LEADS

Longitudinal Early-Onset Alzheimer's Disease Study

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

Contact Information

- Questions?

  Please contact NCRAD Coordinators at:

  - Phone: 1-800-526-2839 or 317-274-7546
  - E-mail: alzstudy@iu.edu or wilmesk@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 for CI (Cognitively Impaired) Participants:

CI Participants					
# Collection Tubes	**Draw Order**	**Visit Collected**	**Collection Container**	**Specimen Type**	**Container Received**
1	**1st**	**Baseline, 12-Month, 24-Month, 36-Month, 48-Month**	2.5ml PAXgene™ Blood Collection Tube	RNA	2.5ml PAXgene™ Blood Collection Tube
1	**2nd**		10ml Plain (Red-Top) Serum Blood Collection Tube	Serum	2ml cryovials
2	**3rd**		10ml Sodium Heparin (Green Top) Blood Collection Tube	PBMC	10ml Sodium Heparin (Green Top) Blood Collection Tube
1	**4th**		10ml EDTA (Lavender-Top) Blood Collection Tube	Plasma	2ml cryovials
				Buffy Coat	2ml cryovial
1	**5th**	**Baseline Only**	6ml EDTA (Lavender-Top) Blood Collection Tube	Whole Blood	6ml EDTA (Lavender-Top) Blood Collection Tube
1	**N/A**	**Baseline, 12-Month, 24-Month, 36-Month**	Sterile Container	CSF	2ml cryovials
					2ml cryovials
					2ml cryovials

Biofluids Collection Schedule for CN (Cognitively Normal) Participants

CN Participants					
# Collection Tubes	**Draw Order**	**Visit Collected**	**Collection Container**	**Specimen Type**	**Container Received**
1	**1st**	**Baseline, 12-Month, 24-Month**	2.5ml PAXgene™ Blood Collection Tube	RNA	2.5ml PAXgene™ Blood Collection Tube
1	**2nd**		10ml Plain (Red-Top) Serum Blood Collection Tube	Serum	2ml cryovials
2	**3rd**		10ml Sodium Heparin (Green Top) Blood Collection Tube	PBMC	10ml Sodium Heparin (Green Top) Blood Collection Tube
1	**4th**		10ml EDTA (Lavender-Top) Blood Collection Tube	Plasma	2ml cryovials
				Buffy Coat	2ml cryovial
1	**N/A**	**Baseline, 24-Month** (*can be drawn at M12 if not drawn at Baseline)	Sterile Container	CSF	2ml cryovials
					2ml cryovials
					2ml cryovials

Kit Request Module

http://kits.iu.edu/leads

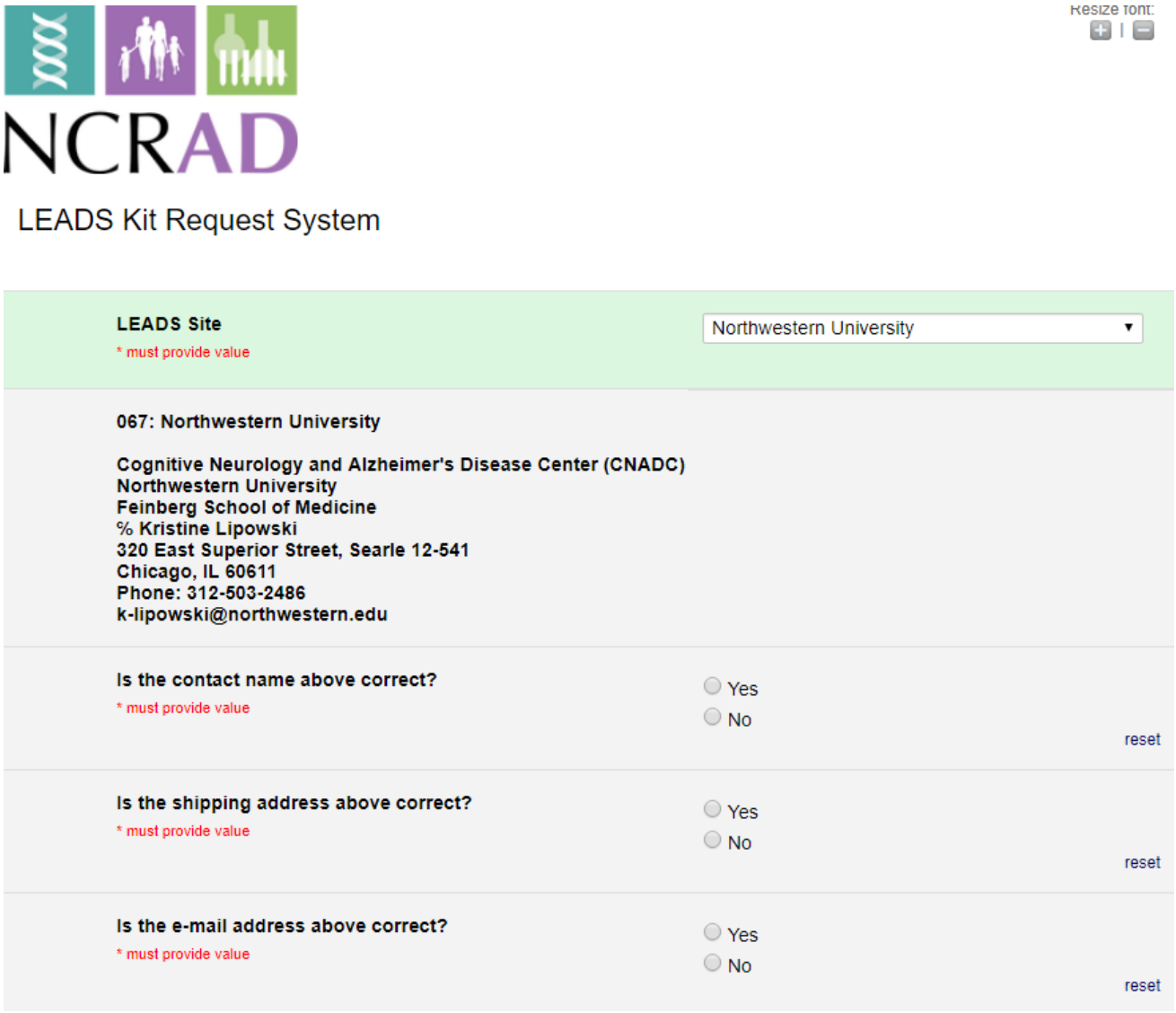
NCRAD

Kit Request Module

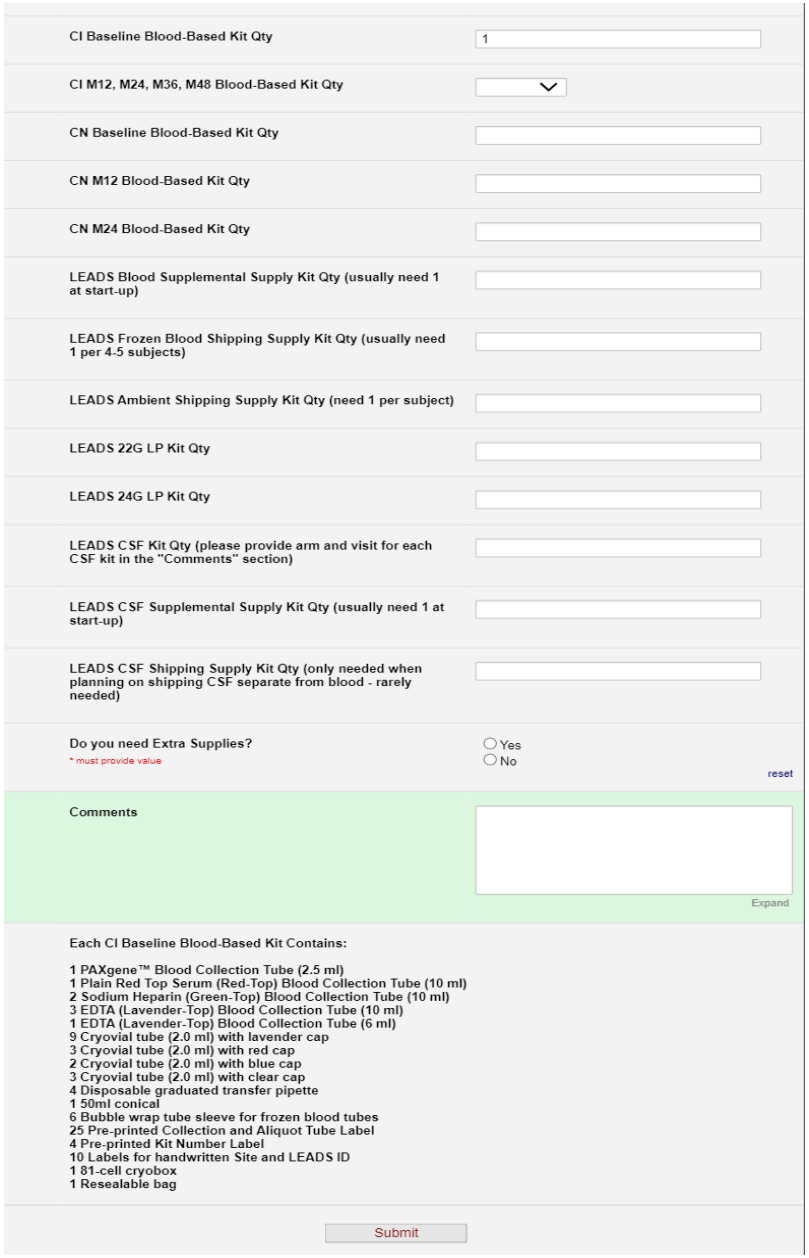
- An initial stock of kits will be delivered prior to the designated site specific start date.
- Kits and individual supplies are available to order:
  - CI Baseline Blood-Based Kit
  - CI Month 12, Month 24, Month 36, Month 48 Blood-Based Kits
  - CN Baseline, Month 12, Month 24 Blood-Based Kits
  - 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

NCRAD 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**



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)
- Click “Submit” to turn in your request.
- The IU staff will notify you that your request has been received and address any issues.
- **Note: You can order more than one type of kit in a single kit request**

Hints When Ordering Kits…

- For every set of CN or CI blood kits that are ordered, please indicate # of CSF kits needed. For example, if you need 20 blood kits and 10 CSF kits, how will those 10 be divided between study arms? 5 CI and 5 CN?
- Will need an LP tray in addition to CSF kit.
- Will need 1 ambient shipping kit per blood kit.
- Will need 1 frozen shipping kit per every 4-5 subjects.
- Should only need CSF shipping kit on rare occasions.
- Will need CSF Supplemental and Blood Supplemental with 1st order.

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 **2 weeks** for your order to be processed and delivered.

Specimen Labels

Label Type Summary

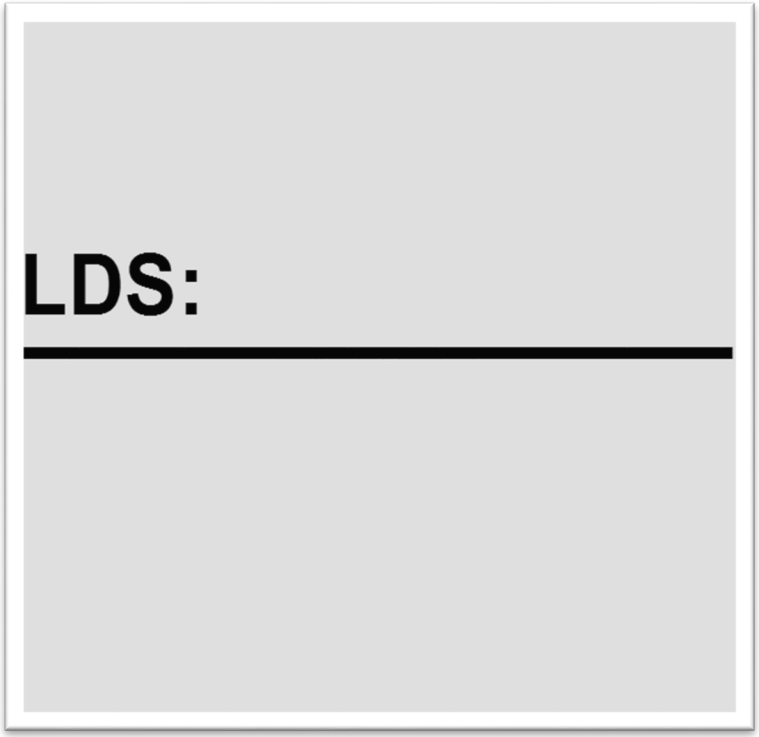
1. Kit Number Labels
2. Site and LEADS ID Labels
3. Collection and Aliquot Tube Labels
   - Differ by specimen type

Kit Number Labels

Provided by NCRAD in the kits

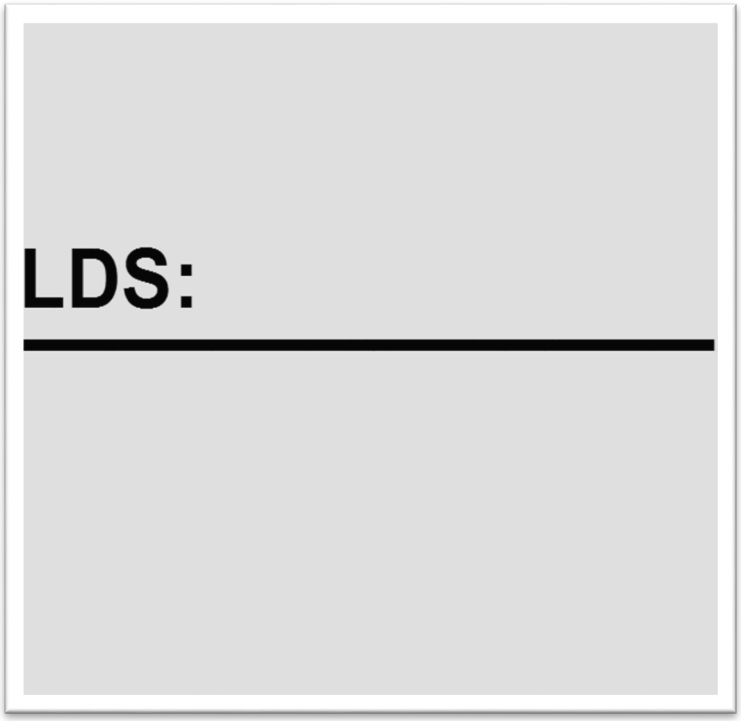
- Used to track patient samples and provide quality assurance
- Will be placed on the following locations:
  1. Biological Sample and Shipment Notification Form
  2. Outside cryobox that houses aliquot tubes during storage and shipment
  3. CSF Sample and Shipment Notification Form (IF COLLECTED)
  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

Site and LEADS ID Label



- 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
  - Each site will receive 4 markers in initial kit supply

Site and LEADS ID Label Cont.



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

Collection and Aliquot Tube Labels

Specimen Number (assigned by NCRAD)

Study Name

Sample Type

Kit # (assigned by NCRAD) unique to the subject and visit

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

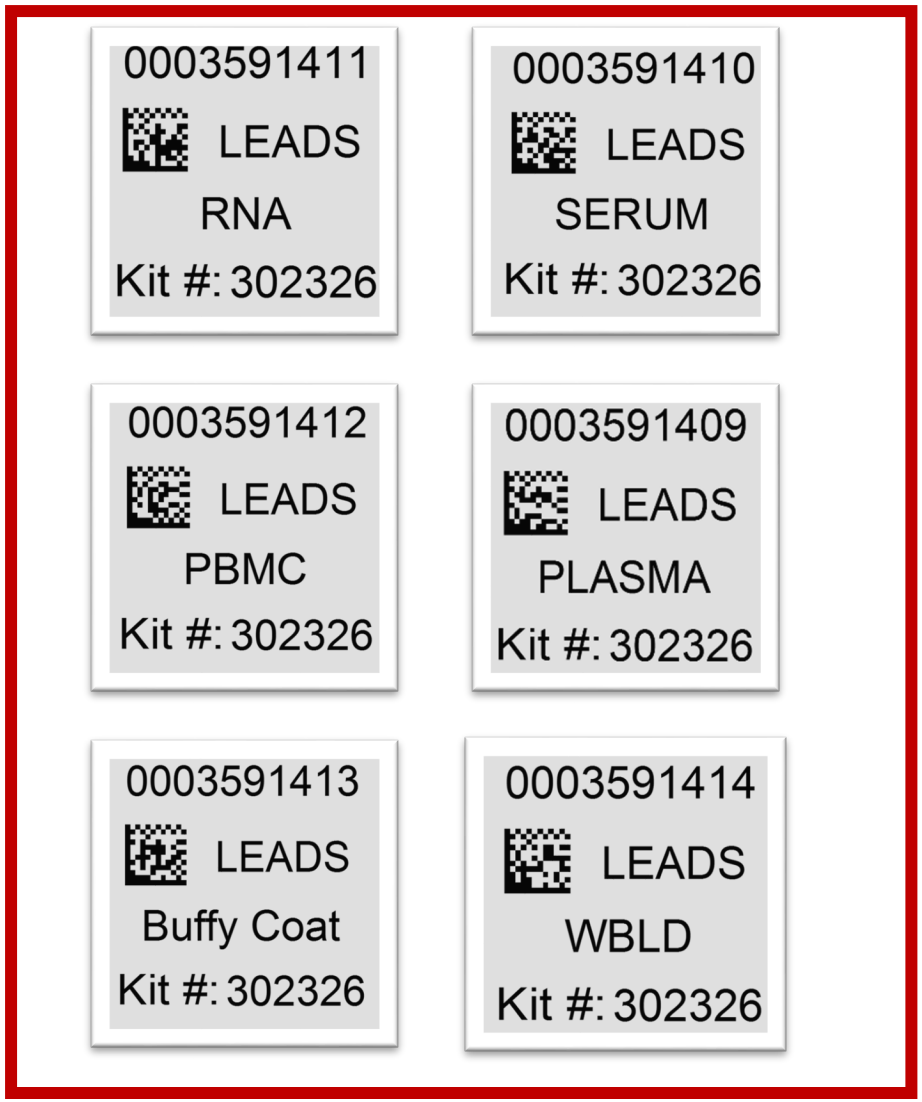
- **Collection and Aliquot tube label only**
- **Please place barcode near cap**

Collection and Aliquot Tube Labels

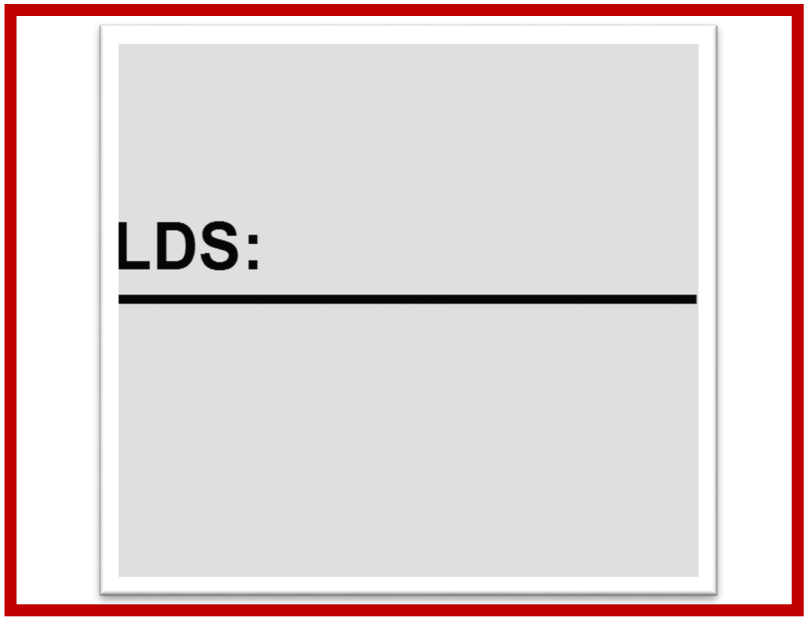
- Labels to be placed on ALL collection and aliquot tubes
  1. PAXgene™ Blood Collection Tube (2.5 ml) for RNA
  2. Plain Red-Top Serum Blood Collection Tube (10 ml) for Serum
     - Serum aliquots
  3. Sodium Heparin (Green-Top) Blood Collection Tube (10 ml) for PBMC x 2
  4. EDTA (Lavender-Top) Blood Collection Tube x 3
     - Plasma aliquots
     - Buffy coat aliquot
  5. EDTA (Lavender-Top) Blood Collection Tube (6 ml) for CLIA lab testing
     *CI Baseline ONLY
  6. CSF – Only place labels on aliquot tubes

Collection Tubes - Blood

Label 1: Collection Tube Label



Label 2: Site and LEADS ID Label

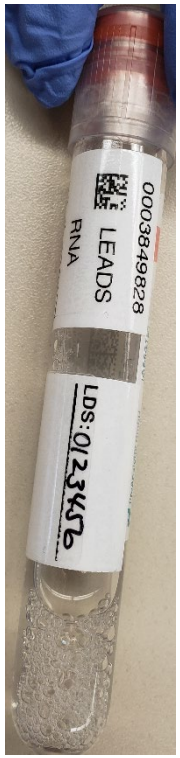


- All collection tubes will have two labels
  - The Collection Tube Labels
  - The handwritten Site and LEADS ID Label

Collection Tubes – Blood

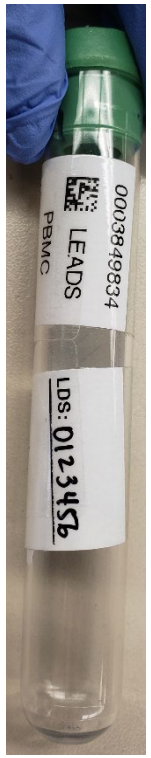
Collection/Aliquot tube label *place barcode near top

Site and Subject ID label



PAXgene™ Blood Collection Tube (2.5 ml)

Plain Red Top Serum Blood Collection Tube (10 ml)



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

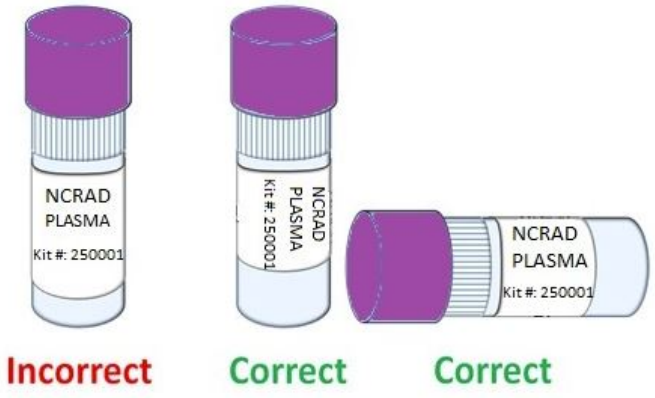
EDTA (Lavender-Top) Blood Collection Tube (10 ml) x 3

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

Labeling Biologic Samples

Please...

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



Handling/Processing Study Specimens

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 ≥2000 rcf with refrigeration to $4^{o}C$
2. $-80^{o}C$ Freezer
3. Wet Ice Bucket

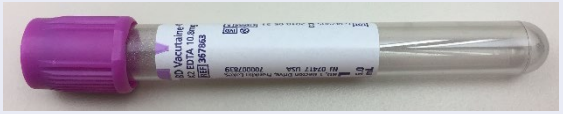
Blood Draw Order

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:

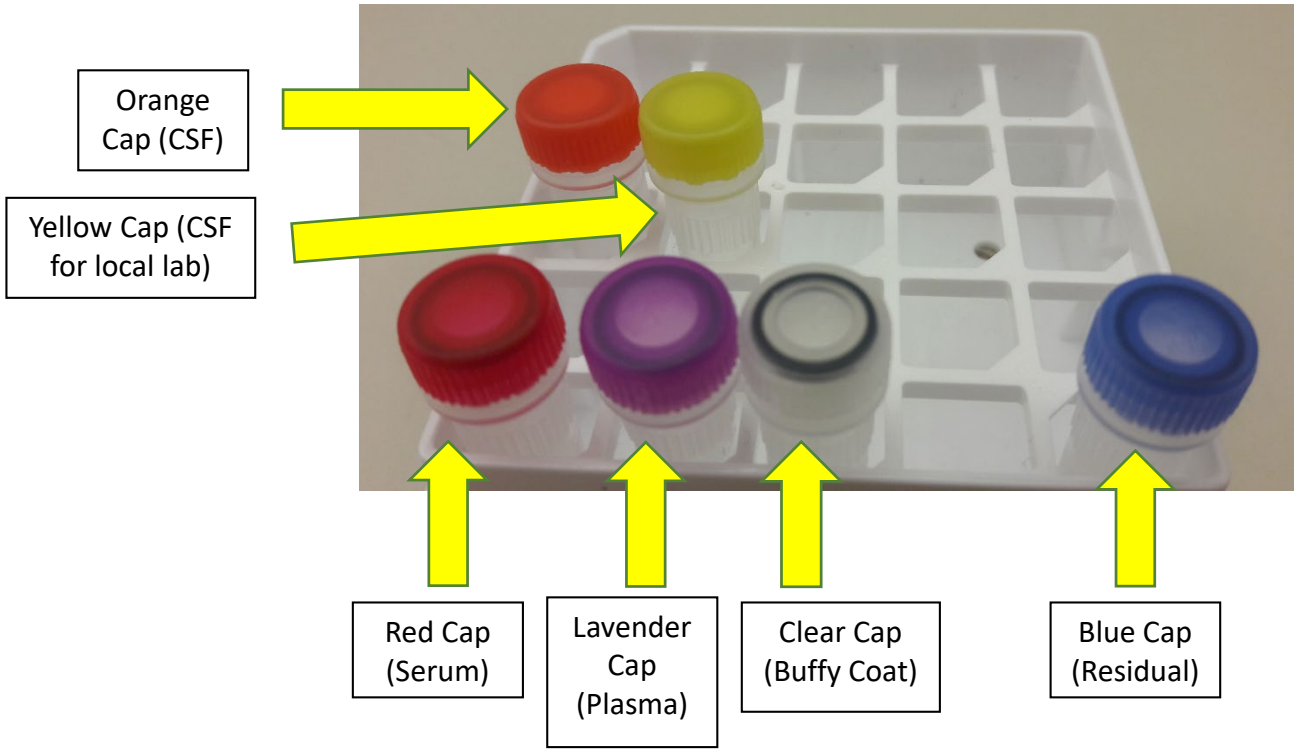
1. **PAXgene™ Blood Collection Tube (2.5 ml) for RNA**
2. **Plain Red Top Serum Blood Collection Tube (10 ml) for Serum**
3. **Sodium Heparin (Green-Top) Blood Collection Tube (10 ml) x 2**
4. **EDTA (Lavender-Top) Blood Collection Tube (10 ml) for DNA and Plasma x 3**
5. **EDTA (Lavender-Top) Blood Collection Tube (6 ml) for CLIA lab testing **CI Baseline ONLY****

Sample Collection - Blood

Tube Type	Number of Tubes Drawn	Tube Image
1. PAXgene™ Blood Collection Tube (2.5 ml) for RNA	x1	
2. Plain Red-Top Serum Blood Collection Tube (10 ml) for Serum	x1	
3. Sodium Heparin (Green-Top) Blood Collection Tube (10 ml) for PBMC	x2	
4. EDTA (Lavender-Top) Blood Collection Tube (10 ml) for Plasma	X3	
5. EDTA (Lavender-Top) Blood Collection Tube (6ml) for CLIA lab testing **CI Baseline ONLY**	x1	

Aliquot Cap Colors

Cap Color	Sample Type
Red Cap	Serum
Lavender Cap	Plasma
Clear Cap	Buffy Coat
Blue Cap	Residual
Orange Cap	CSF
Yellow Cap	CSF for local lab

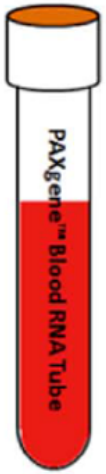


RNA Preparation (2.5ml PAXgene™ Tube)

Step One

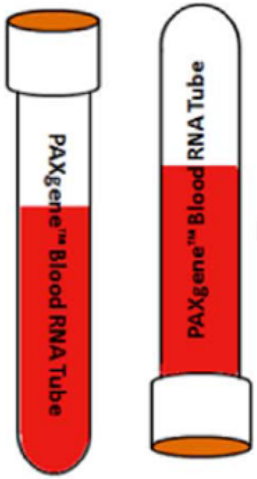
- Store tubes at room temperature.
- Label tubes with pre-printed labels prior to blood draw.

Step Two



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

Step Three



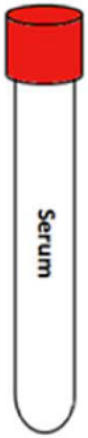
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

Step Four

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

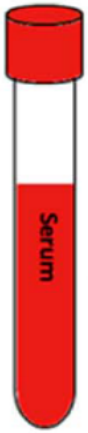
Serum Preparation (10ml Red Top Tube)

Step One



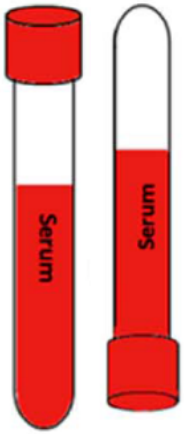
- Store tubes at room temperature.
- Label tubes and cryovials with pre-printed subject labels prior to blood draw.

Step Two



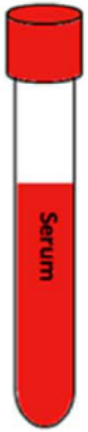
- Collect blood in Serum Tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



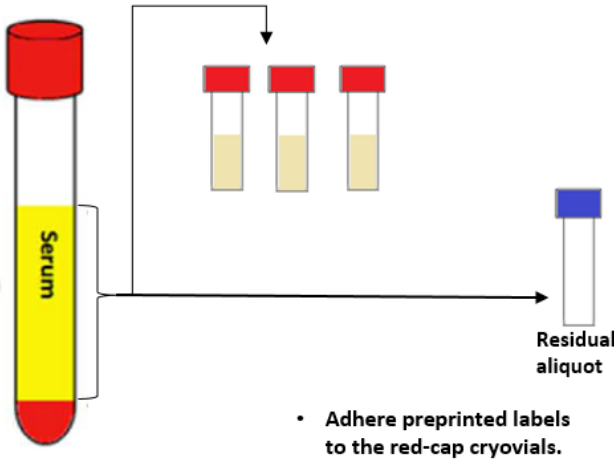
- Immediately after blood draw, invert tube 5 times to mix samples.

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



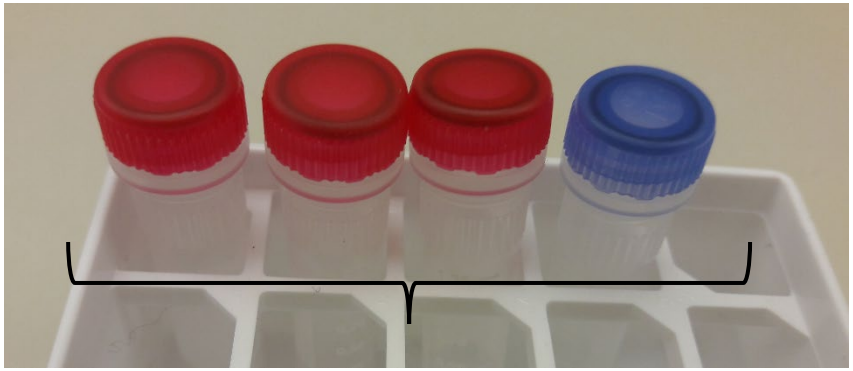
- Must be spun, aliquoted, and stored in -80°C freezer within 2 hours of collection.

- 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.

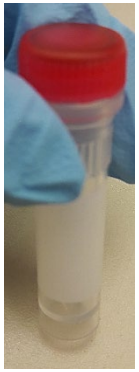
Plain Red-Top Serum Tube (Serum Collection)

Serum

RBC, WBC & Platelet Clot



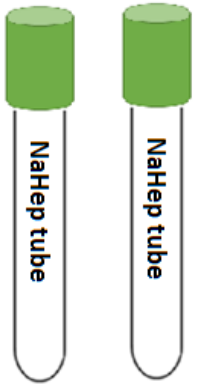
Serum Aliquots (up to 4 possible)



Close up view of 2.0 ml cryovial

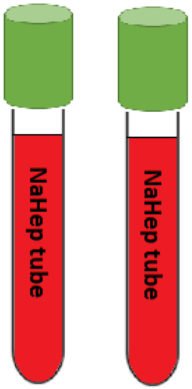
PBMC Preparation (10ml Sodium Heparin Tube) x 2

Step One



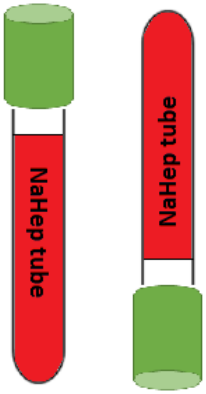
- Store tubes at room temperature.
- Label tubes with pre-printed labels prior to blood draw.

Step Two



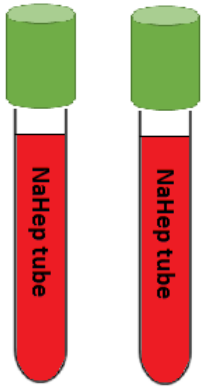
- Collect blood in Sodium Heparin Tubes allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



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

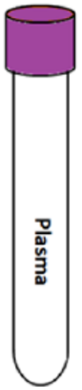
Step Four



- Store tubes at room temperature until shipment.
- <u>Ship ambient same day as blood draw</u>

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

Step One

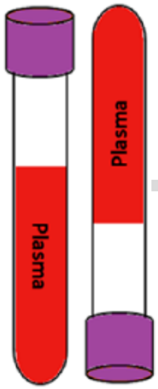


- Store tubes at room temperature.
- Label tubes with preprinted labels prior to blood draw.

Step Two

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

Step Three



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

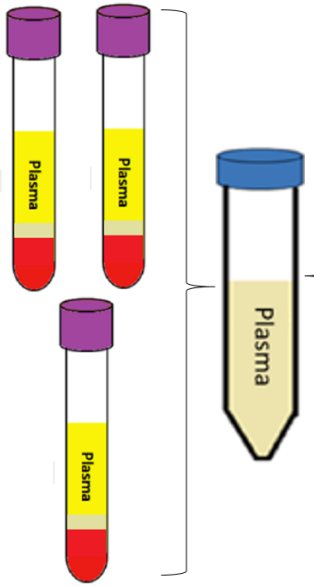
Step Four

- Place thoroughly mixed tubes on wet ice until centrifugation begins.

Step Five

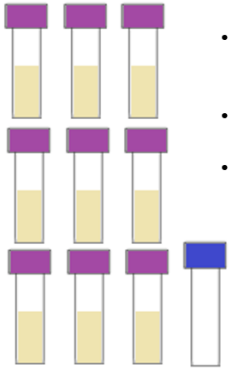
- Preferably within 30 minutes, centrifuge samples at 2000 x g at 4°C for 10 minutes.
- Samples need to be spun, aliquoted, and in the freezer within 2 hours from the time of collection.

Step Six



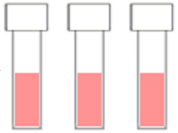
- Pool all plasma from the 3 EDTA tubes into a 50ml conical tube and invert gently 3 times to mix the plasma.

Step Seven



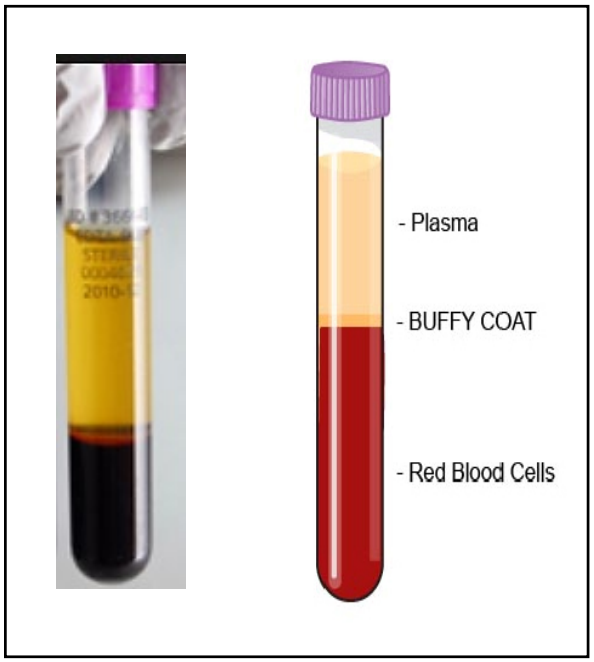
- Adhere preprinted labels to the lavender cap cryovials.
- Aliquot 1.5 ml into each cryovial tube.
- If a residual aliquot is created, document specimen number and volume on Sample Notification Form. Store plasma aliquots at -80°C until shipment.

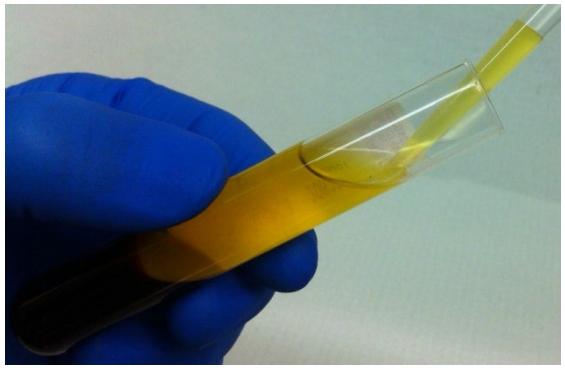
Step Eight

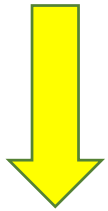


- Adhere preprinted labels to the clear cap cryovials.
- Using a clean pipette tip, collect the buffy coats (may have residual plasma and some RBCs included).
- Transfer the buffy coats into the cryovial tubes.
- Store buffy coat aliquots at -80°C until shipment.

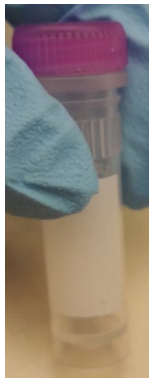
EDTA Tube (Plasma Collection)







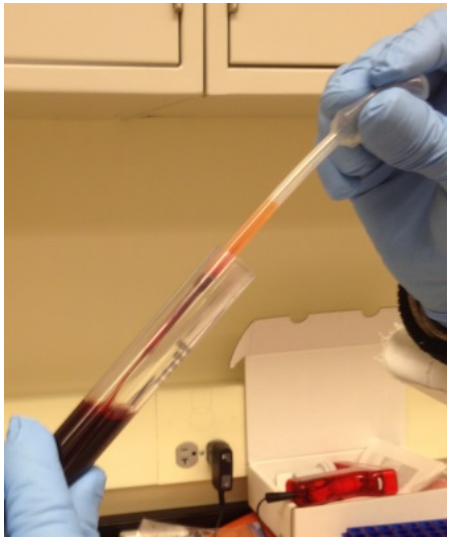
Plasma Aliquots
(10 possible)



Close up view of 2.0 ml cryovial

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.

Whole Blood Preparation (6 mL Lavender-Top Tube)

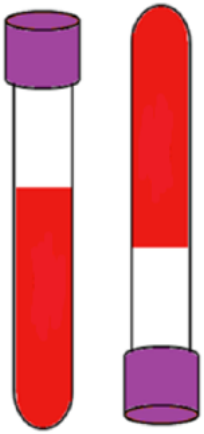
Step One

- 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.

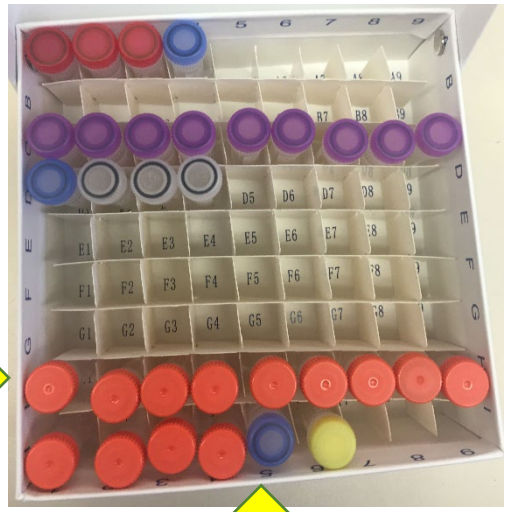
CI Subjects at Baseline Only

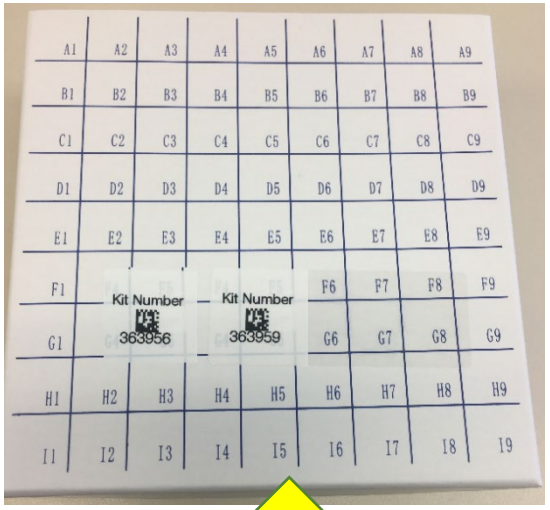
CSF Collection and Processing

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.

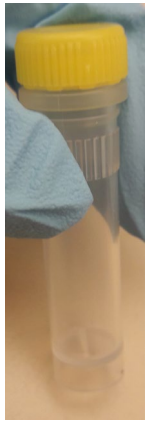
1.5 ml Aliquots (ORANGE CAP)





Residual Aliquot (BLUE CAP)

Kit numbers for blood and CSF will be different



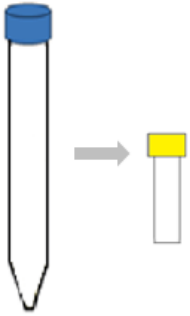
- **CSF aliquot tube for local lab**
- **Label not provided**

CSF Preparation (15-20 ml total)

Step One

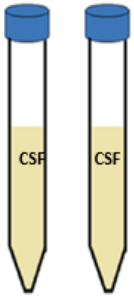
- Label tubes with pre-printed subject labels prior to collection.
- Pre-chill all cryovials on wet ice.

Step Two



- Collect initial 1-2ml (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

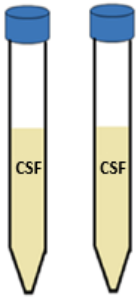


- Collect 15-20 ml total, including the 1-2 ml sent to the local lab.
- Collect sample into 2 15 ml conical tubes.

Step Four

- Place samples upright on wet ice until centrifugation begins.

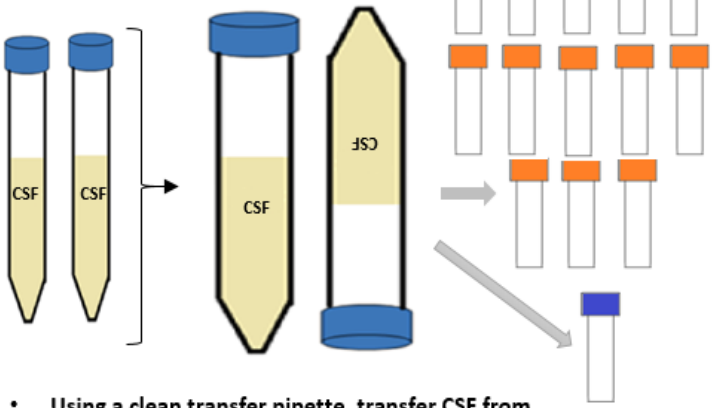
Step Five



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

Step Six

Step Seven



- 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.
- 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.

Sample Shipping

NCRAD

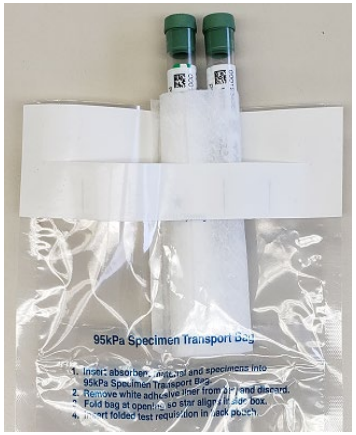
Sample Shipment Summary

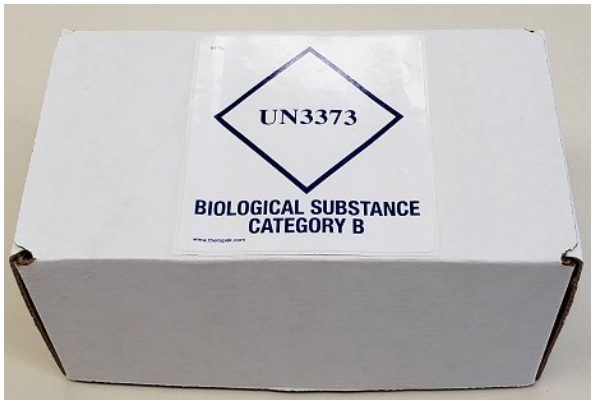
Sample Type	Processing/ Aliquoting	Tubes to NCRAD	Ship	Days to Ship
Whole blood for RNA extraction	N/A	1	Frozen	Monday-Wednesday
Whole blood (Plain Red-Top Serum Tube) for isolation of serum	1.5 ml serum aliquots per 2.0 ml cryovial (red cap) ; residual volume placed in 2.0 ml cryovial with blue cap	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

Ambient Sample

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

Ambient Sample Shipping



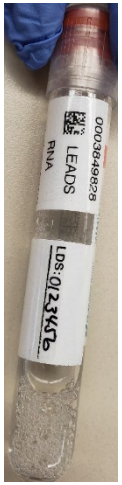


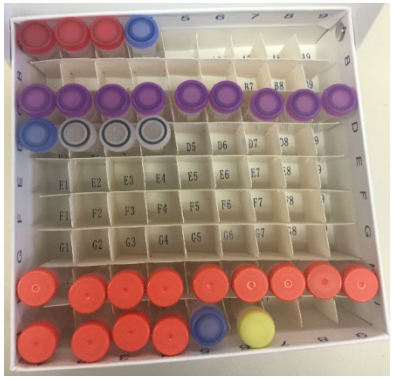
- **Place refrigerant pack in the freezer 24 hours prior to shipment.**
- Place filled and labeled Sodium Heparin tubes within the slots in the absorbent pad and place in biohazard bag.
- Place the kit number label on biohazard bag.
- Place the refrigerant pack into the cooler on top of the filled biohazard 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.

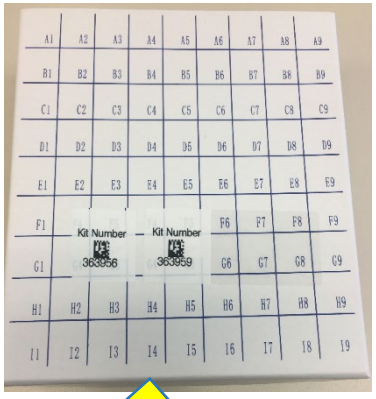
Frozen Sample Shipping

- **Ship Monday-Wednesday Only**
  - RNA, Serum, Plasma, Buffy Coat, and CSF
    (**and whole blood for CI Baseline visit**)
- Hold packaged samples in a -80°C freezer until pickup.
- Batch Samples together
  - 5 Cryoboxes
  - **Batch shipping should be performed every 3 months or as a full shipment of specimens accumulates, whichever is sooner.**

Frozen Shipping - Cryoboxes







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

If participant donates CSF…

- This cryobox will have two kit number stickers adhered to the outside.

Place cryobox and frozen tubes in one Biohazard Bag.

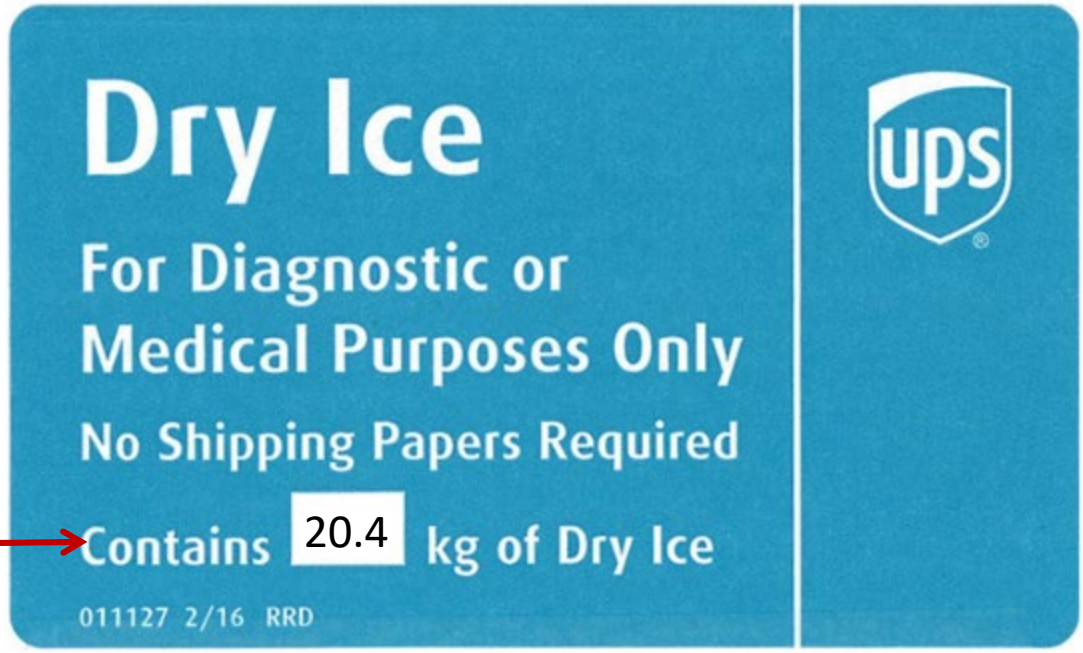
Frozen Shipping – Dry Ice Requirements

- Fully cover the cryoboxes with about 2 inches of dry ice in the provided shipper.
- Each Styrofoam shipper must contain about 45 lbs (20 kg) of dry ice.

Frozen Shipping – Dry Ice Requirements

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

Net weight of dry ice in **kg**



Shipping Frozen Samples

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

Shipping Regulations and Training

PLEASE NOTE:

- All study personnel responsible for shipping should be certified in biospecimen shipping.
- It is the responsibility of each site to ensure that the appropriate training has been provided and conducted in regards to IATA shipping.

Please see following slides for resources.

Federal Regulations/Training

- Sites are responsible for ensuring proper training is obtained.
- Current federal and international regulations require anyone directly involved with the shipment of potentially infectious materials and other regulated biological materials (including biological specimens and cultures) **be properly trained on pertinent shipping requirements.**
  - **International Air Transport Association (IATA) Training**

DGI Training Center 800-338-2291 DGItraining.com Provides IATA Certified Air Seminars and online courses	IATA Training Schools North America 1(514)390-6726 Europe, Africa & Middle East 41 (22) 799 2751 Asia, Australia & the Pacific 65 239 7232 www.iata.org Training schools located in 30 countries
Saf-T Pak Inc. www.saftpak.com Provides dangerous goods training via CD or on-site instruction for North America and Europe	Aiconsult Email: Airconsult@wanadoo.fr www.airconsult-bf.com
Bureau of Dangerous Goods LTD., TIANJIN Addr.: No.3 Yingshui road, Nankai district, Tianjin China Tel: 022-23495890 83326960 83326854 / Fax: 022-83326959 Email: cdmin@bdg-china.com.cn www.bdg-china.com.cn	

UN3373 Biological Substance, Category B Training

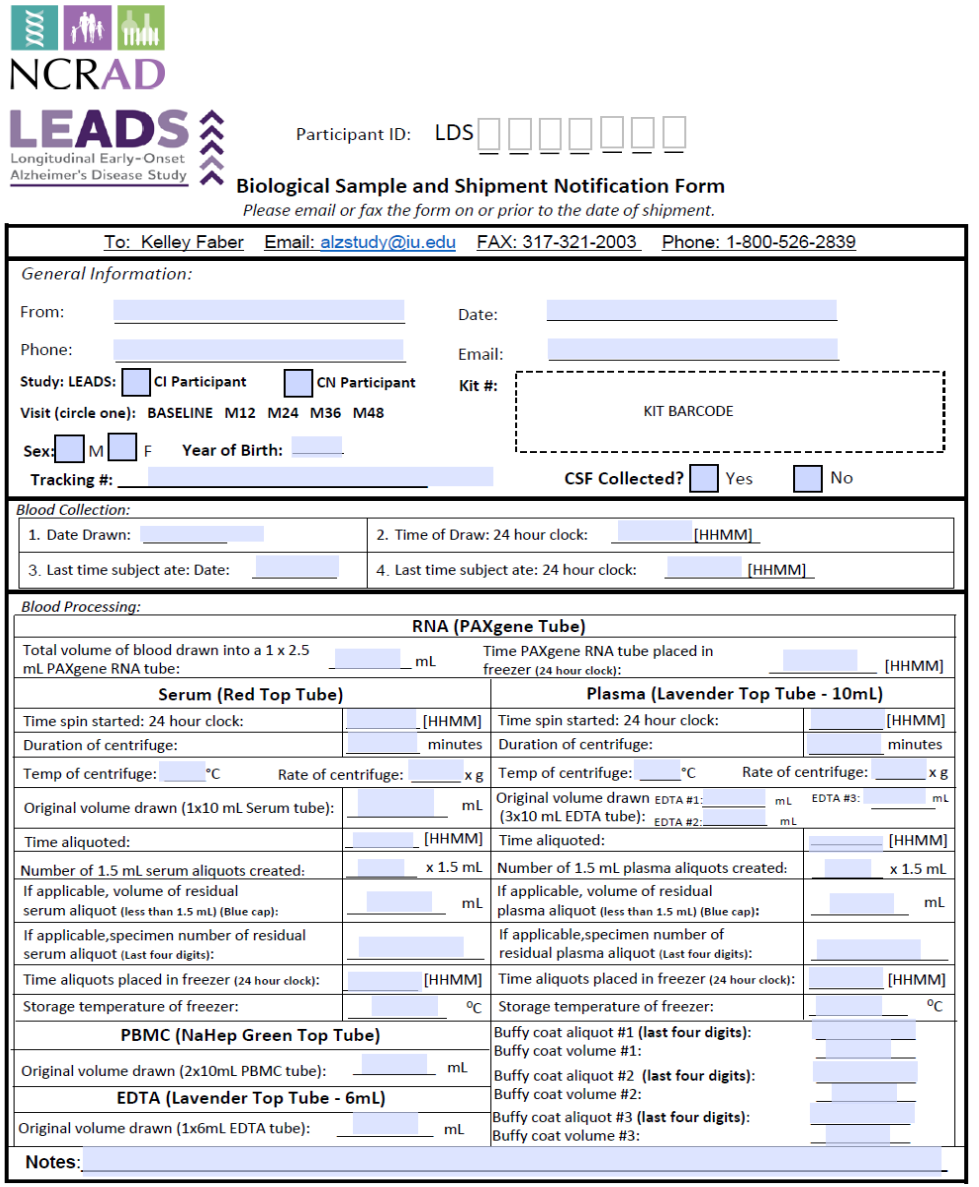
- Biological Substance, Category B are specimens being transported for “investigational purposes”
- Recommend: investigator sites document training of category B/dangerous goods
- We recommend establishing a record of your staff’s training and date of instruction
- The training records must be made available upon request by the appropriate national authority
  - Additional information from the Department of Transportation (DOT) can be found on their website http://hazmat.dot.gov

Biological Sample and Shipment Notification Forms

- A copy of the sample form *must* be emailed or faxed to NCRAD prior to the date of sample arrival.
- Please include sample forms in all shipments of frozen and ambient samples.
- Email: alzstudy@iu.edu
- Fax: 317-321-2003

NCRAD

Biological Sample Notification Form- Blood



NCRAD

LEADS Longitudinal Early-Onset Alzheimer's Disease Study

Participant ID: LDS_____

Biological Sample and Shipment Notification Form

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

To: Kelley Faber Email: alzstudy@iu.edu FAX: 317-321-2003 Phone: 1-800-526-2839

General Information:

From: Date:

Phone: Email:

Study: LEADS: ☐ CI Participant ☐ CN Participant Kit #: KIT BARCODE

Visit (circle one): BASELINE M12 M24 M36 M48

Sex: ☐ M ☐ F Year of Birth:

Tracking #: CSF Collected? ☐ Yes ☐ No

Blood Collection:

1. Date Drawn:	2. Time of Draw: 24 hour clock: [HHMM]
3. Last time subject ate: Date:	4. Last time subject ate: 24 hour clock: [HHMM]

Blood Processing:

RNA (PAXgene Tube)

Total volume of blood drawn into a 1 x 2.5 mL PAXgene RNA tube: mL

Time PAXgene RNA tube placed in freezer (24 hour clock): [HHMM]

Serum (Red Top Tube)		Plasma (Lavender Top Tube - 10mL)	
Time spin started: 24 hour clock:	[HHMM]	Time spin started: 24 hour clock:	[HHMM]
Duration of centrifuge:	minutes	Duration of centrifuge:	minutes
Temp of centrifuge: °C Rate of centrifuge: x g		Temp of centrifuge: °C Rate of centrifuge: x g	
Original volume drawn (1x10 mL Serum tube):	mL	Original volume drawn (3x10 mL EDTA tube): EDTA #1: mL EDTA #2: mL EDTA #3: mL	
Time aliquoted:	[HHMM]	Time aliquoted:	[HHMM]
Number of 1.5 mL serum aliquots created:	x 1.5 mL	Number of 1.5 mL plasma aliquots created:	x 1.5 mL
If applicable, volume of residual serum aliquot (less than 1.5 mL) (Blue cap):	mL	If applicable, volume of residual plasma aliquot (less than 1.5 mL) (Blue cap):	mL
If applicable,specimen number of residual serum aliquot (Last four digits):		If applicable,specimen number of residual plasma aliquot (Last four digits):	
Time aliquots placed in freezer (24 hour clock):	[HHMM]	Time aliquots placed in freezer (24 hour clock):	[HHMM]
Storage temperature of freezer:	°C	Storage temperature of freezer:	°C

PBMC (NaHep Green Top Tube)

Original volume drawn (2x10mL PBMC tube): mL

EDTA (Lavender Top Tube - 6mL)

Original volume drawn (1x6mL EDTA tube): mL

Buffy coat aliquot #1 **(last four digits)**:
Buffy coat volume #1:
Buffy coat aliquot #2 **(last four digits)**:
Buffy coat volume #2:
Buffy coat aliquot #3 **(last four digits)**:
Buffy coat volume #3:

Notes:

Ver: 09.2020

Blood collected for:

- RNA
- Serum
- PBMC x 2
- Plasma x 3
- DNA
- CLIA testing

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

Biological Sample Notification Form-CSF

NCRAD

LEADS
Longitudinal Early-Onset Alzheimer's Disease Study

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: alzstudy@iu.edu FAX: 317-321-2003 Phone: 1-800-526-2839

General Information:

From: _____ Date: _____

Phone: _____ Email: _____

Study: LEADS ☐ CI Participant ☐ CN Participant **Kit #:** KIT BARCODE

Visit (circle one): **BASELINE M12 M24 M36 M48**

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): **(Orange cap cryovials):**	_____ x 1.5 mL
If applicable, volume of CSF residual aliquot (less than 1.5 mL): **(Blue cap cryovial):**	_____ mL
If applicable, specimen number of residual aliquot tube: **(Last four digits):**	_____
Time frozen:	_____ [HHMM]
Storage temperature of freezer:	_____ °C

Notes: _____

Ver: 09.2020

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

NCRAD Website

Helpful Pages

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

What to do for Friday Blood Draws

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

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

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

Holiday Closures

Date	Holiday
January 1	New Year's Day
3rd Monday in January	Martin Luther King, Jr Day
4th Monday in May	Memorial Day
July 4	Independence Day (observed)
1st Monday in September	Labor Day
4th Thursday in November	Thanksgiving
4th Friday in November	Friday after Thanksgiving
December 25	Christmas

LEADS Active Study Page

LEADS Active Study Page

LEADS
Longitudinal Early-Onset Alzheimer's Disease Study

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 (800) 526-2839 or directly at (317) 278-1170.

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.

CN (Cognitively Normal) Participants

	Baseline	M12	M24
RNA	✓	✓	✓
Serum	✓	✓	✓
Plasma	✓	✓	✓
DNA	✓	✓	✓
PBMC	✓	✓	✓
CSF**	✓		✓

** Please note that CSF is to be drawn at Baseline and M24 for CN participants. Can be drawn at M12 if not drawn at Baseline.

Study Resources

BANK SAMPLES with NCRAD

SAMPLE TYPES we Bank

Download Documents

- Blood Sample Form
- CSF Sample Form
- Manual of Procedures
- Master Transfer Agreement (MTA)
- Appendix C
- Appendix F
- Appendix G
- Appendix I
- Training Slides

Additional Resources

- Kit Request System
- Web-based Blood Sample Form
- Web-based CSF Sample Form
- Shipping Address
- Holiday Closures

Questions/Comments

Email: alzstudy@iu.edu
Phone: 800-526-2839

Contact Information

- Questions?

  Please contact NCRAD Coordinators at:

  - Phone: 1-800-526-2839 or 317-274-7546
  - E-mail: alzstudy@iu.edu or wilmesk@iu.edu
  - Website: www.ncrad.org