Risk Factors for Future Cognitive Decline and Alzheimer’s Disease in Older African Americans (Pathways) Study and
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 317-278-1133
  • E-mail: alzstudy@iu.edu or agericks@iu.edu
  • Website: www.ncrad.org
Training Overview

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

Specimen Collection Schedule

<table>
<thead>
<tr>
<th>Collection Tube</th>
<th>Drawn At</th>
<th>Specimen Type</th>
<th>Aliquot Volume</th>
<th>Total Number of Aliquots</th>
<th>Shipping Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 EDTA (Purple-Top) Blood Collection Tube (10 ml)</td>
<td>All Visits</td>
<td>Plasma</td>
<td>1.5 ml plasma aliquots</td>
<td>Up to 4</td>
<td>Frozen</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.5 ml plasma aliquot</td>
<td>1</td>
<td>Kept locally at site</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Buffy Coat</td>
<td>1.0 ml buffy coat aliquots</td>
<td>1</td>
<td>Frozen</td>
</tr>
</tbody>
</table>
Kit Request Module

https://redcap.uits.iu.edu/surveys/?s=AJYP4X7MMKRNWTD3

- Kits and individual supplies available to order:
  - Blood Collection Kit
  - Blood Supplemental Kit
  - Frozen Shipping Kit
  - Individual Supplies
Kit Request Module

1. The coordinator name and contact information will populate.
2. Verify that this information is correct.
3. If needed, update information.
Kit Request Module

**Plasma & Buffy Coat Kit Quantity (10/17)**

- 1 x EDTA (purple-top) blood collection tube (19 mL) - CT001
- 3 x Cryotube (2.0 mL) with purple cap - CV027
- 1 x Cryotube (2.0 mL) with blue cap - CV004
- 1 x Cryotube (2.0 mL) with clear cap - CV014
- 6 x Preprinted Collection Tube and Aliquot Labels (for plasma and 1x buffy coat) - LB003
- 3 x Preprinted Kit Number Label (1 for sample form, 1 for cryobox, 1 extra) - LB003
- 2 x Label for handwritten Sequence ID (1 for EDTA, 1 extra) - LB003
- 2 x Disposable graduated transfer pipettes (3 mL) - CV015
- 1 x Reusable bag - ST020
- 1 x Reusable small poly bag (4" x 6") - ST010

Please indicate which visit(s) each of your requested kits will be used for:

(A, AAL, or COV and 1, 2, 3, 4, 5, 6, 7, or 8)

*Note: You can order kits for different visits in a single kit request*

**Supplemental Kit Quantity (10/17)**

*Only needed at study start up*

- 4 x EDTA (purple-top) blood collection tube (19 mL) - CT001
- 12 x Cryotube (2.0 mL) with purple cap - CV007
- 2 x Cryotube (2.0 mL) with blue cap - CV014
- 4 x Cryotube (2.0 mL) with clear cap - CV014
- 5 x Label for handwritten Sequence ID - LB003
- 1 x 25 cell Cryotube box - CV005
- 6 x Disposable graduated transfer pipettes (3 mL) - CV015
- 1 x Reusable bag - ST020
- 6 x Reusable small poly bag (4" x 6") - ST010

Frozen Blood Shipping Supply Kit Quantity (10/17)

*Will fit samples from 24 subjects (8 x 3-cell cryoboxes with samples from 3 subject visits per box)*

- 8 x Plastic Biohazard bag with absorbent sheet (small) - SH015
- 8 x 25 cell cryotube box (64 samples from 3 participants per cryotube) - CV005
- 1 x Shipping pouch - SH008
- 1 x Shipping box/cryotube container - SH009
- 1 x Uni373 label - LB006
- 1 x Fragile label - SH004
- 1 x Dry ice label - LB016
- 1 x Reusable bag - ST020

**Notes:**

- Indicate the quantity of Plasma & Buffy Coat Kits needed.
- Kit components are listed for your convenience.
- Please indicate which visit(s) the kits will be used for.
- Supplemental kits should primarily be ordered at study start up, and rarely throughout the course of the study.
- Frozen shipping kits can be ordered for samples shipping back to NCRAD
- Kit components are listed for your convenience.
Kit Request Module

- If individual supplies are needed, select yes, and then select the correct quantity of supplies needed.
- Extra PATH Sequence ID Labels can also be ordered.

Sequence ID:

### PATH Sequence ID Labels (LB001)

- Add any relevant comments
- Click “Submit” to turn in your request.
- The IU staff will notify you that your request has been received and address any issues.

**Our standard shipping time for all orders is 3 weeks.**

We can ship this kit request by: 02-15-2024

If you need any supplies in this order prior to 02-15-2024, you must contact the NCRAD coordinator for this study: agericks@iu.edu.
Kit Request Module

• You are responsible for ordering kits and maintaining supplies on site for scheduled participants.

• To order kits, sites will use the Indiana University online kit ordering module: https://redcap.uits.iu.edu/surveys/?s=AJYP4X7MMKRNWTD3

• Allow around 3 weeks for your order to be processed and shipped.

Specimen Labels
Specimen Labels

• Label type summary:
  • Kit Number Labels
  • Sequence ID Labels
  • Collection and Aliquot Tube Labels
    • Differ by specimen type

• All labels are provided in the kits

Specimen Labels: Kit Number Labels

• Used to track patient samples and provide quality assurance

• Will be placed on:
  • Biological Sample and Shipment Notification Form
  • Outside of cryobox(es) that houses aliquot tubes during storage and shipment
Specimen Labels: Sequence ID Labels

- Participants will be identified by their Sequence ID
- Sites will be responsible for handwriting the IDs on the provided labels
  - Fill in labels prior to adhering to tubes
  - Must use fine-point marker
- Placed on the blood collection tube (EDTA (Purple-Top) 10 ml Blood Collection Tube).

Specimen Labels: Collection & Aliquot Tube Labels

- Study Name
- Specimen Number (Assigned by NCRAD)
- Sample Type (Plasma, Buffy Coat, or Whole Blood)
- Kit # (Assigned by NCRAD and unique to the participant and visit)
Specimen Labels: Blood Collection Tube

- EDTA 10ml blood collection tube will have two labels:
  - Collection & Aliquot Tube Label (PLASMA)
  - Sequence ID Label

Specimen Labels: Plasma & Buffy Coat Aliquot Tubes

- Each 2ml cryovial will have one label: Collection & Aliquot Tube Label
- Purple & blue cap cryovials should have a collection & aliquot tube label with PLASMA on it.
- Clear cap cryovial should have a collection & aliquot tube label with BUFFY COAT on it.
- Place the left-hand barcode near the cap
### Plasma & Buffy Coat Kit – Labels Provided

<table>
<thead>
<tr>
<th>3 x Kit Number Labels</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Place one on the Sample Form.</td>
</tr>
<tr>
<td>• Place the other on the outside of the cryobox holding the sample</td>
</tr>
<tr>
<td>• There will also be one extra label</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2 x Sequence ID Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Place on the 10mL EDTA purple-top blood collection tube</td>
</tr>
<tr>
<td>• There will also be one extra label</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5 x Collection and Aliquot Tube Label - PLASMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Place the label with the lowest specimen number on the 10mL EDTA purple-top blood collection tube</td>
</tr>
<tr>
<td>• Place the 3 on the purple-top cryovials</td>
</tr>
<tr>
<td>• Place the label with the highest specimen number on the blue-top cryovial</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1 x Collection and Aliquot Tube Label – BUFFY COAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Place the label on the clear-top cryovial</td>
</tr>
</tbody>
</table>

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### Specimen Labels: Labeling Biologic Samples

- Label all collection and aliquot tubes **before** collecting, processing or freezing samples.

- Label only 1 participant’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 xg
  2. -80°C Freezer

• Shipping Equipment:
  1. Dry ice pellets
Blood Collection & Processing: Sample Collection Tube

1 x 10ml EDTA (Lavender-Top) Tube

Blood Collection & Processing: Aliquot Cryovials & Cap Colors

<table>
<thead>
<tr>
<th>Cap Color</th>
<th>Sample Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lavender Cap</td>
<td>Plasma</td>
</tr>
<tr>
<td>Clear Cap</td>
<td>Buffy Coat</td>
</tr>
<tr>
<td>Blue Cap</td>
<td>Residual plasma</td>
</tr>
</tbody>
</table>


Sample Packaging

- Place the labeled, filled cryovials in a 25 cell cryobox.
- Label the cryobox lid with a Kit Number Label.
- Place samples from 3 participant visits per 25 cell cryobox.
- An individual participant’s samples should be placed in a single row.
- An empty row should separate each participant’s samples from another participant’s samples.
- Be sure to place the buffy coat sample in the correct participant visit row and immediately to the right of the last plasma aliquot.
- Place on pelleted dry ice and Transfer to -80°C Freezer when possible.
- Store all samples at -80°C until shipped to NCRAD on pelleted dry ice.
Sample Packaging

Cryoboxes should contain samples from 3 participant visits.

a. Each participant visit will have up to 4 x Plasma Aliquots and 1 x Buffy Coat Aliquot.
b. This means there should be no more than 15 samples per cryobox (up 12 x plasma aliquots and 3 x buffy coat aliquots)

Biological Sample and Shipment Notification Form
Biological Sample and Shipment Notification Form

- Blood Collection for:
  - Plasma
  - Buffy Coat

- Please make sure this form is filled out completely by the person collecting the samples AND the person processing.

Biological Sample and Shipment Notification Form

- Participant Sequence ID will be in one of the three following formats: A###, L###, or C###
  - Participant Sequence ID format A### corresponds to study AA
Biological Sample and Shipment Notification Form

- Participant Sequence ID will be in one of the three following formats: A###, L###, or C###
  - Participant Sequence ID format L### corresponds to study AAL

- Participant Sequence ID format C### corresponds to study COV
Biological Sample and Shipment Notification Form

- Participant Sequence ID will be in one of the three following formats: A###, L###, or C###
  - Participant Sequence ID format A### corresponds to study AA
  - Participant Sequence ID format L### corresponds to study AAL
  - Participant Sequence ID format C### corresponds to study COV

- No other combination of Participant Sequence ID and Study should be used.

- If a form is received where the Participant Sequence ID is in the format A###, but the study chosen is NOT AA, our team will flag this as an error and follow up with you.

Biological Sample and Shipment Notification Forms

- A scanned copy of the sample form must be emailed to NCRAD prior to the date of sample arrival: alzstudy@iu.edu

- Please include a hard copy of sample forms in all shipments of frozen samples.
Sample Shipping

Frozen Shipping: Guidelines

• **Ship Monday-Wednesday Only**
  • Hold packaged samples in a -80°C freezer until pickup.
  • Batch Samples together
    • Up to 8 Cryoboxes
    • **Batch shipping should be performed every month or as a full shipment of specimens accumulates, whichever is sooner.**
Sample Shipping Summary

<table>
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<th>Drawn At</th>
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Frozen Shipping: Cryoboxes

- Place a filled cryobox in a biohazard bag. Seal biohazard bag according to the instructions on the bag.

- **IMPORTANT**: Place only ONE cryobox per Biohazard bag.
Shipping Dry Ice Requirements

• Each Styrofoam shipper can hold 8 cryoboxes.
• Place approximately 2-3 inches of pelleted dry ice in the bottom of the Styrofoam shipping container.
• Place the biohazard bags into the Styrofoam-lined shipping container on top of the pelleted dry ice.
• Please ensure that cryovial boxes are placed so the cryovials are upright.
• Completely fill the inner Styrofoam with pelleted dry ice pellets to ensure the frozen state of the specimens during transit.
• Each Styrofoam shipper should contain about 45 lbs (20 kg) of pelleted dry ice.

Shipping: Dry Ice Requirements

• Package must be labeled with a UPS Dry Ice Label
• Class 9 Dry Ice label should not be covered with other stickers and must be completed, or the shipping carrier will reject/return your package!
• Fill out the amount of dry ice in the package
Shipping Frozen Samples

- Scan the *Biological Sample and Shipment Notification Form* and email it to alzstudy@iu.edu ahead of the shipment.

Shipping Frozen Samples

- Log in to ShipExec™ Thin Client: https://kits.iu.edu/ups
- Click on the “Shipping” dropdown and click on “Shipping and Rating”
Shipping Frozen Samples

• Select your study from the “Study Group” drop down on the right side of the main screen (PATH). Choosing your study will automatically filter the address book to only addresses within this study.

• Click on the magnifying glass icon in the “Ship From” section to search for your shipping address.

Shipping Frozen Samples

• Enter Package Information
  • Enter the total weight of your package
  • Enter the pelleted dry ice weight

• Click Ship in the bottom right of the page when complete.

• Click the blue Pickup Request button to schedule a UPS pickup. Enter the earliest pickup time and latest pickup time in 24-hr format.

• Click Save.
Shipping Frozen Samples

• Print the airbill that is automatically downloaded.

• Fold airbill, and place inside plastic UPS sleeve. Peel the back off of the UPS sleeve and stick the sleeve to the top of the package. Do NOT overlap other labels or package seams.

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

<table>
<thead>
<tr>
<th></th>
<th>DGI Training Center</th>
<th>IATA Training Schools</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>800-338-2291</td>
<td>North America 1(514)390-6726</td>
</tr>
<tr>
<td></td>
<td>DGItraining.com</td>
<td>Europe, Africa &amp; Middle East 41 (22) 799</td>
</tr>
<tr>
<td></td>
<td>Provides IATA Certified Air Seminars and online courses</td>
<td>2751</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Asia, Australia &amp; the Pacific 65 239 7232</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="http://www.iata.org">www.iata.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Training schools located in 30 countries</td>
</tr>
</tbody>
</table>

Saf-T Pak Inc.
www.saftpak.com
Provides dangerous goods training via CD or on-site instruction for North America and Europe

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
NCRAD Website

Helpful Pages:

- [https://ncrad.org/holiday_closures.html](https://ncrad.org/holiday_closures.html)

### HOLIDAY CLOSURES

<table>
<thead>
<tr>
<th>DATE</th>
<th>HOLIDAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 1</td>
<td>New Year's Day</td>
</tr>
<tr>
<td>3rd Monday in January</td>
<td>Martin Luther King, Jr Day</td>
</tr>
<tr>
<td>4th Monday in May</td>
<td>Memorial Day</td>
</tr>
<tr>
<td>4th July</td>
<td>Independence Day (observed)</td>
</tr>
<tr>
<td>4th Monday in September</td>
<td>Labor Day</td>
</tr>
<tr>
<td>4th Thursday in November</td>
<td>Thanksgiving</td>
</tr>
<tr>
<td>4th Friday in November</td>
<td>Friday after Thanksgiving</td>
</tr>
<tr>
<td>December 25</td>
<td>Christmas</td>
</tr>
</tbody>
</table>

NCRAD Website: PATH Active Study Page

Training videos, manual of procedures, and sample form are available for reference on the PATH Active Study Page.
Contact Information

• Questions?

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