

Asian Cohort for Alzheimer's Disease
in collaboration with
**The National Centralized Repository for Alzheimer's Disease
and Related Dementias (NCRAD)**

Biospecimens
Manual of Procedures
Version 1.0
March 2021



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1.0 ABBREVIATIONS

AD	Alzheimer's Disease
DNA	Deoxyribonucleic Acid
EDTA	Ethylene Diamine Tetra-acetic Acid
GUID	Globally Unique Identifier
IATA	International Air Transport Association
IUGB	Indiana University Genetics Biobank
NACC	National Alzheimer's Coordinating Center
NCRAD	National Centralized Repository for Alzheimer's Disease and Related Dementias
PHI	Protected Health Information
RBC	Red Blood Cells
RCF	Relative Centrifugal Force
RPM	Revolutions Per Minute
UPS	United Parcel Service

2.0 PURPOSE

The collection of blood-based biofluids is an important part of the Asian Cohort for Alzheimer's Disease (ACAD) Study. The purpose of this manual is to provide study staff (PIs, study coordinators, phlebotomists) at the various study sites with instructions for collection and submission of blood-based biological samples for ACAD study visits. It includes instructions for blood-based biospecimen submission to NCRAD located in Indianapolis at Indiana University.

The following samples will be sent to NCRAD:

- Plasma
- Buffy Coat (DNA extraction)

OR

- Saliva (for DNA extraction), if not able to collect blood samples (see [Section 10.0](#))

This manual includes instructions for collection of blood, fractionation of blood from collection tubes, aliquoting, labeling, storage prior to shipping, and shipping to NCRAD.

This manual also includes instructions for collection of saliva, labeling, storage prior to shipping, and shipping to NCRAD.

These procedures are relevant to all study personnel responsible for processing blood specimens being provided to NCRAD for the ACAD protocol.



3.0 NCRAD INFORMATION

3.1 NCRAD Contacts

Tatiana Foroud, PhD, NCRAD Leader

Phone: 317-274-2218

Kelley Faber, MS, CCRC, Project Manager

Phone: 317-274-7360

Email: kelfaber@iu.edu

Colleen Mitchell, Laboratory Manager

Phone: 317-278-9016

Email: mitchechm@iu.edu

General NCRAD Contact Information

Phone: 1-800-526-2839

Fax: 317-321-2003

Email: alzstudy@iu.edu

Website: www.ncrad.org

ACAD Study Specific Webpage:

https://www.ncrad.org/resource_acad.html

Kristi Wilmes, MS, CCRP, Study Coordinator

Phone: 317-274-7546

Email: wilmesk@iu.edu

Sample Shipment Mailing Address

NCRAD

Indiana University School of Medicine

351 West 10th Street

TK-217

Indianapolis, IN 46202

3.2 Hours of Operation

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

Frozen samples must be shipped **Monday-Wednesday only**. For packaging and shipment details of frozen samples, please refer to [Section 9.1](#) of this protocol.

Ambient samples must be shipped **Monday-Thursday only**. For packaging and shipment details of ambient samples, please refer to [Section 10.5](#) of this protocol.

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

3.3 Holiday Schedules

- 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.

3.4 Holiday Observations

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

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 at all 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.

4.0 GLOBALY UNIQUE IDENTIFIER (GUID)

The GUID is a subject ID that allows researchers to share data specific to a study participant, without exposing personally identifiable information. A GUID is made up of random alpha-numeric characters and does not include any PHI in the identifier. By using GUIDs in your research data, the system can associate a single research participant's genetic, imaging, and clinical assessment data even if the data was collected at different locations or throughout different studies. No PHI will be sent to NCRAD, only the GUID.

To create a GUID follow these steps:

1. Create an account: <https://bricsguid.nia.nih.gov/portal/jsp/login.jsp>
2. Once you have an account, go to the GUID Tool – Create GUID
3. To open the 'Launch GUID Tool' you will need to have Java installed on your device
4. In order to generate a GUID, the following PHI is required ([Appendix A](#)):
 - Complete legal given (first) name of subject at birth
 - If the subject has a middle name
 - Complete legal family (last) name of subject at birth
 - Day of birth
 - Month of birth
 - Year of birth
 - Name of city/municipality in which subject was born
 - Country of birth

5.0 NCRAD LABORATORY COLLECTION

5.1 Site Required Equipment

The following materials and equipment are necessary for the processing of specimens at the collection site and are to be **supplied by the local site**:

- Personal Protective Equipment: lab coat, nitrile/latex gloves, safety glasses
- Tourniquet
- Alcohol Prep Pad
- Gauze Pad
- Bandage
- Butterfly needles and hub
- Microcentrifuge tube rack
- Sharps bin and lid
- Wet Ice Bucket
- Wet Ice

In order to process samples consistently across all projects and ensure the highest quality samples possible, project sites must have access to the following equipment:

- Centrifuge capable of ≥ 2000 rcf
- -80°C Freezer

In order to ship specimens, you must provide:

- Dry ice (about approximately 45 lbs per shipment)

5.2 BIOSPECIMEN COLLECTION SCHEDULE

Frozen samples are to be submitted according to the shipping methods outlined in [Section 9.1](#). Guidelines for the processing, storage location, and timing of sample collection are listed in the tables below.

ACAD Blood-Based Biomarker Collection Schedule:

	Visit 1	Visit 2
DNA	X	X
Plasma	X	X

Whole blood is collected in one type of tube (purple top 10 ml EDTA tube) for shipment to NCRAD. This tube is processed locally for plasma and buffy coat fractions; they are then aliquoted, frozen at the study site, and shipped to NCRAD.

Consent forms must specify that any biological samples and de-identified clinical data may be shared with academic and/or industry collaborators through NCRAD. Recommended consent language can be found on the NCRAD website at: https://ncrad.org/recommended_consent_language.html. A copy of the consent form for each subject should be kept on file by the site investigator.

5.3 BIOSPECIMEN COLLECTION CHART

5.3.1 Blood Collection

Sample Type	Tube Type	Number of Tubes Supplied in Kit	Aliquot Volume	Tubes to NCRAD	Ship
Whole blood for isolation of plasma & buffy coat (for DNA extraction)	EDTA (Purple-Top) Blood Collection Tube (10 ml)	1	N/A	N/A	N/A
	PLASMA: 2.0 ml cryovials with purple cap (residual volume placed in 2.0 ml cryovial with blue cap)	4	1.5 ml plasma aliquot per 2.0 ml cryovial (purple cap)	Up to 4	Frozen
	BUFFY COAT: 2.0 ml cryovial	1	1.0 ml buffy coat aliquot per 2.0 ml cryovial (gray cap)	1	Frozen

If a sample is not obtained at a particular visit, this should be recorded in the notes section of the **Biological Sample and Shipment Notification Form** (see [Appendix C](#)). Submit a copy to NCRAD with a reason provided for the omission.

6.0 SPECIMEN COLLECTION KITS, SHIPPING KITS, AND SUPPLIES

NCRAD will provide: 1) Blood based sample collection kits for research specimens to be stored at NCRAD, the Blood Supplemental Supply Kit, the Frozen Blood Shipment Supply Kit and 2) clinical lab supplies (with the exception of dry ice and equipment supplies listed in [Section 5.1](#)). The provided materials include blood tubes, pipettes, boxes for plasma/buffy coat aliquots, as well as partially completed shipping labels to send materials to NCRAD. Kit Number Labels, PTID Labels, Collection Tube Labels and Cryovial Labels will all be provided by NCRAD. Collection Tube and Cryovial Labels will be pre-printed with study information specific to the type of sample being drawn. Ensure that all tubes are properly labeled during processing and at the time of shipment according to [Section 7.1](#).

6.1 Specimen Collection Kit Contents

Collection kits contain the following (for each participant) and provide the necessary supplies to collect samples from a given participant. Do not replace or supplement any of the tubes or kit components provided with your own supplies unless you have received approval from the NCRAD Study team to do so. Please store all kits at room temperature until use.

ACAD Blood-Based Kit

Quantity	ACAD Blood-Based Kit Components
1	EDTA (Purple-Top) Blood Collection Tube (10 ml)
3	Cryovial (2.0 ml) with purple cap
1	Cryovial (2.0 ml) with blue cap
1	Cryovial (2.0 ml) with gray cap
2	Disposable graduated transfer pipette
1	Pre-printed Collection Tube Label
5	Pre-printed Cryovial Label
3	Pre-printed Kit Number Label
2	Label for handwritten PTID
1	Resealable bag
1	Cryovial box (holds up to 25 cryovials)

ACAD Blood-Based Supplemental Supply Kit

10	EDTA (Purple-Top) Blood Collection Tube (10 ml)
30	Cryovial (2.0 ml) with purple cap
5	Cryovial (2.0 ml) with blue cap
10	Cryovial (2.0 ml) with gray cap
10	Disposable graduated transfer pipette
10	Label for handwritten PTID
5	Resealable bag
5	Cryovial box (holds up to 25 cryovials)

ACAD Frozen Blood Shipping Supply Kit

Quantity	Frozen Shipping Kit Components for Blood-Based Biomarkers
8	Plastic Biohazard bag with absorbent sheet
1	Shipping box/Styrofoam container
1	Warning label packet with dry ice sticker

Individual Supplies

Quantities	Items Available upon request within the NCRAD kit module.
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By Request	EDTA (Purple-Top) Blood Collection Tube (10 ml)
By Request	Cryovial (2.0 ml) with purple cap
By Request	Cryovial (2.0 ml) with blue cap
By Request	Cryovial (2.0 ml) with gray cap
By Request	Disposable graduated transfer pipette
By Request	Label for handwritten PTID
By Request	Cryovial box (holds up to 25 microcryovials)
By Request	Shipping container for dry ice shipment (shipping and Styrofoam box)
By Request	Styrofoam shipping containers (11"x9"x8" 1 1/2" wall)
By Request	Plastic biohazard bag with absorbent sheet (small)
By Request	Warning label packet
By Request	UN3373 label
By Request	Biohazard label
By Request	Dry ice shipping label
By Request	Fine point permanent markers

6.2 Kit Supply to Study Sites

Each individual site will be responsible for ordering and maintaining a steady supply of kits from NCRAD. We advise sites to keep a supply of each kit type available. Be sure to check your supplies and order additional materials before you run out or supplies expire so you are prepared for study visits. Please go to <http://kits.iu.edu/acad> to request additional kits and follow the prompts to request the desired supplies. Options include ordering a specific number of kits; we are also including the option of simply ordering the desired amount of extra supplies.

Please allow **TWO weeks** for kit orders to be processed and delivered.

7.0 BLOOD COLLECTION AND PROCESSING PROCEDURES

*****Important Note*****

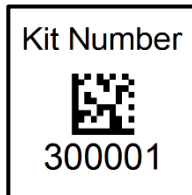
In order to ensure the highest quality samples are collected, processed, and stored, it is essential to follow the specific collection, processing, and shipment procedures detailed in the following pages. Please read the following instructions first before collecting any specimens. Have all your supplies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

SPECIFIC INSTRUCTIONS FOR COLLECTION AND PROCESSING OF EACH SAMPLE ARE DETAILED ON THE FOLLOWING PAGES.

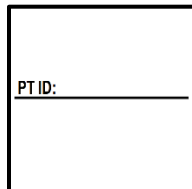
7.1 Labeling Samples

****Label Type Summary****

1. Kit Number Label
2. PTID Label
3. Collection Tube Label
4. Cryovial Label



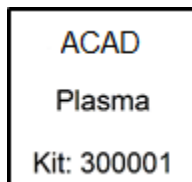
The **Kit Number Labels** do not indicate a specimen type, but are affixed on the Biological Sample and Shipment Notification Forms and on the outside of each cryovial box.



The **PTID Labels** are used to document the individual's unique PTID. Place one label on each blood collection tube.



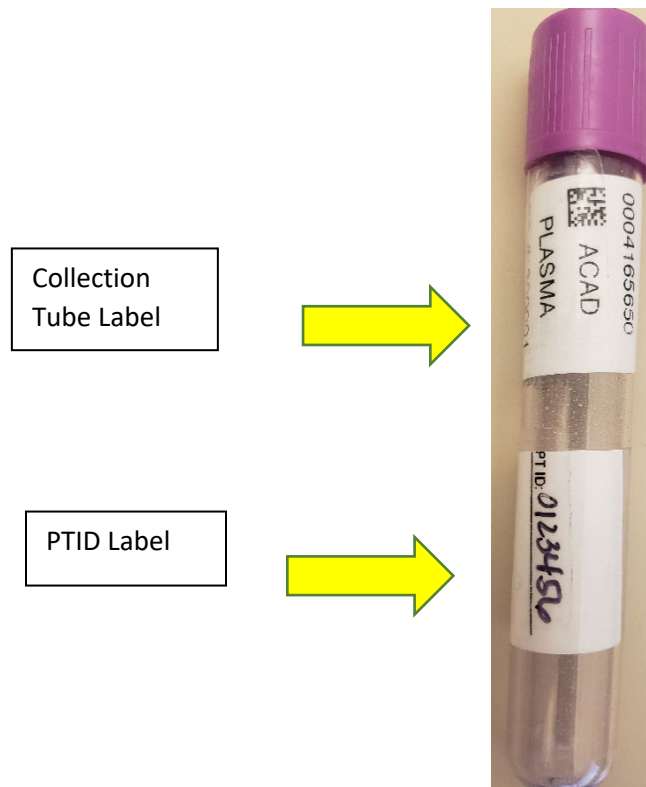
The **Collection Tube Labels** for blood derivatives are placed on all collection tubes.



Place one **Cryovial Label** on each cryovial.

****Important Note****

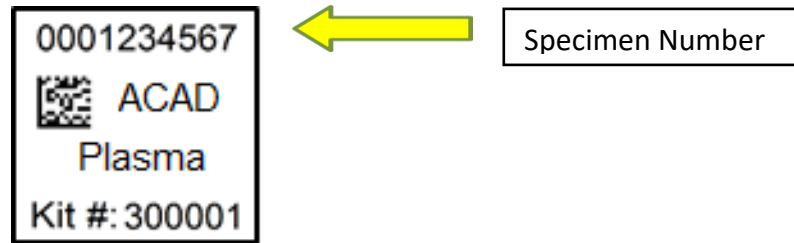
Each collection tube will contain two labels: the Collection Tube Label and the PTID Label. Be sure to place labels in the same configuration consistently among tubes, with the barcoded label near the top of the tube and the handwritten PTID label.



**EDTA (Purple-Top) Blood
Collection Tube (10 ml)**

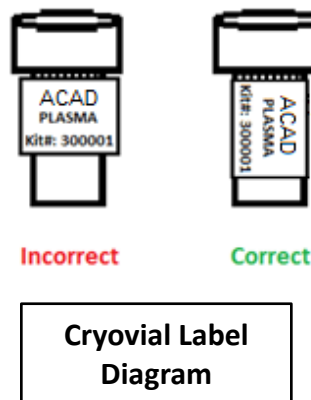
In order to ensure the label adheres properly and remains on the tube, please follow these instructions:

- Place Cryovial Labels on **ALL** cryovials **BEFORE** sample collection, sample processing, or freezing. This should help to ensure the label properly adheres to the tube before exposure to moisture or different temperatures.
- Place cryovials in numerical order based on the specimen number, located at the top of the label. This ensures that no aliquot is misplaced or lost during the shipment process.



- Using a fine point permanent marker, fill-in and place the PTID Labels on the collection tubes only (EDTA) **BEFORE** sample collection, processing, or freezing. 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.

If there are any unused cryovials, please do not send the empty cryovials to NCRAD. These unused cryovials are specific to each kit and must be disposed of per your site's requirements.



7.2 Video List

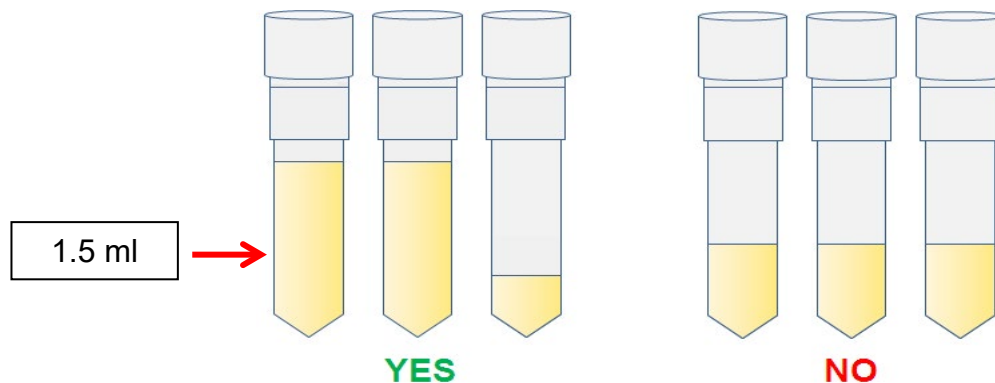
- The following training videos are available to assist you with the specimen processing, aliquoting, and shipping processes. The videos are available at: https://ncrad.org/resource_acad.html.
 - ACAD MOP Training
 - Plasma and Buffy Coat Processing and Aliquoting
 - Frozen Shipping

7.3 Filling Aliquot Tubes (Plasma)

In order to ensure that NCRAD receives a sufficient amount of sample for processing and storage, and to avoid cracking of the tubes prior to shipment, each cryovial should be filled to the assigned volume with the respective biological material after processing is completed (refer to detailed processing instructions for average yield per sample).

Over-filled tubes may burst once placed in the freezer, resulting in a loss of that sample.

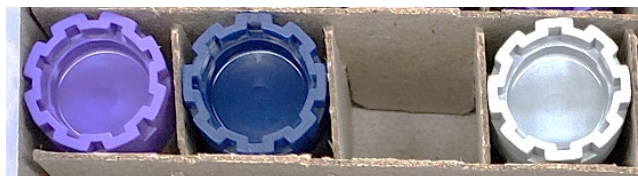
Aliquot the remaining biological material as the residual volume and ship to NCRAD. Essentially, all material should be shipped to NCRAD, ensuring maximum amount in as many cryovials as will allow after processing the sample. For example, if 3.6 ml of sample is obtained, you should fill 2 cryovial tubes each with 1.5 ml, and one additional cryovial tube with the remaining 0.6 ml.



Please note: It is critical for the integrity of the samples that study staff note if an aliquot tube contains a residual volume (anything under 1.5 ml). Please record the specimen number and volume of the residual aliquot on the Biological Sample and Notification Form.

To assist in the preparation and aliquoting of samples, colored caps are used for the cryovial tubes. The chart below summarizes the association between cap color and type of cryovial.

Cap Color	Sample Type
Purple Cap	Plasma
Blue Cap	Residual
Gray Cap	Buffy Coat



Purple cap

Blue Cap

Gray Cap

7.4 EDTA (Purple-Top) Blood Collection Tube (10 ml) for Plasma and Buffy Coat

Whole Blood Collection for Isolation of Plasma and Buffy Coat: EDTA (Purple-Top) Blood Collection Tube (10 ml) (for processing of plasma aliquots and buffy coat aliquot).

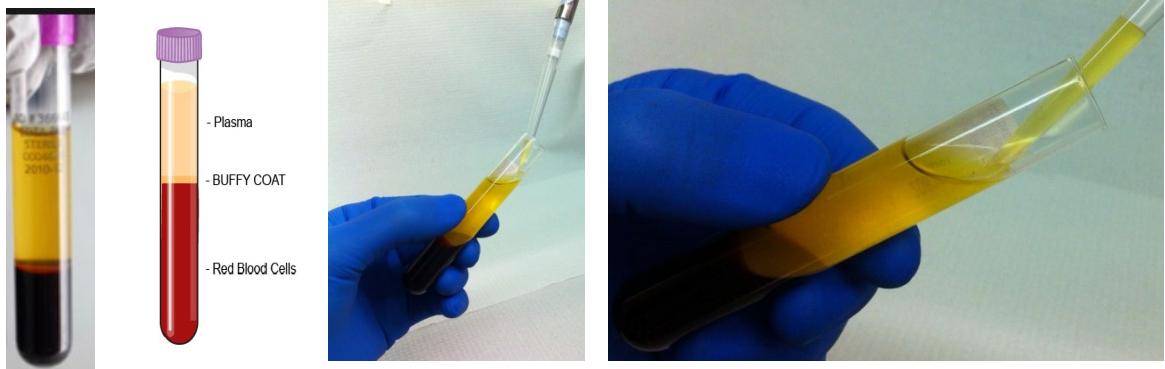
1. Set centrifuge to room temperature before use.
2. Place completed PTID Label and pre-printed “**PLASMA**” Collection Tube Label on the purple-top EDTA tube. Place pre-printed “**PLASMA**” Cryovial Labels on the (3) 2 ml cryovial tubes with purple caps and (1) 2 ml cryovial tube with blue cap (if necessary, for residual). Place pre-printed “**BUFFY COAT**” Cryovial Label on the (1) 2 ml cryovial with a gray lid.
3. Please ensure that aliquots are kept in numerical order (by specimen number) throughout the aliquoting and shipping process.
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 donor's arm in a downward position.

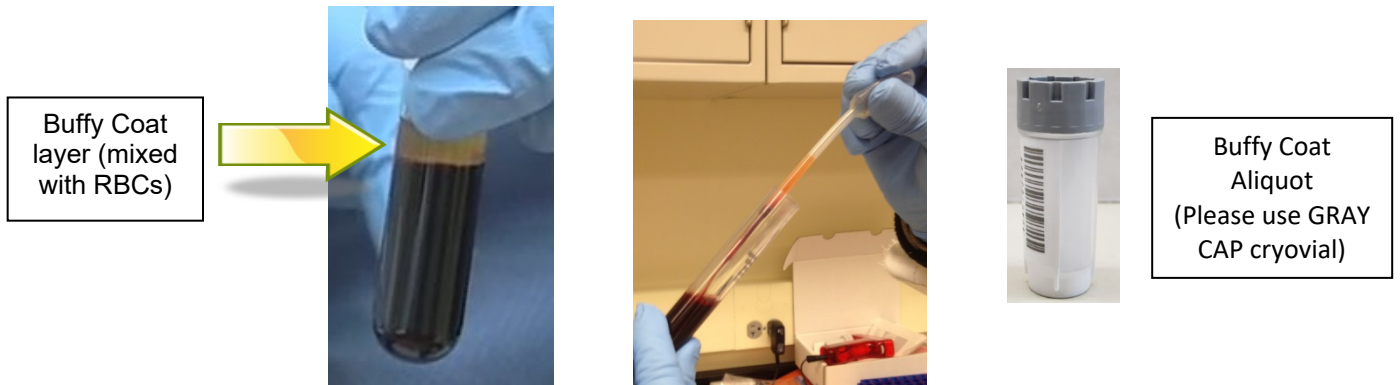
- b. Hold tube in a vertical position, below the donor's arm during blood collection.
 - c. Release tourniquet as soon as blood starts to flow into tube.
 - d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.
5. Allow at least 10 seconds for a complete blood draw 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 'Biological Sample and Shipment Notification Form'. Do not attempt to draw an additional EDTA tube at this time. Process blood obtained in existing EDTA tube.
6. **CRITICAL STEP: Immediately after blood collection, gently invert/mix (180 degree turns) the EDTA tube 8-10 times.**
7. **CRITICAL STEP: Immediately after inverting the EDTA tube, place it on wet ice until centrifugation begins.**
8. Centrifuge balanced tubes for 10 minutes at 2000 x g at room temperature . **It is critical that the tubes be centrifuged at the appropriate speed and room temperature to ensure proper plasma separation (see worksheet in [Appendix B](#) to calculate RPM.)**
 - a. Equivalent rpm for spin at 2000 x g
 - b. While centrifuging, remember to record all times, temperatures and spin rates on the Biological Sample and Shipment Notification Form.
 - c. Plasma samples need to be spun, aliquoted, and placed in the freezer within 3 hours from the time of collection.
 - d. Record time aliquoted on the Biological Sample Shipment and Notification Form.
9. Remove the plasma, being careful not to agitate the packed red blood cells at the bottom of the tube. Tilt the tube and place a disposable pipette tip along the lower side of the wall without touching the pellet (buffy coat) so that plasma is not contaminated (see below).
10. Aliquot 1.5 ml per cryovial (total vials = up to 4 with 1.5 ml each). Each EDTA tube should yield, on average, 4-5 ml of plasma. Be sure to only place **plasma** in cryovials with purple caps and labeled with "PLASMA" labels. Take caution not to disturb the red blood cells at the bottom of the tube. If there is extra plasma left, use 1 extra cryovial provided (blue cap) for another <1.5 ml aliquot

of plasma. If a residual aliquot (<1.5 ml) is created, document the sample number and volume on the Biological Sample and Shipment Notification Form.



NOTE: When pipetting plasma from the plasma tube into the cryovials, be very careful to pipette the plasma top layer only, leaving the buffy coat and the red blood cell layers untouched.

11. Place the labeled cryovials in the 25 cryovial box and place on dry ice. Transfer to **-80°C Freezer when possible**. Store all samples at **-80°C until shipped** to NCRAD on dry ice. Record time aliquots placed in freezer and storage temperature of freezer on Biological Sample Shipment and Notification Form.
12. After plasma has been removed from the EDTA (Purple-Top) Blood Collection Tubes (10 ml), aliquot buffy coat layer (in the top layer of cells, the buffy coat is mixed with RBCs-see figure) into labeled cryovial with gray cap using a micropipette. The buffy coat aliquot is expected to have a reddish color from the RBCs. Be sure to place buffy coat into cryovial with the gray cap and "BUFFY COAT" label.

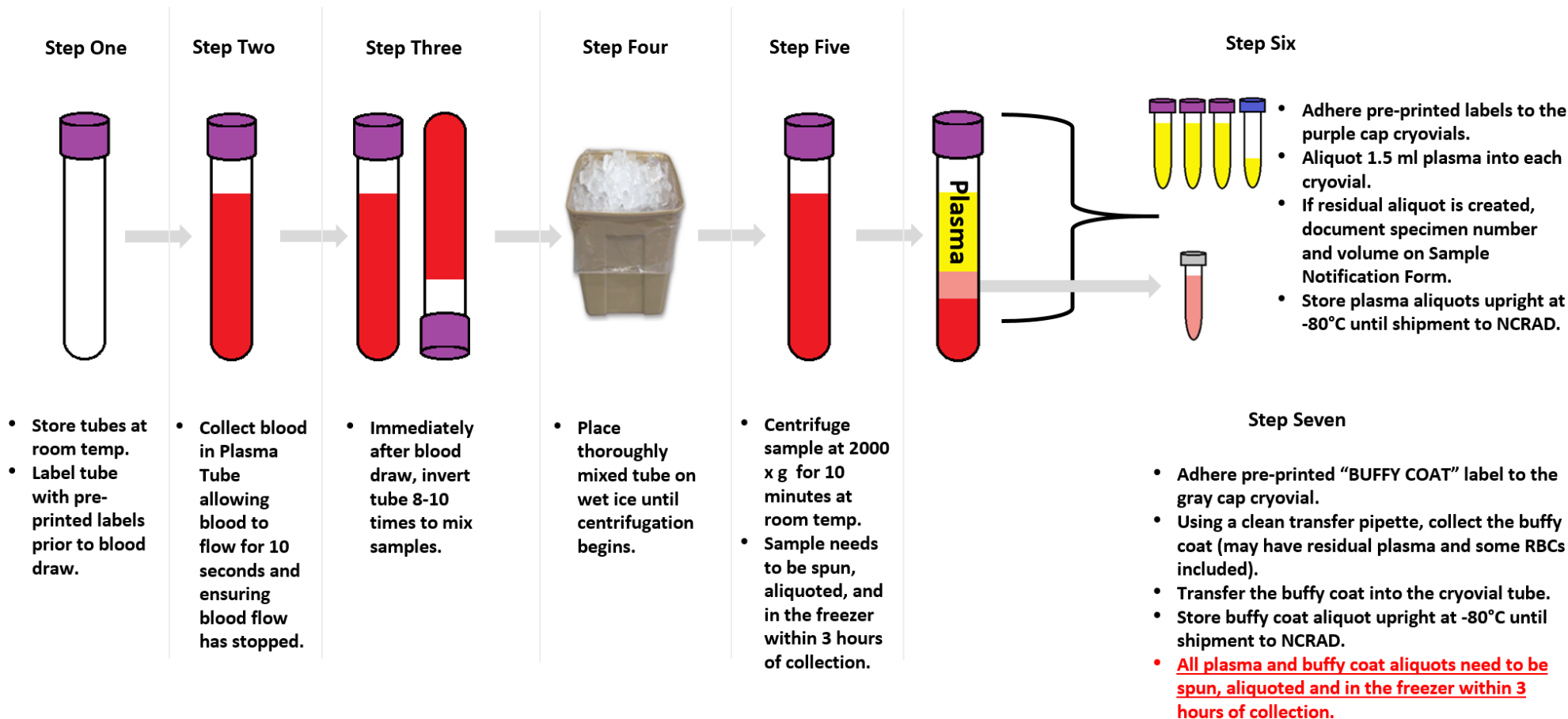


13. Dispose of tube with red blood cell pellet according to your site's guidelines for disposing of biomedical waste.
14. Place the labeled cryovials in the 25 cryovial box and place on dry ice. Transfer to **-80°C Freezer when possible**. Store all samples at **-80°C until shipped** to NCRAD on dry ice. Record volumes and last four of specimen barcode on Biological Sample and Shipment Notification Form.



Plasma Aliquots (up to 4 possible) and Buffy Coat (1)

Plasma and Buffy Coat Preparation (10ml Purple Top Tube)



8.0 INCOMPLETE OR DIFFICULT BLOOD DRAWS

Important Note

If challenges arise during the blood draw process, it is advised that the phlebotomist discontinue the draw. Attempt to process and submit any blood-based specimens that have already been collected to NCRAD.

Redraws will not be scheduled for samples submitted to NCRAD as participants are seen longitudinally.

Situations may arise that prevent study coordinators from obtaining the total amount scheduled for biospecimens. In these situations, please follow the below steps:

1. *If the biospecimens at a scheduled visit **are partially** collected:*
 - a. Attempt to process and submit any samples that were able to be collected during the visit
 - b. Document difficulties on the 'Biological Sample and Shipment Notification Form' prior to submission to NCRAD
 - i. Indicate blood draw difficulties at the bottom of the 'Biological Sample and Shipment Notification Form' within the "Notes" section.
 - ii. Complete the 'Biological Sample and Shipment Notification Form' with tube volume approximations and number of aliquots created.
 - c. Contact a NCRAD coordinator and alert them of the challenging blood draw
2. *If the blood biospecimens at a scheduled visit **are not** collected:*
 - a. See [Section 10.0](#) Saliva Collection for instructions on how to collect saliva samples.

9.0 PACKAGING AND SHIPPING INSTRUCTIONS

ALL study personnel responsible for shipping should be certified in biospecimen shipping. If not available at your University, please contact NCRAD with questions and information regarding resources.

Sample Type	ACAD	Processing/ Aliquoting	Tubes to NCRAD	Ship
Whole blood (Purple-Top EDTA) for isolation of plasma & buffy coat (for DNA extraction)	Yes	1.5 ml plasma aliquots	Up to 4	Frozen
	Yes	1.0 ml buffy coat aliquot	1	Frozen

***** Packing and Labeling Guidelines *****

- The primary receptacle (frozen cryovials) 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 dry ice contained



IMPORTANT!

**FROZEN SAMPLES MUST BE SHIPPED
MONDAY-WEDNESDAY ONLY!**

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.

9.1 Frozen Packaging Instructions

1. Notify NCRAD of shipment by emailing NCRAD coordinators at: alzstudy@iu.edu
Attach the following to the email:
 - Completed Biological Sample and Shipment Notification Form to the email notification.
(See [Appendix C](#) for an example of the NCRAD sample form)
 - If email is unavailable please call NCRAD and do not ship until you've contacted and notified NCRAD coordinators about the shipment in advance.
2. Place all frozen labeled aliquots of plasma and buffy coat aliquots from the same subject in the cryovial cryobox.
 - a. Each 25-slot cryobox will hold approximately 5 cryovial samples. Place plasma and buffy coat within one cryobox (4 plasma, 1 buffy coat) per participant blood draw (see below).



One cryobox to contain Plasma
and Buffy Coat Aliquots

- b. Cryoboxes should contain all of the specimens from the same patient, per time point.

c. Batch shipping should be performed every 3 months or when specimens from 8 participants accumulates, whichever is sooner.

3. Label the outside of the cryoboxes with the kit number label.
4. Place the cryoboxes in the clear plastic biohazard bag (do NOT remove the absorbent material found in the bag) and seal according to the instructions on the bag.



Place kit
number label on
each cryobox

5. Place approximately 2-3 inches of dry ice in the bottom of the Styrofoam shipping container.
6. Place the biohazard bag into the provided Styrofoam-lined shipping container on top of the dry ice. Please ensure that cryoboxes are placed so the cryovials are upright in the shipping container (as pictured below).
7. Fully cover the cryoboxes with approximately 2 inches of dry ice.
8. The inner Styrofoam shipping container must contain approximately 30-45 lbs (or 21kg) of dry ice. The dry ice should entirely fill the inner box to ensure the frozen state of the specimens.

Full Shipping Container with
Batched Samples and Dry Ice



9. 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.
10. Complete the UPS Dry Ice Label
 - a. Net weight of dry ice in kg (must match amount on the airbill)
 - b. Do not cover any part of this label with other stickers, including pre-printed address labels.
11. Apply all provided warning labels and the pre-printed UPS return label to the outside of package, taking care not to overlap labels.

IMPORTANT!

Complete the UPS Dry Ice label or UPS may reject or return your package.

12. Hold packaged samples in -80°C freezer until time of UPS pick-up/drop-off.
13. Specimens should be sent to the below address via **UPS Next Day Air**. Frozen shipments should be sent **Monday through Wednesday** to avoid shipping delays on Thursday or Friday. UPS does not replenish dry ice if shipments are delayed or held over during the weekend.

NCRAD
351 West 10th Street
TK-217
Indianapolis, IN 46202
Phone: 1-800-526-2839

14. 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.

*****Important Note*****

For frozen shipments, include no more than eight cryovial boxes (separated by patient within 8 biohazard bags) per shipping container in order to have room for a sufficient amount of dry ice to keep samples frozen up to 24 hours.

The labeled, processed, aliquoted, and frozen cryovials of plasma and buffy coat will be shipped to NCRAD as outlined above.

SHIP ALL FROZEN SAMPLES MONDAY - WEDNESDAY ONLY!

BE AWARE OF HOLIDAYS!!

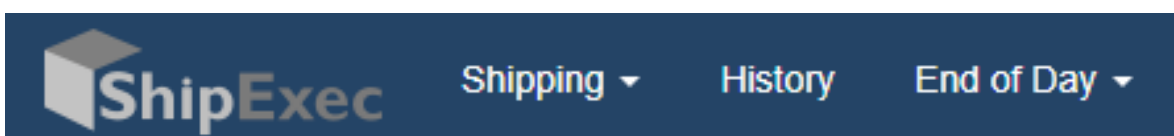
**BE AWARE OF IMMINENT INCLEMENT WEATHER THAT MAY DELAY
SHIPMENT/DELIVERY OF SAMPLES**

Remember to complete the Biological Sample and Shipment Notification ([Appendix C](#)), include a copy in your shipment AND notify the NCRAD Study Coordinator by email at alzstudy@iu.edu (include UPS tracking number in email) IN ADVANCE to confirm the shipment.

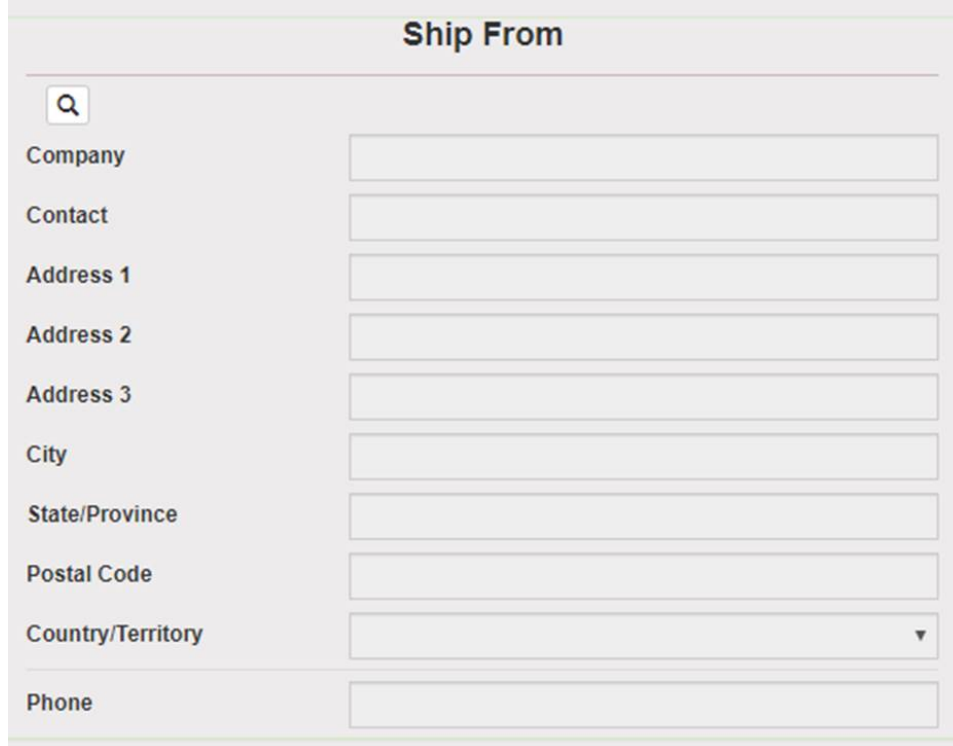
In addition to tracking and reconciliation of samples, the condition and amount of samples received are tracked by NCRAD for each sample type. Investigators and clinical coordinators for each project are responsible to ensure the requested amounts of each fluid are collected to the best of their ability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

9.2 Frozen Shipping Instructions

1. Log into the ShipExec Thin Client at kits.iu.edu/UPS.
 - 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 on the right side of the main screen. Choosing your study will automatically filter the address book to only



- addresses within your study.
4. Click on the magnifying glass icon on 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 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 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 will need to schedule one.

- 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.
 - b. Click Detailed Report from the dropdown menu on the right side of the page.
 - c. Enter tracking number if known. Otherwise, search by ship date. Click Search.
 - d. 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.
11. A UPS Pickup is automatically scheduled at the address you are shipping from, and the pickup is charged to NCRAD.
 - a. If shipment occurs too late in the day for an automatic UPS pickup, you will receive an email stating that the pickup could not be scheduled, and you will need to make other arrangements.

10.0 SALIVA COLLECTION

10.1 Saliva Specimens sent to NCRAD

Saliva will be collected in an Oragene Saliva Collection Tube. After collection, these samples are then shipped to NCRAD.

Consent forms must specify that any biological samples and de-identified clinical data may be shared with academic and/or industry collaborators through the NCRAD Biorepository. A copy of the consent form for each subject should be kept on file by the site investigator.

Ambient samples are to be submitted according to the shipping methods outlined in [Section 10.5](#). Guidelines for the timing of sample collection and storage of samples are detailed in the tables below.

10.2 Biospecimen Collection Chart

	Visit 1	Visit 2
Saliva	X	X

Sample Type	Tube Type	Number of Tubes Supplied in Kit	Tubes to NCRAD	Volume	Ship
Saliva for for DNA extraction)	Saliva Kit (DNA Genotek) OGR-500	1	1	2.0 ml of Saliva collected in each 4.0 ml tube	Ambient

If a sample is not obtained at a particular visit, this should be recorded in the notes section of the **Biological Sample and Shipment Notification Form** (see [Appendix D](#)). Submit a copy to NCRAD with a reason provided for the omission.

Saliva collection should occur **only** after waiting **30 minutes after the subject has last ingested any substance**.

If the subject did not wait 30 minutes before providing a sample, this should be noted in the field provided on the **Biological Sample and Shipment Notification Form** (see [Appendix D](#)).

10.3 Specimen Collection Kits, Shipping Kits, and Supplies

Saliva collection kits as well as shipment supplies will be provided by the NCRAD Biorepository. These materials include items listed below. Kit Number Labels, PTID Labels, and Collection Tube Labels will all be provided by NCRAD. Collection Tube labels will be pre-printed with study information specific to the type of sample being drawn. Ensure that all tubes are properly labeled during processing and at the time of shipment according to [Section 10.5](#)

10.3.1 Specimen Collection Kit Contents

Collection kits contain the following (for each participant) and provide the necessary supplies to collect samples from a given participant. Do not replace or supplement any of the tubes or kit components provided with your own supplies unless you have received approval from the NCRAD Study team to do so. Please store all kits at room temperature until use.

ACAD Saliva Kit

Quantity	ACAD Saliva Collection Kit Components
1	Oragene Saliva Collection Kit
2	Specimen Labels
1	PTID Label
1	Small Saliva Biohazard Bag
1	Large Resealable Bag

ACAD Saliva Shipping Kit

Quantity	ACAD Saliva Collection Kit Components
1	Saliva Shipping Box (holds 36 saliva specimens)
1	Large Biohazard Bag
1	250ml Absorbent Sheet
1	Large Resealable Bag
1	Human Exempt Specimen Label
1	UPS ClinPak
1	UPS Return Shipping Label

Individual Supplies

Quantity	ACAD Saliva Collection Kit Components
By Request	Oragene Saliva Collection Kit
By Request	PTID Label
By Request	Small Saliva Biohazard Bag
By Request	Large Resealable Bag
By Request	Saliva Shipping Box (holds 36 saliva specimens)
By Request	250ml Absorbent Sheet
By Request	Human Exempt Specimen Label
By Request	UPS ClinPak
By Request	UPS Return Shipping Label

10.3.2 Kit Supply to Study Sites

Each site will be responsible for ordering and maintaining a steady supply of kits from NCRAD. We advise sites to keep a supply of each kit type available. Be sure to check your supplies and order additional materials before you run out or supplies expire so you are prepared for study visits. Please go to: <http://kits.iu.edu/acad> to request additional kits and follow the prompts to request the desired supplies. Options include ordering a specific number of kits; we are also including the option of simply ordering the desired amount of extra supplies.

Please allow **TWO weeks** for kit orders to be processed and delivered.

10.4 Saliva Collection and Processing Procedures

*****Important Note*****

In order to ensure the highest quality samples are collected, processed, and stored, it is essential to follow the specific collection, processing, and shipment procedures detailed in the following pages. Please read the following instructions before collecting any specimens. **A minimum of 30 minutes must elapse after ingesting any substance, chewing gum, or smoking prior to drawing saliva.** Have all supplies and equipment out and prepared prior to saliva collection.

10.4.1 Labeling Samples

Label Type Summary	
1.	PTID Label
2.	Specimen Label

Each kit is supplied with labels for specimens destined for the NCRAD Biorepository.

PTID:

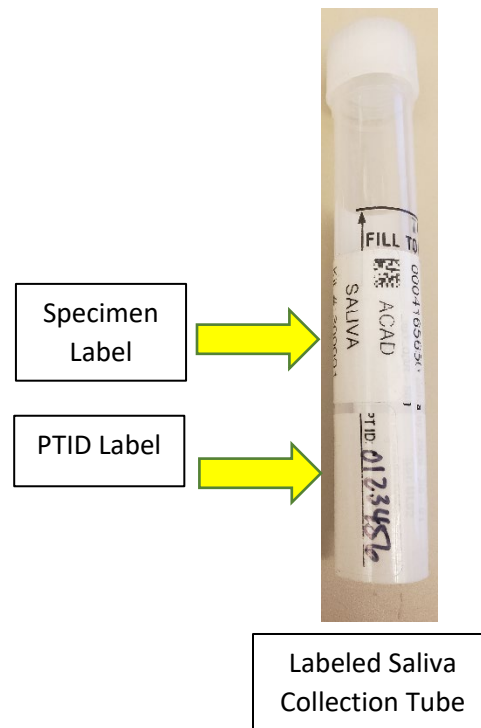
The **PTID Labels** are used to document the individual's unique PTID. Place one label on the saliva collection tube.

0001234567
 ACAD
SALIVA
Kit #: 300001

Place one **Specimen Label** on the saliva collection tube. The second, matching **Specimen Label** should be affixed to the subject's corresponding **Biological Sample and Shipment Notification Form** (see [Appendix D](#)).

****Important Note****

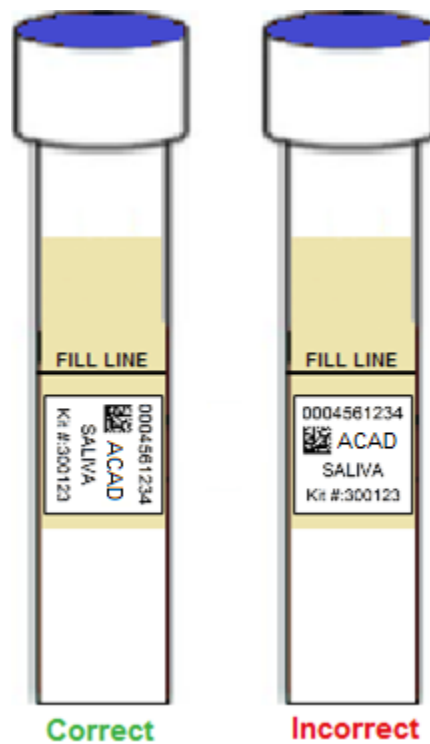
Each collection tube will contain two labels: the Specimen Label and the PTID Label. Be sure to place labels in the same configuration, with the Specimen Label near the top of the tube and the PTID label at the bottom of the tube.



To ensure the label adheres properly and remains on the tube, please follow these instructions:

- Using a fine point permanent marker, fill in and place the PTID Label on the Oragene collection tube BEFORE sample collection.
- Specimen Labels contain a 2D barcode on the left hand side of the label. Affix the label so this barcode is oriented toward the tube cap.
- Place label **horizontally** on the tube (wrapped around sideways if the tube is upright).
- Be sure not to cover the “Fill To” line.
- Take a moment to ensure the label is **completely adhered** to the tube. It may be helpful to roll the tube between your fingers after applying the label.

Saliva Tube Labeling



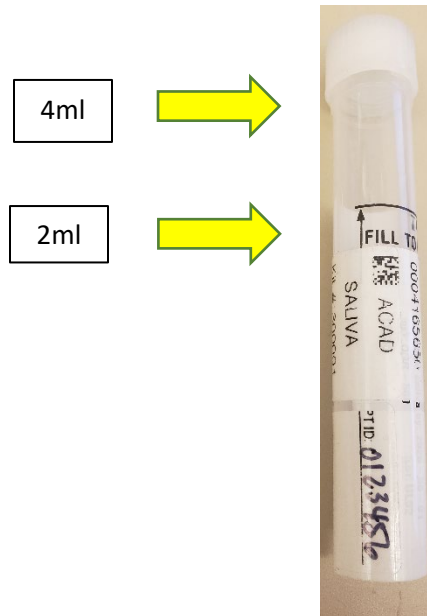
10.4.2 Saliva Collection Video

The following training video is available to assist you with the saliva collection:
<http://www.dnagenotek.com/ROW/support/ciOG500.html>

10.4.3 Saliva Collection Tube Maximum Volume

In order to ensure that the NCRAD Biorepository receives a sufficient amount of sample for processing and storage, the saliva collection tube should be filled to the assigned volume. Over-filled tubes may leak during shipment, resulting in a loss of sample. Volume should be recorded by the site on the Saliva Sample Form.

Saliva Tube Volume



10.4.4 Saliva Collection

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. The saliva tube has a false bottom, so you will only need to provide 2 ml of saliva to reach the fill line. Do NOT fill above the line.

Please Note: Most people take between 2 and 5 minutes to deliver a saliva sample. If the subject finds it difficult to produce a sample, instruct them to relax and rub their cheeks gently for 30 seconds to generate saliva.

2. After collection, 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. Discard the funnel.
3. Shake the capped tube for 5 seconds. Complete the **Biological Sample and Shipment Notification Form** (see [Appendix D](#)). Place sample into the provided biohazard bag. Peel the protective wrapping off to seal the bag. Roll packaging around the tube.

4. Place sample into the provided Bulk Saliva Shipping Box.

Oragene Saliva Collection Kit Contents and Warnings

Intended Use: This product is designed for the safe collection of human saliva samples.

Contents: The funnel lid contains 2 mL of Oragene • DNA liquid. The solution should be clear and colorless.

Warnings: Do not ingest the Oragene • DNA liquid. Wash with water if the Oragene • DNA liquid comes in contact with eyes or skin. Small cap, choking hazard.

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

10.5 Packaging and Shipping Instructions

IMPORTANT!

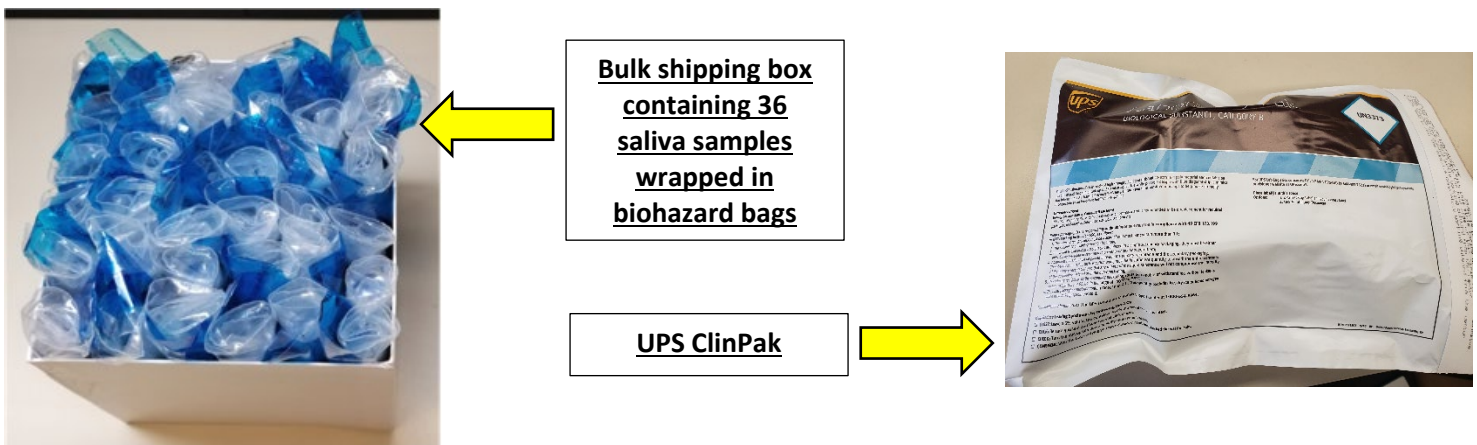
**AMBIENT SAMPLES MUST BE SHIPPED
MONDAY-THURSDAY ONLY!**

Saliva specimens being shipped to the NCRAD Biorepository should be considered as Exempt Human Specimens and as such must be packaged and compliant with IATA Packing Instructions. *See the Latest Edition of the IATA Regulations for complete documentation.*

***** Packing and Labeling Guidelines *****

- The primary receptacle (saliva tube) must be leak proof and in total must not contain more than 4ml of fluid.
- The secondary packaging (bulk shipping box and biohazard bag) must be leak proof and, if multiple saliva tubes are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent direct contact with adjacent saliva tubes.
- Absorbent material must be placed between the primary receptacle (within the biohazard bag) 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 included in shipment 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 "Exempt Human Specimen"

1. Contact UPS to confirm service is available and schedule package to be picked up. The easiest way to schedule a UPS pickup is to visit <https://www.apps.ups.com/pickup/schedule>.
2. Notify NCRAD of shipment by emailing NCRAD coordinators at: alzstudy@iu.edu
Attach the following to the email:
 - Completed Biological Sample and Shipment Notification Form to the email notification.
(See [Appendix D](#) for an example of the NCRAD sample form)
 - 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. Ensure all ambient, labeled saliva samples, are appropriately packaged (see below).



4. Place the completed Biological Sample and Shipment Notification Forms in the ClinPak.
5. Apply all provided warning labels and the pre-printed UPS return label to the outside of package, taking care not to overlap labels.
6. 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.

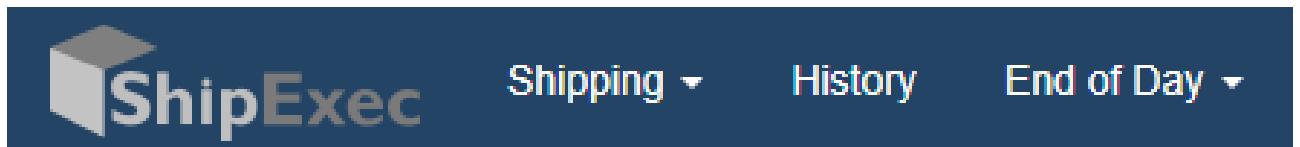
**SHIP ALL AMBIENT SAMPLES MONDAY - THURSDAY ONLY.
BE AWARE OF HOLIDAYS.
BE AWARE OF INCIPIENT INCLEMENT WEATHER THAT MAY DELAY
SHIPMENT/DELIVERY OF SAMPLES.**

In addition to the tracking and reconciliation of samples, the condition and amount of samples received are recorded for each sample type. Investigators and clinical coordinators at each site are responsible for ensuring the requested amounts of each fluid are collected to the best of their ability and that samples are packed correctly.

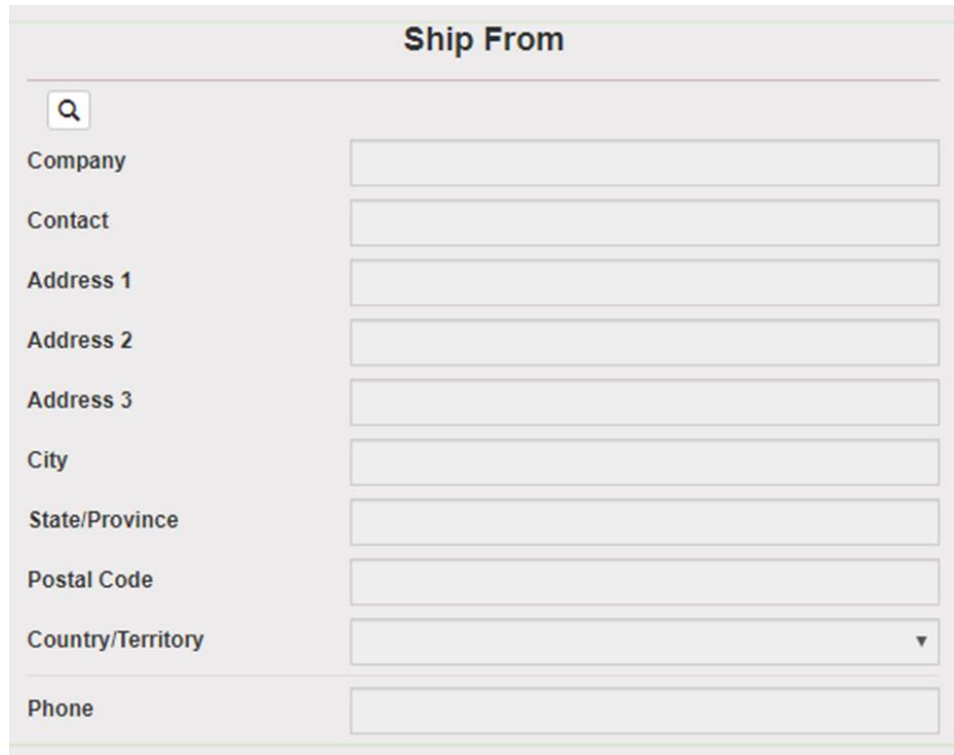
10.5.1 Saliva Shipping Instructions

1. Log into the ShipExec Thin Client at kits.iu.edu/UPS.

- 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



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



- c. Search by Company (site), Contact (name), or Address 1 (first line of your site’s street address). Click Search.
- d. Click Select to the left of the correct contact information.
4. 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.
5. 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 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 and need to reenter these values.
- c. Click Ship in the bottom right of the page when complete.
6. Print the airbill that is automatically downloaded.
 - a. To reprint airbill, click History at the top left of the page.
 - b. Click Detailed Report from the dropdown menu on the right side of the page.
 - c. Enter tracking number if known. Otherwise, search by ship date. Click Search.
 - d. Click print icon on right side of the tracking number line.
7. Fold airbill, and place inside plastic UPS sleeve.
8. Peel the back off of the UPS sleeve, and stick the sleeve to the package.
9. A UPS Pickup is automatically scheduled at the address you are shipping from, and the pickup is charged to NCRAD.
 - a. If shipment occurs too late in the day for an automatic UPS pickup, you will receive an email stating that the pickup could not be scheduled, and you will need to make other arrangements.

11.0 DATA QUERIES AND SAMPLE RECONCILIATION

Sample and Shipment Notification forms must be completed on the day that samples are collected since they capture information related to the details of the sample collection and processing. These forms include information that will be used to reconcile sample collection and receipt, as well as information essential to future analyses.

NCRAD will collaborate with the data team to reconcile information captured in the database compared to samples received and logged at NCRAD. Additional discrepancies may be sent directly to the Center staff to reconcile.

Data queries or discrepancies with samples shipped and received at NCRAD may result from:

- Incorrect samples collected and shipped
- Damaged or incorrectly prepared samples
- Unlabeled samples, samples labeled with incomplete information, or mislabeled samples
- Discrepant information documented on the Blood Sample and Shipment Notification Form and logged at NCRAD compared to information entered into the database.



12.0 APPENDICES LIST

[Appendix A: GUID Demographics Form](#)

[Appendix B: Rate of Centrifugation Worksheet](#)

[Appendix C: Blood Sample and Shipment Notification Form](#)

[Appendix D: Saliva Sample and Shipment Notification Form](#)



Appendix A: GUID Demographics Form

Please be certain to collect the following demographic information to generate a Global Unique Identifier. **Do NOT** return this information to NCRAD. Only send the GUID to NCRAD.

1. Complete legal given (first) name of subject at birth: _____
2. Complete additional (middle) name or names at birth: _____
3. Complete legal family (last) name of subject at birth: _____
4. Suffix: _____
5. Date of Birth: _____
6. Name of city/municipality in which subject was born: _____
7. Country of birth: _____



Appendix B: 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:

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

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

317-321-2003 (Fax)

alzstudy@iu.edu



Appendix C: Blood Sample and Shipment Notification Form



Appendix C



Site ID: _____ Participant ID: _____

Blood Sample and Shipment Notification Form

Please email or fax this from prior to the date of shipment.

To: Kelley Faber Email: alzstudy@iu.edu FAX: 317-321-2003 Phone: 1-800-526-2839	
General Information: UPS tracking #: _____	
From: _____	Date: _____
Phone: _____	Email: _____
Study: ACAD GUID: _____ Kit #: _____	
Visit (circle one): V01 V02	
Sex: <input type="checkbox"/> M <input type="checkbox"/> F	KIT BARCODE
Year of Birth: _____	
Blood Collection:	
1. Date Drawn: _____ [MMDDYY]	2. Time of Draw: _____ [HHMM]
3. Last time subject ate: _____ [MMDDYY]	4. Last time subject ate: _____ [HHMM]
Blood Processing:	
Plasma & Buffy Coat (Purple-top) Tube (10 mL)	
Time spin started: _____	_____ [HHMM]
Duration of centrifuge: _____	_____ Minutes
Temp of Centrifuge: _____ °C Rate of centrifuge: _____ x g	
Time aliquoted: _____	_____ [HHMM]
Number of 1.5 mL plasma aliquots created (lavender cap): _____	
If applicable, volume of residual plasma aliquot (less than 1.5 mL in blue cap): _____ mL	
If applicable, specimen number of residual plasma aliquot (last four digits): _____	
Buffy coat last four digits of specimen number: _____	
Buffy coat volume: _____	_____ mL
Original blood volume drawn: _____ mL	
Time aliquots placed in freezer: _____	_____ [HHMM]
Storage temperature in freezer: _____ °C	
Notes: _____	



Appendix D: Saliva Sample and Shipment Notification Form



Appendix D



Site ID: _____ Participant ID: _____
Saliva Sample and Shipment Notification Form
Please email or fax this from prior to the date of shipment.

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

General Information:

UPS tracking #: _____

From: _____

Date: _____

Phone: _____

Email: _____

Study: ACAD GUID: _____

Specimen
Label:

Specimen Label

Visit(circle one): V01 V02

Sex: ☐ M ☐ F

Year of Birth: _____

Saliva Collection:

- | | | |
|---------------------------|-------|----------|
| 1. Date collected: | _____ | [MMDDYY] |
| 2. Time of collection: | _____ | [HHMM] |
| 3. Last date subject ate: | _____ | [MMDDYY] |
| 4. Last time subject ate: | _____ | [HHMM] |

Internal NCRAD Use-Do Not Complete:

Saliva Volume: _____ ml

Notes: