

International 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 M12	CN M12*	CI M24	CN M24	CI M36	CI M48 /Annual visit
Serum	Χ	X	X	X	Χ	X	X	X
Plasma	Χ	X	X	X	Χ	X	Χ	X
Buffy Coat (DNA)	Χ	X	X	X	Χ	X	Χ	X
Whole blood for	Χ							
CLIA lab testing								
Whole blood for			Collected only once over the entire course of a participant's					ipant's
long read	Χ	X	participation in the iLEADS Study.					
sequencing			May be collected at longitudinal visits if not collected at Baseline				Baseline	
RNA	Χ	X	X	X	Χ	Χ	Χ	X
PBMC	V	V	V	V	V	V	V	V
*optional	Х	X	X	X	X	X	X	X
CSF	Χ	X	X		Χ	Χ	Χ	
*optional								

^{*}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

https://redcap.uits.iu.edu/surveys/?s=DRE4RPAR K3R7D8KL



National Centralized Repository for Alzheimer's Disease and Related Dementias

Kit Request Module

- 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 (only needed at site start-up)
 - CSF Kit: CI BL M72 & CN BL M72
 - CSF Kit: Supplemental (only needed at site start-up)
 - LP Kit: 24G



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. Try to only order kits/supplies that will be used within 90 days of receipt.
- 1. Enter your email address this is how you will receive updates about your order.



National Centralized Repository for Alzheimer's Disease and Related Dementias

iLEADS Kit Request System

Due to ongoing supply limitations, we ask that you please only supplies that you will be able to use in the 90 days of receipt. Doing so allows us to fulfill as many kit requests as possible without depleting stock for other kit requests in our queue. If we are not able to fulfill any part of your request due to supplies being out of stock, we will reach out about those individually.

Please enter your email address here to receive a confirmation email after completing the survey:

* must provide value

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.

123: Test Site ATTN: Site Coordinator Contact Address Line 1 Address Line 2 Address Line 3 Address Line 4 Phone: 111-111-1111 Email: alzstudy@iu.edu		
Is the contact name above correct? * must provide value	○ Yes ○ No	reset
Is the e-mail address above correct? * must provide value	○ Yes ○ No	reset
Is the shipping address for kit delivery above correct? * must provide value	○ Yes ○ No	reset
Where will the samples delivered to NCRAD be shipping from? * must provide value	Same as shipping address for kit deliveryDifferent address	reset

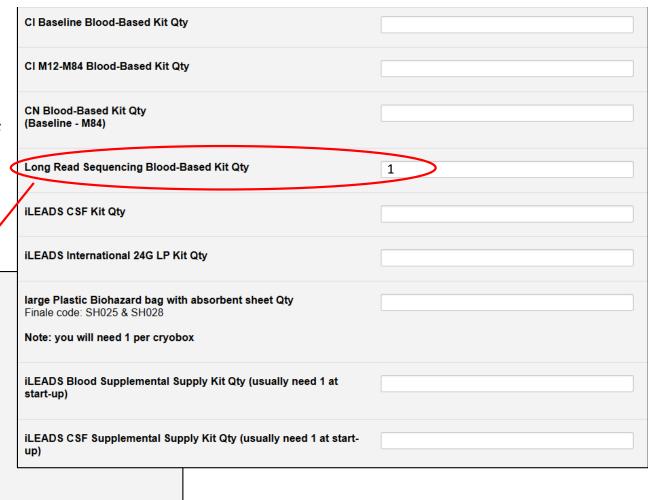


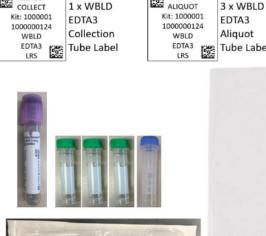
- Indicate the quantity needed of each kit
- Once selected, kit components of the chosen kit will appear at the bottom of the screen (Pictured)

Each <u>Long Read Sequencing</u> Blood-Based Kit Contains:

Finale: 11191

- 1 Resealable Bag ST002
- 1 EDTA (Lavender-Top) Blood Collection Tube (3 ml) CT021
- 3 Cryovial tube (2.0 ml) with green cap CV064
- 1 Cryovial tube (2.0 ml) with blue cap CV034
- 1 Disposable graduated transfer pipette (3ml) CV015
- <u>Labels</u>:
 - o 1 Pre-printed Collection Tube Label LB003
 - o 3 Pre-printed Aliquot Tube Labels LB003
 - 5 Pre-printed Kit Number Labels LB003
 - 1 Labels for handwritten Site and iLEADS ID LB003







5 x Kit

Number

Labels

1 x iLDS ID

Label

Kit Number



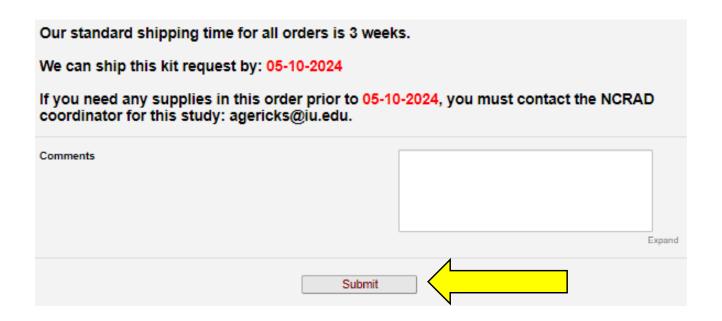
Do you need Extra Supplies? *must provide value	⊚Yes ○ No
25 cell Cryobox (CV005)	○5 ○10
81 cell Cryobox (CV021)	○ 5 ○ 10
Cryovial tubes (2.0 ml) with lavender cap (CV027)	○ 10 ○ 25
Cryovial tubes (2.0 ml) with red cap (CV028)	○ 10 ○ 25
Cryovial tubes (2.0 ml) with orange cap (CV017 & CV018)	○ 25 ○ 50
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. Leave any needed comments in the box provided.
- 3. Click Submit.



Things to Remember When Ordering Kits

- Allow a minimum of 3 weeks for your order to be processed and delivered.
- For a visit where you will draw CSF, you will need an LP tray in addition to CSF kit.
- Upon site start up, you should order 1 CSF Supplemental and Blood Supplemental kit.
- For every cryo box of samples you have to ship back to NCRAD, you will need to order a "large plastic biohazard bag with absorbent sheet"
- 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://redcap.uits.iu.edu/surveys/?s=DRE4RPARK3R7D8KL



Specimen Labels



National Centralized Repository for Alzheimer's Disease and Related Dementias

Label Type Summary

- Kit Number Labels
- 2. iLEADS ID Labels
- 3. Collection Tube Labels
 - Differ by specimen type
- 4. Aliquot Tube Labels
 - Differ by specimen type



Kit Number Labels



 Used to track patient samples and provide quality assurance

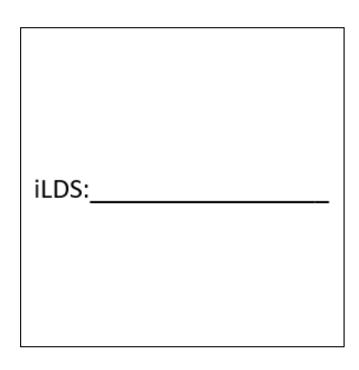
- Will be placed on the following locations:
 - 1. Sample and Shipment Notification Form: Blood & CSF (where applicable)
 - CSF samples will have a different kit number than the blood collection specimens
 - 2. Outside cryobox that houses aliquot tubes during storage and shipment

Provided by NCRAD in the kits

 Kits will include extra kit labels that should be thrown away if not used



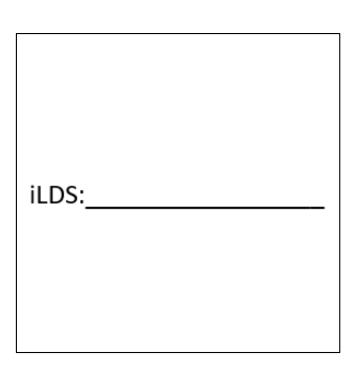
iLEADS ID Label



- Participants will be identified by their iLEADS ID
- The iLEADS 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



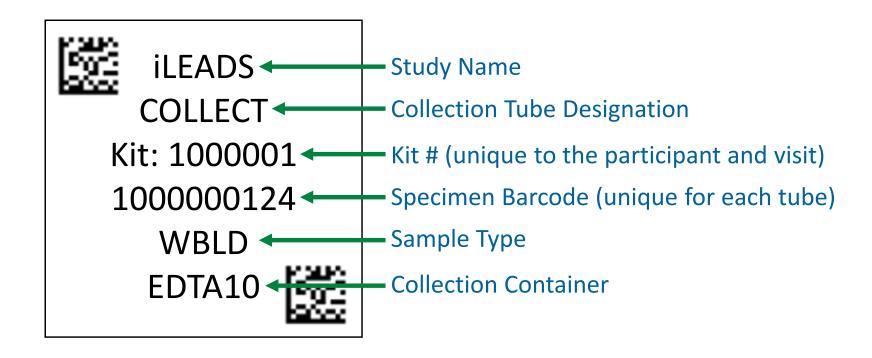
iLEADS ID Label Cont.



- 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 may include extra label



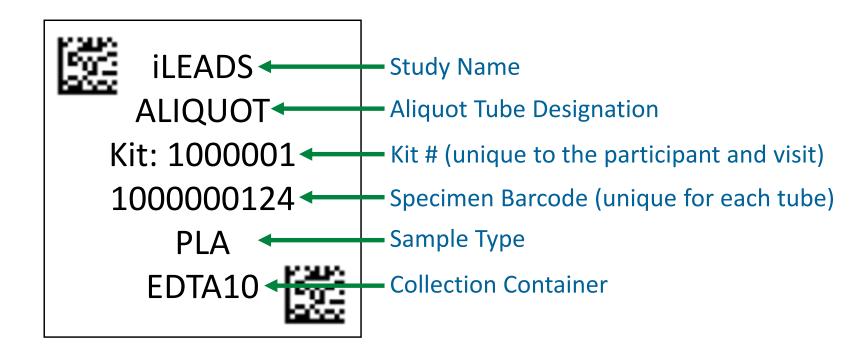
Collection Tube Labels



Labels to be placed on ALL collection tubes



Aliquot Tube Labels



Labels to be placed on ALL aliquot tubes



Collection and Aliquot Tube Labels







iLEADS
ALIQUOT
Kit: 1000001
1000000124
PLA
EDTA10













Look to the **Sample Type** & Collection Tube lines to determine what tube / cryovial the label should be placed on





Every combination of Sample Label you may encounter



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)

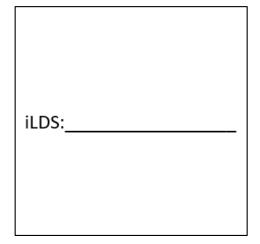


Specimen Labels: Blood Collection Tubes

Label 1:

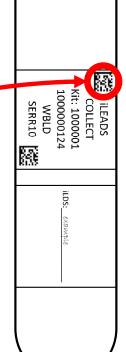


Label 2:

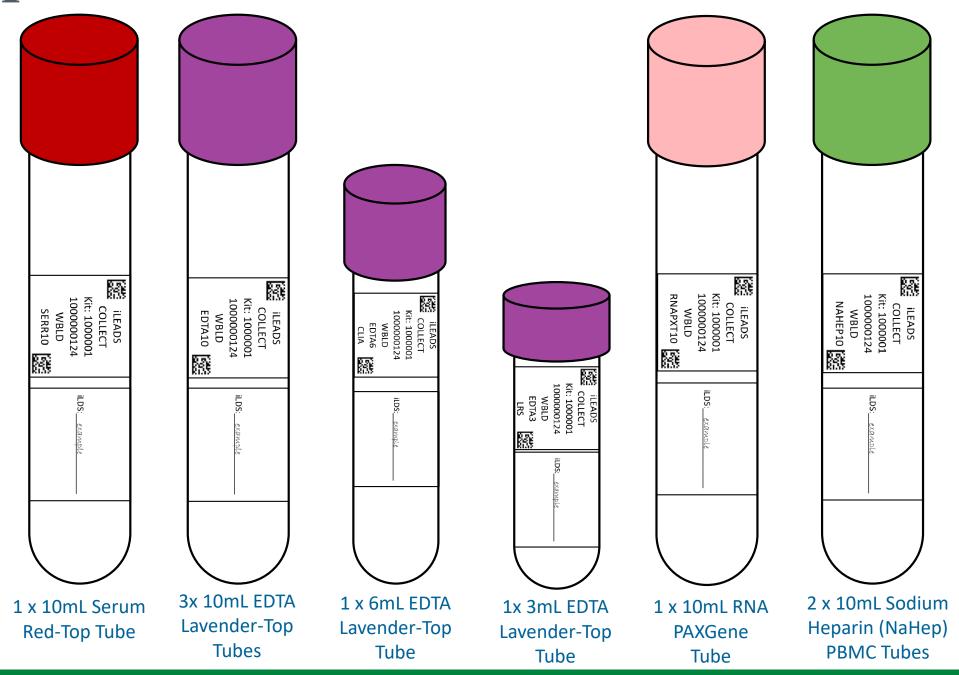


Please ensure the left-hand barcode is near the cap



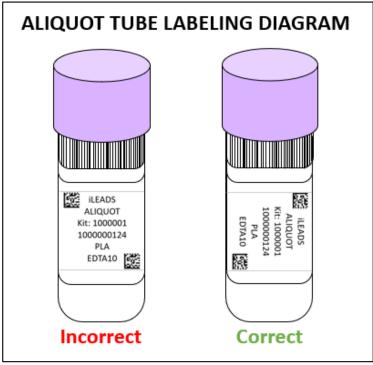


Specimen Labels: Blood Collection Tubes



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
- 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 *optional*

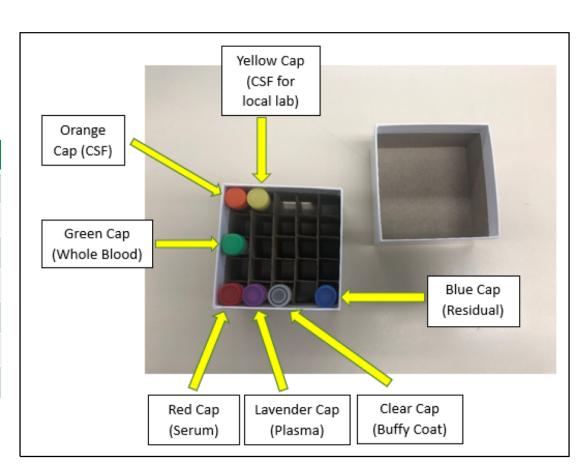


Sample Collection - Blood

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	LAMENTAL OF THE PROPERTY OF TH
4. EDTA (Lavender-Top) Blood Collection Tube (3ml) for LRS **only collected once per participant**	X1	Marie of the state
1. PAXgene™ Blood Collection Tube (2.5 ml) for RNA	x1	
3. Sodium Heparin (Green-Top) Blood Collection Tube (10 ml) for PBMC *optional*	x2	CETTORIS SO-PLOK & COSPELIP (200) PARTITION OF THE PROPERTY O

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





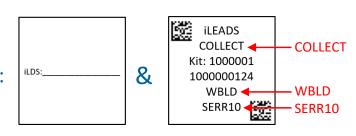
Serum Preparation (10ml Red Top Tube)

Prior to blood draw, label all tubes:

1 x 10mL Serum Tube



Label with:



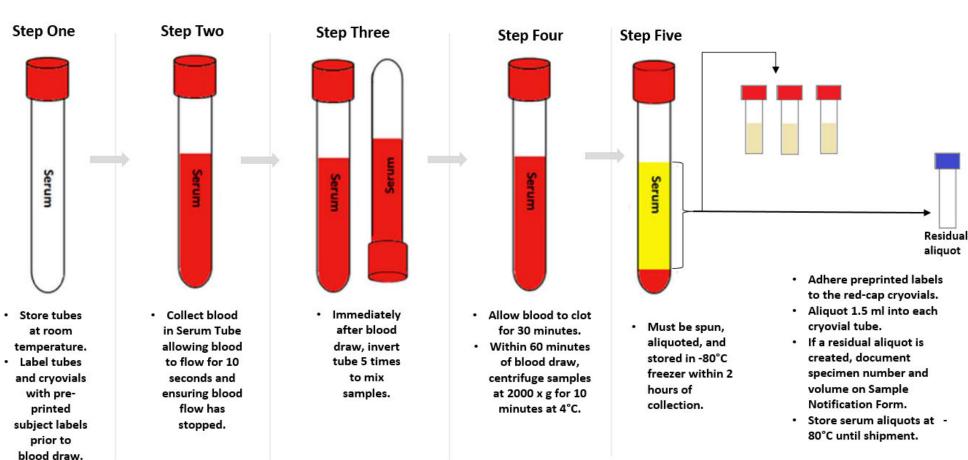
3 x 2ml Red Cap Cryovials & 1 x 2ml Blue Cap Cryovial



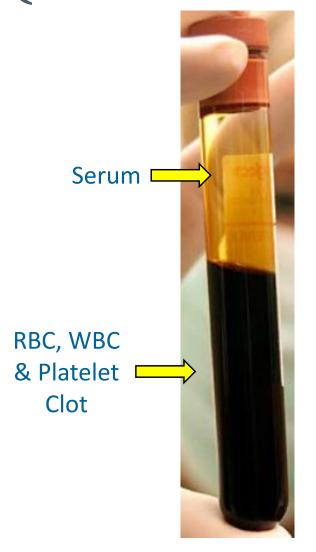


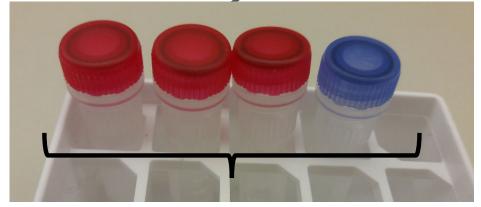
Serum Preparation (10ml Red Top Tube)





Plain Red-Top Serum Tube (Serum Collection)





Serum Aliquots (up to 4 possible)



Close up view of 2.0 ml cryovial



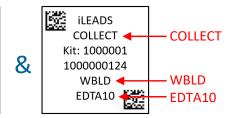
Plasma and Buffy Coat Preparation (10ml Lavender-Top Tube x 3)

Prior to blood draw, label all tubes:

3 x 10mL EDTA Tubes



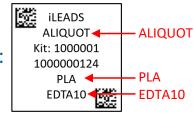




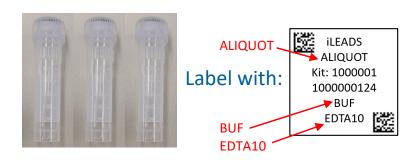
9 x 2ml Purple Cap Cryovials & 1 x 2ml Blue Cap Cryovial



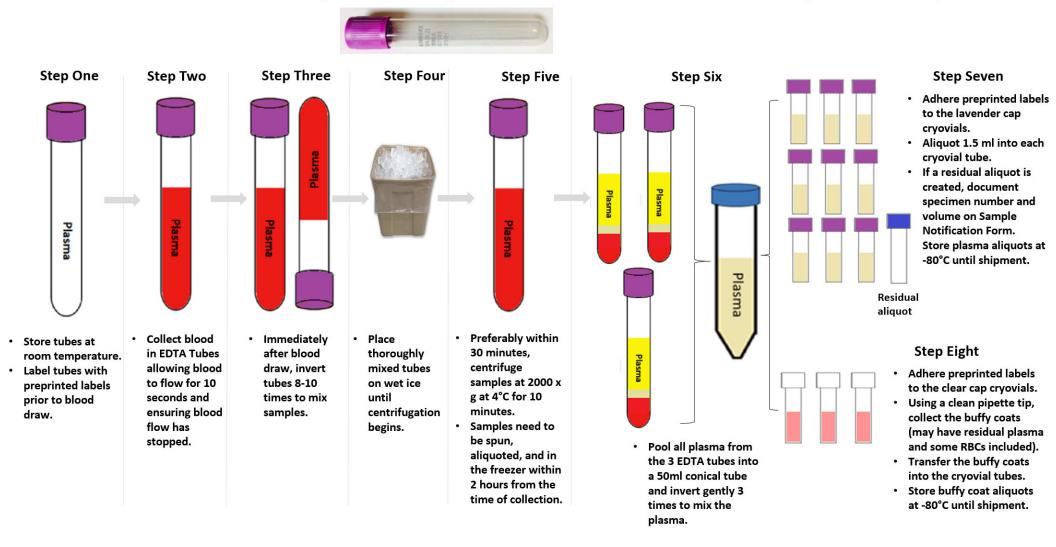




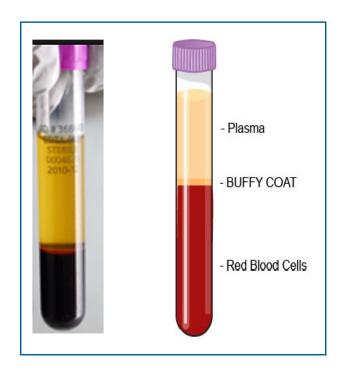
3 x 2ml Clear Cap Cryovials



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



EDTA Tube (Plasma Collection)







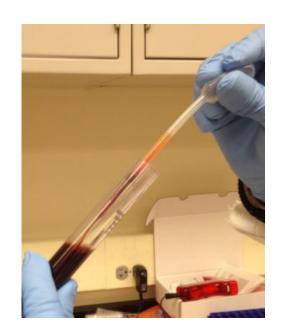
Plasma Aliquots (10 possible)





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.



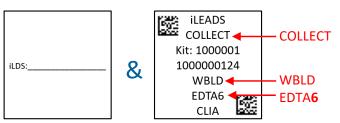
Whole Blood Preparation (6 mL Lavender-Top Tube)

Prior to blood draw, label all tubes:

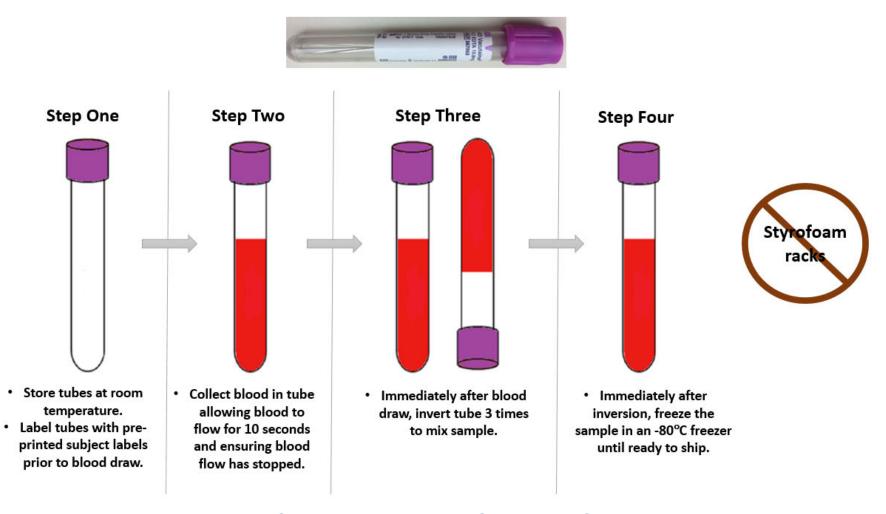
1 x 6mL EDTA Tube



Label with:



Whole Blood Preparation (6 mL Lavender-Top Tube)



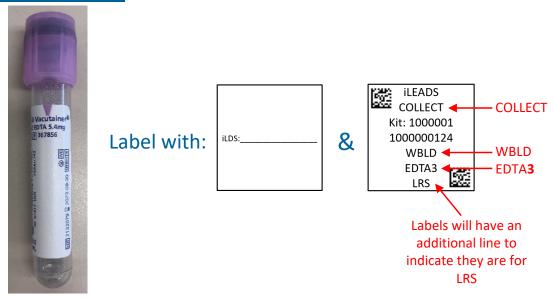
CI Subjects at Baseline Only



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

Prior to blood draw, label all tubes:

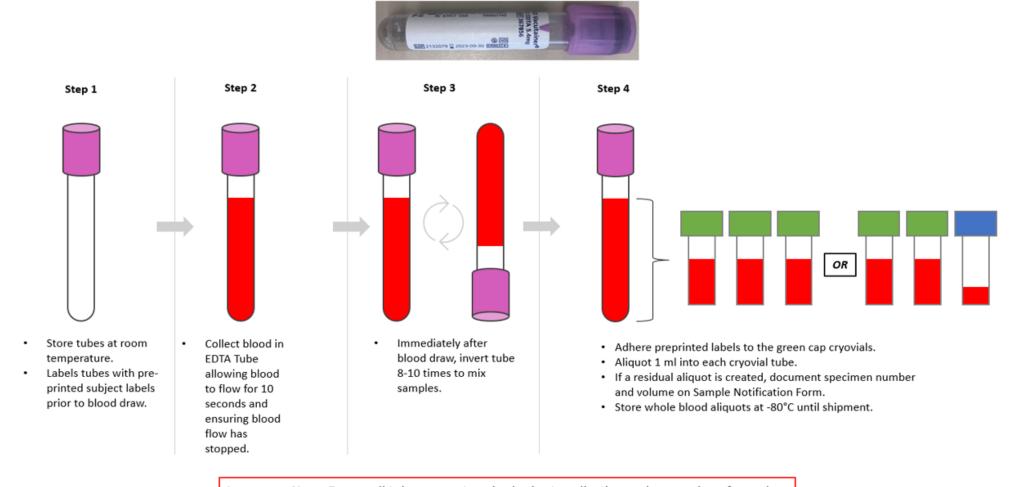
1 x 3mL EDTA Tube



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



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.



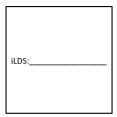
RNA Preparation (2.5ml PAXgene™ Tube)

Prior to blood draw, label all tubes:

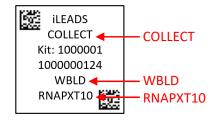
1 x RNA PAXGeneTM Tube



Label with:

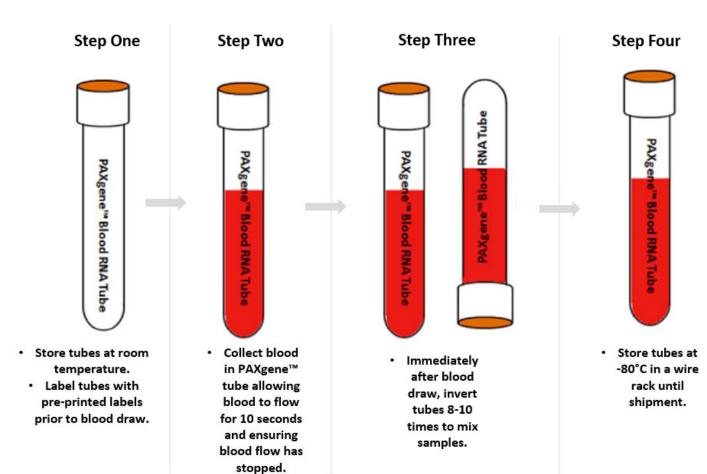


&



RNA Preparation (2.5ml PAXgene™ Tube)









PBMC Preparation (10ml Sodium Heparin Tube) x 2

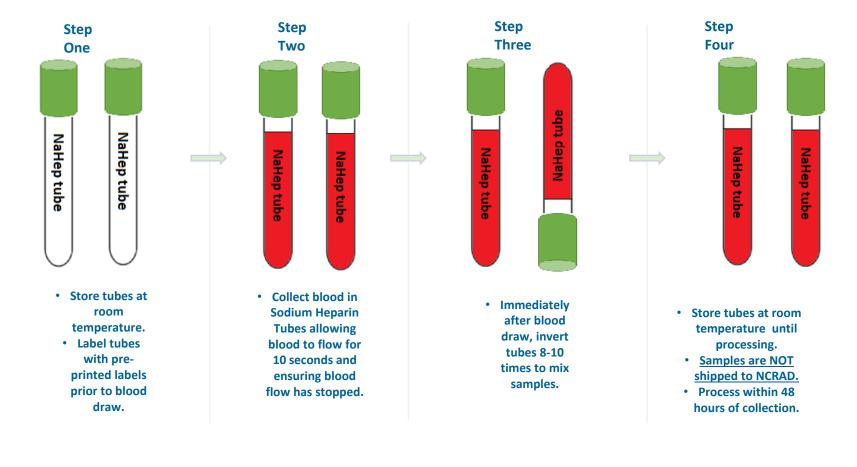
Prior to blood draw, label all tubes:

2 x 10mL Sodium Heparin (NaHep) PBMC Tubes



PBMC Preparation (10ml Sodium Heparin Tube) x 2



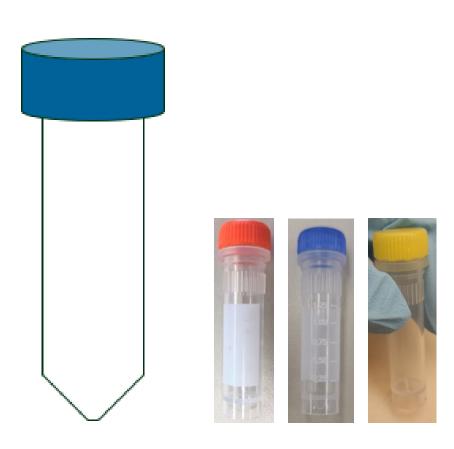


CSF Collection and Processing



Important Note

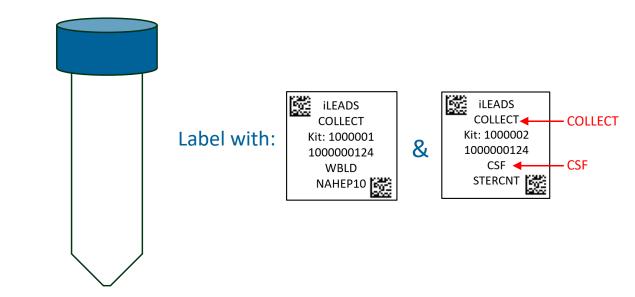
CSF samples should be collected in the morning before breakfast and after an overnight fast. Collection of biomarker fluids and CSF should be collected after a minimum 6-hour fast. Only water is permitted until blood draws and the lumbar puncture are completed. Please remember to record "Last time eaten"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



CSF

Prior to CSF draw, label all tubes:

1 x 50ml Sterile Container

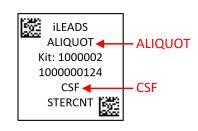


13 x 2ml Orange Cap Cryovials & 1 x 2ml Blue Cap Cryovial



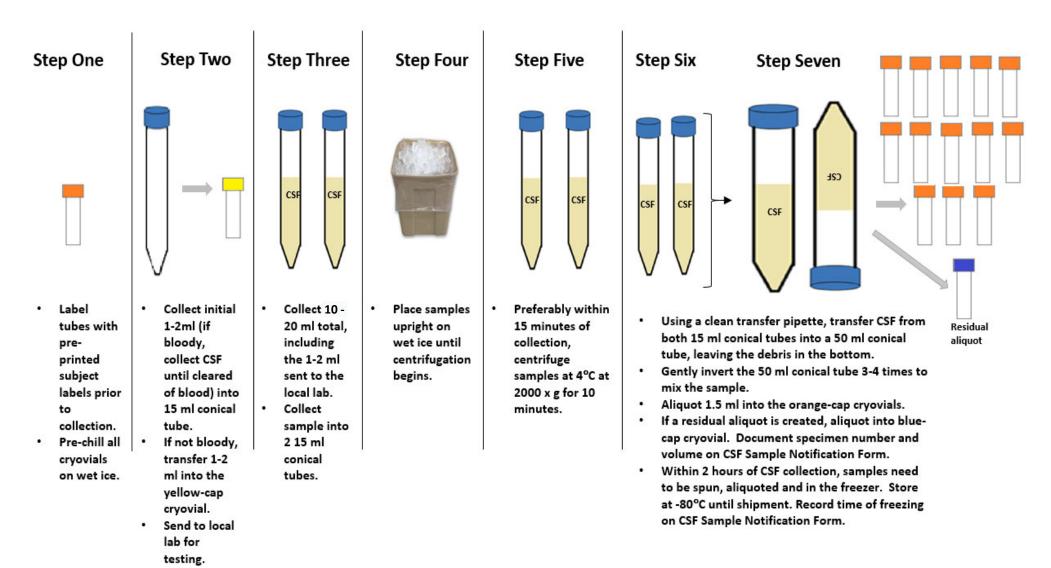


Label with:



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

CSF Preparation (15-20 ml total)





Previously Collected CSF

- International sites may send pre-existing CSF samples to LEADS if:
 - Collected within the 12 months prior to a participant's consent date and
 - Approval is received by the Genetics and Biorepository Core and
 - Applicable language must be included in the site's consent form.
- When this scenario arises, the site coordinator should contact NCRAD to prepare the previously collected CSF for shipment.
- The site will work with NCRAD to ensure that samples meet NCRAD requirements.
- Do not ship to NCRAD until receiving direct approval from LEADS Admin and NCRAD staff.



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	N/A – Kept at site if collected		fcollected
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)	2 buffy coat (for DNA 1 ml buffy coat aliquot per 2.0 ml		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		Frozen	Monday- Wednesday

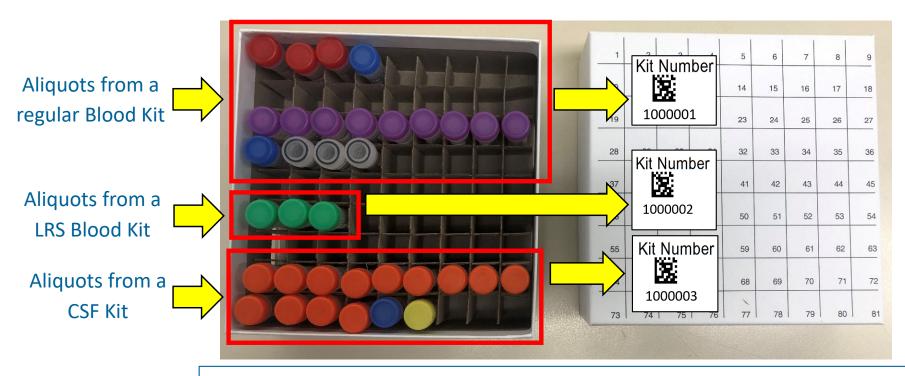
Frozen Sample Shipping

Sites will ship samples back to NCRAD using the applicable courier listed below

Site	Courier	When Ready to Ship
Lund	World Courier	Contact NCRAD
Sant Pau-Barcelona	World Courier	Contact NCRAD
Fleni-Argentina	World Courier	Contact NCRAD
UCL	World Courier	Contact NCRAD
Vumc – Amsterdam	SGS	Contact SGS Directly

- You should ship back to NCRAD when you have accumulated samples from 4
 participant visits, or every six months, whichever is sooner
- The most important issue for shipping is to maintain the temperature of the samples.
 The frozen samples must never thaw; not even the outside of the tubes should be allowed to defrost

Frozen Shipping - Cryoboxes



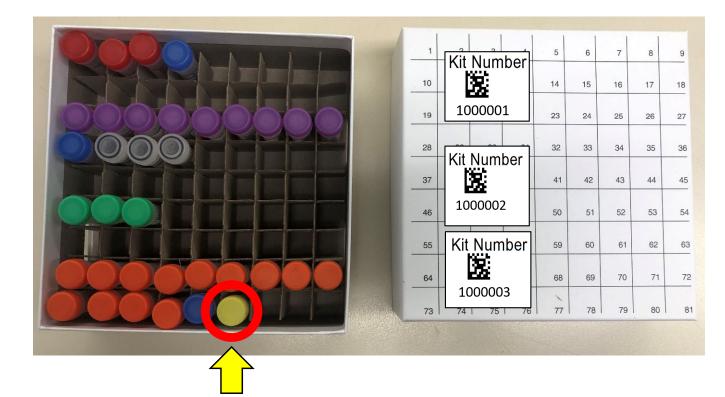
A cryobox may have up to three kit number labels on its lid, depending on what samples were collected during the participant's visit.

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.

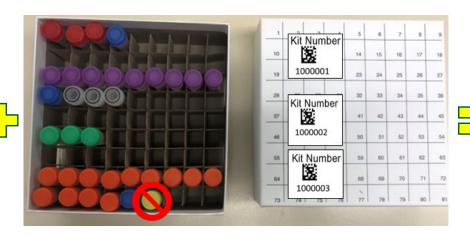


Frozen Shipping - Cryoboxes













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.



Shipping with World Courier

- When you are ready to ship samples back to NCRAD, contact the NCRAD coordinator (agericks@iu.edu). NCRAD will work with your site and World Courier to arrange a shipment. Prior to pick up, please keep samples stored in a -80°C freezer.
- There will be a waiting period between when you contact NCRAD to instigate a shipment and when the shipment occurs, which is expected to be up to 7 business days. For this reason, you should contact NCRAD about shipment approximately two weeks before you intend to ship.
- World Courier will arrive with all of the supplies necessary for packaging and shipping the samples. Please note that World Courier will not handle unpackaged samples. Therefore, a site coordinator will need to place the samples into the packaging provided by World Courier. It is imperative that a site coordinator is available to assist World Courier when they arrive.



Shipping with SGS (Amsterdam Only)

- The Amsterdam site has chosen to coordinate shipping samples back to NCRAD via SGS.
- Amsterdam should obtain all shipping supplies through SGS.
- Specimens being shipped to NCRAD should be considered as Category B UN3373 specimens and as such must be tripled packaged and compliant with IATA Packing Instructions 650. There is additional helpful information in the iLEADS Manual of Procedures.
- See the Latest Edition of the IATA Regulations for complete documentation.
- It is the site's responsibility to ensure that all packaging, labeling, and forms are completed correctly and safely.



Shipping Frozen Samples – All Sites

- Email Biological Sample and Shipment
 Notification Form to IU <u>ahead of shipment</u>
 - Email: alzstudy@iu.edu



Shipping Regulations and Training – All Sites

PLFASE 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 – All Sites

- 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 – All Sites

- 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



It is the responsibility of the site to ensure that all appropriate training has been obtained regarding the shipment of study specimens.



Biological Sample and Shipment Notification Forms



Biological Sample and Shipment Notification Forms

- A copy of the sample form must be emailed 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>



Biological Sample Notification Form-Blood

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



Participant ID: LDS	
al Sample and Shipment Notification	Form



To: Kelley Faber	Email: alzstudy@	iu.edu	Phone: 1-800-5	26-2839
General Information:		Kit #:		
From:				
Phone:	-			i
Email:		i	KIT BARCODE	į
Date:	_	į	KII BARCODE	į
		i		
Study: iLEADS: ☐ CI Participant ☐ CN			ly if 3ml EDTA tube used for LRS)	:
Visit (circle one): BASELINE M12 M24 M3	6 M48 M60 M	172		i
Sex: □ M □ F		į		į
Year of Birth:			KIT BARCODE	
Tracking #:		į		
Blood Collection:		L		
1. Date Drawn (MM/DD/YYYY):		2. Time of D	rawn (24 hour clock):	[HHMM]
3. Last time subject ate (MM/DD/YYYY):			subject at (24 hour clock):	[HHMM]
			. ,	
Blood Processing:				
RNA (PAXgene Tube)		ı	ma & Buffy Coat (Lavender Top	Tube – 10mL)
Total Volume of blood drawn (1 x 2.5 mL PAXgene	mL		tarted (24 hour clock):	
RNA tube): Time PAXgene RNA tube placed in freezer (24			centrifuge:	[HHMM] °C
hour clock):	[HHMM]	Temp of cer		
Storage temperature of freezer:	°C	Rate of cent	trifuge: ume drawn (3x10 mL EDTA tubes):	xg
Serum (Red Top Tube)		Original von	unie drawn (sx10 mc EDTA tubes).	
Time spin started (24 hour clock):	THAMMI	EDTA #1.	mL EDTA#2:mL EI	DTA #3: mL
Duration of centrifuge:		Time aliquo		[HHMM]
Temp of centrifuge:			1.5 mL plasma aliquots created:	Inniviivii
Rate of centrifuge:			e, volume of residual plasma	
Original volume drawn (1x10 mL Serum tube):			than 1.5 mL-Blue cap):	mL
Original volume drawn (1x10 mL Serum tube):			e, specimen number of residual	
Time aliquoted:			UOT (Last four digits):	
Number of 1.5 mL serum aliquots created:			ts placed in freezer (24 hour clock):	[HHMM]
If applicable, volume of residual serum			nperature of freezer:	°C
aliquot (less than 1.5 mL-Blue cap):	ml.		liquot #1 (last four digits):	
If applicable, specimen number of residual		Buffy coat v		mL
serum aliquot (Last four digits):			liquot #2 (last four digits):	
Time aliquots placed in freezer (24 hour clock):	[HHMM]	Buffy coat v		mL
Storage temperature of freezer:	· °c	Buffy coat a	liquot #3 (last four digits):	
EDTA (Lavender Top Tube – 3n	nL)	Buffy coat v	olume #3:	mL
3mL EDTA tube for LRS collected?	Yes 🗆 No	Buffy coat a	liquot #4 (last four digits):	
Original volume drawn (1x3mL EDTA tube):	mL	Buffy coat v	olume #4:	mL
Time aliquoted:	[HHMM]		EDTA (Lavender Top Tube –	6mL)
Whole blood aliquot #1 (last four digits):		6mL EDTA t	ube for CLIA testing collected?	☐ Yes ☐ No
Whole blood volume #1:	mL	Original vol	ume drawn (1x6mL EDTA tube):	mL
Whole blood aliquot #2 (last four digits):		Notes:		
Whole blood volume #2:	mL			
Whole blood aliquot #3 (last four digits):				
Whole blood volume #3:	mL			
Whole blood aliquot #4 (last four digits):				
Whole blood volume #4:	mL			

Biological Sample Notification Form-Blood

ILEADS

Participant ID: LDS______

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

International Biological Sa	mple and SI	hipment Notification Form	NCRA
r rease email o	Email: alzstudy@		26-2839
General Information:		Kit #:	
From:			
Phone:			
Email:	_	KIT BARCODE	
Date:	_	KIT BARCOBE	
Study: iLEADS: CI Participant CN F		(it # (Only if 3ml EDTA tube used for LRS):	
Visit (circle one): BASELINE M12 M24 M36	6 M48 M60 N	172	
Sex: □ M □ F			
Year of Birth:		KIT BARCODE	
Tracking #:			
Blood Collection:			
1. Date Drawn (MM/DD/YYYY):		2. Time of Drawn (24 hour clock):	[HHMM]
3. Last time subject ate (MM/DD/YYYY):	·	4. Last time subject at (24 hour clock):	[HHMM]
		, , , , , <u>—</u>	
Blood Processing:		Diamage Buffe Cont II amada Tan S	Ful - 1011
RNA (PAXgene Tube) Total Volume of blood drawn (1 x 2.5 mL PAXgene		Plasma & Buffy Coat (Lavender Top	rube – Tomt)
RNA tube):	mL	Time spin started (24 hour clock): Duration of centrifuge:	[HHMM]
Time PAXgene RNA tube placed in freezer (24		Temp of centrifuge:	°C
hour clock):	[HHMM]	Rate of centrifuge:	xg
Storage temperature of freezer:	°C	Original volume drawn (3x10 mL EDTA tubes):	
Serum (Red Top Tube)		1	
Time spin started (24 hour clock):	[HHMM]	EDTA #1: mL EDTA #2: mL EDTA)TA #3: mL
Duration of centrifuge:		Time aliquoted:	[HHMM]
Temp of centrifuge:		Number of 1.5 mL plasma aliquots created:	
Rate of centrifuge:		If applicable, volume of residual plasma	mL
Original volume drawn (1x10 mL Serum tube):	mL	aliquot (less than 1.5 mL-Blue cap):	
Original volume drawn (1x10 mL Serum tube):		If applicable, specimen number of residual	
Time aliquoted:	[HHMM]	plasma aliquot (Last four digits):	
Number of 1.5 mL serum aliquots created:		Time aliquots placed in freezer (24 hour clock):	
If applicable, volume of residual serum		Storage temperature of freezer:	°c
aliquot (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): Time aliquots placed in freezer (24 hour clock):	IMMHI	Buffy coat aliquot #2 (last four digits): Buffy coat volume #2:	mL
Storage temperature of freezer:		Buffy coat aliquot #3 (last four digits):	
EDTA (Lavender Top Tube – 3m		Buffy coat volume #3:	mL
	•	Buffy coat aliquot #4 (last four digits):	
Original volume drawn (1x3mL EDTA tube):	mL	Buffy coat volume #4:	mL
Time aliquoted:	[HHMM]	EDTA (Lavender Top Tube –	6mL)
Whole blood aliquot #1 (last four digits):		6mL EDTA tube for CLIA testing collected?	☐ Yes ☐ No
Whole blood volume #1:	mL		mL
Whole blood aliquot #2 (last four digits):		Notes:	
Whole blood volume #2:	mL		
Whole blood aliquot #3 (last four digits):			
Whole blood volume #3:	mL		
Whole blood aliquot #4 (last four digits):			
Whole blood volume #4:	mL		

Biological Sample Notification Form-

Blood

Provide this information about the site:

From: Site coordinator name

Phone: Site phone number

Email: Site email or site coordinator's email

	articipant ID: LDS		NCDA
Alatinian Birmin Santu 🌣	•	nipment Notification Form n or prior to the date of shipment	NCRA
To: Kelley Faber	Email: alzstudy@	Phone: 1-800-5	26-2839
General Information:		Kit #:	
From:		[
Phone:			
Email:	-	KIT BARCODE	
		KII BARCODE	
Date:	_	i	
Study: iLEADS: □ CI Participant □ CN P		Kit # (Only if 3ml EDTA tube used for LRS):	:
Visit (circle one): BASELINE M12 M24 M36	6 M48 M60 N	172	
Sex: □ M □ F		į	
Year of Birth:		KIT BARCODE	
rear or birth:		KII BARCODE	
Tracking #:			
Blood Collection:			
1. Date Drawn (MM/DD/YYYY):		2. Time of Drawn (24 hour clock):	[HHMM]
3. 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	mL	Time spin started (24 hour clock):	
RNA tube):		Duration of centrifuge:	[HHMM]
Time PAXgene RNA tube placed in freezer (24	[HHMM]	Temp of centrifuge:	
hour clock):		Rate of centrifuge:	x
Storage temperature of freezer:		Original volume drawn (3x10 mL EDTA tubes):	
Serum (Red Top Tube)			
Time spin started (24 hour clock):		EDTA #1:mL EDTA #2:mL EDTA	
Duration of centrifuge:		Time aliquoted:	[HHMM]
Temp of centrifuge:		Number of 1.5 mL plasma aliquots created:	
Rate of centrifuge:		If applicable, volume of residual plasma	mL
Original volume drawn (1x10 mL Serum tube):		aliquot (less than 1.5 mL-Blue cap):	
Original volume drawn (1x10 mL Serum tube):	mL	If applicable, specimen number of residual	
Time aliquoted:	[HHMM]	plasma aliquot (Last four digits):	
Number of 1.5 mL serum aliquots created:		Time aliquots placed in freezer (24 hour clock):	
If applicable, volume of residual serum		Storage temperature of freezer:	°C
aliquot (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:		Buffy coat aliquot #3 (last four digits):	
EDTA (Lavender Top Tube – 3m	•	Buffy coat volume #3:	mL
		Buffy coat aliquot #4 (last four digits):	
Original volume drawn (1x3mL EDTA tube):		Buffy coat volume #4:	mL
Time aliquoted:	[HHMM]	EDTA (Lavender Top Tube –	
Whole blood aliquot #1 (last four digits):		6mL EDTA tube for CLIA testing collected?	☐ Yes ☐ No
Whole blood volume #1:	mL		m
Whole blood aliquot #2 (last four digits):		Notes:	
Whole blood volume #2:	mL		
Whole blood aliquot #3 (last four digits):			
Whole blood volume #3:	mL		
Whole blood aliquot #4 (last four digits):			

Biological Sample Notification Form –

Send by E-mail prior to shipment and include a hard copy in each shipment

To: Kelley Faber Email: alzstudy@ meral Information:	@iu.edu	Phone: 1-800-526-28	
•		Filone: 1-000-320-20	39
om:	Kit #:		
one:	[
nail:	KIT BARO	ODE	
te:udy: iLEADS:			
sit (circle one): BASEUNE M12 M24 M36 M48 M60 x:	M72		
ar of Birth:	CSF Colle	ected? 🗆 Yes	□ No
acking #:	Gauge needle used	for LP: 🗆 22G	□ 24G
F Collection:			
Date of Collection (MM/DD/YYYY):			
2. Time of Collection (24 hour clock):			
3. Last date subject ate (MM/DD/YYYY):			
4. Last time subject at (24 hour clock):	[HHMM]		
F Processing:			
Total amount of CSF collected:		m	nL
Time spin started (24 hour clock):		[1	нимм]
Duration of centrifuge:		m	inutes
Temp of centrifuge:		°c	
Rate of centrifuge		>	(g
Time aliquoted:			HHMM]
Number of 1.5mL aliquots created (up to 14 total): ((Orange cap cryovial)		
f applicable, volume of CSF residual aliquot (Blue ca	ap cryovial)		
f applicable, specimen number of residual CSF aliqu	uot (Last four digits):		
Time aliquots placed in freezer (24 hour clock):		[HHMN	1]
Storage temperature of freezer:			c
Notes:			

Biological Sample Notification Form –

CSF

Provide this information about the site:

From: Site coordinator name

Phone: Site phone number

Email: Site email or site coordinator's email

	ı.edu Phone	e: 1-800-526-283	9
General Information: From:	Kit #:		
Phone:	[
Email:	KIT BARCODE		
Date:	!		
Visit (circle one): BASELINE M12 M24 M36 M48 M60 M	M72		
Sex: □ M □ F			
Year of Birth:	CSF Collected?		□ No
Tracking #:	Gauge needle used for LP	: 🗆 22G	□ 240
CSF Collection:			
1. Date of Collection (MM/DD/YYYY):			
Time of Collection (24 hour clock): Last date subject ate (MM/DD/YYYY):			
	[HHMM]		
CSF Processing:			
CSF Processing: Total amount of CSF collected:		ml	L
			нмм]
Total amount of CSF collected:		[H	
Total amount of CSF collected: Time spin started (24 hour clock):		[H	нмм]
Total amount of CSF collected: Time spin started (24 hour clock): Duration of centrifuge:		(H	HMM] nutes
Total amount of CSF collected: Time spin started (24 hour clock): Duration of centrifuge: Temp of centrifuge:		.c wii	HMM] nutes
Total amount of CSF collected: Time spin started (24 hour clock): Duration of centrifuge: Temp of centrifuge: Rate of centrifuge	ange cap cryovial)	.c wii	HMM] nutes
Total amount of CSF collected: Time spin started (24 hour clock): Duration of centrifuge: Temp of centrifuge: Rate of centrifuge Time aliquoted:		.c wii	HMM] nutes
Total amount of CSF collected: Time spin started (24 hour clock): Duration of centrifuge: Temp of centrifuge: Rate of centrifuge Time aliquoted: Number of 1.5mL aliquots created (up to 14 total): (Or	cryovial)	.c wii	HMM] nutes
Total amount of CSF collected: Time spin started (24 hour clock): Duration of centrifuge: Temp of centrifuge: Rate of centrifuge Time aliquoted: Number of 1.5mL aliquots created (up to 14 total): (Or If applicable, volume of CSF residual aliquot (Blue cap	cryovial)	.c wii	HMM] nutes HMM]

NCRAD Website

Helpful Pages

• https://ncrad.iu.edu/contact/holiday-closures

♠ / 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



iLEADS Active Study Page



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COORDINATE STUDIES ~

GENETICS & FAMILIES >

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NIA-AD FBS

NAPS2

PATH

APOE

4RTNI-2

90+ Study ABC-DS

ACAD

ACE

ACT

ADCFB

ADNI-3,4

AGMP ALLFTD

BBBSR

BenfoTeam

BEYONDD

CADASIL

CLARITI

♠ / Coordinate Studies / LEADS

ILEADS ACTIVE STUDY PAGE

WelcomeiLEADS 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/Annual Visit	
Serum	~	~	~	~	✓	
Plasma	~	~	~	~	~	
Buffy Coat (DNA)	~	~	~	~	✓	
Whole Blood for CLIA lab testing	~					
Whole Blood for Long Read Sequencing	~	Collected only once over the entire course of a participant's participation in the iLEADS Study. May be collected at longitudinal visits if not collected at Baseline				
Whole Blood for RNA	~	~	~	~	✓	
Whole Blood for PBMC *optional	~	~	~	~	~	
CSF *optional	~	~	~	~		



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>

