



**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**



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## Contact Information

- Questions?

Please contact NCRAD Coordinators at:

- Phone: 1-800-526-2839 or 317-274-7546
- E-mail: [alzstudy@iu.edu](mailto:alzstudy@iu.edu) or [agericks@iu.edu](mailto:agericks@iu.edu)
- Website: [www.ncrad.org](http://www.ncrad.org)



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# Training Overview:

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



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## 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	X	X	X	X	X	X
Plasma	X	X	X	X	X	X	X	X
DNA	X	X	X	X	X	X	X	X
Whole blood for CLIA lab testing	X							
Whole blood for long read sequencing	X	X	Collected only once over the entire course of a participant's participation in the LEADS Study. May be collected at longitudinal visits if not collected at Baseline					
RNA	X	X	X	X	X	X	X	X
PBMC	X	X	X	X	X	X	X	X
CSF	X	X	X		X	X	X	

\*CN M12 CSF may be collected if CSF was not collected at Baseline.



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Biofluids Collection Schedule for CI (Cognitively)					
Sample Type	Tube Type	Number of Tubes Supplied in Kit	Aliquot Volume	Tubes to NCRAD	Ship
Whole blood for isolation of serum	Plain Red-Top Serum Blood Collection Tube (10 ml)	1	N/A	N/A	N/A
	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
Whole blood for isolation of plasma & buffy coat (for DNA extraction)	EDTA (Lavender-Top) Blood Collection Tube (10 ml)	3	N/A	N/A	N/A
	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 yellow cap.	Up to 14	Frozen

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Biofluids Collection Schedule for CN Participants					
Sample Type	Tube Type	Number of Tubes Supplied in Kit	Aliquot Volume	Tubes to NCRAD	Ship
Whole blood for isolation of serum	Plain Red-Top Serum Blood Collection Tube (10 ml)	1	N/A	N/A	N/A
	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
Whole blood for isolation of plasma & buffy coat (for DNA extraction)	EDTA (Lavender-Top) Blood Collection Tube (10 ml)	3	N/A	N/A	N/A
	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 with yellow cap.	Up to 14	Frozen

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# Kit Request Module

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



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# 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:
  - CI Baseline Blood-Based Kit
  - CI Month 12, Month 24, Month 36, Month 48 Blood-Based Kits
  - CN Baseline, Month 12, Month 24 Blood-Based Kits
  - Long Read Sequencing Kit
  - Blood Supplemental Supply Kit
  - Frozen Blood Shipping Kit
  - Ambient Blood Shipping Kit
  - LEADS 22G LP Kit
  - LEADS 24G LP Kit
  - LEADS CSF Kit
  - CSF Supplemental Supply Kit
  - CSF Shipping Supply Kit



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# 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.



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# 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.



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

## Study Visit Kits

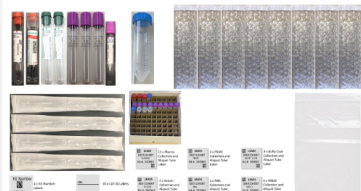
- Indicate the quantity needed of each kit
- Once selected, kit components of the chosen kit will appear at the bottom of the screen (Pictured)

Each **CI (EQM)** Baseline Blood-Based Kit Contains:  
 (U site: Finale KIT312)  
 All other sites: Finale 104 2.2

- 1 PANigene™ Blood Collection Tube (2.5 ml) - CT004
- 1 Plain Red Top Serum (Red-Top) Blood Collection Tube (10 ml) - CT006
- 2 Serum Heparin (Green-Top) Blood Collection Tube (10 ml) - CT008
- 3 EDTA (Lavender-Top) Blood Collection Tube (10 ml) - CT021
- 1 EDTA (Lavender-Top) Blood Collection Tube (8 ml) - CT023
- 2 Cryovial tube (2.0 ml) with LAVENDAR cap - CV027
- 2 Cryovial tube (2.0 ml) with RED cap - CV028
- 2 Cryovial tube (2.0 ml) with BLUE cap - CV034
- 2 Cryovial tube (2.0 ml) with CLEAR cap - CV014
- 4 Disposable graduated transfer pipette (3 ml) - CV015
- 1 Some optional (Unshipped) - CV016: Bubble wrap tube sleeve - SH032 (Note to sites: Reuse 3 for frozen blood tubes for shipping)
- 1 5l cell cryobox - CV021
- 1 Reusable bag - ST002

**LEADS**

- 25 Pre-printed Collection and Aliquot Tube Label (13 x PLASMA, 5 x SERUM, 2 x PBMC, 1 x RNA, 3 x BUFFY COAT, & 1 x WBCT) - LB003
- 4 Pre-printed Kit Number Label - LB003
- 10 Labels for handwritten Site and LEADS ID - LB003



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Do you need Extra Supplies?  Yes  No

\* must provide value

25 cell Cryobox (CV005)	<input type="radio"/> 5 <input type="radio"/> 10
81 cell Cryobox (CV021)	<input type="radio"/> 5 <input type="radio"/> 10
Cryovial tubes (2.0 ml) with lavender cap (CV027)	<input type="radio"/> 10 <input type="radio"/> 25
Cryovial tubes (2.0 ml) with red cap (CV028)	<input type="radio"/> 10 <input type="radio"/> 25
Cryovial tubes (2.0 ml) with orange cap (CV017 & CV018)	<input type="radio"/> 25 <input type="radio"/> 50
Cryovial tubes (2.0 ml) with clear cap (CV014)	<input type="radio"/> 5 <input type="radio"/> 10
Cryovial tubes (2.0 ml) with yellow cap (CV037)	<input type="radio"/> 5 <input type="radio"/> 10
Cryovial tubes (2.0 ml) with blue cap (CV034)	<input type="radio"/> 10 <input type="radio"/> 25
UPS Laboratory Paks (SH053)	<input type="radio"/> 5 <input type="radio"/> 10
UN3373 labels (LB008)	<input type="radio"/> 5 <input type="radio"/> 10
Biohazard label (LB009)	<input type="radio"/> 5

## Study Visit Kits

- 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.



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## Study Visit Kits

Our standard shipping time for all orders is 3 weeks.

We can ship this kit request by: **05-10-2024**

If you need any supplies in this order prior to **05-10-2024**, you must contact the NCRAD coordinator for this study: [agericks@iu.edu](mailto:agericks@iu.edu).

Comments

Expand

←

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

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## 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.

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## 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.

The logo for NCRAD, consisting of the letters "NCRAD" in a blue, sans-serif font. The "AD" is slightly larger and bolder than the "NCR".

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## Specimen Labels

The logo for NCRAD, consisting of the letters "NCRAD" in a blue, sans-serif font. The "AD" is slightly larger and bolder than the "NCR".

National Centralized Repository for  
Alzheimer's Disease and Related Dementias

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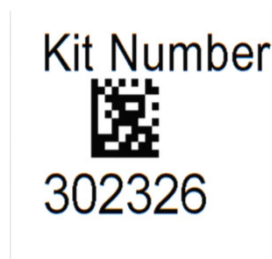
# Label Type Summary

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

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## Kit Number Labels



*Provided by NCRAD in the kits*

- Used to track patient samples and provide quality assurance
- Will be placed on the following locations:
  1. Biological Sample and Shipment Notification Form
  2. Outside cryobox that houses aliquot tubes during storage and shipment
  3. CSF Sample and Shipment Notification Form **(IF COLLECTED)**
    - CSF samples will have a different kit number than the blood collection specimens

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## Site and LEADS ID Label

**LDS:**

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- 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

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## Site and LEADS ID Label Cont.

**LDS:**

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- 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 ( ml) for CLIA lab testing **\*\*CI Baseline ONLY\*\***
  - EDTA (Lavender-Top) Blood Collection Tube (3ml) for LRS **\*\*collected only once\*\***
- Kits will include one extra label

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# Collection and Aliquot Tube Labels

**LEADS** ← Study Name

**0001234567** ← Specimen Barcode (assigned by NCRAD)

**PLASMA** ← Sample Type

**Kit #: 300001** ← Kit # (assigned by NCRAD) unique to the subject and visit

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# Collection and Aliquot Tube Labels

		<ul style="list-style-type: none"> <li>• Labels to be placed on ALL collection and aliquot tubes</li> <li>1. PAXgene™ Blood Collection Tube (2.5 ml) for RNA</li> <li>2. Plain Red-Top Serum Blood Collection Tube (10 ml) for Serum                             <ul style="list-style-type: none"> <li>• Serum aliquots</li> </ul> </li> <li>3. Sodium Heparin (Green-Top) Blood Collection Tube (10 ml) for PBMC x 2</li> <li>4. EDTA (Lavender-Top) Blood Collection Tube x 3                             <ul style="list-style-type: none"> <li>• Plasma aliquots</li> <li>• Buffy coat aliquot</li> </ul> </li> <li>5. EDTA (Lavender-Top) Blood Collection Tube (6 ml) for CLIA lab testing <b>*CI Baseline ONLY</b></li> <li>6. CSF – Only place labels on aliquot tubes</li> </ul>

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## Collection and Aliquot Tube Labels

<div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <b>LEADS</b>              0001234570              PLASMA              Kit #: 300001         </div> <p style="font-size: small; margin-left: 20px;">13 x PLASMA</p> <ul style="list-style-type: none"> <li>3 x for 10mL EDTA Tubes</li> <li>10 x for 2ml cryovials (9 purple &amp; 1 blue)</li> </ul>	<div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <b>LEADS</b>              0001234567              RNA              Kit #: 300001         </div> <p style="font-size: small; margin-left: 20px;">1 x RNA for PAXgene Tube</p>
<div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <b>LEADS</b>              0001234571              Buffy Coat              Kit #: 300001         </div> <p style="font-size: small; margin-left: 20px;">3 x Buffy Coat for clear cap cryovials</p>	<div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <b>LEADS</b>              0001234572              WBLD              Kit #: 300001         </div> <p style="font-size: small; margin-left: 20px;">1 x WBLD for 6ml EDTA Tube</p>
<div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <b>LEADS</b>              0001234569              PBMC              Kit #: 300001         </div> <p style="font-size: small; margin-left: 20px;">2 x PBMC for 10ml NaHep Tubes</p>	<div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <b>LEADS</b>              0001234590              DNA              Kit #: 300002         </div> <p style="font-size: small; margin-left: 20px;">5 x DNA</p> <ul style="list-style-type: none"> <li>1 x for 3ml EDTA Tube</li> <li>4 x for 2ml cryovials (3 green &amp; 1 blue)</li> </ul>
<div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <b>LEADS</b>              0001234568              Serum              Kit #: 300001         </div> <p style="font-size: small; margin-left: 20px;">5 x Serum</p> <ul style="list-style-type: none"> <li>1 x for 10mL Serum Tube</li> <li>4 x for 2ml cryovials (3 red &amp; 1 blue)</li> </ul>	<div style="border: 1px solid gray; padding: 5px; margin-bottom: 5px;"> <b>LEADS</b>              0001234590              CSF              Kit #: 300002         </div> <p style="font-size: small; margin-left: 20px;">14 x CSF for 2ml cryovials (13 orange &amp; 1 blue)</p>

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## 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:

**LEADS**  
 0001234567  
 PLASMA  
 Kit #: 300001

Label 2:

**LDS:**  

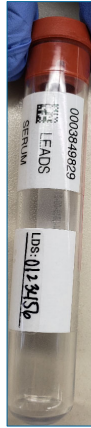

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Collection Tube Label  
\*place barcode near top

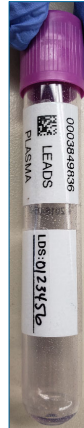
Site and NAPS2 ID Label

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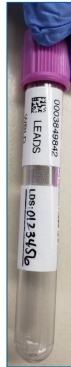
## Specimen Labels: Blood Collection Tubes



Plain Red Top Serum Blood Collection Tube (10 ml)



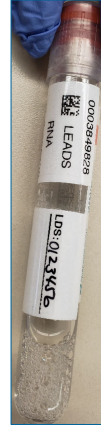
EDTA (Lavender-Top) Blood Collection Tube (10 ml) x 3



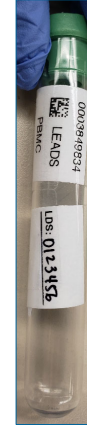
EDTA (Lavender-Top) Blood Collection Tube (6 ml)



EDTA (Lavender-Top) Blood Collection Tube (3 ml)



PAXgene™ Blood Collection Tube (2.5 ml)



Sodium Heparin (Green Top) Blood Collection Tube (10 ml) x 2



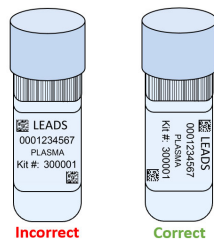
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## Specimen Labels: Aliquot Tubes



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

### ALIQOT TUBE LABELING DIAGRAM



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

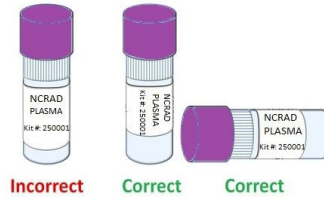


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## Labeling Biologic Samples

### Please...

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



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## Handling/ Processing Study Specimens



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## Site Required Equipment

### Blood Collection/Safety Equipment

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

### Processing/Storage Equipment

1. Centrifuge capable of  $\geq 2000$  rcf with refrigeration to  $4^{\circ}\text{C}$
2.  $-80^{\circ}\text{C}$  Freezer
3. Wet Ice Bucket



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## 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



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### Sample Collection - Blood

Tube Type	Number of Tubes Drawn	Tube Image
1. Plain Red-Top Serum Blood Collection Tube (10 ml) for Serum	x1	
2. EDTA (Lavender-Top) Blood Collection Tube (10 ml) for Plasma	x3	
3. EDTA (Lavender-Top) Blood Collection Tube (6ml) for CLIA lab testing <b>**CI Baseline ONLY**</b>	x1	
4. EDTA (Lavender-Top) Blood Collection Tube (3ml) for LRS <b>**only collected once per participant**</b>	x1	
1. PAXgene™ Blood Collection Tube (2.5 ml) for RNA	x1	
3. Sodium Heparin (Green-Top) Blood Collection Tube (10 ml) for PBMC	x2	

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### 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


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### Serum Preparation (10ml Red Top Tube)

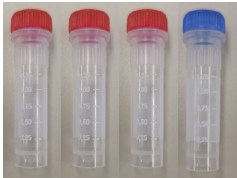
**Prior to blood draw, label all tubes:**

1 x 10mL Serum Tube



Label with: LDS: \_\_\_\_\_ & LEADS  
0001234567  
Serum  
Kit #: 300001


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



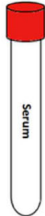
Label with: LEADS  
0001234567  
Serum  
Kit #: 300001

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### Serum Preparation (10ml Red Top Tube)




**Step One**



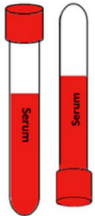
- Store tubes at room temperature.
- Label tubes and cryovials with pre-printed labels prior to blood draw.

**Step Two**




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

**Step Three**



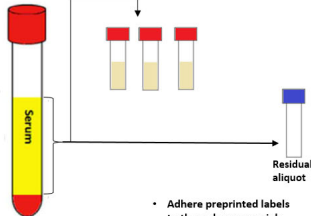
- Immediately after blood draw, invert tube 5 times to mix samples.

**Step Four**



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

**Step Five**



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

Residual aliquot

- Adhere preprinted labels to the red-cap cryovials.
- Aliquot 1.5 ml into each cryovial tube.
- If a residual aliquot is created, document specimen number and volume on Sample Notification Form.
- Store serum aliquots at -80°C until shipment.

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# Plain Red-Top Serum Tube (Serum Collection)

Serum

RBC, WBC & Platelet Clot

Serum Aliquots (up to 4 possible)

Close up view of 2.0 ml cryovial

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## 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: LDS: \_\_\_\_\_ & LEADS 0001234567 PLASMA Kit #: 300001

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



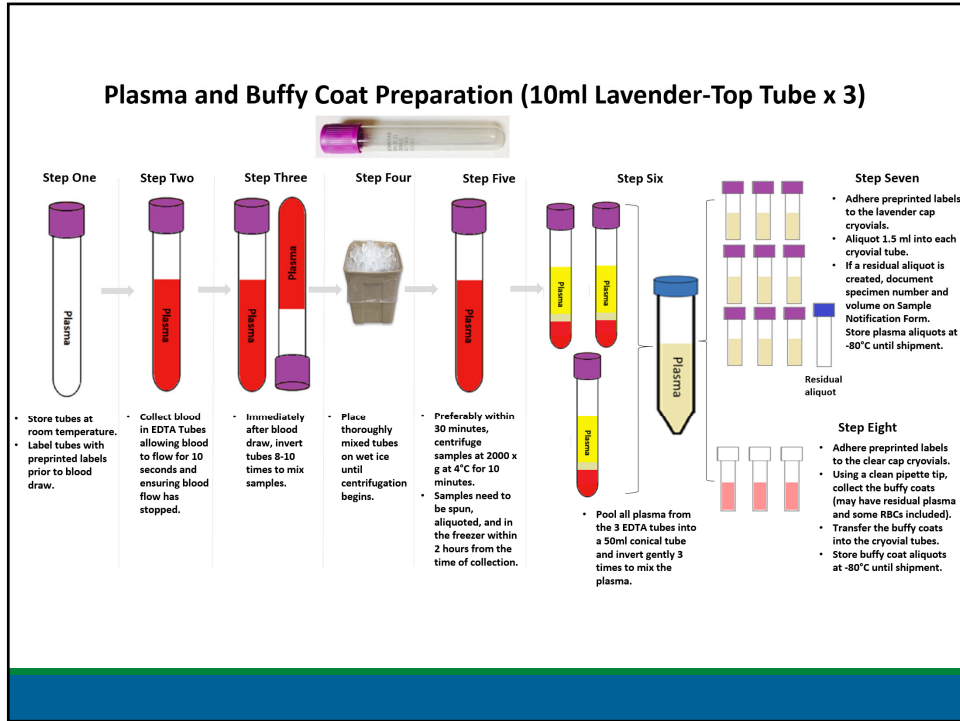
Label with: LEADS 0001234567 PLASMA Kit #: 300001

3 x 2ml Clear Cap Cryovials

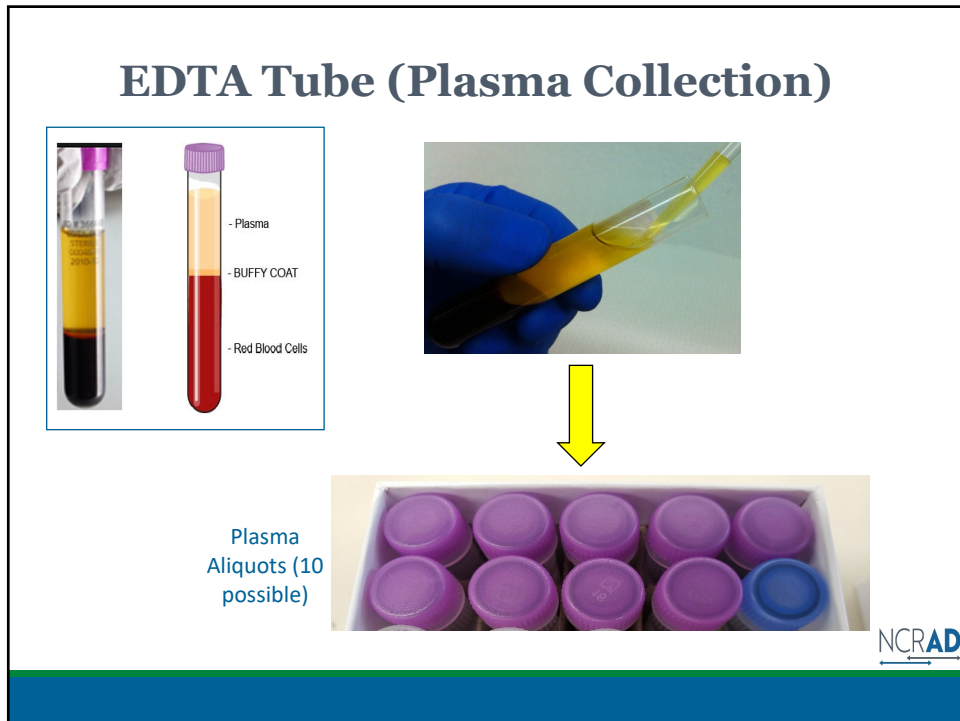


Label with: LEADS 0001234567 BUFFY COAT Kit #: 00001

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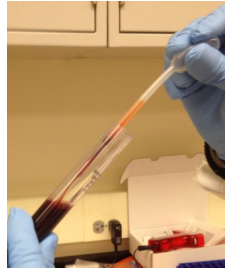
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## EDTA Tube (Buffy Coat Collection)

Buffy Coat layer (mixed with RBCs)



Buffy Coat Aliquot  
(Please use CLEAR CAP cryovial)

**Important Note:**  
Buffy Coat aliquots will be distinguished from the plasma aliquots through a clear cap.



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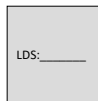
## Whole Blood Preparation (6 mL Lavender-Top Tube)

Prior to blood draw, label all tubes:

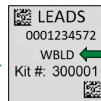
1 x 6mL EDTA Tube



Label with:



&



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### Whole Blood Preparation (6 mL Lavender-Top Tube)

**Step One**

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

**Step Two**

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

**Step Three**

- Immediately after blood draw, invert tube 3 times to mix sample.

**Step Four**

- Immediately after inversion, freeze the sample in an -80°C freezer until ready to ship.

**CI Subjects at Baseline Only**

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

**Prior to blood draw, label all tubes:**

1 x 3mL EDTA Tube

Label with:

LDS: \_\_\_\_\_

&

LEADS

0001234590

DNA ←

Kit #: 300002

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

Label with:

LEADS

0001234590

DNA ←

Kit #: 300002

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

**Step 1**

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

**Step 2**

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

**Step 3**

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

**Step 4**

- Adhere preprinted labels to the green cap cryovials.
- Aliquot 1 ml into each cryovial tube.
- If a residual aliquot is created, document specimen number and volume on Sample Notification Form.
- Store whole blood aliquots at -80°C until shipment.

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

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### RNA Preparation (2.5ml PAXgene™ Tube)

**Prior to blood draw, label all tubes:**

1 x RNA PAXgene™ Tube

Label with:

LDS: \_\_\_\_\_

&

LEADS

0001234567

RNA

Kit #: 300001

←

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### RNA Preparation (2.5ml PAXgene™ Tube)

**Step One**      **Step Two**      **Step Three**      **Step Four**

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

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

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

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

**Styrofoam racks** (with a red prohibition sign)

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### PBMC Preparation (10ml Sodium Heparin Tube) x 2

**Prior to blood draw, label all tubes:**

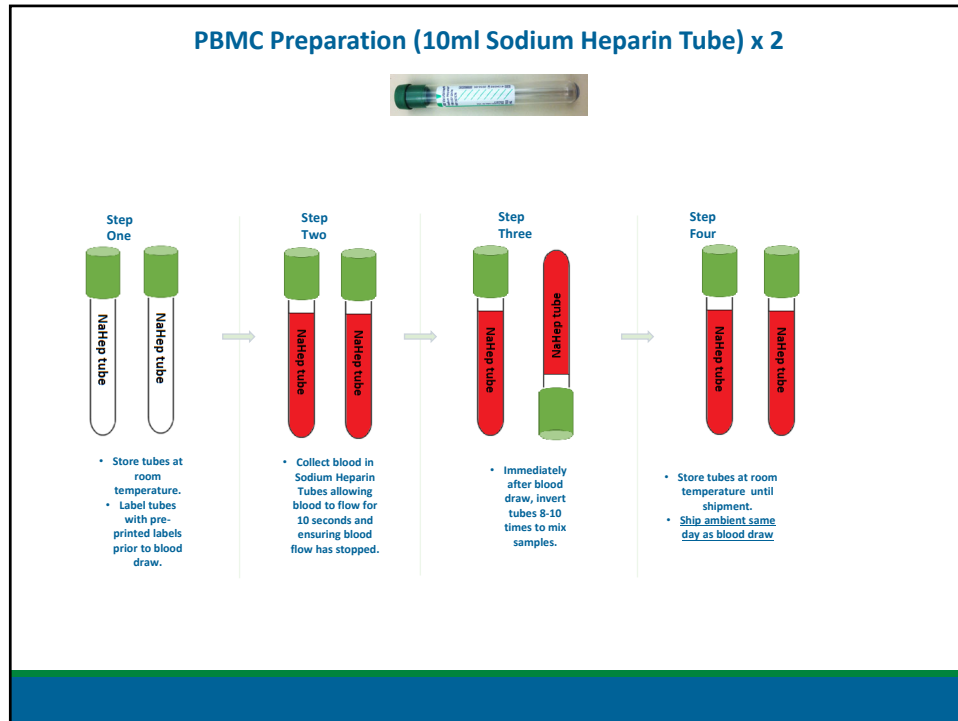
2 x 10mL Sodium Heparin (NaHep) PBMC Tubes

Label with:

LDS: \_\_\_\_\_ & LEADS

0001234569  
PBMC  
Kit #: 300001

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## CSF Collection and Processing

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**\*\*\*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.

1.5 ml Aliquots (ORANGE CAP)

Residual Aliquot (BLUE CAP)

Kit numbers for blood and CSF will be different

- CSF aliquot tube for local lab
- Label not provided

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### CSF Preparation (15-20 ml total)

**Step One**

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

**Step Two**

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

**Step Three**

- Collect 15-20 ml total, including the 1-2 ml sent to the local lab.
- Collect sample into 2 15 ml conical tubes.

**Step Four**

- Place samples upright on wet ice until centrifugation begins.

**Step Five**

- Preferably within 15 minutes of collection, centrifuge samples at 4°C at 2000 x g for 10 minutes.

**Step Six**

- Using a clean transfer pipette, transfer CSF from both 15 ml conical tubes into a 50 ml conical tube, leaving the debris in the bottom.
- Gently invert the 50 ml conical tube 3-4 times to mix the sample.

**Step Seven**

- Aliquot 1.5 ml into the orange-cap cryovials.
- If a residual aliquot is created, aliquot into blue-cap cryovial. Document specimen number and volume on CSF Sample Notification Form.
- Within 2 hours of CSF collection, samples need to be spun, aliquoted and in the freezer. Store at -80°C until shipment. Record time of freezing on CSF Sample Notification Form.

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# Sample Shipping



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## 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 & buffy coat (for DNA extraction)	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
	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

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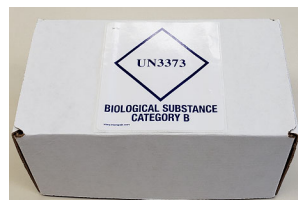
## Ambient Sample

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

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## 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 FedEx ClinPak, seal, and place FedEx label on outside of package.

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## Frozen Sample Shipping

### •Ship Monday-Wednesday Only

• RNA, Serum, Plasma, Buffy Coat, CSF, Whole Blood for CLIA\*, and Whole Blood for LRS\*

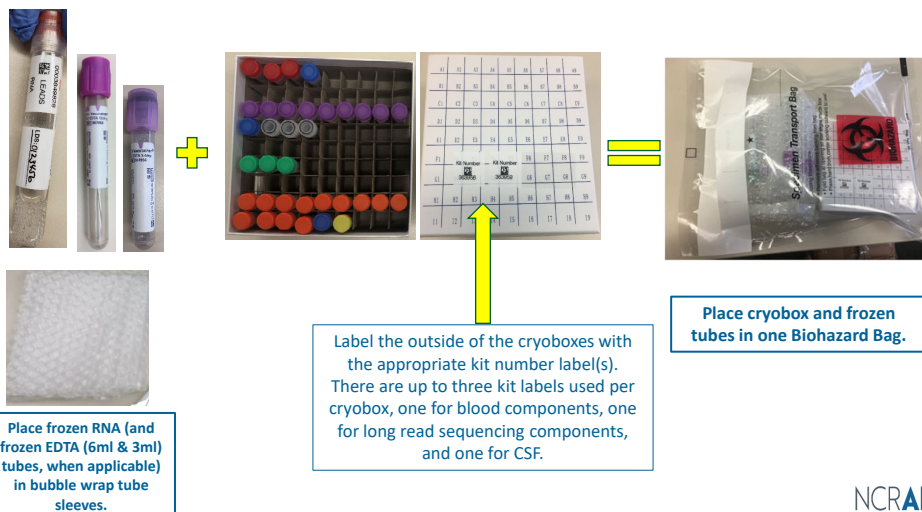
(\*when applicable)

- 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.

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## Frozen Shipping - Cryoboxes



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## 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.

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## 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!



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## Shipping Frozen Samples

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

The logo for NCRAD, consisting of the letters "NCRAD" in a blue, sans-serif font. The "A" is stylized with a horizontal line through its center. Below the letters is a blue horizontal bar.

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## 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.

The logo for NCRAD, consisting of the letters "NCRAD" in a blue, sans-serif font. The "A" is stylized with a horizontal line through its center. Below the letters is a blue horizontal bar.

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## 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 <a href="http://www.iata.org">www.iata.org</a> Training schools located in 30 countries
Saf-T Pak Inc. <a href="http://www.saftpak.com">www.saftpak.com</a> Provides dangerous goods training via CD or on-site instruction for North America and Europe	Aiconsult Email: <a href="mailto:Aiconsult@wanadoo.fr">Aiconsult@wanadoo.fr</a> <a href="http://www.aiconsult-bf.com">www.aiconsult-bf.com</a>
Bureau of Dangerous Goods LTD., TIANJIN Addr.: No.3 Yingshui road, Nankai district, Tianjin China Tel: 022-23495890 83326960 83326854 / Fax: 022-83326959 Email: <a href="mailto:cdmin@bdg-china.com.cn">cdmin@bdg-china.com.cn</a> <a href="http://www.bdg-china.com.cn">www.bdg-china.com.cn</a>	



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## 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>



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# 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](mailto:alzstudy@iu.edu)
- Fax: 317-321-2003



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# Biological Sample Notification Form- Blood

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.

Participant ID: LDS \_\_\_\_\_

**LEADS** Alzheimer's Disease Study **Biological Sample and Shipment Notification Form** **NCRAD**

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

To: Kelley Faber      Email: [alzstudy@iu.edu](mailto:alzstudy@iu.edu)      Phone: 1-800-526-2839


<b>General Information:</b>		Kit #
From:	_____	
Phone:	_____	
Email:	_____	
Date:	_____	
Study: LEADS: <input type="checkbox"/> CI Participant <input type="checkbox"/> CN Participant	Kit # (Only if 3 mL EDTA tube used): _____	
Visit (circle one): BASELINE M12 M24 M36 M48 M60	_____	
Sex: <input type="checkbox"/> M <input type="checkbox"/> F	_____	
Year of Birth: _____	_____	
Tracking #:	_____	
<b>Blood Collection:</b>		
1. Date Drawn (MM/DD/YYYY): _____	2. Time of Drawn (24 hour clock): _____	(HH:MM)
3. Last time subject ate (MM/DD/YYYY): _____	4. Last time subject awoke (24 hour clock): _____	(HH:MM)
<b>Blood Processing:</b>		
<b>RNA (PAXgene) Tubes</b>		<b>Plasma &amp; Buffy Coat (Lavender Top Tube - 10mL)</b>
Total Volume of blood drawn (3 x 1.5 mL PAXgene mL tube): _____ mL	Time spin started (24 hour clock): _____ (HH:MM)	Time spin started (24 hour clock): _____ (HH:MM)
Time PAXgene RNA tube placed in freezer (24 hour clock): _____ (HH:MM)	Duration of centrifuge: _____ minutes	Duration of centrifuge: _____ minutes
Temp of centrifuge: _____ °C	Temp of centrifuge: _____ °C	Temp of centrifuge: _____ °C
Rate of centrifuge: _____ x g	Rate of centrifuge: _____ x g	Rate of centrifuge: _____ x g
Original volume drawn (3x1.5mL Serum tube): _____ mL	Original volume drawn (3x10 mL EDTA tubes): _____ mL	Original volume drawn (3x10 mL EDTA tubes): _____ mL
Time aliquoted: _____ (HH:MM)	EDTA #1: _____ mL EDTA #2: _____ mL EDTA #3: _____ mL	EDTA #1: _____ mL EDTA #2: _____ mL EDTA #3: _____ mL
Time spin started (24 hour clock): _____ (HH:MM)	Time aliquoted: _____ (HH:MM)	Time aliquoted: _____ (HH:MM)
Duration of centrifuge: _____ minutes	Number of 1.5 mL plasma aliquots created: _____	Number of 1.5 mL plasma aliquots created: _____
Temp of centrifuge: _____ °C	If applicable, volume of residual plasma aliquot (less than 1.5 mL draw cap): _____ mL	If applicable, volume of residual plasma aliquot (less than 1.5 mL draw cap): _____ mL
Rate of centrifuge: _____ x g	If applicable, specimen number of residual plasma aliquot (last four digits): _____	If applicable, specimen number of residual plasma aliquot (last four digits): _____
Original volume drawn (3x1.5mL Serum tube): _____ mL	Time aliquots placed in freezer (24 hour clock): _____ (HH:MM)	Time aliquots placed in freezer (24 hour clock): _____ (HH:MM)
Time aliquoted: _____ (HH:MM)	Storage temperature of freezer: _____ °C	Storage temperature of freezer: _____ °C
Number of 1.5 mL serum aliquots created: _____	Buffy coat aliquot #1 (last four digits): _____ mL	Buffy coat aliquot #1 (last four digits): _____ mL
If applicable, volume of residual serum aliquot (less than 1.5 mL draw cap): _____ mL	Buffy coat aliquot #2 (last four digits): _____ mL	Buffy coat aliquot #2 (last four digits): _____ mL
If applicable, specimen number of residual serum aliquot (last four digits): _____	Buffy coat aliquot #3 (last four digits): _____ mL	Buffy coat aliquot #3 (last four digits): _____ mL
Time aliquots placed in freezer (24 hour clock): _____ (HH:MM)	Buffy coat aliquot #4 (last four digits): _____ mL	Buffy coat aliquot #4 (last four digits): _____ mL
Storage temperature of freezer: _____ °C	Buffy coat aliquot #5 (last four digits): _____ mL	Buffy coat aliquot #5 (last four digits): _____ mL
<b>EDTA (Lavender Top Tube - 3mL)</b>	<b>EDTA (Lavender Top Tube - 6mL)</b>	<b>FBMC (NaHep Green Top Tube)</b>
3mL EDTA tube for LRS collected? <input type="checkbox"/> Yes <input type="checkbox"/> No	Original volume drawn (3x10mL EDTA tube): _____ mL	Original volume drawn (3x10mL EDTA tube): _____ mL
Original volume drawn (3x10mL EDTA tube): _____ mL	EDTA Lavender Top Tube - 6mL	EDTA Lavender Top Tube - 6mL
Time aliquoted: _____ (HH:MM)	3mL EDTA tube for CLIA testing collected? <input type="checkbox"/> Yes <input type="checkbox"/> No	3mL EDTA tube for CLIA testing collected? <input type="checkbox"/> Yes <input type="checkbox"/> No
Whole blood aliquot #1 (last four digits): _____ mL	Original volume drawn (last 4 digits EDTA tube): _____ mL	Original volume drawn (last 4 digits EDTA tube): _____ mL
Whole blood aliquot #2 (last four digits): _____ mL	Notes:	Notes:
Whole blood aliquot #3 (last four digits): _____ mL	_____	_____
Whole blood aliquot #4 (last four digits): _____ mL	_____	_____
Whole blood aliquot #5 (last four digits): _____ mL	_____	_____

Version 06.2024


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# Biological Sample Notification Form – CSF



Participant ID: LDS



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

To: **Kelley Faber** Email: [kfaber@iu.edu](mailto:kfaber@iu.edu) FAX: 317-321-2003 Phone: 1-800-526-2839

---

**General Information:**

From: \_\_\_\_\_ Date: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Email: \_\_\_\_\_  
 Study: LEADS  CI Participant  CN Participant  KIR #: \_\_\_\_\_  
 Visit (circle one): BASELINE M12 M24 M36 M48 KIT BARCODE  
 Sex:  M  F Year of Birth: \_\_\_\_\_ CSF Collected?  Yes  No  
 Tracking #: \_\_\_\_\_ Gauge needle used for LP:  22G  24G

---

**CSF Collection:**

1. Date of Collection: \_\_\_\_\_ 2. Time of Collection: 24 hour clock: \_\_\_\_\_ [HHMM]  
 3. Last time subject ate: Date: \_\_\_\_\_ 4. Last time subject ate: 24 hour clock: \_\_\_\_\_ [HHMM]  
 5. Collection process:  Gravity Method **OR**  Aspiration

---


**CSF Processing:**

Time spin started: 24 hour clock: \_\_\_\_\_ [HHMM]  
 Duration of centrifuge: \_\_\_\_\_ minutes  
 Temp of centrifuge: \_\_\_\_\_ °C Rate of centrifuge: \_\_\_\_\_ x g  
 Total amount of CSF collected (mL): \_\_\_\_\_ mL  
 Time aliquoted: \_\_\_\_\_ [HHMM]  
 Number of 1.5 mL aliquots created (up to 14 total): \_\_\_\_\_ x 1.5 mL  
 (Orange cap cryovials): \_\_\_\_\_ mL  
 If applicable, volume of CSF residual aliquot (less than 1.5 mL): \_\_\_\_\_ 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: \_\_\_\_\_

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

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## 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 courier 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	PEMAC	Ambert	DO NOT DRAW ON FRIDAY. Must be drawn on Monday – Thursday
Whole Blood	EDTA Tube	DNA Only	Ambert	Do NOT refrigerate. Please keep sample at room temperature until specimen can be shipped via next day delivery methods the follow Monday.
Whole Blood	EDTA Tube	DNA Only	Frozen	Whole blood in EDTA may be frozen in a -80°C freezer within 5 day collection time allowed. <a href="https://ncrad.iu.edu/ncrad/ncrad-sample-storage">https://ncrad.iu.edu/ncrad/ncrad-sample-storage</a>


[Contact / Holiday Closures](#)

### HOLIDAY CLOSURES

DATE	HOLIDAY
January 1	New Year's Day
3 <sup>rd</sup> Monday in January	Martin Luther King, Jr Day
4 <sup>th</sup> Monday in May	Memorial Day
June 19	Juneteenth (observed)
July 4	Independence Day (observed)
1 <sup>st</sup> Monday in September	Labour Day
4 <sup>th</sup> Thursday in November	Thanksgiving
4 <sup>th</sup> Friday in November	Friday after Thanksgiving
December 25	Christmas

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# LEADS Active Study Page



Donate Get Updates

ABOUT ▾ BANK SAMPLES ▾ ACCESS SAMPLES ▾ BIOMARKER ANALYSIS ▾ COORDINATE STUDIES ▾ GENETICS & FAMILIES ▾ CONTACT ▾

COORDINATE STUDIES


- LEADS
- NIA-AD/FBS
- NAPSG
- PATH
- APOE
- 4RTNI-2
- 90+ Study
- ABC-D5
- ACAD
- ACE
- ACT
- ADCFB
- ADNI-3.4
- AGMP
- ALLFTD
- BBBSR
- BerfoTeam
- BEYONDO
- 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	✓	✓	✓	✓	

\*\*Please note that this EDTA tube is used for the purpose of confirmation testing and is only drawn during the Baseline visit for CI participants.




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## Contact Information

- Questions?

Please contact NCRAD Coordinators at:

- Phone: 1-800-526-2839 or 317-278-1133
- E-mail: [alzstudy@iu.edu](mailto:alzstudy@iu.edu) or [agericks@iu.edu](mailto:agericks@iu.edu)
- Website: [www.ncrad.org](http://www.ncrad.org)



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