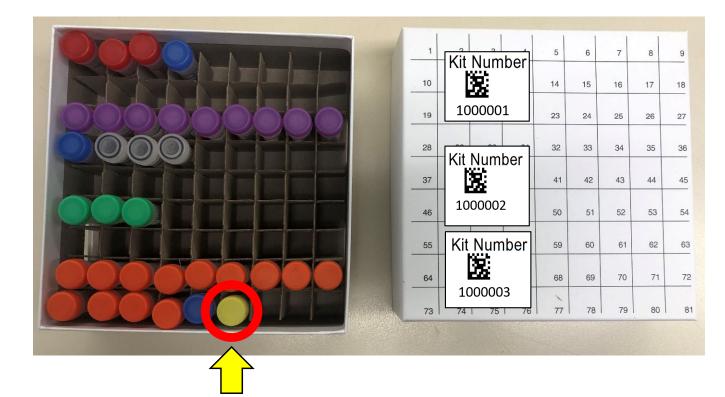
A cryobox may have up to three kit number labels on its lid, depending on what samples were collected during the participant's visit.

This is an example of a cryobox with 3 kit number labels, one for each: regular blood kit, LRS blood kit, and CSF kit



Frozen Shipping - Cryoboxes

Aliquots from a regular Blood Kit



Please note that the yellow-cap cryovial of CSF should NOT be sent back to NCRAD. If used, you should provide it to your local lab.

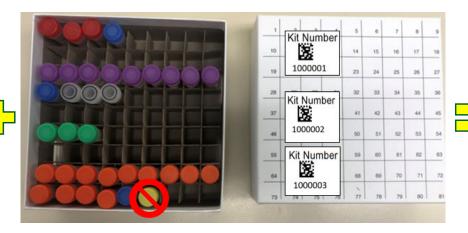


Frozen Shipping - Cryoboxes













Place frozen RNA (and frozen EDTA (6ml & 3ml) tubes, when applicable) in bubble wrap tube sleeves.

Place cryobox and frozen tubes 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 must contain about 45 lbs (20 kg) of dry ice.



Frozen Shipping – Dry Ice Requirements

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





Shipping Frozen Samples

- Schedule UPS
- Send Biological Sample and Shipment
 Notification Form to IU <u>ahead of shipment</u>
 - 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



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: <u>alzstudy@iu.edu</u>

• Fax: 317-321-2003



Biological Sample Notification Form-Blood

Biological Sample and Shipment Notification Form



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

You will need to scan and print a second hard copy so that you can include the sample form in both the ambient and frozen shipments.

To: Kelley Faber	Email: alzstudy@iu.edu		lu Phone: 1-800-526-2839		
General Information:		Kit #:			
rom:					
hone:					
mail:	_	i	KIT BARCODE		
rate:		į	KIT BANCOBE		
tudy: LEADS: CI Participant CN F		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	2-15074 - 1-1517		
		Kit # (Only if	3ml EDTA tube used):		
isit (circle one): BASELINE M12 M24 M3	6 M48 M60	į			
ex: 🗆 M 🗆 F		!			
ear of Birth:		-	KIT BARCODE		
racking #:		į			
		L			
ood Collection: 1. Date Drawn (MM/DD/YYYY):		2 Time of Draw	n (24 hour clock):	[HHMM]	
Last time subject ate (MM/DD/YYYY):			ject at (24 hour clock):	[HHMM]	
3. Last time subject ate (MM/DD/1111).		4. Last time sub	Ject at (24 flour clock).	[[111101101]	
ood Processing:					
RNA (PAXgene Tube)			& Buffy Coat (Lavender Top Tube -		
Total Volume of blood drawn (1 x 2.5 mL PAXgene	mL		ed (24 hour clock):	[ННММ	
RNA tube):		Duration of cen		minutes	
Time PAXgene RNA tube placed in freezer (24	[HHMM]	Temp of centrif		°C	
hour clock):		Rate of centrifu	He.	XE	
Storage temperature of freezer:	°C	Original volume	drawn (3x10 mL EDTA tubes):		
Serum (Red Top Tube)					
Time spin started (24 hour clock):			mL EDTA #2: mL EDTA #3:		
Duration of centrifuge:		Time aliquoted:		[HHMM]	
Temp of centrifuge:			mL plasma aliquots created:		
Rate of centrifuge:	x g		lume of residual plasma	mL	
Original volume drawn (1x10 mL Serum tube):	mL	aliquot (less than			
Time aliquoted:	[HHMM]	If applicable, sp plasma aliquot	ecimen number of residual (Last four digits):		
Number of 1.5 mL serum aliquots created:		Time aliquots p	laced in freezer (24 hour clock):	[HHMM]	
If applicable, volume of residual serum aliquot		Storage temper	ature of freezer:	°C	
(less than 1.5 mL-Blue cap):	mL	Buffy coat aliqu	ot #1 (last four digits):		
If applicable, specimen number of residual		Buffy coat volu	me #1:	mL	
serum aliquot (Last four digits):		Buffy coat aliqu	ot #2 (last four digits):		
Time aliquots placed in freezer (24 hour clock):	[HHMM]	Buffy coat volu		mL	
Storage temperature of freezer:			ot #3 (last four digits):		
EDTA (Lavender Top Tube – 3r	•	Buffy coat volu		mL	
	Yes 🗆 No		ot #4 (last four digits):		
Original volume drawn (1x3mL EDTA tube):	mL	Buffy coat volu		mL	
Time aliquoted:	[HHMM]		PBMC (NaHep Green Top Tube)		
Whole blood aliquot #1 (last four digits):		Original volume	drawn (2x10mL PBMC tube):	m	
Whole blood volume #1:	mL		EDTA (Lavender Top Tube – 6mL)		
Whole blood aliquot #2 (last four digits):		4	for CLIA testing collected?		
Whole blood volume #2:	mL		drawn (1x6mL EDTA tube):	m	
Whole blood aliquot #3 (last four digits):		Notes:			
Whole blood volume #3:	mL				
Whole blood aliquot #4 (last four digits):					
Whole blood volume #4:	mL.				

Version 06.2024

Biological Sample Notification Form-Blood

There should be a second Kit Number Label placed on the form if a 3mL EDTA tube was collected and aliquoted for LRS



To: Kelley Faber Email: alzstudy@		Piu.edu Phone: 1-800-526-2839			
General Information:		Kit #:			
From:		!			
Phone:		!			
Email:		KIT BARCODE			
		KII BARCODE			
Date:					
Study: LEADS: □ CI Participant □ CN P		Kit # (Only if 3ml EDTA tube used):			
Visit (circle one): BASELINE M12 M24 M36	6 M48 M60	i			
Sex: □ M □ F		i i			
Year of Birth:		KIT BARCODE			
		i KII BANCODE			
Tracking #:		i	!		
Blood Collection:					
1. Date Drawn (MM/DD/YYYY):		2. Time of Drawn (24 hour clock):	[HHMM]		
Last time subject ate (MM/DD/YYYY):		4. Last time subject at (24 hour clock):	[HHMM]		
Blood Processing:					
RNA (PAXgene Tube)		Plasma & Buffy Coat (Lavender Top	Tube – 10mL)		
Total Volume of blood drawn (1 x 2.5 mL PAXgene		Time spin started (24 hour clock):	[HHMM]		
RNA tube):	mL	Duration of centrifuge:	minutes		
Time PAXgene RNA tube placed in freezer (24	[MMHH]	Temp of centrifuge:	°C		
hour clock):	[HHIVIVI]	Rate of centrifuge:	xg		
Storage temperature of freezer:	°C	Original volume drawn (3x10 mL EDTA tubes):			
Serum (Red Top Tube)					
Time spin started (24 hour clock):	[HHMM]	EDTA #1: mL EDTA #2:	OTA #3: mL		
Duration of centrifuge:		Time aliquoted:	[HHMM]		
Temp of centrifuge:	°€	Number of 1.5 mL plasma aliquots created:			
Rate of centrifuge:	x g	If applicable, volume of residual plasma	mL		
Original volume drawn (1x10 mL Serum tube):	mL	aliquot (less than 1.5 mL-Blue cap):			
Time aliquoted:	[HHMM]				
		plasma aliquot (Last four digits):			
Number of 1.5 mL serum aliquots created:		Time aliquots placed in freezer (24 hour clock):	[HHMM]		
If applicable, volume of residual serum aliquot		Storage temperature of freezer:	°C		
(less than 1.5 mL-Blue cap):	mL	Buffy coat aliquot #1 (last four digits):			
If applicable, specimen number of residual		Buffy coat volume #1:	mL		
serum aliquot (Last four digits):		Buffy coat aliquot #2 (last four digits):			
Time aliquots placed in freezer (24 hour clock):	[HHMM]	Buffy coat volume #2:	mL		
Storage temperature of freezer:	°C	buily cour andage in has roar albis.			
EDTA (Lavender Top Tube – 3m 3mL EDTA tube for LRS collected?	Yes 🗆 No	Buffy coat volume #3: Buffy coat aliquot #4 (last four digits):	mL		
Original volume drawn (1x3mL EDTA tube):	res 🗆 NO		mL		
Time aliquoted:	[HHMM]	Buffy coat volume #4: PBMC (NaHep Green Top T			
Whole blood aliquot #1 (last four digits):	[HHIVIVI]	Original volume drawn (2x10mL PBMC tube):	mL		
Whole blood volume #1:	mL	EDTA (Lavender Top Tube –			
Whole blood aliquot #2 (last four digits):		6mL EDTA tube for CLIA testing collected?	☐ Yes ☐ No		
Whole blood volume #2:	mL	Original volume drawn (1x6mL EDTA tube):	mL		
Whole blood aliquot #3 (last four digits):	mL	Notes:	mL		
Whole blood volume #3:	mL	notes.			
Whole blood aliquet #4 (lest four digits):					
Marie de la lace de colores de la		i			

Version 06.2024

Biological Sample Notification Form –

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 FA	X: 317-321-2003 Phone: 1-800-526-2839				
General Information:					
From: Date:					
Phone: Email:					
Study: LEADS CI Participant CN Participant Kit #:					
Visit (circle one): BASELINE M12 M24 M36 M48	KIT BARCODE				
VISIT (CITCLE OTIE). BASELINE WILZ WIZE WISO WHO	L				
Sex: M F Year of Birth:	CSF Collected? Yes No				
Tracking #: Ga	uge needle used for LP: 22G 24G				
CSF Collection:	9				
1. Date of Collection: 2. Time of Collect	tion: 24 hour clock: [HHMM]				
Last time subject ate: Date: 4. Last time subject.	ect ate: 24 hour clock: [HHMM]				
5. Collection process: Gravity Method OR As	piration				
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 14 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:	15 of 2002 And Albert 1815 Feb. 1917 In 18 18				

NCRAD Website Helpful Pages

https://ncrad.iu.edu/contact/holiday-closures
 https://ncrad.iu.edu/contact/friday-blood-draws

♠ / Contact / Friday Blood Draws

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 courie 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 specimen can be shipped via next day delivery methods the followi Monday.
Whole	EDTA Tubo	DNA Oply	Frozon	Whole blood in EDTA may be frozen in a -80°C freezer within 5 days

♠ / Contact / Holiday Closures

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
June 19	Juneteenth (observed)
July 4	Independence Day (observed)
1 st Monday in September	Labor Day
4 th Thursday in November	Thanksgiving
4 th Friday in November	Friday after Thanksgiving
December 25	Christmas

LEADS Active Study Page



Donate

Get Updates

ABOUT ~

BANK SAMPLES V

ACCESS SAMPLES >

BIOMARKER ANALYSIS V

COORDINATE STUDIES ~

GENETICS & FAMILIES >

CONTACT ~

COORDINATE STUDIES

LEADS

NIA-AD FBS

NAPS2

PATH

APOE

4RTNI-2

90+ Study

ABC-DS ACAD

ACT

ADCFB

ADNI-3,4

AGMP

ALLFTD

BBBSR

BenfoTeam

BEYONDD

CADASIL

CLARITI

♠ / Coordinate Studies / LEADS

LEADS ACTIVE STUDY PAGE

Welcome LEADS 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 **1-800-526-2839** or directly at **317-278-8413**.



CI (COGNITIVELY IMPAIRED) PARTICIPANTS					
	BASELINE	M12	M24	M36	M48
RNA	~	~	~	~	~
Serum	~	~	~	~	~
Plasma	✓	~	~	~	~
DNA	~	~	~	~	~
PBMC	✓	~	~	~	~
EDTA for CLIA testing**	~				
CSF	~	~	~	~	





Contact Information

• Questions?

Please contact NCRAD Coordinators at:

• Phone: 1-800-526-2839 or 317-278-1133

• E-mail: <u>alzstudy@iu.edu</u> or <u>agericks@iu.edu</u>

• Website: <u>www.ncrad.org</u>

