

WRAP Collection and Shipment Training



**Wisconsin Registry
for Alzheimer's Prevention**

UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH



NCRAD

Training Overview: WRAP

- Study Overview
- Kit Review
- Sample Collection and Processing
- Sample Shipping
- Sample Form
- NCRAD Website
- Common Nonconformance Issues
- Questions?

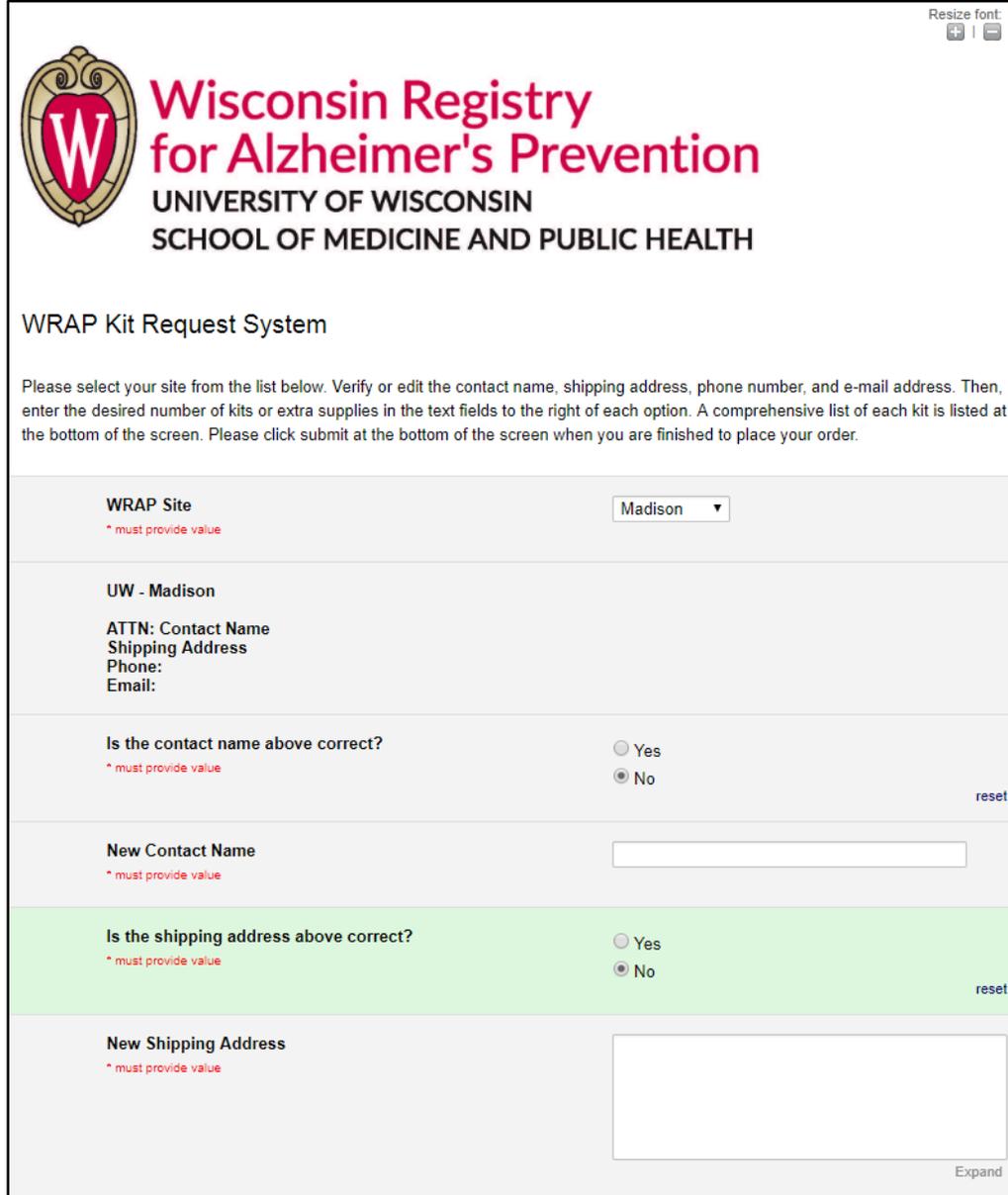
WRAP Study Specimens

| Biospecimen | Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | Visit 7 | Visit 8 | Visit 9 |
|------------------|--------------|---------|---------|---------|---------|---------|---------|---------|---------|
| PBMC | X | X | X | X | X | X | X | X | X |
| Plasma | X | X | X | X | X | X | X | X | X |
| Buffy Coat (DNA) | X | X | X | X | X | X | X | X | X |
| Whole Blood | X | X | X | X | X | X | X | X | X |
| Serum | X | X | X | X | X | X | X | X | X |
| CSF | Madison only | | | | | | | | |

Kit Request Module

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

NCRAD Kit Request Module



The screenshot shows a web form titled "WRAP Kit Request System" from the Wisconsin Registry for Alzheimer's Prevention. The form includes a logo, a "WRAP Site" dropdown menu set to "Madison", a section for "UW - Madison" contact information, two confirmation questions with radio buttons, and text input fields for "New Contact Name" and "New Shipping Address".

Wisconsin Registry for Alzheimer's Prevention
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WRAP Kit Request System

Please select your site from the list below. Verify or edit the contact name, shipping address, phone number, and e-mail address. Then, enter the desired number of kits or extra supplies in the text fields to the right of each option. A comprehensive list of each kit is listed at the bottom of the screen. Please click submit at the bottom of the screen when you are finished to place your order.

WRAP Site
* must provide value
Madison

UW - Madison
ATTN: Contact Name
Shipping Address
Phone:
Email:

Is the contact name above correct?
* must provide value
 Yes
 No
reset

New Contact Name
* must provide value
[Text Input Field]

Is the shipping address above correct?
* must provide value
 Yes
 No
reset

New Shipping Address
* must provide value
[Text Input Field]
Expand

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

WRAP Kits

Madison site only



| Specimen Collection Kits | |
|--|---|
| NCRAD Blood Kit | <input type="text"/> |
| NCRAD CSF Kit | <input type="text"/> |
| Shipping Kits | |
| NCRAD Ambient Shipping Kit | <input type="text"/> |
| NCRAD Frozen Shipping Kit (holds up to 8 cryoboxes) | <input type="text"/> |
| Supplemental Kits | |
| NCRAD Supplemental Supply Kit | <input type="text"/> |
| Extra Supplies | |
| Do you need extra NCRAD supplies? <small>* must provide value</small> | <input type="radio"/> Yes <input type="radio"/> No |
| Comments | <input type="text"/> <small>Expand</small> |
| <input type="submit" value="Submit"/> | |

WRAP Kits

Specimen Collection Kits

| | |
|-----------------|--------------------------------|
| NCRAD Blood Kit | <input type="text" value="1"/> |
| NCRAD CSF Kit | <input type="text"/> |

Shipping Kits

| | |
|---|----------------------|
| NCRAD Ambient Shipping Kit | <input type="text"/> |
| NCRAD Frozen Shipping Kit (holds up to 8 cryoboxes) | <input type="text"/> |

Supplemental Kits

| | |
|-------------------------------|----------------------|
| NCRAD Supplemental Supply Kit | <input type="text"/> |
|-------------------------------|----------------------|

Extra Supplies

Do you need extra NCRAD supplies? Yes No
* must provide value reset

Comments

Expand

Each NCRAD Blood Kit Contains:

- 2 Sodium Heparin (Green-Top) Blood Collection Tube (10ml)
- 4 Cryovial (2 ml) with purple cap
- 4 Cryovial (2 ml) with red cap
- 2 Cryovial (2 ml) with clear cap
- 12 Pre-printed labels for blood Specimen tubes
- 4 Pre-printed labels with kit number
- 3 Labels for handwritten WRAP ID
- 1 Cryovial box (holds up to 25 cryovials)

- 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.
- ****Note: You can order more than one type of kit in a single kit request****

Specimen Labels

Three Label Types

Kit Number



300001

Kit Number

WRAP ID:

Kit #:
300001

WRAP ID

0001234567



WRAP
PBMC

Kit #: 300001

Specimen

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. Blood and CSF Sample and Shipment Notification Forms
 2. Cryoboxes that houses aliquots during shipping
 3. One extra label provided

WRAP ID Label

| |
|--------------------------------|
| WRAP ID: |
| Kit #: 300001 |

- Subjects will be identified by their WRAP ID
- Sites will be responsible for handwriting this onto the provided labels
 - Must use Fine Point Sharpie Marker
 - Each site will receive 3 markers in initial kit supply

PBMC Tubes

Label 1: WRAP ID label

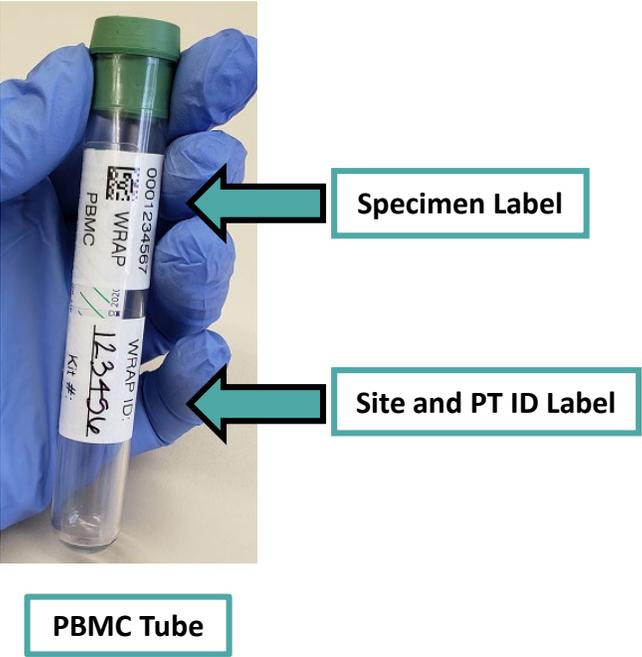
| |
|------------------|
| WRAP ID: |
| Kit #: 300001 |

Label 2: Specimen label

| |
|--|
| 0001234567 |
|  WRAP |
| PBMC |
| Kit #: 300001 |

- All PBMC tubes will have two labels:
 - The handwritten WRAP ID label
 - The specimen label

Labeled PBMC Tube



Specimen Labels – Serum, Plasma, and Buffy Coat



Serum Tube



EDTA Tube



EDTA Tube

- Only one label to be placed on ALL aliquot tubes
- **Serum**
 - From Serum tube
- **Plasma**
 - From EDTA tube
- **Buffy Coat**
 - From EDTA tube

Specimen Labels – Serum, Plasma, Buffy Coat, and CSF

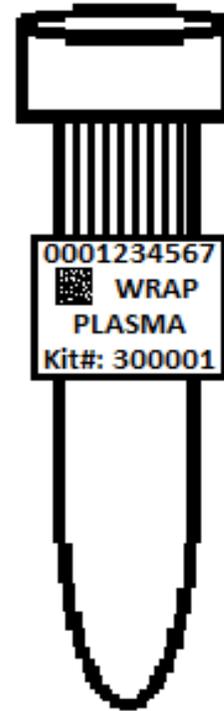


- Specimen tube label only
- Please place barcode near cap

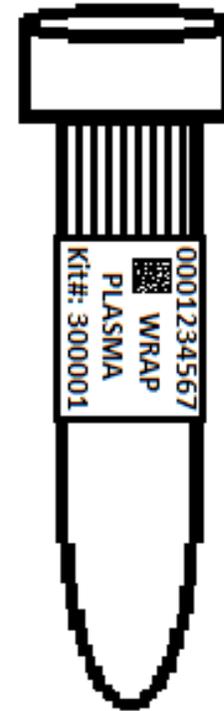
Labeling Biologic Samples

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

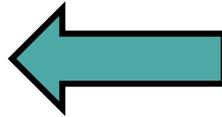


Incorrect



Correct

Specimen Labels - CSF



- Separate Kit Number for CSF collection
 - Kit number will differ from kit number used for the blood samples for the same subject at the same visit
- CSF label
 - CSF aliquots

Handling/Processing Study Specimens

Blood Draw Order: Madison

Research Kit

| Tube Type | Number of Tubes Drawn |
|--|-----------------------|
| 1. 9 ml Serum Determination (Red-Top) Tube | 1 |
| 2. 4 ml Serum Determination (Red-Top) Tube | 1 |
| 3. 10 ml Sodium Heparin (Green-Top) Tube | 2 |
| 4. 10 ml EDTA (Purple-Top) Tube | 4 |



OR



Able to Confirm Fasting for 12 hours

One 4 ml red-top serum determination tube for Vitamin D 25-Hydroxy, Insulin, and B12

One 4 ml PST for Lipid panel, hs-CRP, and glucose

Unable to Confirm Fasting for 12 hours

One 4 ml red-top serum determination tube for Vitamin D 25-Hydroxy and B12

One 4 ml PST for Lipid panel and hs-CRP

Blood Draw Order: Milwaukee

| Tube Type | Number of Tubes Drawn |
|--|-----------------------|
| 1. 9 ml Serum Determination (Red-Top) Tube | 1 |
| 2. 5 ml Gold-Top Tube | 3 |
| 3. 10 ml Sodium Heparin (Green-Top) Tube | 2 |
| 4. 10 ml EDTA (Purple-Top) Tube | 4 |

Blood Draw Order: LaCrosse

| Tube Type | Number of Tubes Drawn |
|--|-----------------------|
| 1. 6 ml Serum Determination (Red-Top) Tube | 2 |
| 2. 9 ml Serum Determination (Red-Top) Tube | 1 |
| 3. 5 ml Yellow-Top Tube | 2 |
| 4. 10 ml Sodium Heparin (Green-Top) Tube | 2 |
| 5. 10 ml EDTA (Purple-Top) Tube | 4 |

Cryovial Cap Colors (Samples going to NCRAD)

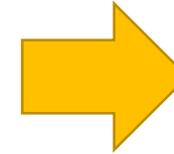
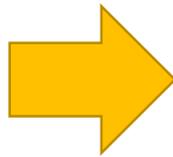
| Cap Color | Sample Type | Cap Image |
|-----------|-------------|---|
| Red | Serum |  |
| Purple | Plasma |  |
| Clear | Buffy Coat |  |
| Clear | CSF |  |

Serum Tube



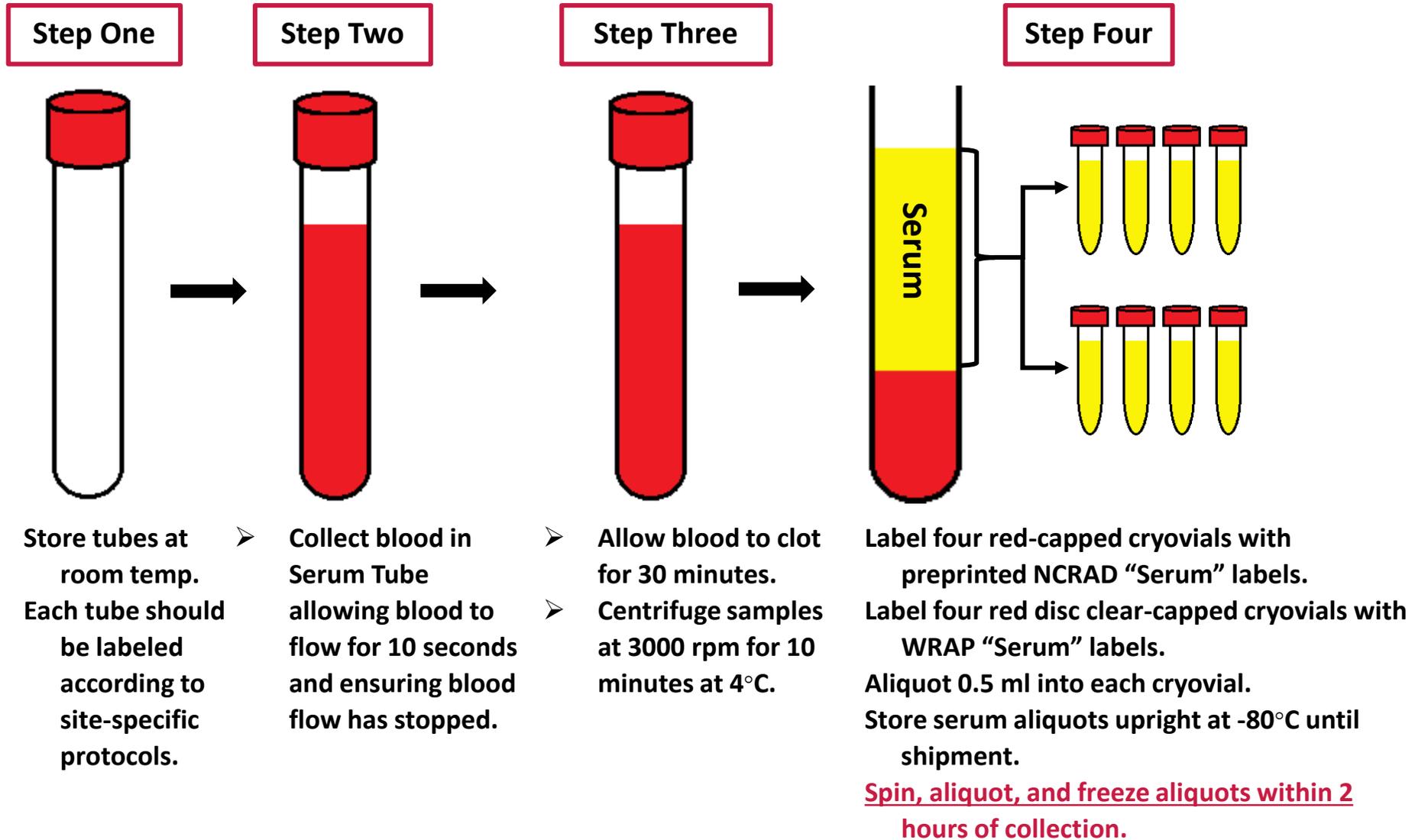
Serum Tube (unfilled)

Serum Tube
(Immediately after blood draw – pictured below)
** Please note: After standing at room temperature for 30 minutes, blood will be clotted and immobile**

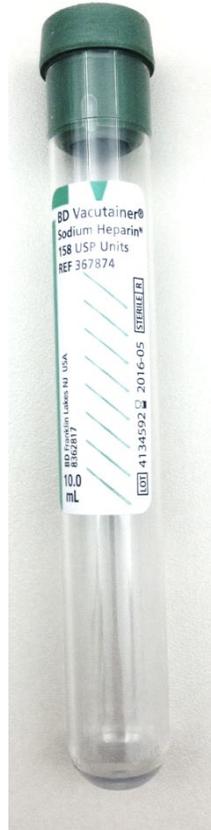


Serum Tube (after centrifuge)

Serum Preparation



PBMC Collection



- 2 x Sodium heparin (green top) BD Vacutainer® (10 ml)
 - Not processed at site
 - *NOTE*: Must be shipped **AMBIENT** to NCRAD the day sample is drawn. No Friday Draws.

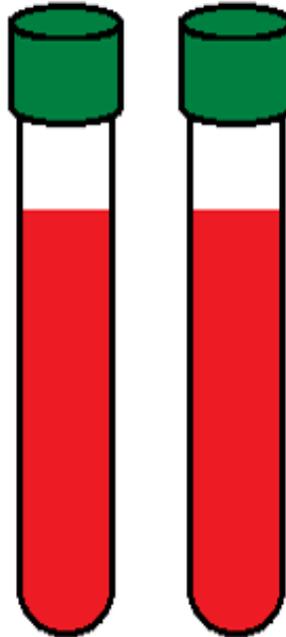
PBMC Preparation (10ml Sodium Heparin Tube x 2)

Step One



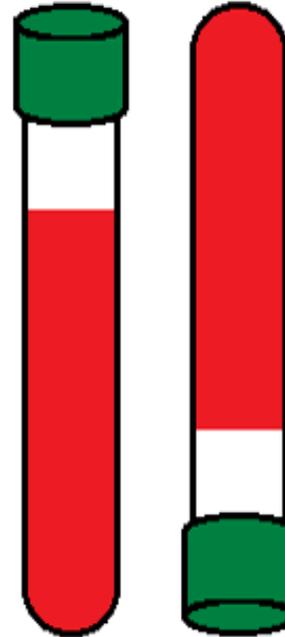
- Store tubes at room temp.
- Label tubes per site-specific protocols.

Step Two



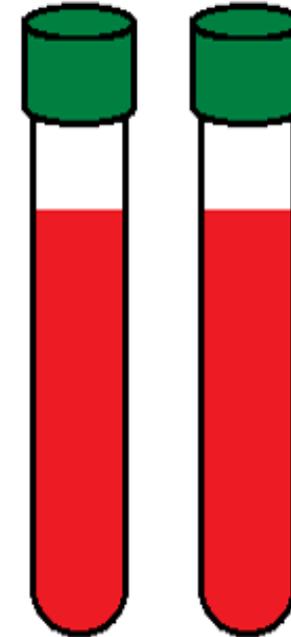
- Collect blood in Sodium Heparin tubes allowing blood to flow for 10 seconds, and ensuring blood flow has stopped.

Step Three



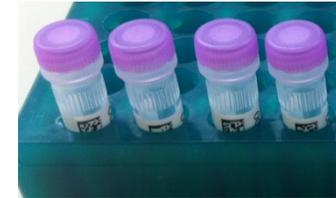
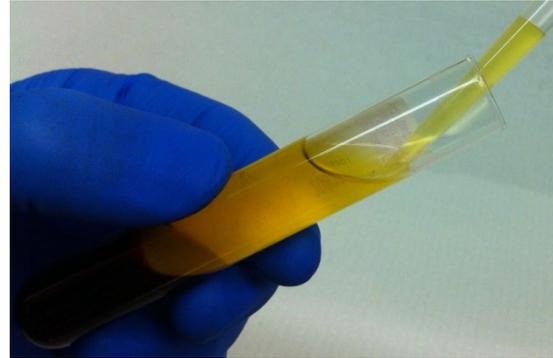
- Immediately after blood draw, invert tubes 8-10 times to mix sample.

Step Four



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

Plasma Collection

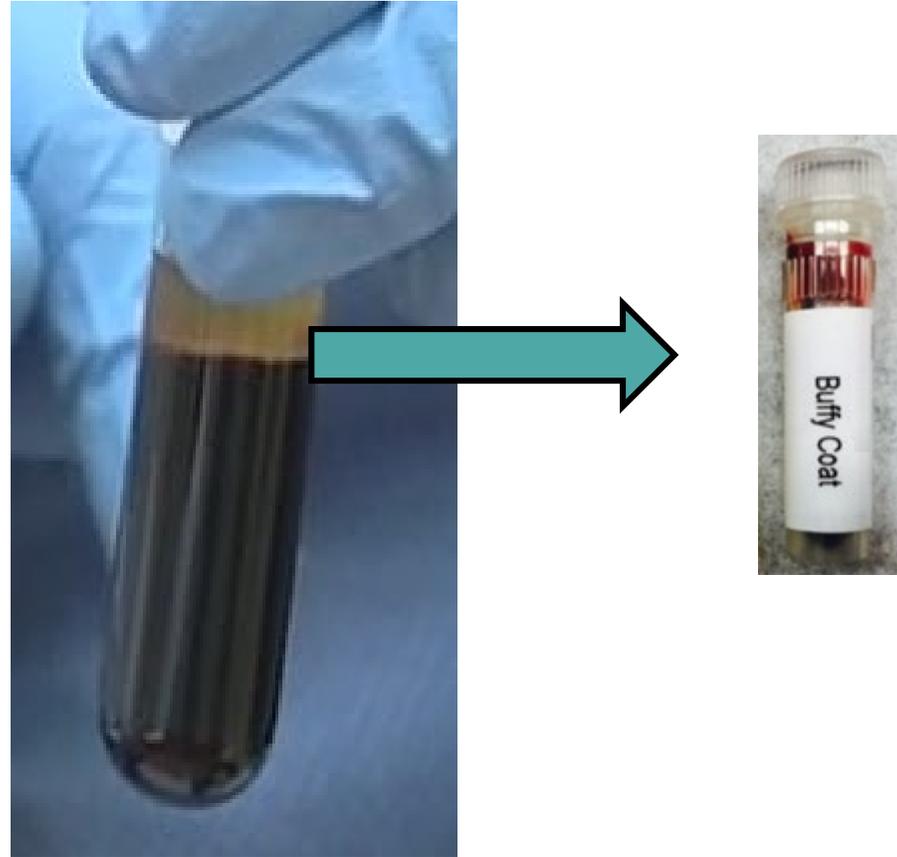


Create up to 4 aliquots

Please see the NCRAD YouTube Channel for tutorials:

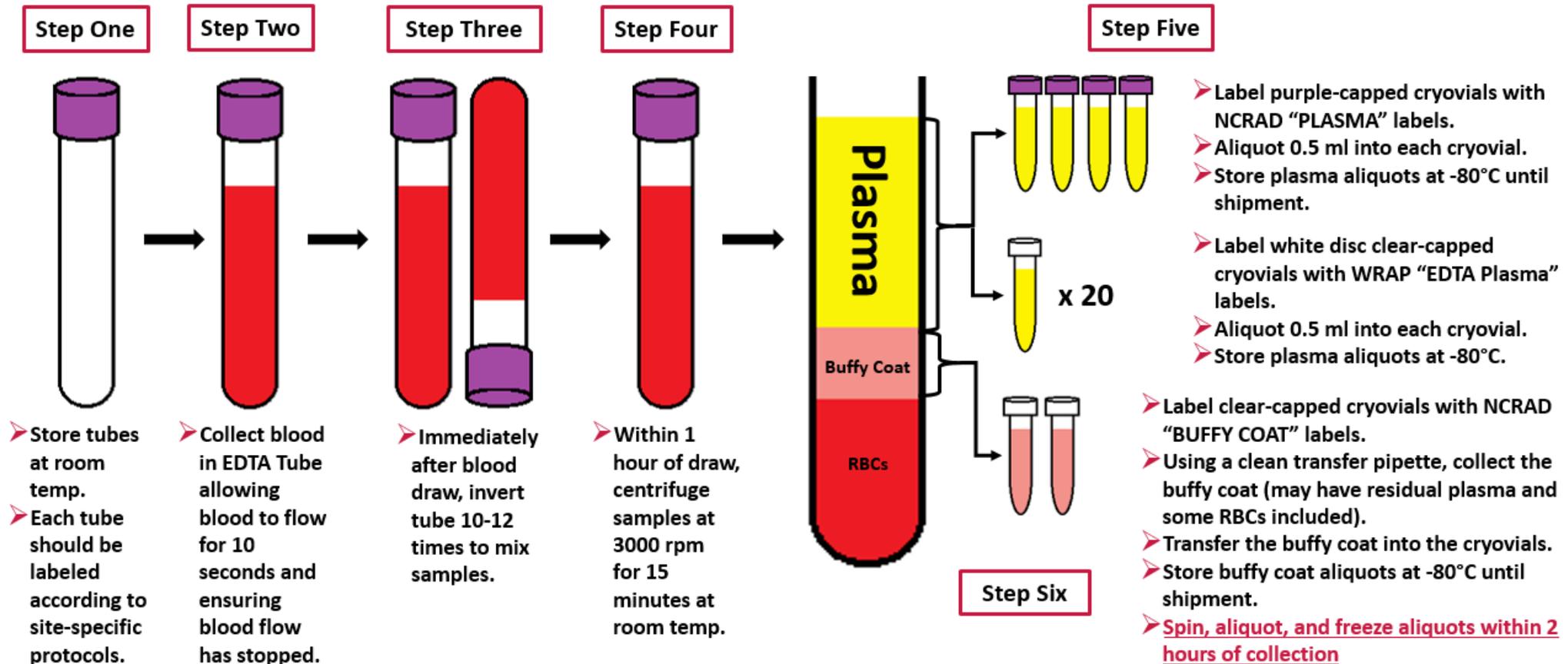
<http://kits.iu.edu/artfl-lefstds/videos>

Buffy Coat Collection



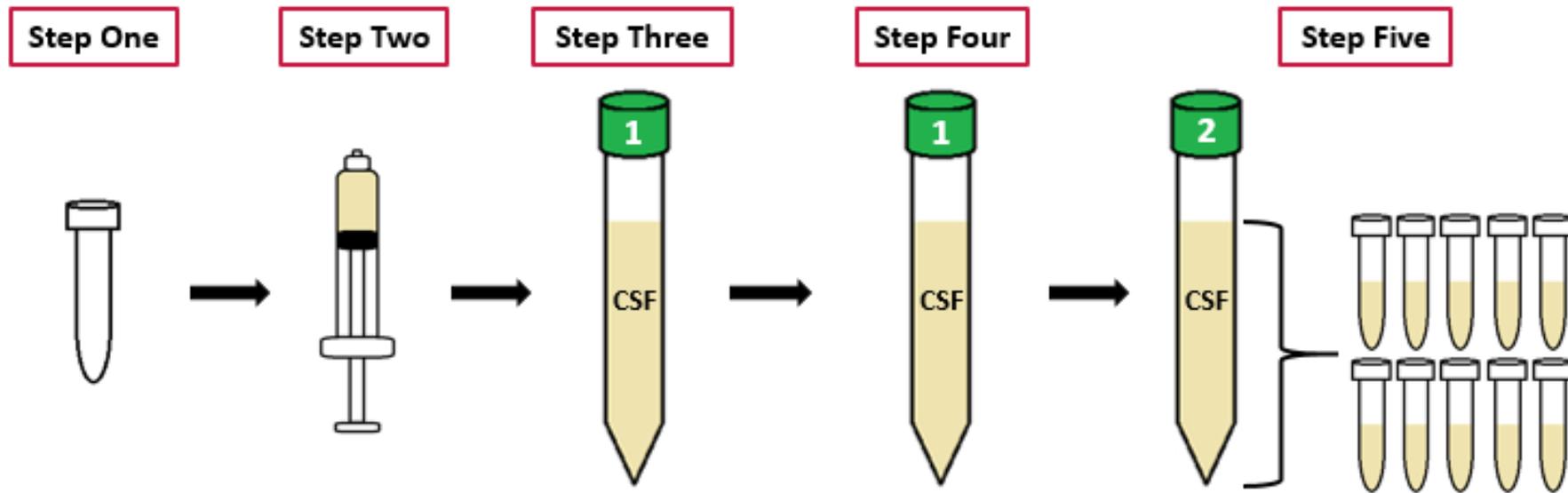
NCRAD Tutorials: <http://kits.iu.edu/artfl-lefftds/videos>

Plasma/Buffy Coat Collection and Processing



CSF Collection and Processing

CSF Collection and Processing



➤ Label cryovials with pre-printed specimen labels prior to collection.

➤ Collect initial 0.5-1 ml CSF for waste (if bloody, collect CSF until cleared of blood). Discard syringe #1.

➤ Collect 1 ml CSF in syringe #2 and transfer syringe to local lab for cell count.

➤ Collect 20 ml CSF using syringes #3-6 into one 30 ml conical tube.

➤ Within 15 mins of collection, centrifuge samples at 4°C at 3000 rpm for 10 minutes.

➤ Using a clean transfer pipette, transfer all CSF into a new 30 ml conical tube leaving the pellet in the bottom of the first conical tube.

➤ Gently invert the 30 ml conical tube 3-4 times to mix the sample.

➤ Aliquot 0.5 ml into the CLEAR-capped cryovials.

➤ Store CSF aliquots upright at -80°C until shipment.

Sample Shipments to NCRAD

Sample Shipment Summary

| Collection Tube | Drawn At | Specimen Type | Aliquot Volume | Total Number of Aliquots | # of Samples sent to NCRAD | Shipping Temperature |
|---|------------|---------------|-----------------------------|--------------------------|----------------------------|----------------------|
| 2 Serum (Red-Top) Blood Collection Tube (9 ml) | All Visits | Serum | 0.5 ml serum aliquots | 8 | 4 | Frozen |
| 2 Sodium Heparin (Green-Top) Blood Collection Tube (10ml) | All Visits | Whole Blood | N/A | N/A | 2 | Ambient |
| 3 EDTA (Purple-Top) Blood Collection Tube (10 ml) | All Visits | Plasma | 0.5 ml plasma aliquots | 24 | 4 | Frozen |
| | All Visits | Buffy Coat | ~1.0 ml buffy coat aliquots | 2 | 2 | Frozen |
| 1 EDTA (Purple-Top) Blood Collection Tube (10 ml) | All Visits | Whole Blood | 5 ml whole blood aliquots | 2 | 0 | N/A |

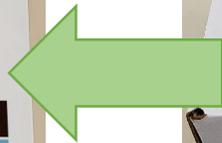
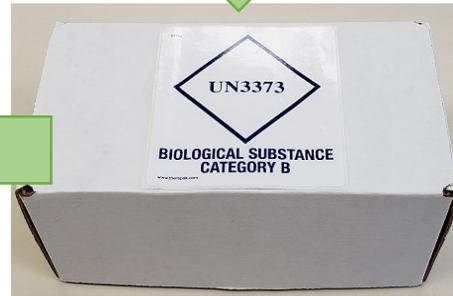
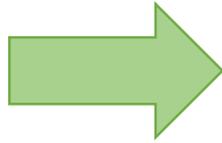
Madison Site only

| Collection Tube | Drawn At | Specimen Type | Aliquot Volume | Total Number of Aliquots | Number of Samples sent to NCRAD | Shipping Temperature |
|---|------------|---------------|----------------------------------|--------------------------|---------------------------------|----------------------|
| 30 ml screw top centrifuge tubes with blue caps | All Visits | CSF | 0.5 ml CSF aliquots | 40 | 10 | Frozen |
| | All Visits | | 1 ml CSF aliquot (for local lab) | N/A | N/A | N/A |

Ambient Samples

- **Two 10 ml PBMC samples**
- **Only Monday-Thursday collection and same day shipping. Plan ahead to schedule FedEx.**
- **Samples must be received at NCRAD one day after collection.**
- **Do NOT draw or ship ambient samples on Friday**
- **Include copy of Blood Sample Shipment and Notification Form**

Ambient Shipment Packaging



- Place the ambient PBMC tubes in the absorbent slots and biohazard bag.
- Place the bag inside the small shipping box, and then set the refrigerant pack on top of it.
- Place small shipping box within a provided UPS Laboratory Pak, seal, and place UPS label on outside of package.

*Gel packs must be put in a freezer at minimum the night before shipping.

Frozen Shipment Packaging

- **All other samples shipped frozen to NCRAD**
 - Serum, Plasma, Buffy Coat, and CSF
 - **Ship Monday-Wednesday Only**
- Hold packaged samples in a -80°C freezer until pickup.
- Include copy of Blood and/or CSF Sample Shipment and Notification Form
- Batch samples together
 - 8 participant samples (Serum, Plasma, Buffy, CSF)
 - **Batch shipping should be performed quarterly or as a full shipment of specimens accumulates, whichever is sooner.**

Shipping Frozen Samples



Plasma, Buffy Coat,
Serum, and CSF Samples



Plasma, Buffy Coat,
and Serum Samples

Frozen Shipment Packaging

- Use the biohazard bag to package the 25-Slot Cryobox



Cryovial box placed in clear biohazard bag

Frozen Shipping Packaging

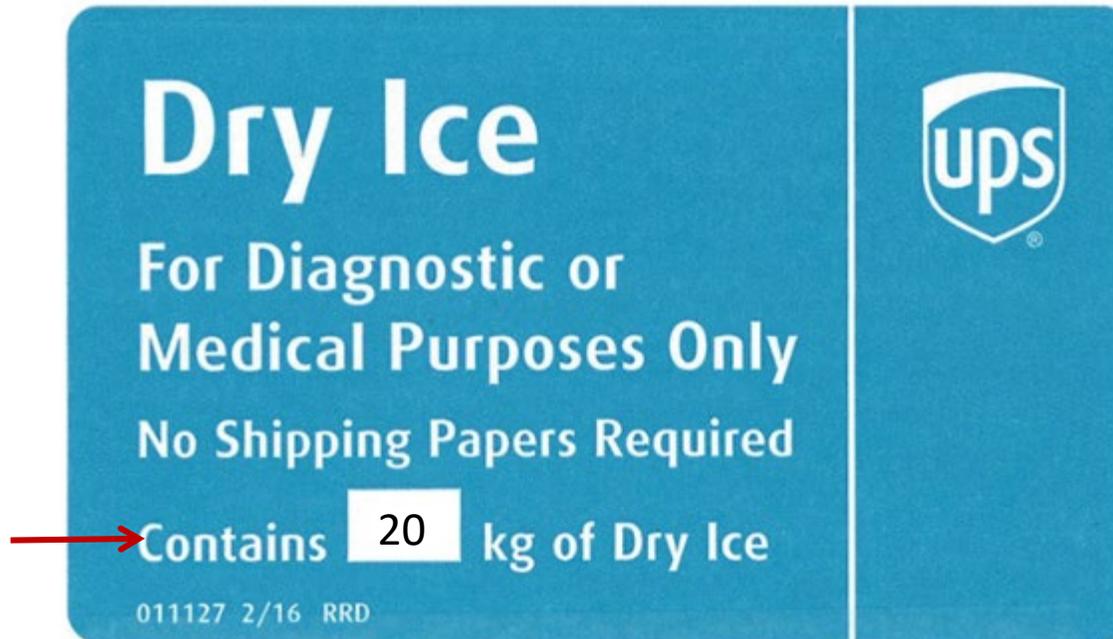


- Place 2-3 inches of dry ice in the bottom of the Styrofoam shipping container, then insert the cryoboxes laying upright.
- Fully cover the cryoboxes with about 2 inches of dry ice in the provided shipper.
- Each Styrofoam shipper must contain about 30-45 lbs (20 kg) of dry ice.

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



Blood and/or CSF Sample and Shipment Notification Form

- 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



Blood and CSF Sample and Shipment Notification Form

Appendix A: Blood 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 | |
| From: _____ | | UPS tracking #: _____ | | Phone: _____ | | Email: _____ | |
| Site (circle one): Madison Milwaukee La Crosse | | | | Kit #: _____ KIT BARCODE | | | |
| WRAP ID: _____ | | | | | | | |
| Visit Number (1-10): _____ | | | | | | | |
| Sex: <input type="checkbox"/> M <input type="checkbox"/> F | | Year of Birth: _____ | | | | | |
| Blood Collection: | | | | | | | |
| Date of Draw: _____ | | Time of Draw: _____ | | <input type="checkbox"/> AM <input type="checkbox"/> PM | | | |
| Date subject last ate: _____ | | Time subject last ate: _____ | | <input type="checkbox"/> AM <input type="checkbox"/> PM | | | |
| PBMC drawn? <input type="checkbox"/> Yes <input type="checkbox"/> No | | CSF Collected? <input type="checkbox"/> Yes <input type="checkbox"/> No | | | | | |
| Blood Processing: | | | | | | | |
| Serum (Red-top) Tube (9 ml) | | | | Plasma & Buffy Coat (Purple-top) Tube (10 ml) | | | |
| Original volume drawn: _____ ml | | Original volume drawn: _____ ml | | Time spin started: _____ | | Time spin started: _____ | |
| Time spin started: _____ | | Time spin started: _____ | | <input type="checkbox"/> AM <input type="checkbox"/> PM | | <input type="checkbox"/> AM <input type="checkbox"/> PM | |
| Duration of centrifuge: _____ minutes | | Duration of centrifuge: _____ minutes | | Temp of centrifuge: _____ °C | | Temp of centrifuge: _____ °C | |
| Temp of centrifuge: _____ °C | | Temp of centrifuge: _____ °C | | Rate of centrifuge: _____ rpm | | Rate of centrifuge: _____ rpm | |
| Rate of centrifuge: _____ rpm | | Rate of centrifuge: _____ rpm | | Time aliquoted: _____ | | Time aliquoted: _____ | |
| Time aliquoted: _____ | | Time aliquoted: _____ | | <input type="checkbox"/> AM <input type="checkbox"/> PM | | <input type="checkbox"/> AM <input type="checkbox"/> PM | |
| # of 0.5 ml serum aliquots (red-capped cryovials): _____ | | # of 0.5 ml plasma aliquots (purple-capped cryovials): _____ | | # of buffy coat aliquots (clear-capped cryovials): _____ | | # of buffy coat aliquots (clear-capped cryovials): _____ | |
| Time aliquots placed in freezer: _____ | | Time aliquots placed in freezer: _____ | | <input type="checkbox"/> AM <input type="checkbox"/> PM | | <input type="checkbox"/> AM <input type="checkbox"/> PM | |
| Storage temperature in freezer: _____ °C | | Storage temperature in freezer: _____ °C | | | | | |
| Notes: _____ | | | | | | | |

Appendix B: 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 | |
| From: _____ | | UPS tracking #: _____ | | Phone: _____ | | Email: _____ | |
| Site: Madison | | | | Kit #: _____ KIT BARCODE | | | |
| WRAP ID: _____ | | | | | | | |
| Visit Number (1-10): _____ | | | | | | | |
| Sex: <input type="checkbox"/> M <input type="checkbox"/> F | | Year of Birth: _____ | | | | | |
| CSF Collection: | | | | | | | |
| Date of Draw: _____ | | Time of Draw: _____ | | <input type="checkbox"/> AM <input type="checkbox"/> PM | | | |
| Date subject last ate: _____ | | Time subject last ate: _____ | | <input type="checkbox"/> AM <input type="checkbox"/> PM | | | |
| Collection process: <input type="checkbox"/> Gravitational OR <input type="checkbox"/> Pull | | | | | | | |
| CSF Processing: | | | | | | | |
| Original volume drawn: _____ ml | | Time spin started: _____ | | Duration of centrifuge: _____ minutes | | Temp of Centrifuge: _____ °C | |
| Time spin started: _____ | | Time spin started: _____ | | Temp of Centrifuge: _____ °C | | Rate of centrifuge: _____ rpm | |
| Duration of centrifuge: _____ minutes | | Temp of Centrifuge: _____ °C | | Rate of centrifuge: _____ rpm | | Time aliquoted: _____ | |
| Temp of Centrifuge: _____ °C | | Rate of centrifuge: _____ rpm | | Time aliquoted: _____ | | Time aliquoted: _____ | |
| Rate of centrifuge: _____ rpm | | Time aliquoted: _____ | | Time aliquoted: _____ | | <input type="checkbox"/> AM <input type="checkbox"/> PM | |
| Time aliquoted: _____ | | Time aliquoted: _____ | | <input type="checkbox"/> AM <input type="checkbox"/> PM | | Number of 0.5 ml CSF aliquots created (clear-capped cryovials): _____ | |
| Number of 0.5 ml CSF aliquots created (clear-capped cryovials): _____ | | Time aliquots placed in freezer: _____ | | <input type="checkbox"/> AM <input type="checkbox"/> PM | | Storage temperature in freezer: _____ °C | |
| Time aliquots placed in freezer: _____ | | Time aliquots placed in freezer: _____ | | <input type="checkbox"/> AM <input type="checkbox"/> PM | | Storage temperature in freezer: _____ °C | |
| Storage temperature in freezer: _____ °C | | Storage temperature in freezer: _____ °C | | | | | |
| Notes: _____ | | | | | | | |

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

Nonconformance Issues

- Sample aliquots and collection tubes frozen at an angle/inverted



Recommendation:

Place aliquots in Argos boxes/tube rack in freezer *upright* until shipment

- Fields left blank on Blood/CSF Sample and Shipment Notification Forms
 - Last time subject ate often left blank/unknown
- Incorrect data reported on Sample and Shipment Notification Forms



Recommendation:

Complete Sample Notification forms during the participant study visit as samples are processed.

- Multiple low volume aliquots

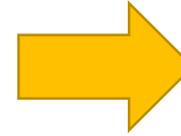


Recommendation:

Lay out cryovials in a row and aliquot in order until plasma/CSF is depleted

Nonconformance Cont.

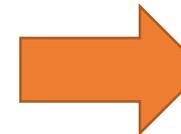
- Aliquots arriving to NCRAD without labels
- Sample forms not faxed or scanned to NCRAD the day before shipment



Recommendation:

Ship Samples to NCRAD utilizing the Notification Form, by WRAP ID. Do not throw away labels until samples are packed and shipped.

- Ambient PBMC samples not shipped to NCRAD the day of blood draw



Recommendation:

No samples should be held ambient for any period of time at the site. Ensure all ambient PBMC samples are shipped by end of the day.

Contact Information

- Questions?
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