NATIONAL INSTITUTE ON AGING ALZHEIMER DISEASE FAMILY BASED STUDY

in collaboration with the

National Centralized Repository for Alzheimer's Disease and Related Dementias



Biospecimen Collection, Processing, and Shipment Manual of Procedures

Version 08.2025

Contents

1.0 Abbreviations 4
2.0 Purpose 4
3.0 NIAAD-FBS Information 5
3.1 Participating Sites 5
3.2 NCRAD Contact Information 6
3.3 NCRAD Hours of Operations 6
3.4 NCRAD Holiday Observations 7
4.0 NCRAD Kit Contents 8
5.0 Blood Collection 11
5.1 Labeling Blood Samples 11
5.1.1 Label Type Summary 12
5.2 Kit Overviews and Sample Notification Forms 15
5.2.1 Blood Kit A (PBMC, Plasma/Buffy Coat, and RNA Kit) and Blood Kit C (Mobile Phlebotomy Kit) 15
5.2.2 Blood Kit B: PBMC, DNA, and RNA Kit 17
5.2.3 Blood Kit D: Genetic Testing Kit Overview 20
5.3 Blood Collection 22
5.3.1 Whole Blood for PBMC Isolation 22
5.3.2 Whole Blood for DNA Isolation OR Plasma and Buffy Coat Isolation 25
5.3.3 Whole Blood for Genetic Testing 31
5.3.4 Whole Blood for RNA Isolation 34
6.0 Blood Packaging 37
6.1 Ambient Blood Package 37
6.1.1 NCRAD Packaging Instructions—Ambient Shipments 38
6.2 Frozen Blood Packaging 39
6.2.1 NCRAD Packaging Instructions – Frozen Shipments 41
7.0 Blood Shipping Instructions – Ambient and Frozen 43
7.1.1 Special Instructions for Returning Blood Kit B: PBMC, DNA, and RNA 46

7.1.2 Special Instructions for Contracted Mobile Phlebotomist 46
8.0 Saliva Collection, Packaging, and Shipping 47
8.1 Saliva Kit Overview 47
8.2 Saliva Sample Form 48
8.3 Saliva Collection, Packaging, and Shipping – Site Instructions 49
8.4 Saliva Collection, Packaging, and Shipping – Participant Instructions 50
9.0 Sample Redraws 52
10.0 Data Collection 52
10.1 Data Collection Schedule 52
10.2 Data Cleaning 52
11.0 Brain Autopsy 52
11.1 Deceased Family Member with a Previous Autopsy: 53
11.2 Current Participants and Family Members Program Enrollment: 53
11.3 Autopsy Results: 53
11.4 Brain Shipment and Coordinator Contacts: 53
12.0 Appendices 54
Appendix A: Rate of Centrifuge Worksheet 55
Appendix B: NYBB Fresh Tissue shipping instructions 56
Appendix C: Sample form for frozen and fixed brain tissue 59
Appendix D: Processing Schematic for DNA Collection and Processing from Blood Kit B. 60
Appendix E: Sample Packaging and Shipping Instructions for the participant for Blood Kit B.. 61

1.0 Abbreviations

AD	Alzheimer's Disease
ADRC	Alzheimer Disease Research Center
CT	Computer assisted Tomography
CUMC	Columbia University Medical Center
DNA	Deoxyribonucleic Acid
EDTA	Ethylene Diamine Tetra-acetic Acid
FBS	Family Based Study
FTD	Frontotemporal Dementia
IATA	International Air Transport Association
IRB	Internal Review Board
LBD	Lewy Body Dementia
LOAD	Late Onset Alzheimer's Disease
EOAD	Early Onset Alzheimer's Disease
MDS	Minimum Data Set
MRI	Magnetic Resonance Imaging
NaHep	Sodium Heparin (Green-Top) Blood Collection Tube (10 mL)
NCRAD	National Centralized Repository for Alzheimer's Disease and Related Dementias
NYBB	New York Brain Bank
NIA	National Institute on Aging
PBMC	Peripheral Blood Mononuclear Cell

2.0 Purpose

The purpose of this manual is to provide NIA AD-FBS staff (PIs and study coordinators) at the various study sites with instructions for sample collection, processing, and shipping. These procedures are relevant to all study personnel responsible for data and biological specimen collection.

3.0 NIAAD-FBS Information

The National Institute on Aging -Alzheimer's Disease Family Based Study (NIAAD-FBS) is a U24 proposal in which the main purpose is to develop or maintain unique resources to be shared with the scientific community. Dr. Richard Mayeux at Columbia University, Dr. Tatiana Foroud at Indiana University, and Dr. Alison Goate at the Icahn School of Medicine at Mount Sinai are the co-principal investigators for this study.

3.1 Participating Sites

Site #	Site Name
4	Columbia University (coordinating center)
8	Indiana University
10R	Mayo Clinic Rochester
15	Rush University
22	University of Pittsburgh
25	University of Texas Southwestern
26	University of Washington
27	Washington University
61	University of Miami
62	Wakehealth University
63	Case Western University
64	University of California, Los Angeles
67	Icahn School of Medicine at Mount Sinai
68	UTHSCSA

3.2 NCRAD Contact Information

Tatiana Foroud, PhD, Core Leader
Phone: 317-274-2218

Kelley Faber, MS, CCRC, Senior Project Manager
Phone: 317-274-7360
Email: kelfaber@iu.edu

Ronae Williams, MSW, Clinical Research Coordinator
Phone: 317-278-9082
Email: rdw2@iu.edu

General NCRAD Contact Information
Phone: 1-800-526-2839 or 317-278-8413
Email: alzstudy@iu.edu
Website: www.ncrad.org

Sample Shipment Mailing Address
NCRAD
Indiana University School of Medicine
351 W. 10th St. TK-342
Indianapolis, IN 46202
Phone: 1-800-526-2839

3.3 NCRAD Hours of Operations

Indiana University business hours are from 8 AM to 5 PM Eastern Time, Monday through Friday.

Ambient Blood samples must be shipped **Monday-Thursday only.**

Frozen Blood samples must be shipped **Monday-Wednesday only.**

For blood packaging information, please refer to section 6.0 and for blood shipment details, please refer to section 7.0 of this protocol.

For Saliva packaging and shipment information, please refer to section 8.0 of this protocol.

Check the weather report to make sure impending weather events (blizzards, hurricanes, etc.) will not impact the shipping or delivery of the samples.

3.4 NCRAD Holiday Observations

Date	Holiday
January 1	New Year's Day
3rd Monday in January	Martin Luther King, Jr Day
4th Monday in May	Memorial Day
June 19	Juneteenth
July 4	Independence Day
1st Monday in September	Labor Day
4th Thursday in November	Thanksgiving
4th Friday in November	Friday after Thanksgiving
December 25 – December 31	Winter Holiday

Please note that between December 24th and January 2nd, Indiana University will be open Monday through Friday for essential operations **ONLY** and will re-open for normal operations on January 2nd. If possible, biological specimens for submission to Indiana University should **NOT** be collected and shipped to Indiana University after the second week in December. Should it be necessary to ship blood samples for DNA extraction to Indiana University during this period, please contact the Indiana University staff before December 20th by e-mailing alzstudy@iu.edu, so that they can arrange to have staff available to process incoming samples. **Please see: https://ncrad.org/holiday_closures.html for additional information.**

- Please note that courier services may observe a different set of holidays.
- Please be sure to verify shipping dates with your courier prior to any holiday.
- **Weekend/holiday delivery must be arranged in advance with NCRAD staff.**

4.0 NCRAD Kit Contents

Blood Kit A: PBMC, Plasma / Buffy Coat, and RNA Kit

This kit is to be used on site by a study coordinator.

Quantity	Kit Component
2	EDTA (Purple-Top) Blood Collection Tube (10ml)
1	15mL Conical Tube
20	Micronic tubes - 2mL PURPLE cap
2	Micronic tubes - 2mL GREY cap
1	Micronic tube - 2mL BLUE cap
2	Disposable transfer pipette (1mL)
23	Micronic Tube Labels (21 x plasma & 2 buffy coat)
5	Kit Number Labels
5	Collection Tube Labels (2 x plasma, 2 x PBMC, & 1 x RNA)
6	Site and ID Labels
1	Cryobox 48-Slot Rack
1	Biohazard Bag w/ absorbent sheet
1	Large resealable bag
1	Small label bag 4"x6"
2	PBMC (Green-Top) Blood Collection Tube (10mL)
1	PAXgene™ Blood Collection Tube (2.5 ml)
1	Ambient Mailer kit containing:
	1 - Biohazard bag w/absorbent sheet
	1 - Refrigerant Pack
	1 - Ambient Shipper w/Insulated Cooler
	1 - UN3373 Category B Label
	1 - UPS Laboratory Pak
	1 – Airbill pouch
	1 - List of Contents Card

Blood Kit B: PBMC, DNA, and RNA Kit

This kit is to be used by a subject-selected location.

Quantity	Kit Component
2	EDTA (Purple-Top) Blood Collection Tube (10mL)
2	PBMC (Green-Top) Blood Collection Tube (10mL)
1	PAXgene™ Blood Collection Tube (2.5 ml)
5	Labels for handwritten Site ID, Family ID, and Individual ID
5	Pre-Printed labels for blood collection tubes (2 x plasma, 2 x PBMC, & 1 x RNA)
5	Kit number labels
1	Resealable bag
1	UPS Laboratory Pak
1	Airbill pouch
1	Biohazard bag w/absorbent tube sleeves
1	Refrigerant Pack
1	Small IATA shipping box
1	UN3373 Category B Label
1	List of Contents Card

Blood Kit C: Mobile Phlebotomy Kit

This kit is only to be ordered and used by the contracted Mobile Phlebotomy company.

Quantity	Kit Component
Plasma/Buffy Coat Components:	
2	EDTA (Purple-Top) Blood Collection Tube (10mL)
1	15mL Conical Tube
20	Micronic tubes - 2mL PURPLE cap
2	Micronic tubes - 2mL GREY cap
1	Micronic tube - 2mL BLUE cap
2	Disposable transfer pipette (1mL)
1	Cryobox 48-Slot Rack
1	Biohazard Bag w/ absorbent sheet
1	Large resealable bag
1	Small label bag 4"x6"
Frozen Shipping Components:	
1	Small Insulated Frozen Shipper
1	Dry Ice Label
1	UN3373 Label
1	UPS Return Label w/Waybill (provided to RN by PCM management)
1	Airbill pouch
PBMC & RNA Components:	
2	PBMC (Green-Top) Blood Collection Tube (10mL)
1	PAXgene™ Blood Collection Tube (2.5 ml)
1	UPS Return Label (provided to RN by PCM management)
1	UPS Laboratory Pak
Ambient Mailer Kit:	
1	Biohazard bag w/absorbent sheet
1	Refrigerant Pack
1	Ambient Shipper w/Insulated Cooler
1	UN3373 Category B Label
1	List of Contents Card
1	Airbill pouch
Labels:	
23	Micronic Tube Labels (21 x plasma & 2 x buffy coat)
5	Collection Tube Labels (2 x plasma ; 2 x PBMC ; 1 x RNA)
5	Kit Number Labels
6	Site ID, Family ID, and Individual ID Labels

Blood Kit D: Whole Blood Collection Kit for Genetic Testing

This kit is only to be used on one participant per family at one visit.

Genetic Testing is now done primarily through Invitae. This kit should only be ordered and used for rare cases that are approved by FBS study management.

Quantity	Kit Component
1	EDTA (Lavender-Top) Blood Collection Tube (3 mL)
1	Pre-printed Collection Tube label for whole blood
1	Label for handwritten Site ID, Family ID, and Individual ID
5	Pre-printed labels with kit number
1	Bubble wrap tube sleeve

Frozen Shipping Supply Kit

Quantity	Kit Component
1	Airbill pouch
1	Frozen Shipper (Small frozen shipper/Sm brain box)
1	Dry Ice Label
1	UN3373 Label

Saliva Kit

Quantity	Kit Component
1	Oragene Saliva Collection Kit
2	Kit number labels
1	Label for handwritten Site ID, Family ID, and Individual ID
1	Small Saliva Biohazard Bag with Absorbent Sheet
1	Resealable Bag
1	Exempt Human Specimen Label
1	Airbill pouch
1	Shipping Envelope

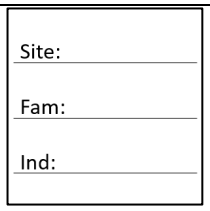
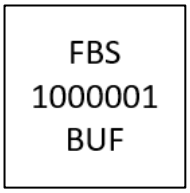
5.0 Blood Collection

5.1 Labeling Blood Samples

In order to ensure the highest quality samples are collected, it is essential to follow the specific collection and shipment procedures detailed in the following pages. Please read the following instructions first before collecting any specimens. Have all your supplies and equipment out and prepared prior to drawing blood.

5.1.1 Label Type Summary

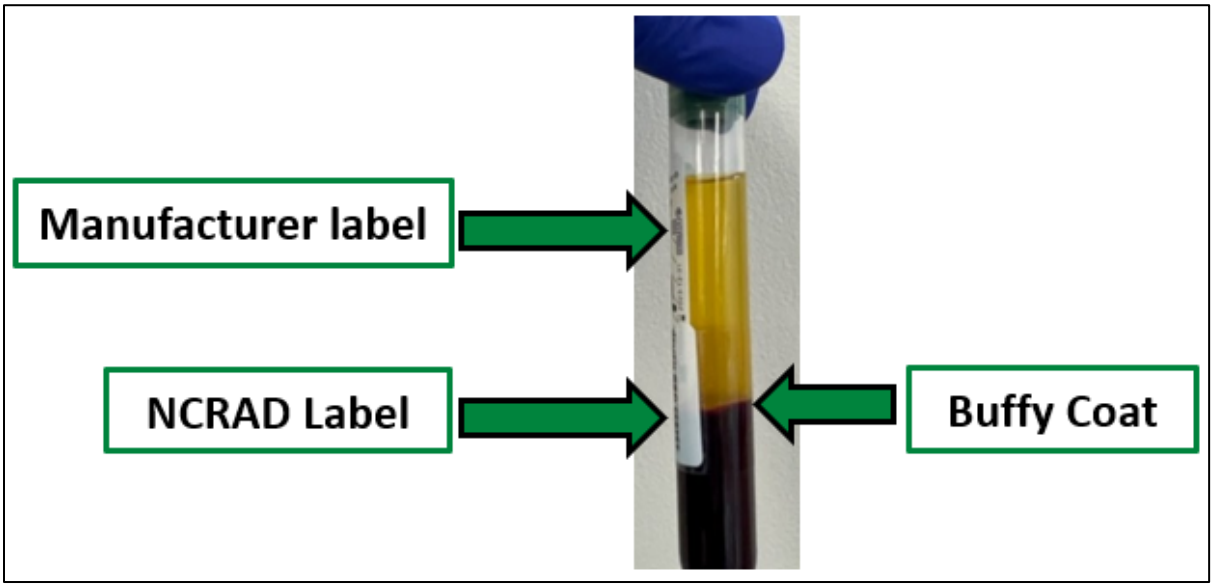
1. Kit Number Label
2. Site ID, Family ID, and Individual ID Label
3. Collection Tube Label
4. Cryovial Label

	**Kit Number Labels** tie together all specimens collected from one participant at one visit. They should be placed on each cryobox, and in the designated location on the Blood Sample and Shipment Notification Forms.
	**Site ID/Family ID/Individual ID Labels** are used to document the individual's unique Sit, Family, and Individual. Place one label on each blood collection tube.
	Place one **Collection Tube Label** on each blood collection tube.
	Place one **Cryovial Label** on each blood aliquot cryovial. *Note: these are only applicable to Blood Kits A & C.*

Each collection tube will contain two labels: the Collection Tube Label and the Site ID, Family ID, and Individual ID Label. Be sure to place labels in the same configuration consistently among tubes, with the barcoded label near the top of the tube and the handwritten Site ID/Family ID/Individual ID Labels label near the bottom of the tube.

- Collection tubes in Blood Kit A: 2 x PBMC tubes, 2 x EDTA tubes (10mL), and 1 x $PAXgene^{TM}$ tube.
- Collection tubes in Blood Kit B: 2 x PBMC tubes, 2 x EDTA tubes (10mL), and 1 x $PAXgene^{TM}$ tube.
- Collection tubes in Blood Kit C: 2 x PBMC tubes, 2 x EDTA tubes (10mL), and 1 x $PAXgene^{TM}$ tube.
- Collection tubes in Blood Kit D: 1 x EDTA tube (3mL).
    - *Genetic Testing is now done primarily through Invitae. This kit should only be ordered and used for rare cases that are approved by FBS study management.*

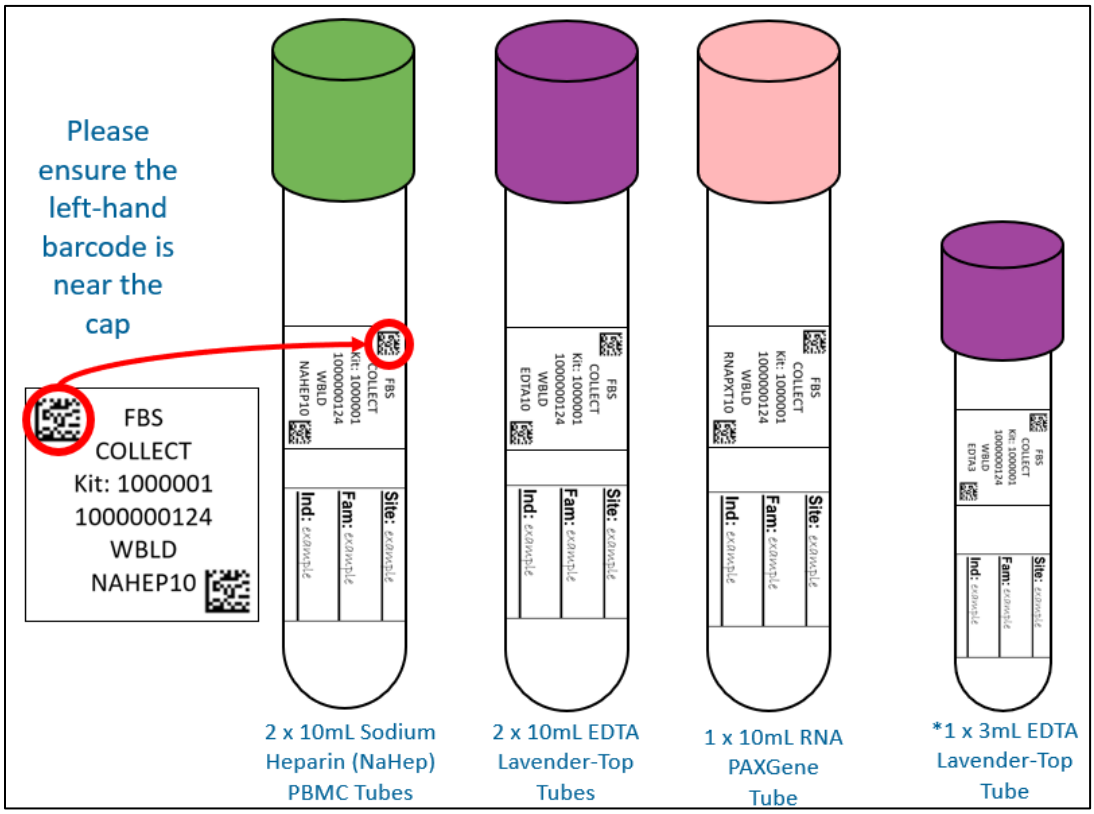
For Sodium Heparin tubes, please align the Collection Tube Label and Site ID/Family ID/Individual ID Label with the manufacturer's label on the tube so that the buffy coat is visible to the NCRAD laboratory staff during processing as shown in the following picture:

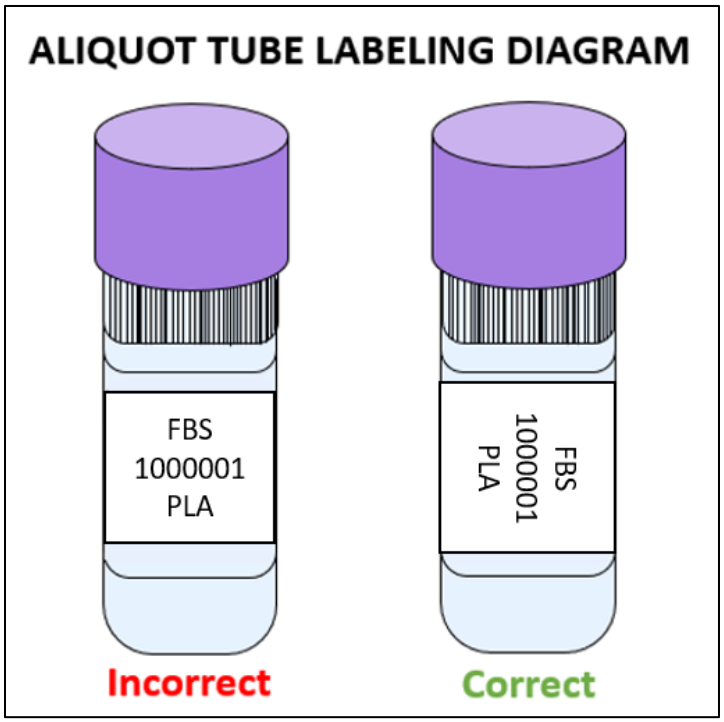


In order to ensure the label adheres properly and remains on the tube, please follow these instructions:

- Place Collection Tube and Aliquot Labels on **ALL** collection tubes and cryovials **BEFORE** sample collection. This should help to ensure the label properly adheres to the tube before exposure to moisture or different temperatures.
- Using a fine point permanent marker, fill-in and place the Site ID/Family ID/Individual ID Labels on the Collection Tubes **BEFORE** sample collection. These labels are placed on collection tubes in addition to the Collection Tube Label.
- The Collection Tube Labels contain a 2D barcode on the left-hand side of the label. Place this barcode toward the tube cap.
- Place label **horizontally** on the tube (wrapped around sideways if the tube is upright).

Take a moment to ensure the label is **completely adhered** to each tube. It may be helpful to roll the tube between your fingers after applying the label. The following pictures show the correct placement of the labels on the collection tubes and cryovials. Further instructions explaining the number and type of labels in each specific kit can be found in section 5.2.


Please ensure the left-hand barcode is near the cap
FBS
COLLECT
Kit: 1000001
1000000124
WBLD
NAHEP10
2 x 10mL Sodium Heparin (NaHep) PBMC Tubes
2 x 10mL EDTA Lavender-Top Tubes
1 x 10mL RNA PAXGene Tube
*1 x 3mL EDTA Lavender-Top Tube


ALIQUOT TUBE LABELING DIAGRAM
FBS
1000001
PLA
FBS
1000001
PLA
Incorrect
Correct

5.2 Kit Overviews and Sample Notification Forms

5.2.1 Blood Kit A (PBMC, Plasma/Buffy Coat, and RNA Kit) and Blood Kit C (Mobile Phlebotomy Kit)

Blood Kit A (PBMC, Plasma/Buffy Coat, and RNA) & Blood Kit C (Mobile Phlebotomy)

This is applicable to samples collected by a mobile phlebotomist or on site by a study coordinator.

Kit Overview

Draw Order	Sample Collected	Collection Tube	Site Processing	Sample Shipped	Shipment Tube	Shipment Temperature
1	Whole Blood (for PBMC isolation)	2 x Sodium Heparin (GreenTop) Blood Collection tube (10 ml)	N/A	Whole Blood	2 x Sodium Heparin (GreenTop) Blood Collection tube (10 ml)	Ambient
2	Whole Blood (for plasma & buffy coat isolation)	2 x EDTA (Lavender-Top) Blood Collection Tube (10 ml)	Isolation of plasma and buffy coat	Plasma & Buffy Coat	Up to 21 x 2mL purple top cryovials with plasma *AND* Up to 2 x 2mL grey top cryovials with buffy coat	Frozen
3	Whole Blood (for RNA isolation)	1 x PAXgeneTM Blood Collection Tube (2.5 ml)	N/A	Whole Blood	1 x PAXgeneTM Blood Collection Tube (2.5 ml)	Ambient

**Please note: If a Whole Blood sample for Genetic Testing is also being drawn, the draw order will change so that Whole Blood for Genetic Testing is drawn 3rd and Whole Blood for RNA isolation is done 4th.*

Kit Labeling

Kit Number Labels



- 1 x placed on the Sample Form
- 1 x placed on the outside of the cryobox that houses aliquot tubes during storage and shipment
- 3 x extra *(dispose if not used)*

Site ID, Family ID, and Individual ID Labels



- 2 x EDTA (Lavender-Top) Blood Collection Tube (10 ml)
- 2 x PBMC Sodium Heparin (Green-Top) Tubes 10ml
- 1 x RNA PAXgene™ (Red-Top) Tubes 2.5 ml
- 1 x extra

Cryovial Labels



- 20 x Micronic tubes - 2ml PURPLE cap
- 1 x Micronic tube - 2ml BLUE cap



- 2 x Micronic tubes - 2ml GREY cap

Collection Tube Labels



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



- 2 x PBMC Sodium Heparin (Green-Top) Tubes 10ml



- 1 x RNA PAXgene™ (Red-Top) Tubes 2.5 ml

Sample Collection & Processing

1. Whole Blood for PBMC isolation: refer to section 5.3.1.
2. Whole Blood for plasma & buffy coat isolation: refer to section 5.3.2.
3. Whole Blood for RNA isolation: refer to section 5.3.4.

Sample Packaging

1. Ambient: Whole Blood for PBMC isolation and Whole Blood for RNA isolation - refer to section 6.1.
2. Frozen: Whole Blood for plasma & buffy coat isolation - refer to section 6.2.

Kit Sample Shipping

1. Refer to section 7.0.

Biological Sample and Shipment Notification Form - Blood Kit A and C: PBMC, Plasma/Buffy Coat, and RNA

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

Sample Type	Collection Tube Type	Shipment
Whole blood for PBMC isolation	2 x Sodium Heparin (Green-Top) Blood Collection Tube (10ml)	Room Temperature Must be shipped and received within 24 hours of collection
Whole blood for isolation of plasma & buffy coat (for DNA extraction)	2 x EDTA (Lavender-Top) Blood Collection Tube (10ml)	Dry Ice
Whole blood for RNA isolation	1 x PAXgeneTM Blood Collection Tube (2.5 ml)	Room Temperature Must be shipped and received within 24 hours of collection

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

General Information:

Kit Barcode

UPS Tracking # (ambient): _____

UPS Tracking # (frozen): _____

Site Coordinator: _____ **Date:** _____

Phone: _____ **Email:** _____

Study: AD Family-Based Study

Site ID: _____ **Family ID:** _____ **Individual ID:** _____

Sex: M F **Year of Birth:** _____

Visit (please circle one): 1 2 3 4 5 6 7 8 9 10

Blood Collection:

Date Drawn: _____ [MM/DD/YYYY] Time of Draw: _____ [HH:MM]

Date Subject Last Ate: _____ [MM/DD/YYYY] Time Subject Last Ate: _____ [HH:MM]

Original Volume Drawn (2 x NaHep Green-Top): #1: _____ (mL) #2 _____ (mL)

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

Blood Processing:

Plasma & Buffy Coat (Lavender-top) Tube (2x10ml)			
Original Volume Drawn (2 x Lavender-Top):			_____ mL
Time spin started:	_____ [HH:MM]	Duration of centrifuge:	_____ Minutes
Temp of centrifuge:	_____ °C	Rate of centrifuge:	_____ x g
Time aliquoted:			_____ [HH:MM]
Number of 0.5ml plasma aliquots created (lavender cap, up to 20):			_____
If applicable, volume of residual plasma aliquot (less than 0.5ml in blue cap):			_____ mL
If applicable, specimen number of residual plasma aliquot (last four digits):			_____
Buffy Coat #1 last four digits of specimen number:			_____
Buffy Coat #1 volume:			_____ mL
Buffy Coat #2 last four digits of specimen number:			_____
Buffy Coat #2 volume:			_____ mL

Notes:

_____

_____

***If collected by contracted mobile phlebotomist: complete at time of blood collection*

Blood collection completed by: _____ (name)

Company: _____ Contact phone: _____

Version 2.2024

5.2.2 Blood Kit B: PBMC, DNA, and RNA Kit

Blood Kit B: PBMC, DNA, and RNA Kits

This kit is to be sent to a subject, who then selects a blood draw location of their choosing.

Kit Overview

Draw Order	Sample Collected	Collection Tube	Site Processing	Sample Shipped	Shipment Tube	Shipment Temperature
1	Whole Blood (for PBMC isolation)	2 x Sodium Heparin (GreenTop) Blood Collection tube (10 ml)	N/A	Whole Blood	2 x Sodium Heparin (GreenTop) Blood Collection tube (10 ml)	Ambient
2	Whole Blood (for DNA isolation)	2 x EDTA (Lavender-Top) Blood Collection Tube (10 ml)	N/A	Whole Blood	2 x EDTA (Lavender-Top) Blood Collection Tube (10 ml)	Ambient
3	Whole Blood (for RNA isolation)	1 x PAXgeneTM Blood Collection Tube (2.5 ml)	N/A	Whole Blood	1 x PAXgeneTM Blood Collection Tube (2.5 ml)	Ambient

Kit Labeling

Kit Number Labels



- 1 x placed on the Sample Form
- 4 x extra *(dispose if not used)*

Site ID, Family ID, and Individual ID Labels



- 2 x EDTA (Lavender-Top) Blood Collection Tube (10 ml)
- 2 x PBMC Sodium Heparin (Green-Top) Tubes 10ml
- 1 x RNA PAXgene™ (Red-Top) Tubes 2.5 ml
- 1 x extra

Collection Tube Labels



- 2 x PBMC Sodium Heparin (Green-Top) Tubes 10ml



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



- 1 x RNA PAXgene™ (Red-Top) Tubes 2.5 ml

Site Instructions for Sending the Kit to the Participant

1. Following page

Sample Collection & Processing

1. Whole Blood for PBMC isolation: refer to section 5.3.1.
2. Whole Blood for DNA isolation: refer to section 5.3.2. Stop after Step 7. (Appendix D)
3. Whole Blood for RNA isolation: refer to section 5.3.4.

Sample Packaging

1. Ambient: Whole Blood for PBMC isolation, DNA isolation, and RNA isolation - refer to section 6.1.
2. For participant: Appendix E.

Kit Sample Shipping - Refer to section 7.0 and 7.1.1.

For participant: Appendix E.

*Be sure to create and include a return shipping label for the participant using ShipExec™.

Site Instructions for Preparing Blood Kit B for the Participant

1. Place all the labels on the correct tubes and on the Sample Shipment and Notification Form.
    a. Note: Make sure to fill in the handwritten Site, Family, and Individual ID Labels prior to placing them on the tubes.
2. Follow instructions in section 7.0 to create a return shipping label.
    a. Please read through section 7.1.1 as well.
3. Print the return shipping label and place it inside the shipping pouch.
4. Adhere the shipping pouch with the return label to the outside of the UPS Laboratory Pak. This is the envelope that the participant will use to return the sample to NCRAD.
5. Make sure the following are placed in the UPS Laboratory Pak.
    a. The entire contents of Blood Kit B.
        i. Ensure that the UN3373 (Biological Substance Category B) label on the ambient shipping box.
    b. A Biological Sample and Shipment and Notification Form – Blood Kit B.
    c. Instructions on the following for the participant and the phlebotomist of their choosing
        i. Blood collection and processing:
            1. Whole Blood for PBMC isolation: refer to section 5.3.1.
            2. Whole Blood for DNA isolation: refer to section 5.3.2. Stop after Step 7.
                a. You may also choose to print *Appendix D: Processing Schematic for DNA Collection and Processing from Blood Kit B** and include it in the kit.
            3. Whole Blood for RNA isolation: refer to section 5.3.4.
        ii. Blood Packaging: refer to section 6.1.
        iii. Blood Shipment: refer to section 7.0.
            1. You may also choose to print *Appendix E: Sample Packaging and Shipping Instructions for the participant for Blood Kit B** and include in the kit.
    d. Note: do NOT seal the envelope.
6. At your site, locate a larger shipping envelope. Place the labeled UPS Laboratory Pak (containing Blood Kit B and sample notification form) into your site-provided outer shipping envelope.
7. Address the outermost envelope to the subject with your site address as the return address.
    a. Send to the participant's address.
    b. Note: please ensure that there is NO way NCRAD will receive or see the participant's address.

***Any materials intended for participant use should be reviewed and approved by your IRB prior to their use. You may choose to use Appendix E as a starting point, and clarify the instructions, if desired.**

Biological Sample and Shipment Notification Form - Blood Kit B: PBMC, DNA, and RNA

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

Sample Type	Tube Type	Shipment
Whole blood for PBMC isolation	2x Sodium Heparin (Green-Top) Blood Collection Tube (10ml)	Room Temperature Must be shipped and received within 24 hours of collection
Whole blood for DNA extraction	2 x EDTA (Lavender-Top) Blood Collection Tube (10ml)	Room Temperature Must be shipped and received within 24 hours of collection
Whole blood for RNA isolation	1 x PAXgeneTM Blood Collection Tube (2.5ml)	Room Temperature Must be shipped and received within 24 hours of collection

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

General Information:

Kit Barcode

UPS Tracking #: _____

Site Coordinator:_____ **Date:** _____

Phone: _____ **Email:** _____

Study: AD Family-Based Study

Site ID: _____ **Family ID:**_____ **Individual ID:**_____

Sex: M F

Year of Birth: _____

Visit (please circle one): 1 2 3 4 5 6 7 8 9 10

Blood Collection:

Date Drawn: _____ [MM/DD/YYYY] Time of Draw:_____ [HH:MM]

Original Volume Drawn (2 x NaHep Green-Top): #1_____ (mL)

Original Volume Drawn (2 x NaHep Green-Top): #2_____ (mL)

Original Volume Drawn (2 x Lavender-Top): _____ (mL)

Original Volume Drawn (1 x PAXgeneTM Tube): _____ (mL)

Notes:

_____

_____

***If collected by contracted mobile phlebotomist: complete at time of blood collection*

Blood collection completed by: _____ (name)

Company: _____ Contact phone: _____

Version 2.2024

5.2.3 Blood Kit D: Genetic Testing Kit Overview

Blood Kit D: Genetic Testing Kits

This kit is to be used by a mobile phlebotomist or on site by a study coordinator.

Genetic Testing is now done primarily through Invitae. This kit should only be ordered and used for rare cases that are approved by FBS study management.

Kit Overview

Draw Order	Sample Collected	Collection Tube	Site Processing	Sample Shipped	Shipment Tube	Shipment Temperature
Immediately following the 2 x 10mL EDTA tubes	Whole Blood (for Genetic Testing)	1 x EDTA (Lavender-Top) Blood Collection Tube (3 ml)	N/A	Whole Blood	1 x EDTA (Lavender-Top) Blood Collection Tube (3 ml)	Frozen

The genetic testing tube will be collected for only one participant per family. The blood sample for genetic testing may be drawn at visit 1 or at a follow-up visit if needed.

Kit Labeling



Kit Number Labels

- 1 x placed on the Sample Form
- 1 x placed on the outside of the cryobox that houses aliquot tubes during storage and shipment

Site ID, Family ID, and Individual ID Labels



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

Collection Tube Labels



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

Sample Collection & Processing

1. Whole Blood for Genetic Testing: refer to section 5.3.3.

Sample Packaging

1. Frozen: Whole Blood for genetic testing - refer to section 6.2.

Sample Shipping

1. Refer to section 7.0

Biological Sample and Shipment Notification Form - Blood Kit D: Genetic Testing

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

Sample Type	Number of Tubes	Tube Type	Shipment
Whole blood for Genetic Testing	1	EDTA (Lavender-Top) Blood Collection Tube (3ml)	Frozen (Dry Ice)

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

General Information:

Kit Barcode

UPS Tracking #: _____

Site Coordinator:_____ **Date:** _____

Phone: _____ **Email:** _____

Study: AD Family-Based Study

Site ID: _____ **Family ID:**_____ **Individual ID:**_____

Sex: M F

Year of Birth: _____

Visit (please circle one): 1 2 3 4 5 6 7 8 9 10

Blood Collection:

Date Drawn: _____ [MM/DD/YYYY] Time of Draw:_____ [HH:MM]

Original Volume Drawn (1 x Lavender-Top): _____ (mL)

Notes:

_____

_____

_____

_____

_____

_____

***If collected by contracted mobile phlebotomist: complete at time of blood collection*

Blood collection completed by: _____ (name)

Company: _____

Contact phone: _____

Version 12.2023

5.3 Blood Collection

5.3.1 Whole Blood for PBMC Isolation

- Collection & Processing: Whole Blood for isolation of Peripheral Blood Mononuclear Cells (PBMC) - Sodium Heparin (NaHep) Green-Top Blood Collection Tube (10mL) x 2
- **Once drawn, sodium heparin tubes MUST be shipped to NCRAD the day of collection via UPS Next Day Air service. This is to ensure the specimens have the most viable cells available at extraction. These samples should only be collected Monday-Thursday. DO NOT collect these samples on Fridays.**

1. Store empty sodium heparin tubes at room temperature, 64°F - 77°F (18°C – 25°C) before use. Check expiration dates on all collection tubes before visit.

2. Place completed Site ID, Family ID, and Individual ID Label and preprinted **PBMC** collection tube label on each of the sodium heparin (green-top) blood collection tubes.

3. Using a blood collection set and a holder, collect blood into the 10 ml sodium heparin tubes using your institution's recommended procedure for standard venipuncture technique. **The following techniques shall be used to prevent possible backflow:**
    a. Place donor's arm in a downward position.
    b. Hold tube in a vertical position, below the donor’s arm during blood collection.
    c. Release tourniquet as soon as blood starts to flow into last collection tube.
    d. Make sure tube additives do not touch the stopper or the end of the needle during venipuncture.

4. Allow at least 10 seconds for a complete blood draw to take place in the tube. **Ensure that the blood has stopped flowing into each tube before removing the tube from the holder**. The tube with its vacuum is designed to draw 10 ml of blood into the tube.

5. Immediately after blood collection, gently invert/mix (180-degree turns) each tube 8-10 times.

6. Complete Biological Sample and Shipment Notification Form.
    a. If using either Blood Kit A or Blood Kit C: *Biological Sample and Shipment Notification Form: Blood Kit A & Blood Kit C: PBMC, Plasma/Buffy Coat, and RNA Kit*.
    b. If using Blood Kit B: Biological Sample and Shipment Notification Form: *Blood Kit B: PBMC, DNA, & RNA*.

7. Package the filled sodium heparin tube according to the **ambient** packaging instructions in section 6.1

8. Ship the unprocessed sodium heparin (green-top) blood collection tubes **ambient** to NCRAD the day of the participant visit. Please see Section 7.0 for detailed shipping instructions.

PBMC Preparation (10ml Sodium Heparin Tube x 2)

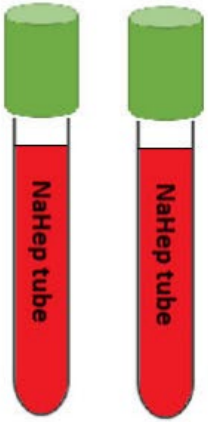


Step One



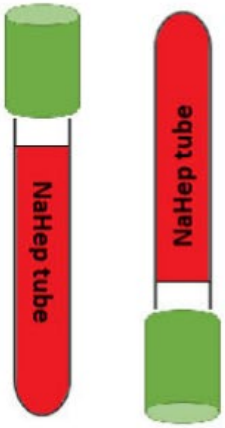
- Store tubes at room temperature.
- Label tubes with pre-printed labels prior to blood draw.

Step Two



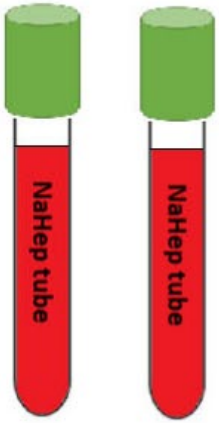
- Collect blood in Sodium Heparin Tubes allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



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

Step Four



- Store tubes at room temperature until shipment.

Ship ambient same day as blood draw

Please be sure to compare the labels on each tube and cryovials to the Biological Sample Form included with each kit

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

5.3.2 Whole Blood for DNA Isolation OR Plasma and Buffy Coat Isolation

- Collection & Processing: Whole Blood using EDTA (Lavender- Top) Blood Collection Tube (10mL) x 2
- Whole blood is collected into 2 x 10mL EDTA (Lavender- Top) Blood Collection Tubes with the goal of isolating *either*:
    - DNA (isolation performed by NCRAD)
      OR
    - Plasma & buffy coat (isolation performed by site)

1. Store empty EDTA tubes at room temperature, 64°F - 77°F (18 °C – 25 °C) before use. Check expiration dates on all collection tubes before visit.

2. Label all tubes prior to sample collection. Ensure that the kit number on the tubes matches the kit number on the sample form.
    a. **Blood Kit A or Kit C:** place completed Site ID, Family ID, and Individual ID Label and preprinted PLASMA Collection Tube Label on the purple-top EDTA tubes. Place preprinted PLASMA Aliquot Labels on the 2 ml cryovials with purple caps and 2 ml cryovial with blue cap (if necessary, for residual). Place preprinted BUFFY COAT Aliquot Label on the 2 ml cryovials with clear caps.
    b. **Blood Kit B:** place completed Site ID, Family ID, and Individual ID Label and preprinted PLASMA Collection Tube Label on the purple-top EDTA tubes.

3. *If using Blood Kit A or Blood Kit C*: set centrifuge to 4°C to pre-chill before use.

4. Using a blood collection set and a holder, collect blood into the EDTA (Purple-Top) Blood Collection Tube (10 ml) using your institution's recommended procedure for standard venipuncture technique. The following techniques shall be used to prevent possible backflow:
    a. Place participant's arm in a downward position.
    b. Hold tube in a vertical position, below the participant’s arm during blood collection.
    c. Release tourniquet as soon as blood starts to flow into last collection tube.

d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

5. Allow at least 10 seconds for a complete blood draw to take place in each tube. **Ensure that the blood has stopped flowing into the tube before removing the tube from the holder**. The tube with its vacuum is designed to draw 10 ml of blood into the tube.
    a. If complications arise during the blood draw, please note the difficulties on the applicable 'Biological Sample and Shipment Notification Form'. Do not attempt to draw an additional EDTA tube at this time. *If using Blood Kit A or Kit C* - Process blood obtained in existing EDTA tube.

6. Document collection on the applicable Biological Sample and Shipment Notification Form
    a. Biological Sample and Shipment Notification Form – *Kit A & C: PBMC, Plasma/Buffy Coat, and RNA*

    OR

    b. Biological Sample and Shipment Notification Form – *Kit B: PBMC, DNA, and RNA*

7. Immediately after blood collection, gently invert/mix (180 degree turns) the EDTA tube 8-10 times.

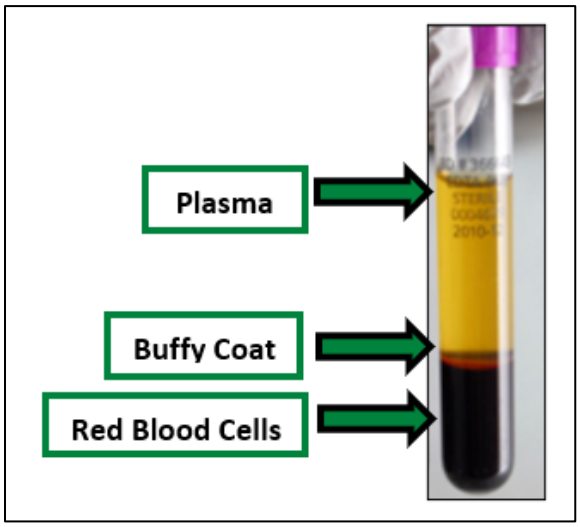
IMPORTANT:
If you are using **Blood Kit B (PBMC, DNA, and RNA)** you are done. Package and ship the 2 x 10 mL EDTA tubes containing whole blood **ambient** same day as collection. Skip to section 6.1 for ambient packaging instructions.
You may also choose to refer to *Appendix D: Processing Schematic for DNA Collection and Processing from Blood Kit B*.
You may also choose to refer *Appendix E: Sample Packaging and Shipping Instructions for the participant for Blood Kit B*.

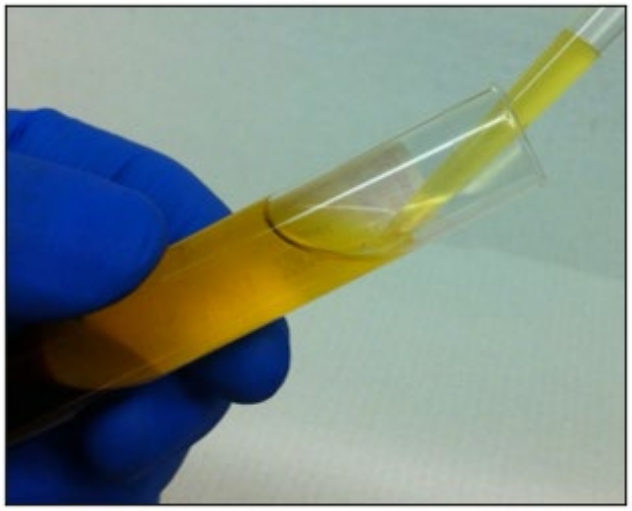
If you are using **Blood Kit A or C** (**PBMC, Plasma/Buffy Coat, and RNA)**, continue to step 8, immediately below.

8. Immediately after inverting the EDTA tube, place it on wet ice until centrifugation begins. Samples need to be spun, aliquoted, and placed on dry ice within 2 hours, from the time of collection.

9. Centrifuge balanced tubes for 10 minutes at 2000 x g at 4°C. **It is critical that the tubes be centrifuged at the appropriate speed and temperature to ensure proper plasma separation (see worksheet in Appendix A to calculate equivalent RPM for spin at 2000 x g).**
    a. While centrifuging, remember to record all times, temperatures and spin rates on the Biological Sample and Shipment Notification Form.
    b. Record original volume drawn for each tube in spaces provided on the Biological Sample Shipment and Notification Form.
    c. Plasma samples need to be spun, aliquoted, and placed in the freezer within 2 hours from the time of collection.
    d. Record time aliquoted on the Biological Sample Shipment and Notification Form.

10. Remove the plasma by tilting the tube and placing the pipette tip along the lower side of the wall being careful not to agitate the packed red blood cells at the bottom of the collection tube.

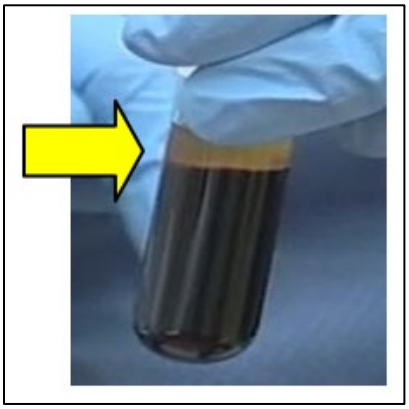


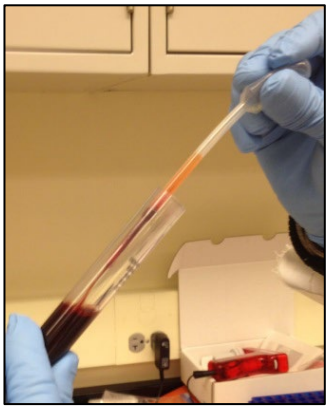


11. Each EDTA tube should yield, on average, 4-5 ml of plasma. Transfer plasma from all EDTA tubes into the 15 ml conical tube and gently invert 3 times. **When pipetting plasma from the EDTA tube into the 15 ml conical tube, be very careful to pipette the plasma top layer only, leaving the buffy coat and the red blood cell layers untouched**.
    a. Note: the 15mL blue top conical will not have a label.

12. Aliquot plasma into the pre-labeled cryovials. Aliquot 0.5 mL per cryovial (up to 20 vials with 0.5 mL each). Be sure to only place plasma in cryovials labeled with "PLASMA" labels. **If a residual aliquot (<0.5 ml) is created, place it in the blue-capped cryovial, and document the specimen number and volume on the Biological Sample and Shipment Notification Form.**

13. After plasma has been removed from the EDTA (Purple-Top) Blood Collection Tubes (10 ml), aliquot the buffy coat layer (in the top layer of cells, the buffy coat is mixed with RBCs-see figure) from one EDTA tube into a labeled, grey-capped cryovial using a micropipette. The buffy coat aliquot is expected to have a reddish color from the RBCs. Be sure to only place the buffy coat from one EDTA tube into each grey cap cryovial. Repeat this step for the second EDTA, placing this buffy coat into the second grey-capped cryovials.







14. Dispose of collection tube with red blood cell pellet according to your site's guidelines for disposing of biomedical waste.

15. Record the specimen number and volumes of the EDTA tubes and corresponding buffy coat samples on the Biological Sample Shipment and Notification Form.

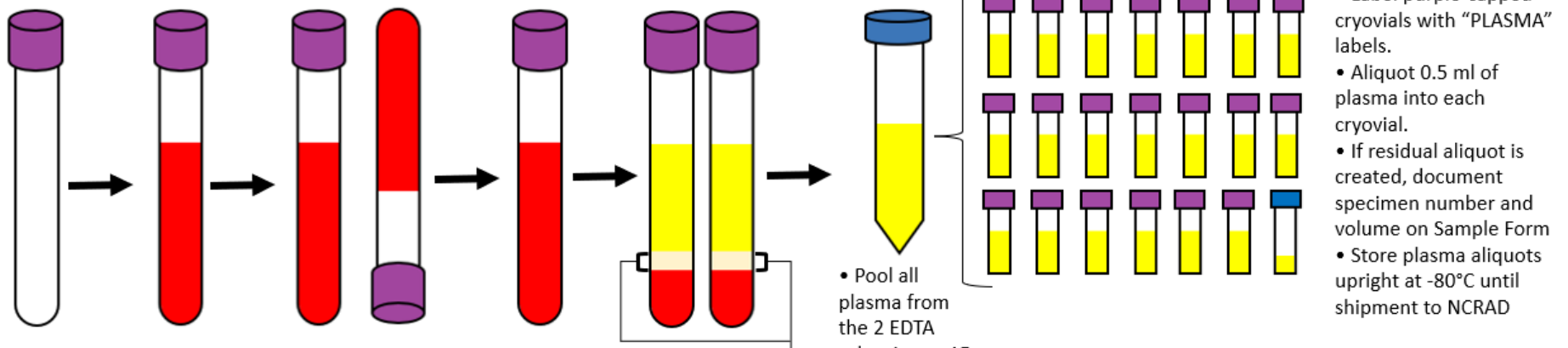
16. Place the labeled cryovials in the 48 cell cryobox and place on pelleted dry ice. **Transfer to -80°C Freezer when possible**. Store all samples at -80°C until shipped to NCRAD on pelleted

dry ice. Record time aliquots frozen and storage temperature of freezer on Biological Sample and Shipment Notification Form.

17. When ready, package samples. Refer to section 6.2 for frozen packaging instructions.

Plasma & Buffy Coat Preparation (EDTA Tube x 2)





- Store tubes at room temp
- Each tube should be labeled with Collection Tube and Site and PTID labels.

- Collect Blood into each EDTA 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.

- If collecting Plasma and Buffy Coat, continue. If you are collecting Whole Blood for DNA isolation, skip ahead to the packaging section.

- Centrifuge samples at 2000 x g for 10 minutes at 4°C. Samples will separate after centrifugation.

- Pool all plasma from the 2 EDTA tubes into a 15 ml conical and invert gently 3 times to mix the plasma

- Label purple-capped cryovials with "PLASMA" labels.
- Aliquot 0.5 ml of plasma into each cryovial.
- If residual aliquot is created, document specimen number and volume on Sample Form
- Store plasma aliquots upright at -80°C until shipment to NCRAD

- Label gray-capped cryovials with "BUFFY COAT" labels.
- using a clean transfer pipette, collect the buffy coat (may have some residual plasma and RBCs included)
- Transfer the buffy coat from each EDTA tube into its own cryovial
- Store buffy coat aliquots upright at -80°C until shipment to NCRAD

Spin, aliquot, and freeze all plasma and buffy cot aliquots within 2 hours of collection

Please be sure to compare the labels on each tube and cryovials to the Biological Sample Form included with each kit

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

5.3.3 Whole Blood for Genetic Testing

- *PLEASE READ BEFORE PROCEDDING: Genetic Testing is now done primarily through Invitae. This kit should only be ordered and used for rare cases that are approved by FBS study management.*

- If needed, whole blood for genetic testing can be collected using Blood Kit D: Genetic Testing Kit.
- Whole blood for genetic testing is collected into 1 x 3mL EDTA (Lavender- Top) Blood Collection Tube.

1. Store empty EDTA tubes at room temperature, 64°F - 77°F (18 °C – 25 °C) before use. Check the expiration date on the 3mL collection tube before visit.

2. Label the 3mL EDTA (purple-top) collection tube with a Site ID, Family ID, and Individual ID Label and a **WBLD** Collection Tube label. Place a Kit Number label on the *Biological Sample and Shipment Notification Form – Blood Kit D: Genetic Testing*.

3. Using a blood collection set and a holder, collect blood into the EDTA (Purple-Top) Blood Collection Tube (3 ml) using your institution's recommended procedure for standard venipuncture technique. The following techniques shall be used to prevent possible backflow:
    a. Place participant's arm in a downward position.
    b. Hold tube in a vertical position, below the participant’s arm during blood collection.
    c. Release tourniquet as soon as blood starts to flow into last collection tube.
    d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

4. Allow at least 10 seconds for a complete blood draw to take place in each tube. **Ensure that the blood has stopped flowing into the tube before removing the tube from the holder**. The tube with its vacuum is designed to draw 3 ml of blood into the tube.
    a. If complications arise during the blood draw, please note the difficulties on the *Biological Sample and Shipment Notification Form – Blood Kit D: Genetic Testing*. Do not attempt to draw an additional EDTA tube at this time.

5. Immediately after blood collection, gently invert/mix (180 degree turns) the EDTA tube 8-10 times.

6. Place the sample in -80°C freezer until shipment. Do NOT place in Styrofoam racks. Refer to section 6.2 for frozen packaging instructions. Refer to section 7.0 for sample shipment instructions.

7. Document collection on the *Biological Sample and Shipment Notification Form – Blood Kit D: Genetic Testing*.

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



Step 1



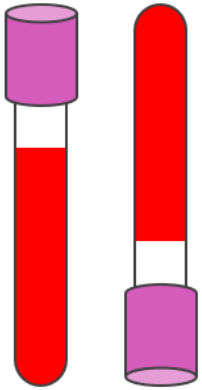
- Store tubes at room temperature.
- Labels tubes with pre-printed subject labels prior to blood draw.

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



- Store whole blood at -80°C until shipment.



Please be sure to compare the labels on the tube to the Biological Sample Form included with each kit

Important Note: Ensure tube is not expired prior to collection and processing of samples.

5.3.4 Whole Blood for RNA Isolation

- Whole Blood for isolation of Ribonucleic Acid (RNA) - PAXgene™ Blood Collection Tube (2.5 ml) x 1.
- **Draw the PAXgene™ tubes LAST, after all other specimens are collected.**
    1. Store PAXgene™ Blood Collection Tube at room temperature 64°F - 77°F (18°C to 25°C) before use.

    2. Place completed Site ID, Family ID, and Individual ID Label and "**RNA**" Collection Tube label on the PAXgene™ Blood Collection Tubes (2.5 ml) prior to blood draw; no processing is required for these tubes; **the tube is to be shipped to NCRAD ambient, without processing at the site.**

    3. Using a blood collection set and a holder, collect blood into the PAXgene™ Blood Collection Tube using your institution's recommended procedure for standard venipuncture technique. **The following techniques shall be used to prevent possible backflow:**
        a. Place donor's arm in a downward position.
        b. Hold tube in a vertical position, below the donor's arm during blood collection.
        c. Release tourniquet as soon as blood starts to flow into last collection tube.
        d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

    4. Allow at least 10 seconds for a complete blood draw to take place in each tube. **Ensure that the blood has stopped flowing into the tube before removing the tube from the holder**. The PAXgene™ Blood RNA Tube with its vacuum is designed to draw 2.5ml of blood into the tube. Record total amount of blood drawn into PAXgene™ blood tube(s) within the Biological Sample and Shipment Notification Form.

    5. Immediately after blood collection, gently invert/mix (180 degree turns) the PAXgene™ Blood RNA Tubes 8 – 10 times.

    6. Store sample **at room temperature until shipped** to NCRAD.

7. Document collection on the applicable Biological Sample and Shipment Notification Form
    a. Biological Sample and Shipment Notification Form – *Kit A & C: PBMC, Plasma/Buffy Coat, and RNA*

    OR

    b. Biological Sample and Shipment Notification Form – *Kit B: PBMC, DNA, and RNA*

8. Package the filled PAXgene™ Blood RNA tube according to the ambient packaging instructions in section 6.1.

9. Ship the unprocessed sodium heparin (green-top) blood collection tubes ambient to NCRAD the day of the participant visit. Please see Section 6.1 for detailed ambient packaging instructions and section 7.0 for shipping instructions.

RNA Preparation (2.5ml PAXgene™ Tube x 1)

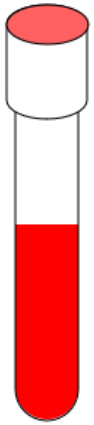


Step One



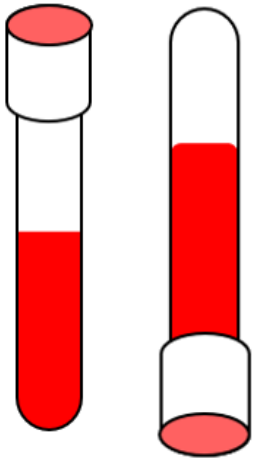
- Store tube at room temperature.
- Label tube with pre-printed labels prior to blood draw.

Step Two



- Collect blood in $PAXgene^{TM}$ Tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



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

Step Four



- Store tube at room temperature until shipment.

Ship ambient same day as blood draw

Please be sure to compare the labels on the tube to the Biological Sample Form included with each kit

Important Note: Ensure tube is not expired prior to collection and processing of samples.

6.0 Blood Packaging

ALL study personnel responsible for shipping should be certified in biospecimen shipping. If you have difficulty finding biospecimen shipping training, please notify a NCRAD coordinator.

In addition to tracking and reconciliation of samples, the condition and number of samples received are tracked by NCRAD for each sample type. Investigators and clinical coordinators for each project are responsible to ensure the requested amounts of each fluid are collected to the best of their ability and that frozen samples are packed with sufficient amounts of pelleted dry ice to avoid thawing in the shipment process.

6.1 Ambient Blood Package

- These samples should follow the ambient packaging procedures:

Sample Type	Tube Type	Kit Type
Whole blood for PBMC isolation	2 x Sodium Heparin (GreenTop) Blood Collection tube (10 ml)	Kit B: PBMC/DNA *AND* Kit A & C: PBMC/Plasma/Buffy Coat
Whole blood for DNA isolation	2 x EDTA (Lavender-Top) Blood Collection Tube (10 ml)	Kit B: PBMC/DNA
Whole blood for RNA isolation	1 x PAXgene™ Blood Collection Tube (2.5 ml)	Kit B: PBMC/DNA *AND* Kit A & C: PBMC/Plasma/Buffy Coat

AMBIENT SAMPLES MUST BE SHIPPED MONDAY-THURSDAY ONLY! Ambient PBMC samples must be shipped the day of blood draw, so do not draw on Fridays.

Ambient sample shipments should be considered as Category B UN3373 and as such must be tripled packaged and compliant with the IATA Packing Instructions 650. *See the Latest Edition of the IATA Regulations for complete documentation.*

Triple packaging consists of a primary receptacle(s), a secondary packaging, and a rigid outer packaging. The primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packaging must be secured in outer packaging with suitable

cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

Ambient Shipping Packing and Labeling Guidelines

- The primary receptacle (sodium heparin tube) must be leak proof and must not contain more than 10 ml total.
- The secondary packaging (small biohazard bag) must be leak proof.
- Absorbent material must be placed between the primary receptacle and the secondary packaging (small biohazard bag). The absorbent material should be of sufficient quantity in order to absorb the entire contents of the specimens being shipped. Examples of absorbent material are paper towels, absorbent pads, cotton balls, or cellulose wadding.
- A shipping manifest of specimens being shipped must be included between the secondary and outer packaging.
- The outer shipping container must display the following labels:
  - ✓ Sender's name and address
  - ✓ Recipient's name and address
  - ✓ Responsible Person
  - ✓ The words "Biological Substance, Category B"
  - ✓ UN3373

6.1.1 NCRAD Packaging Instructions—Ambient Shipments

1. Place refrigerant pack in the freezer 24 hours prior to shipment.

2. Notify NCRAD of shipment by emailing NCRAD coordinators at: alzstudy@iu.edu
   a. Complete and attach the applicable Biological Sample and Shipment Notification Form to the email. For ambient shipments, this could be:
      Biological Sample and Shipment notification form – *Blood Kit A & C: PBMC/Plasma/Buffy Coat/RNA*
      OR
      Biological Sample and Shipment notification form – *Blood Kit B: PBMC/DNA/RNA*

3. Place filled and labeled sodium heparin (green-top), PAXgeneTM, and 10ml EDTA tubes within the slots in the absorbent pad provided.
   a. *Note: If Blood Kit A or C PBMC/Plasma/Buffy Coat/RNA were used, you will only have 2 x sodium heparin (green-top) tubes and 1 x PAXgeneTM tube to ship ambient.*

4. Place sleeve with tubes in the biohazard bag.

5. Remove as much air as possible from the plastic biohazard bag and seal the bag according to the directions printed on the bag.

6. Place the refrigerant pack into the cooler on top of the filled biohazard bag.

7. Place the lid onto the cooler.

8. Place an extra hard copy of the Biological Sample and Shipment Notification Form on top of the cooler lid along with a completed list of contents card.
    a. ***Note**: If Blood Kit A or C (PBMC/Plasma & Buffy Coat/RNA) was used, you will need to print a copy of the Biological Sample and Shipment Notification Form so that a hard copy can also be included with the frozen samples from this participant visit.*

9. Close the shipping box. Label the outside of the cardboard box with the enclosed UN3373 (Biological Substance Category B) label.

10. Place the closed, labeled shipping box within a UPS Laboratory Pak. **Seal the UPS Laboratory Pak.**

11. Place UPS return airbill on the sealed UPS Laboratory Pak.

12. Use UPS tracking to ensure the delivery occurs as scheduled and is received by NCRAD.

6.2 Frozen Blood Packaging

- These samples should follow the frozen packaging procedures:

Sample Type	Tube Type	Kit Type
Plasma & Buffy Coat	Up to 20 x 2mL purple top cryovials with plasma *AND* Up to 2 x 2mL grey top cryovials with buffy coat	Blood Kit A & C: PBMC/Plasma/Buffy Coat/RNA
Whole blood for Genetic Testing	1 x EDTA (Lavender-Top) Blood Collection Tube (3 ml)	Blood Kit D: Genetic Testing Kit

FROZEN SAMPLES MUST BE SHIPPED MONDAY-WEDNESDAY ONLY!

The most important issue for shipping is to maintain the temperature of the samples. The frozen samples must never thaw; not even the outside of the tubes should be allowed to defrost. This is best accomplished by making sure the

Styrofoam container is filled completely with pelleted dry ice. A frozen shipper fits 2 x 48-slot cryoboxes, 2 x 3ml EDTA tubes, and 10lbs of dry ice pellets.



Specimens being shipped to NCRAD should be considered as Category B UN3373 specimens and as such must be tripled packaged and compliant with IATA Packing Instructions 650. *See the Latest Edition of the IATA Regulations for complete documentation.*

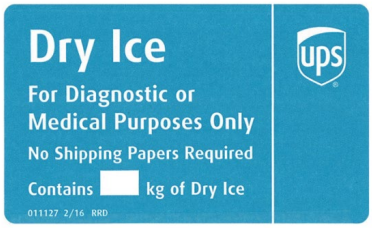
Triple packaging consists of a primary receptacle(s), a secondary packaging, and a rigid outer packaging. The primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging. Secondary packaging must be secured in outer packaging with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

Packing and Labeling Guidelines

- The primary receptacle (cryovial) must be leak proof and must not contain more than 1L total.
- The secondary packaging (biohazard bag) must be leak proof and if multiple blood tubes are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent direct contact with adjacent blood tubes.
- Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material should be of sufficient quantity in order to absorb the entire contents of the specimens being shipped. Examples of absorbent material are paper towels, absorbent pads, cotton balls, or cellulose wadding.
- A shipping manifest of specimens being shipped must be included between the secondary and outer packaging.
- The outer shipping container must display the following labels:
  - ✓ Sender’s name and address
  - ✓ Recipient’s name and address
  - ✓ Responsible Person
  - ✓ The words “Biological Substance, Category B”

- ✓ UN3373
- ✓ UPS Dry Ice label and net weight of pelleted dry ice contained





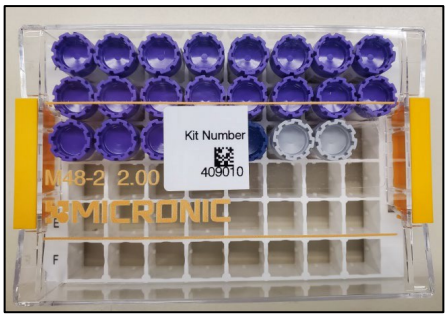
6.2.1 NCRAD Packaging Instructions – Frozen Shipments

1. If possible, hold packaged samples in -80°C freezer until time of UPS pick-up/drop-off. If storage in a -80°C freezer until UPS pick-up is not possible, package samples no more than 4 hours before the expected pick-up time.

2. Notify NCRAD of shipment by emailing NCRAD coordinators at alzstudy@iu.edu. Attach the following to the email:
    a. Completed Biological Sample and Shipment Notification Form to the email notification (email NCRAD coordinator prior to shipment to receive sample form).
        b. For frozen shipments, this could be:
    Biological Sample and Shipment notification form – *Blood Kit A & C: PBMC/Plasma & Buffy Coat/RNA*
    AND/OR
    Biological Sample and Shipment notification form – *Blood Kit D: Genetic Testing*

    b. If email is unavailable, please call NCRAD and do not ship until you've contacted and notified NCRAD coordinators about the shipment in advance.

3. Place all labeled and frozen plasma and buffy coat aliquots from a single participant visit in a cryovial box. Ensure that the outside of the cryovial box is labeled with a kit number label. The kit number on the outside of the cryovial box should match the kit number on the cryovial labels.



4. If collected, place the 3mL EDTA tube in a bubble wrap tube sleeve. *Note: a 3mL EDTA tube is only collected for Blood Kit D: Genetic Testing.*



5. Place the cryovial box (and bubble-wrapped 3mL EDTA tube when applicable) in a clear large biohazard bag.



6. As the cryovial box is placed in the plastic biohazard bag, do NOT remove the absorbent material found in the bag. Seal according to the instructions on the bag.

7. Place approximately 2-3 inches of pelleted dry ice in the bottom of the Styrofoam shipping container.

8. Place the biohazard bags into the provided Styrofoam-lined shipping container on top of the pelleted dry ice. Please ensure that cryovial boxes are placed so the cryovials are upright in the shipping container.

A maximum of 2 x cryoboxes and 2 x 3mL EDTA tubes may be sent in each shipper.

9. After the samples have been placed into the shipping container, completely fill the inner Styrofoam with pelleted dry ice pellets to ensure the frozen state of the specimens during transit. The inner Styrofoam shipping container must contain approximately 10 lbs. (or 4.5kg) of pelleted dry ice.

10. Replace the lid on the Styrofoam carton. Place the completed *Biological Sample and Shipment Notification Form* in the package on top of the Styrofoam lid for each patient specimen, and close and seal the outer cardboard shipping carton with packing tape.

11. Complete the UPS Dry Ice Label with the following information:
    a. Net weight of pelleted dry ice in kg (must match amount on the airbill)
    b. Do not cover any part of this label with other stickers, including preprinted address labels.

12. Apply all provided warning labels and UPS return airbill to the outside of package, taking care not to overlap labels. **Complete the required fields on the UPS Dry Ice label or UPS may reject or return your package.**

13. Use UPS tracking to ensure the delivery occurs as scheduled and is received by NCRAD. Please notify NCRAD by email (alzstudy@iu.edu) that a shipment has been sent and include the UPS tracking number in your email.

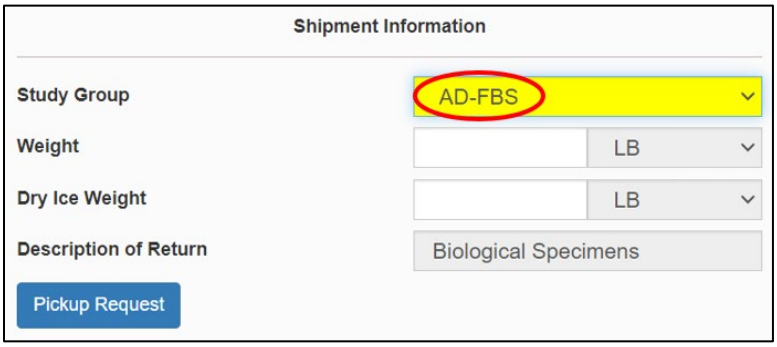
7.0 Blood Shipping Instructions – Ambient and Frozen

1. Log into the ShipExec Thin Client at https://thinclient.shipexec.com/Account/Login?ReturnUrl=%2F.
    a. If a new user or contact needs access, please reach out to your study contact for access.

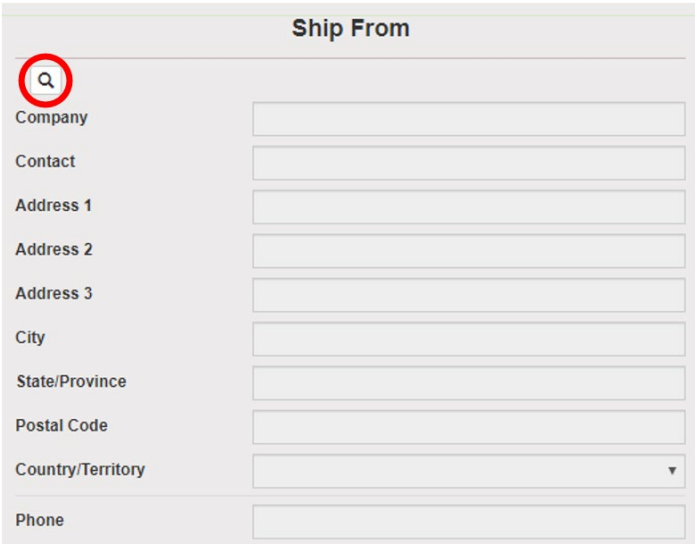
2. Click “Shipping” at the top of the page and select “Shipping and Rating”.



3. Select your study from the "Study Group" drop down (AD-FBS) on the right side of the main screen. Choosing your study will automatically filter the address book to only addresses within this study.



4. Click on the magnifying glass icon in the "Ship From" section to search for your shipping address.



   a. Search by Company (site), Contact (name), or Address 1 (first line of your site's street address). Click Search.
   b. Click Select to the left of the correct contact information.

5. Verify that both the shipping information AND study reference are correct for this shipment.
    a. If wrong study contact or study reference, click Reset in the bottom right of the screen to research for the correct information.

6. Enter Package Information
    a. Ambient shipments
        i. Enter the total weight of your package in the “Weight” field and leave the “Dry Ice Weight” field empty.
    b. Frozen shipments
        i. Enter the total weight of your package in the “Weight” field.
        ii. Enter the pelleted dry ice weight in the “Dry Ice Weight” field.
        iii. If the “Dry Ice Weight” field is higher than the “Weight” field, you will receive an error message after clicking Ship and need to reenter these values.
    c. Click Ship in the bottom right of the page when complete.

7. If your site does not already have a daily UPS pickup, you can schedule one here.
    a. Click the blue Pickup Request button. Enter the earliest pickup time and latest pickup time in 24-hr format.
    b. Give a name & phone number of someone who the UPS driver can call if having issues finding the package.
    c. Give the Floor and Room Number (if needed) to be as descriptive as possible where this package needs to be picked up from. Click Save.

8. Print the airbill that is automatically downloaded.
    a. To reprint airbill, click History at the top left of the page.
        i. Shipments created from the user that day will automatically populate. If shipments from a previous day need to be located, search by ship date.
        ii. Locate the correct shipment, and click on the printer icon to the left of the tracking number under “Action” to reprint the airbill
        iii. Click print icon on right side of the tracking number line.

9. Fold airbill, and place inside plastic UPS sleeve.

10. Peel the back off of the UPS sleeve and stick the sleeve to the package top. Ensure that sleeve does not cover any warning labels (e.g. pelleted dry ice label) or overlap taped seams.

7.1.1 Special Instructions for Returning Blood Kit B: PBMC, DNA, and RNA

- *Blood Kit B: PBMC, DNA, and RNA Kits* are sent to a participant's home, and then the participant selects a blood draw location of their choosing. Once the blood is drawn, the blood draw location, or the participant, will ship the ambient samples back to NCRAD.
- **In order for the participant to ship the samples back to NCRAD, the site coordinator will need to print a UPS return label and include it in the kit sent to the participant.**
- Do not schedule a pickup through ShipExec™. Pickups through ShipExec™ would be at your direct site address only.
- After sample collection, it is the responsibility of the participant or phlebotomist to send the samples back to NCRAD. Here are some options for sample return:
    - The phlebotomist's location may already have a regular UPS pickup scheduled. If they do, that can be used.
    - The participant or the phlebotomist should locate the closest UPS store location to drop off the package for same day shipping.
    - The phlebotomist can schedule a pickup themselves. Note – this may cost them money.
    - If additional help is needed in returning the samples to NCRAD, the participant or phlebotomist should contact the site coordinator.

7.1.2 Special Instructions for Contracted Mobile Phlebotomist

- PCM trials headquarters will be responsible for generating a return label via ShipExec. This will then be included in the kit that the mobile phlebotomist will use.
- It is the responsibility of the mobile phlebotomist to return the samples to NCRAD in a timely manner.
- The mobile phlebotomist should locate the closest UPS store location to drop off the package for same day shipping.
- If additional help is needed in returning the samples to NCRAD, the mobile phlebotomist should contact the site coordinator.

8.0 Saliva Collection, Packaging, and Shipping

8.1 Saliva Kit Overview

Saliva Kits

This kit is to be used when a blood draw is not feasible.

Kit Overview

Draw Order	Sample Collected	Collection Tube	Site Processing	Sample Shipped	Shipment Tube	Shipment Temperature
Not Applicable	Saliva (for DNA)	Oragene Saliva Tube	N/A	Saliva	Oragene Saliva Tube	Ambient

Kit Labeling

Kit Number Labels



- 1 x placed on the Sample Form
- 1 x placed on the saliva tube

Site ID, Family ID, and Individual ID Labels



- 1 x placed on the saliva tube

8.2 Saliva Sample Form

Biological Sample and Shipment Notification Form - Saliva

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

Sample Type	Number of Tubes	Tube Type	Shipment
Saliva	1	Saliva Collection Tube	Ambient

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

General Information:

Kit Barcode

UPS Tracking #: _____

Site Coordinator:_____ Date: _____

Phone: _____ Email: _____

Study: AD Family-Based Study

Site ID: _____ Family ID:_____ Individual ID:_____

Sex: M F GUID: _____

Year of Birth: _____

Visit (please circle one): 1 2 3 4 5 6 7 8 9 10

Saliva Collection:

1. Date Drawn: _____ [MM/DD/YYYY]
2. Time of Draw:_____ [HH:MM]
3. Date Subject Last Ate: _____ [MM/DD/YYYY]
4. Time Subject Last Ate: _____[HH:MM]

INTERNAL NCRAD USE ONLY

Complete Saliva Volume: _____ mL

Notes:

_____

_____

_____

_____

_____

_____

_____

Version 05.2023

8.3 Saliva Collection, Packaging, and Shipping – Site Instructions

1. Prep the saliva kit.
    a. Prep the sample labels.
        i. Place 1 Kit Number Label on the Sample Shipment and Notification Form.
        ii. Place the other Kit Number Label on the saliva collection tube.
        iii. Fill in the handwritten Site ID, Family ID, and Individual ID Label. Adhere it to the saliva collection tube.
        iv. Put the saliva tube back in its plastic container.
    b. Adhere the pre-paid UPS shipping label and biohazard label to the 10 x 13 manilla bubble mailer. This is the envelope that the participant will use to return the sample to NCRAD.
    c. Place the saliva kit, Sample Notification Form, and Biohazard Bag into the provided 10 x 13 manilla bubble mailer.
        i. Note: do NOT seal this envelope.

2. At your site, locate a larger shipping envelope. Place the labeled manilla bubble mailer (containing the labeled saliva kit, sample notification form, and biohazard bag) into your site-provided outer shipping envelope.

3. Address the outermost envelope to the subject with your site address as the return address.
    a. Send to the participant's address.
    b. Note: please ensure that there is NO way NCRAD will receive or see the participant's address.

8.4 Saliva Collection, Packaging, and Shipping – Participant Instructions

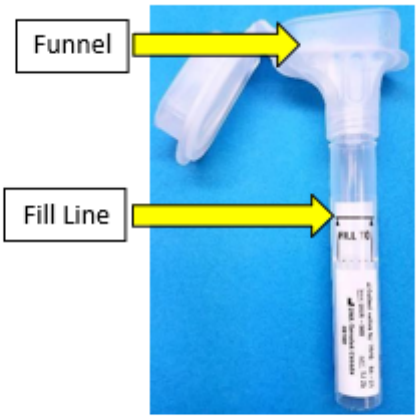
Do not eat, drink, smoke, or chew gum for 30 minutes prior to giving your sample.

Note: Do not rinse your mouth prior to giving your sample. Most people take between 2 and 5 minutes to deliver a saliva sample following steps 1 through 7 below. Before spitting, relax and rub your cheeks gently for 30 seconds to create saliva.

To review a video of the saliva collection procedure, please visit:
http://www.dnagenotek.com/ROW/support/ciOG500.htmL

STEP 1

- Do NOT remove the plastic film from the lid of the container.
- Spit directly into the funnel at the top of the tube until the amount of liquid saliva (not including bubbles) reaches the fill line shown in picture #1.
- **The saliva tube has a false bottom, so you will only need to provide 2 milliliters (less than ½ teaspoon) of saliva to reach the fill line.**
- Do NOT fill above the line.



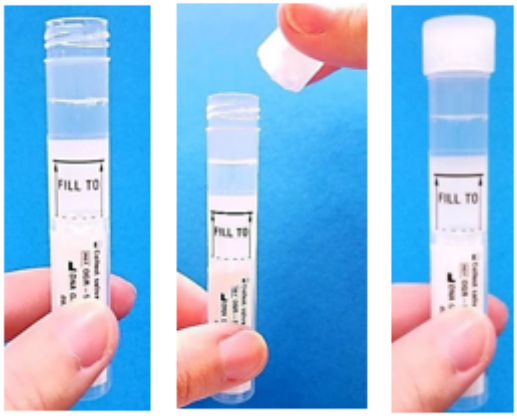
STEP 2

- Once the saliva level reaches the fill line, hold the tube upright with one hand.
- Close the lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click.
- The liquid in the lid will be released into the tube to mix with the saliva. Make sure that the lid is closed tightly.



STEP 3

- Hold the tube upright.
- Unscrew the funnel from the tube.
- Pick up the small cap for the tube.
- Use the small cap to close the tube tightly.



STEP 4

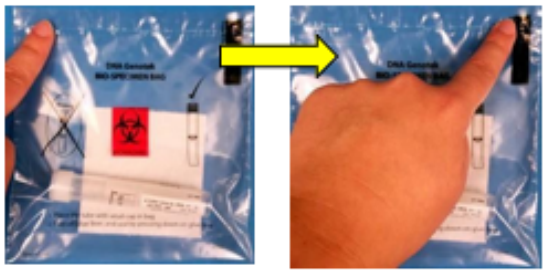
- Shake the capped tube for 5 seconds.
- Discard or recycle the funnel.
- Place sample in provided specimen bag for shipment to Indiana University (IU).



STEP 5

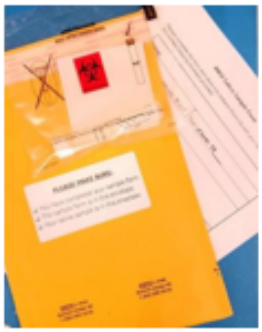
- Peel off blue plastic liner at the top of the specimen bag to expose the adhesive.
- Seal bag by pressing down across the top of the bag.





STEP 6

- Fill out sample form with Sex, Year of Birth, Date Collected, Time of Collection, Last date subject ate, Last time subject ate
- Fold sample form and place into prepaid shipping envelope.
- Also put your specimen (in the provided specimen bag) into this shipping envelope.



STEP 7

- Peel off the white paper at the top of the envelope to expose the adhesive, fold this flap down, and press firmly to seal envelope.
- Send the envelope via UPS as soon as possible after sample collection.





Questions? Please contact a study coordinator at 1-800-526-2839 or email alzstudy@iu.edu

Intended Use: This product is designed for the safe collection of human saliva samples. Contents: The funnel lid contains 2 mL of liquid. The solution should be clear and colorless.

Warnings: Do not ingest this liquid. Wash with water if the saliva container liquid comes in contact with eyes or skin. Small Cap, choking hazard.

Storage: Store at room temperature 15-30˚C (59-86˚F).

9.0 Sample Redraws

There may be situations that arise that require a patient sample to be redrawn. At those times, NCRAD study staff will alert site coordinators via email that a participant sample has failed and should be redrawn. This can happen for several reasons, including insufficient blood at the time the sample was drawn, temperature storage extremes, or even shipping errors.

Redraw kits may vary depending upon the sample that failed and must be redrawn. Tubes that may be redrawn using the redraw kit include the EDTA (Lavender-Top) Blood Collection Tube (10 mL) and the Sodium Heparin (Green-Top) Blood Collection Tube (10 mL). Both of these tubes should be sent back to NCRAD ambient and unprocessed.

10.0 Data Collection

10.1 Data Collection Schedule

Each site is responsible for providing the NIA-AD FBS with the most recent information for participants. All data should be sent to the coordinating site (CUMC) every quarter. The project manager will send a reminder to all coordinators and provide a template for the data submission. Data calls are scheduled to happen in January, April, July and October.

Identifiable information of participants (such as name, etc.) will not be shared with Columbia, NCRAD or with any investigators.

10.2 Data Cleaning

The MDS must be completed on each participant as accurately as possible. Every effort is made to ensure that required fields are not left blank or coded as Missing/Unknown; Columbia will follow-up for required fields not properly coded.

Information that appears incorrect in the NIA-AD FBS database, will be queried through the standard system. Queries (if any) will be sent to the sites after each data call. Additional discrepancies that may be unrelated to data entry will be resolved with the Principal Investigator in a separate follow up communication.

11.0 Brain Autopsy

Brain donation is useful to confirm the clinical diagnosis of AD or the absence of AD pathology and the tissue is useful for genetic research studies.

11.1 Deceased Family Member with a Previous Autopsy:

For deceased individuals who have previously participated in brain donation/autopsy, their brain tissue and neuropathological diagnosis may be used in the study. If an individual is deceased, DNA can be extracted from an autopsy specimen. 2-3 grams of frozen tissue is required. Families may have obtained an autopsy through their own healthcare provider. The research staff will assist the family in obtaining autopsy tissue to send to NCRAD. Family members must obtain copies of medical records for deceased individuals including records that confirm a clinical diagnosis of Alzheimer's disease or other related neurodegenerative disorder.

11.2 Current Participants and Family Members Program Enrollment:

Participating (living) individuals and/or their next of kin/surrogate in these families, will be informed of the brain donation program through the Columbia ADRC and/or the Rush University ADRC. Families who wish to plan for brain donation may call their site coordinator who will put them in touch with one of the brain donation sites. Brain donation flyers may be given to participants in the study. All study staff should be able to answer initial questions about the role of brain donation in the study of Alzheimer's disease and related neurological disorders. The autopsy consent and intent forms are approved by the IRB under Columbia's and Rush's Alzheimer's Diseases Resource Center and AD-FBS can cross- reference those forms.

After autopsy is completed, ~20 grams of frozen dorsal lateral/pre-frontal cortex and/or ~20 grams of fixed dorsal lateral/pre-frontal cortex tissue will be sent to NCRAD for sharing with the scientific community. We will request the same amount of tissue from autopsies done at other institutions. See Appendix C for sample form.

11.3 Autopsy Results:

Once autopsy and the pathology report is completed (usually takes 3-4 months), CU/Rush personnel will return the report to the site where the participant was originally enrolled. The site PI or an appropriate staff member will contact the next of kin or surrogate to explain the autopsy results. A copy of the pathology report may be sent to the family.

11.4 Brain Shipment and Coordinator Contacts:

For fresh brain shipment instructions, please refer to Appendix B. For any inquiries about brain donation and autopsy, please contact:

Scott M. Reid, MA
Clinical Research Coordinator Phone: (212) 305-10086
Fax: (212) 342-5323
Email: SMR2212@COLUMBIA.EDU

Address:
The Taub Institute for Research on Alzheimer's Disease and the Aging Brain
Columbia University Medical Center
630 West 168th Street, P&S Box 16 New York, NY 10032-37105

12.0 Appendices

Appendix A: Rate of Centrifuge Worksheet

Appendix B: NYBB Fresh Tissue shipping instructions

Appendix C: Sample form for frozen and fixed brain tissue

Appendix D: Processing Schematic for DNA Collection and Processing from Blood Kit B.

Appendix E: Sample Packaging and Shipping Instructions for the participant for Blood Kit B

Appendix A: Rate of Centrifuge Worksheet

Rate of Centrifuge Worksheet

Please complete and return this form by fax or email to the NCRAD Project Manager if you have any questions regarding sample processing. The correct RPM will be sent back to you.

Submitter Information

Name: **Site:**

Submitter e-mail:

Centrifuge Information

Please answer the following questions about your centrifuge.

Centrifuge Type

Fixed Angle Rotor: ☐ Swing Bucket Rotor: ☐

Radius of Rotation (mm):

Determine the centrifuge's radius of rotation (in mm) by measuring distance from the center of the centrifuge spindle to the bottom of the device when inserted into the rotor (if measuring a swing bucket rotor, measure to the middle of the bucket).

Calculating RPM from G-Force:

$$RCF = \left(\frac{RPM}{1{,}000}\right)^2 \times r \times 1.118 \quad \Rightarrow \quad RPM = \sqrt{\frac{RCF}{r \times 1.118}} \times 1{,}000$$

RCF = Relative Centrifugal Force (G-Force)
RPM = Rotational Speed (revolutions per minute)
R= Centrifugal radius in mm = distance from the center of the turning axis to the bottom of centrifuge

Comments:

Please send this form to NCRAD Study Coordinator

alzstudy@iu.edu

Appendix B: NYBB Fresh Tissue shipping instructions

New York Brain Bank @ Columbia University (NYBB)

Alzheimer Disease Research Center - Taub Institute

Babies & Children's Hospital of
New York-Presbyterian
3959 Broadway, BHs - T8
New York, NY 10032

Telephone: (212) 305-2299
Fax: (212)342-0083
E-mail: nybb@columbia.edu
http://nybb.hs.columbia.edu

Pathologist Information

Pathologist: _____ Phone: _____

Institution: _____

Address: _____ Fax: _____

_____

_____ E-mail: _____

Donor Information

Donor's Name: _____

Date of Birth: _____ SSN: _____

Autopsy Number: _____

Cause of Death: _____

Clinical Diagnosis: _____

Time of Death (24h): _____ Date: _____

Time Body Placed into Refrigeration (24h): _____ Date: _____

Time Body Removed from Refrigeration (24h): _____ Date: _____

Specimen Information

Fresh Brain Weight (g): _____

Time Fresh Brain Placed in Chilled Water (24h): _____ Date: _____

Time Brain Fixed/Frozen (24h): _____ Date: _____

C. Keller fecit 08/03

Instructions for Shipping Fresh Brains to the NYBB – Taub

http://nybb.hs.columbia.edu – nybb@columbia.edu

These instructions outline the procedures of packing a fresh brain for shipment to the NYBB. Upon request, we provide packing material. For further assistance call 212-305-2299.

1. Recommended items to pack a fresh brain:

<table>
<tr><td>Two clean, dry ziploc plastic bags
(about 22.0 x 30.0 cm)
</td><td>Plastic bucket with a tightly fitting lid
(about 4.0 liters)
</td></tr>
<tr><td>Large plastic
bag (about 40.0 x 50.0 cm)</td><td>Envelope for documents</td></tr>
<tr><td>Thermosafe polyfoam container
(about 38.0 x 33.0 x 31.0 cm)
</td><td>Two refrigerant packs about
(17.0 x 10.0 cm)
</td></tr>
<tr><td colspan="2">Wet ice (about 1.0 kg)</td></tr>
</table>

2. Packing procedure:

Put the fresh brain in the first ziploc bag (A).  A	Ziploc first bag (B).  B
Place bag (B) in second bag and ziploc it (C).  C	Place 0.5 kg of wet ice into the bucket and transfer the double-bagged brain onto the ice (D).  D
Cover double-bagged brain with wet ice (E) and tightly fit the lid on the bucket.  E	Put big plastic bag into the polyfoam container and place wet ice (about 0.3 kg) into the bag (F).  F
Transfer sealed bucket into plastic bag of the container, onto the ice and add refrigerant packs (G).  G	Close plastic bag (H), put polyfoam lid in place, add documents and close cardboard box.  H
Please provide information pertaining to the donor of the specimen and the time intervals between the steps of obtaining and packing the brain. Please refer to the information sheet, which may be downloaded from our Internet site. (http://www.nybb.hs.columbia.edu)	
We use *"Sterling Courier Systems"* as they are familiar with our operations. For pickup call: **1-888-633-6666** and indicate that you would like to send tissue samples to: **"NYBB - Taub"**.	

Appendix C: Sample form for frozen and fixed brain tissue

AD FBS Brain Tissue Specimens

Please complete this form when sending brain tissue to NCRAD. The contact information for emailing the form is in the box below. **Please email the form as soon as possible after tissue is extracted.** NCRAD would like to receive this form BEFORE tissue arrives.

To: Kelley Faber Email: alzstudy@iu.edu

Phone: 1-800-526-2839 **Phone: 317-274-7360**

From: _____ Site ID: _____

Phone: _____

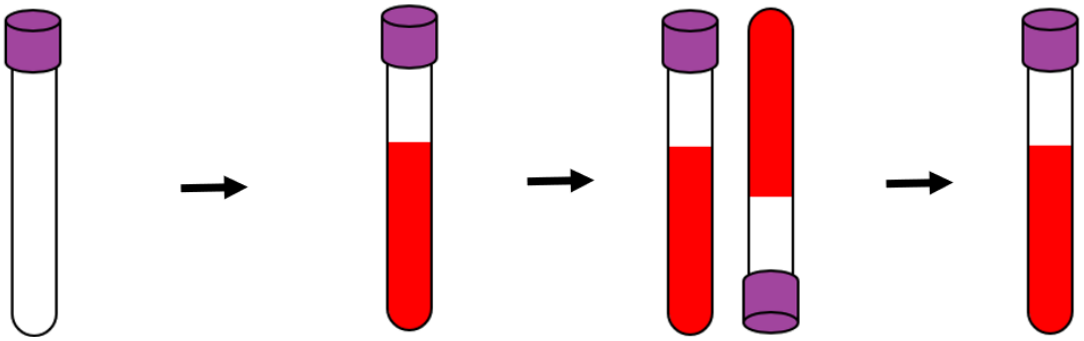
Email: Date:

Site ID	Family ID	Individual ID	GUID	Tissue Removal Date	Section of Brain	Gender	Year of Birth	Fixed or Frozen Tissue

Appendix D: Processing Schematic for DNA Collection and Processing from Blood Kit B.

DNA Preparation (EDTA Tube x 2)





- Store tubes at room temp
- Each tube should be labeled with Collection Tube and Site and PTID labels.

- Collect Blood into each EDTA 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.

Please be sure to compare the labels on each tube and cryovials to the Biological Sample Form included with each kit

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

Appendix E: Sample Packaging and Shipping Instructions for the participant for Blood Kit B

Sample Packaging and Shipping

Print this form and include it in the kit that is sent to the participant with Blood Kit B.

These are instructions for the participant on sending their collected samples back to the study.

SAMPLES MUST BE SHIPPED MONDAY-THURSDAY ONLY!
samples must be shipped the day of blood draw, so do not have blood drawn on Fridays.

- After samples have been collected, there will be (2) green-top tubes, (2) purple-top tubes, and (1) reddish-top tube. These samples need to be packaged and sent back to the study.

Packaging the Study Samples:

1. **Place refrigerant pack in the freezer 24 hours prior to blood draw.**
2. After blood draw, place the filled and labeled (2) sodium heparin (green-top), (1) PAXgeneTM (reddish-top), and (2) 10ml EDTA (purple-top) tubes within the slots in the absorbent pad provided.
3. Place sleeve with tubes in the biohazard bag.
4. Remove as much air as possible from the plastic biohazard bag and seal the bag according to the directions printed on the bag.
5. Place the refrigerant pack into the cooler on top of the filled biohazard bag.
6. Place the lid onto the cooler.
7. Place the completed **Biological Sample and Shipment Notification Form** on top of the cooler lid along with a completed list of contents card.
8. Place the closed, labeled shipping box within a UPS Laboratory Pak. Seal the UPS Laboratory Pak.

Shipping the Study Samples:

- Now these samples need to be sent back to the study. Here are some options for sample return:
    - Option A: The center that drew your blood may already have a daily UPS pickup scheduled. You can ask them about this. If they do, then the center can ship your samples back to the study on your behalf.
    - Option B: If a daily pickup is not already scheduled, then the center that drew your blood may be able to schedule a UPS pickup themselves. You can ask them if they are willing to do this.
    - Option C: you or the center that drew your blood should locate the closest UPS store location to drop off the package for same day shipping. Talk with the center and see what they can offer.
    - If additional help is needed in returning the samples to the study, contact the study site coordinator.