ACAD Manual of Procedures Update: Version 2.3

Section	Change
Document Footer	The version date was updated for this amendment.
Title Page	Title page updated to reflect version change.
Throughout document	1. Added Alternate Text to all graphics and removed most text boxes for ADA accessibility. 2. Updated NCRAD website links. 3. Updated NCRAD logo and document theme. 4. Updated kit contents, procedures, schematic, and graphics to reflect addition of 5 mL SST tube. 5. SST (Gold-Top) Collection Tube (5mL) recommended first in the draw order. 6. Removed redundant notes. 7. Removed wording.
Section 3.4 and 3.5	Section 3.4 and 3.5 combined.
Section 6.1	1. Added small frozen blood shipping kit option. 2. Added note regarding pre-etched cryovials and their kit number assignments.
Section 7.4	1. Added section to accommodate the collection of Serum. a. Serum is 1st in the draw order.
Section 7.5	EDTA (Purple-Top) Blood Collection and Processing Procedures section changed from 7.4 to 7.5.
Section 9.1	Moved step 13 to step 1 for clarity.
Appendices	1. Updated to include serum collection and new NCRAD logo. 2. Added coordinator name and email.

Asian Cohort for Alzheimer's Disease

in collaboration with the

National Centralized Repository for Alzheimer's Disease and Related Dementias

Biospecimen Collection, Processing, and Shipment Manual of Procedures

Version 2.3
April 2025

Table of Contents

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
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
SST	Serum Separator Tube
UPS	United Parcel Service

2.0 Purpose

The collection of 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 biological samples for ACAD study visits. It includes instructions for biospecimen submission to NCRAD located in Indianapolis at Indiana University.

Sites will collect and send the following samples to NCRAD:

- Serum
- 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 specimens being provided to NCRAD for the ACAD protocol.

3.0 NCRAD Information

3.1 NCRAD Contacts

Tatiana Foroud, PhD, NCRAD Principal Investigator
Phone: 317-274-2218

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

Michael Edler, Laboratory Manager
Phone: 317-278-2209
Email: mcedler@iu.edu

Zoë McManus, BA, CCRP, Study Coordinator
Phone: (317) 278-9086
Email: zdpotter@iu.edu

General NCRAD Contact Information
Phone: 1-800-526-2839 or 317-278-8413
Email: alzstudy@iu.edu
Website: https://ncrad.org
ACAD Study Specific Webpage:
NCRAD - The ACAD Active Study Page

3.2 Sample Shipment Mailing Address

NCRAD
Indiana University School of Medicine
351 West 10th Street
TK-217
Indianapolis, IN 46202
alzstudy@iu.edu

3.3 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 from US sites and **Monday-Tuesday** only from Canadian or other international sites.

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.

3.4 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 (observed)
July 4	Independence Day (observed)
1st Monday in September	Labor Day
4th Thursday in November	Thanksgiving
4th Friday in November	Friday after Thanksgiving
December 25	Christmas 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:** NCRAD - Holiday Closures **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 Globally Unique Identifier (GUID)

The GUID is a participant 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 participant at birth
   - If the participant has a middle name
   - Complete legal family (last) name of participant at birth
   - Day of birth
   - Month of birth
   - Year of birth
   - Name of city/municipality in which participant was born
   - Country of birth

5.0 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
- Pelleted dry ice

Remote Blood Collections:

- Cold pack chilled at 4°C
- Paper towel to wrap ice pack

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 x g with refrigeration to 4°C
- -80°C Freezer

In order to ship specimens, you must provide:

- Pelleted dry ice (about approximately 45 lbs. per shipment)

5.2 Biospecimens 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.

5.2.1 Blood-Based Biomarker Collection Schedule

	All Visits
Serum	X
Plasma	X
DNA	X

Whole blood is collected in two different tube types: (1) Serum Separator (Gold-Top) Blood Collection Tube (5 mL) and (2) EDTA (Purple-Top) Blood Collection Tubes (10 mL). The (1) 5mL Gold-Top SST is processed locally into serum fractions then aliquoted, frozen at the study site and shipped to NCRAD. The (2) 10 mL Purple-Top EDTAs are processed locally into plasma and buffy coat fractions then aliquoted, frozen at the study site and shipped to NCRAD.

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 serum	**Serum Separator (Gold-Top) Blood Collection Tube (5 mL)**	1	**N/A**	**N/A**	**N/A**
	SERUM: 2.0 mL cryovials	2	1.5 mL serum aliquot per 2.0 mL cryovial (red-cap and blue-cap residual)	**2**	**Frozen**
Whole blood for isolation of plasma & buffy coat (for DNA extraction)	**EDTA (Purple-Top) Blood Collection Tube (2 x 10 mL)**	2	**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)	7	1.5 mL plasma aliquot per 2.0 mL cryovial (purple-caps and blue-cap residual)	**7**	**Frozen**
	BUFFY COAT: 2.0 mL cryovial	2	1.0 mL buffy coat aliquot per 2.0 mL cryovial (gray-cap)	**2**	**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 pelleted dry ice and equipment supplies listed in Section 5.1). The provided materials include blood tubes,

pipettes, boxes for serum/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.***

Notice: Each ACAD Blood-Based Kit includes cryovials with pre-etched barcodes that are pre-assigned to the kit number on the cryobox/labels included in the kit. Do not mix up the cryovials with other kits.

Blood-Based Kit

Quantity	ACAD Blood-Based Kit Components
1	Serum Separator (Gold-Top) Blood Collection Tube (5 mL) *(BD367986)*
2	EDTA (Purple-Top) Blood Collection Tube (10 mL) *(BD366643)*
1	Cryovial (2.0 mL) with red-cap *for serum*
6	Cryovial (2.0 mL) with purple-cap *for plasma*
2	Cryovial (2.0 mL) with blue-cap *for residual serum or plasma*
2	Cryovial (2.0 mL) with gray-cap *for buffy coat*
1	15 ml conical polypropylene tube (orange cap)
3	Disposable graduated transfer pipette (3.0 mL)
3	Pre-printed Collection Tube Label
11	Pre-printed Cryovial Label
3	Pre-printed Kit Number Label
4	Label for handwritten PTID
1	Resealable bag
1	48-slot Cryovial box

Blood-Based Supplemental Kit

Quantity	ACAD Blood-Based Supplemental Kit Components
5	Serum Separator (Gold-Top) Blood Collection Tube (5 mL)
10	EDTA (Purple-Top) Blood Collection Tube (10 mL)
10	Cryovial (2.0 mL) with red-cap *for serum*
30	Cryovial (2.0 mL) with purple-cap *for plasma*
5	Cryovial (2.0 mL) with blue-cap *for residual serum or plasma*
10	Cryovial (2.0 mL) with gray-cap *for buffy coat*
5	15 ml conical polypropylene tube (orange cap)
10	Disposable graduated transfer pipette (3.0 mL)
10	Label for handwritten PTID
1	Resealable bag

1	48-slot Cryovial box

Frozen Blood Shipping Kits

Quantity	ACAD Frozen Blood Shipping Kit (LARGE)
8	Plastic Biohazard bag with absorbent sheet (small)
1	Shipping box/Styrofoam container (large)
1	UN3373 Sticker
1	UPS Blue Dry Ice Sticker
1	Fragile Label
1	UPS Airbill Sleeve

Quantity	ACAD Frozen Blood Shipping Kit (SMALL)
2	Plastic Biohazard bag with absorbent sheet (small)
1	Shipping box/Styrofoam container (small)
1	UN3373 Sticker
1	UPS Blue Dry Ice Sticker
1	Fragile Label
1	UPS Airbill Sleeve
1	Resealable bag

Quantity	ACAD Frozen Blood Shipping Kit (International Sites)
10	Plastic Biohazard bag with absorbent sheet (small)
1	UN3373 Sticker
1	UPS Blue Dry Ice Sticker
1	UN1845 Class 9 Dry Ice Label (B&W)
1	Fragile Label

Individual Supplies

Quantities	Items Available upon request within the NCRAD kit module.
By Request	Serum Separator (Gold-Top) Blood Collection Tube (5 mL)
By Request	EDTA (Purple-Top) Blood Collection Tube (10 mL)
By Request	Cryovial (2.0 mL) with red-cap *for serum*
By Request	Cryovial (2.0 mL) with purple-cap *for plasma*
By Request	Cryovial (2.0 mL) with blue-cap *for residual serum or plasma*
By Request	Cryovial (2.0 mL) with gray-cap *for buffy coat*
By Request	15 ml conical polypropylene tube (orange cap)
By Request	Disposable graduated transfer pipette (3.0 mL)
By Request	Label for handwritten PTID
By Request	48-slot Cryovial box
By Request	Shipping container for dry ice shipment (shipping and Styrofoam box)
By Request	Plastic biohazard bag with absorbent sheet (small)
By Request	UPS Airbill Sleeve
By Request	UN3373 Label

By Request	Fragile Label
By Request	UPS Blue Dry Ice Sticker
By Request	UN1845 Class 9 Dry Ice Label (B&W)
By Request	Fine point permanent markers
By Request	Cold pack

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 on hand to avoid running out prior to a scheduled study visit. In addition, keep in mind when kits on hand expire so you are prepared for study visits. Please go to https://redcap.link/acadU19 and follow the prompts to request the desired kits and/or extra supplies.
Please allow **THREE** weeks for kit orders to be processed and delivered.
Due to ongoing supply limitations, we ask that you please only order as many kits and extra supplies that you will be able to use in the next 30 days. Doing so allows us to fulfill as many kit requests as possible without depleting stock for other kit requests in our queue. If we are not able to fulfill any part of your request due to supplies being out of stock, we will reach out about those individually.

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. **Please note that the centrifuge may take 30 minutes to cool, so please plan accordingly.**

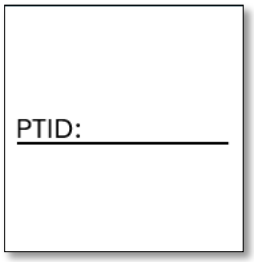
SPECIFIC INSTRUCTIONS FOR COLLECTION AND PROCESSING OF EACH SAMPLE ARE DETAILED ON THE FOLLOWING PAGES.

7.1 Labeling Samples

Label Type Summary:

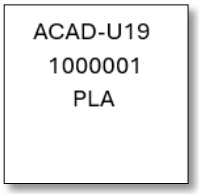
1. Kit Number Label
2. PTID Label
3. Collection Tube Label
4. Cryovial Label

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.



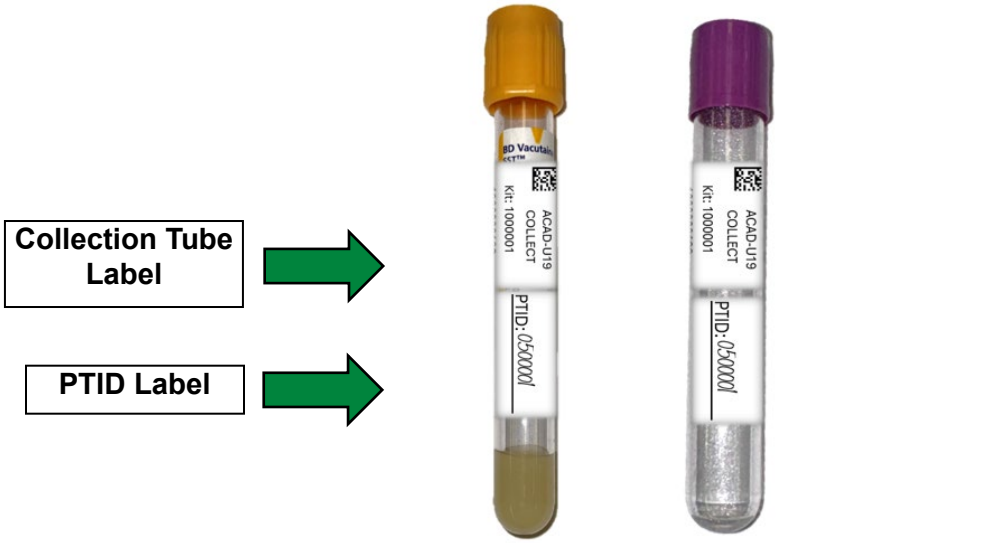
The **PTID Labels** are used to document the individual's unique PTID. Place one label on each blood collection tube.

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



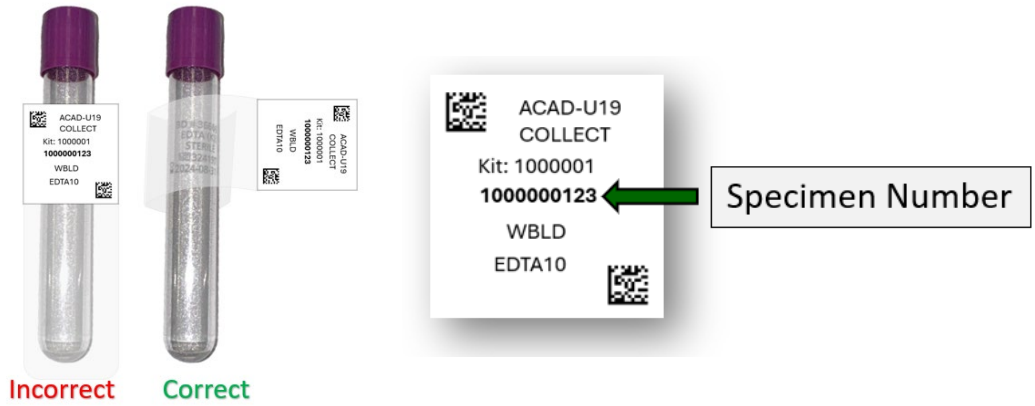
Place one **Cryovial Label** on each cryovial.

<u>Important Note</u>: **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.

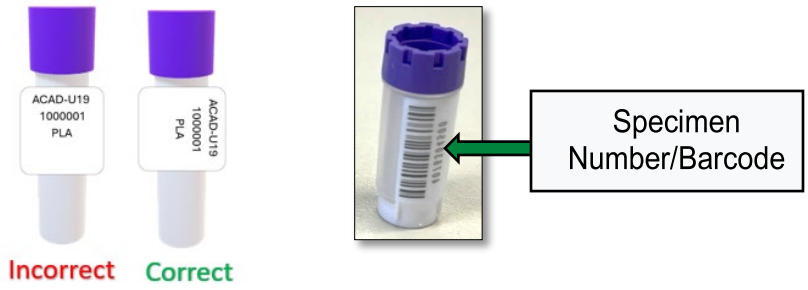


In order to ensure the label adheres properly and remains on the tube, please follow these instructions:

- Place Cryovial Labels on **ALL** cryovials and place Collection Tube Labels on **ALL** collection tubes **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.
- Using a fine point permanent marker, fill-in and place the PTID Labels on the collection tubes only (SST and EDTAs) **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 2D barcodes on the top left-hand and bottom right-hand side of the label. Place label horizontally on the tube with the barcode toward the tube cap.



- Place Cryovial Labels horizontally on the 2.0 mL cryovial tubes (wrapped around sideways if the tube is upright). Make sure to **NOT** cover the barcode etched on the cryovials.



- 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 (ensure labels are removed) can be saved as part of a supplemental supply at your site or the cryovials can be disposed of per your site's requirements.

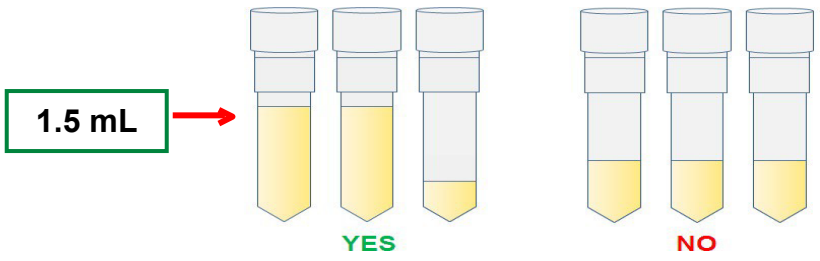
7.2 Video List

The following training videos are available to assist you with the specimen processing, aliquoting, and shipping processes.

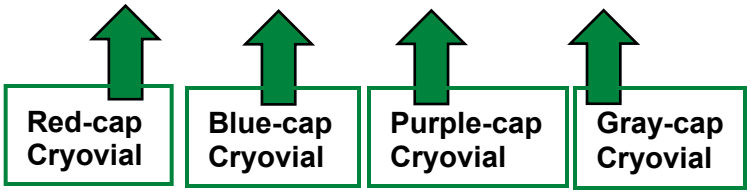
- ACAD MOP Training
- Blood Processing and Aliquoting - Example
  - Please note that this video is an example. The processing procedures shown in this video differ from the ACAD U19 protocol. Please follow the processing procedures outlined in this manual.
- Frozen Shipping

7.3 Filling Aliquot Tubes (Serum and 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
Red-cap Cryovial	Serum
Blue-cap Cryovial	Serum or Plasma Residual
Purple-cap Cryovial	Plasma
Gray-cap Cryovial	Buffy Coat

7.4 Serum Separator (Gold-Top) Blood Collection Tube (5 mL) for Serum x 1

Whole Blood Collection for Isolation of Serum: Serum Separator (Gold-Top) Blood Collection Tube (5 mL) (for processing of serum aliquots).

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

1. Set centrifuge to 4°C to pre-chill before use.

2. Place completed PTID Label and pre-printed "SERUM" Collection Tube Label on the gold-top STT tube. Place pre-printed "SERUM" Cryovial Labels on the (1) 2 mL cryovial tubes with red-cap and (1) 2 mL cryovial tube with blue-cap (if necessary, for residual).

3. Using a blood collection set and a holder, collect blood into **Serum Separator (Gold-Top) Blood Collection Tubes (1 x 5 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 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 each 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 5 mL of blood into the tube.
   a. If complications arise during the blood draw, please note the difficulties on the 'Blood Sample and Shipment Notification Form'. Do not attempt to draw an additional SST at this time. Process blood obtained in existing SST tube.
5. **CRITICAL STEP: Immediately after blood collection, gently invert/mix (180 degree turns) the tube 5 times.**

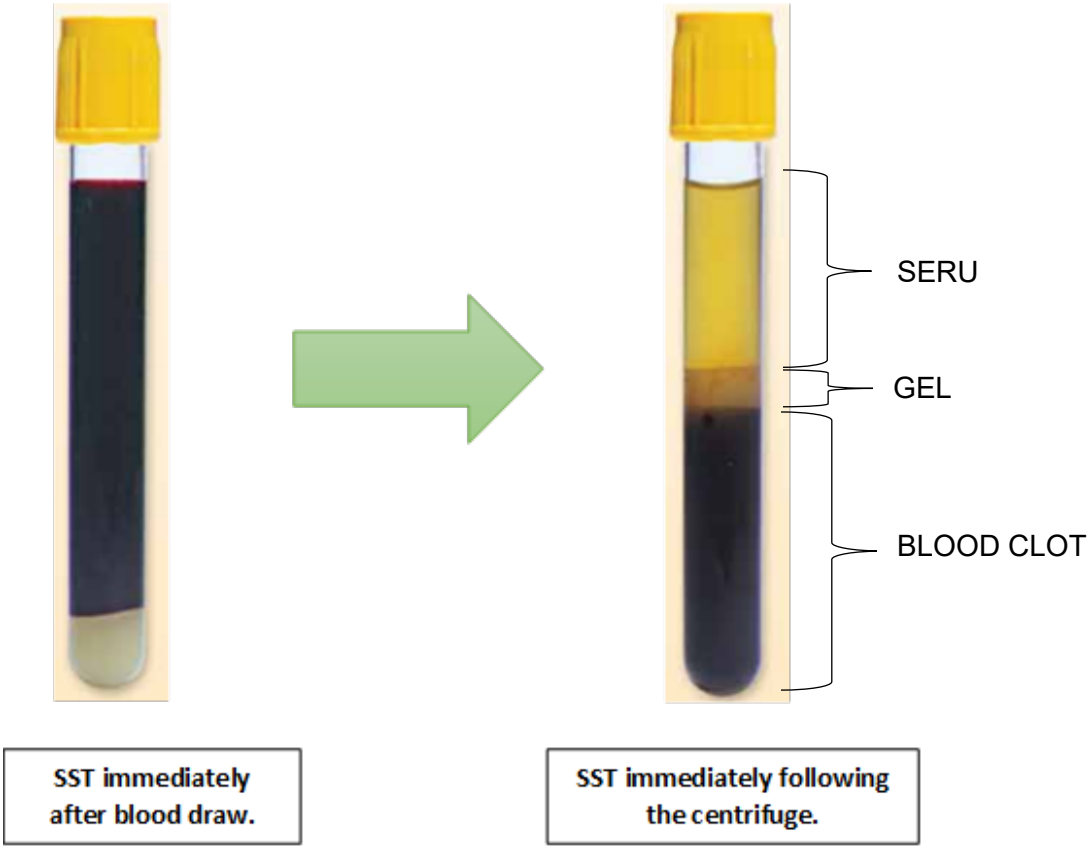
6. **CRITICAL STEP: Allow blood to clot at room temperature by placing it upright in a vertical position in a tube rack for 30 minutes. Serum samples need to be spun, aliquoted, and placed in the freezer within 2 hours from the time of collection.**

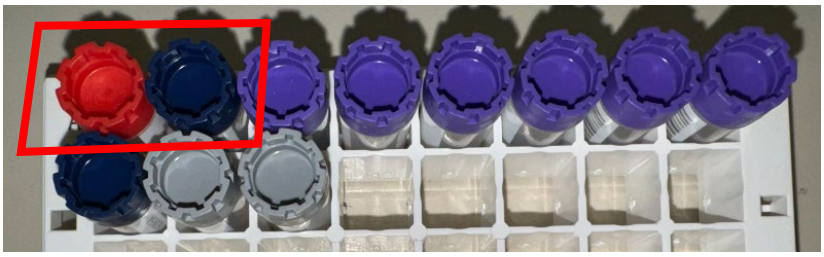
   a. **If remote draw, allow blood to clot at room temperature before placing on 4°C ice pack, upright on rack and transferring to lab for further processing. Please make note on Appendix C if processing takes longer than 2 hours.**

7. After 30 minutes of clotting, centrifuge the collection tubes for 10 minutes at 2000 rcf (x g) at 4°C. **It is critical that the tubes be centrifuged at the appropriate speed and temperature to ensure proper serum 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 Blood Sample and Shipment Notification Form Appendix C.
c. Serum 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 Blood Sample Shipment and Notification Form.

8. Remove the serum by tilting the tube and placing the pipette tip along the lower side of the wall. Transfer serum from Gold-Top Serum Separator tube into the pre-labeled red-cap "SERUM" cryovial. Aliquot 1.5 mL per cryovial (1 total vial with 1.5 mL). One Gold-Top tube should yield, on average, 5 mL of blood serum for a total of (1) aliquot per participant with 1.5 mL per cryovial tube. Be sure to only place **serum** in red-cap cryovial labeled with the "SERUM" Cryovial Label. Place residual serum (<1.5 ml) in the blue-cap cryovial. **If a residual aliquot (<1.5 ml) is created, document the last four digits of the barcode and volume on the Blood Sample and Shipment Notification Form (Appendix C).**





Serum Aliquots (2 possible)

9. Place the labeled cryovial(s) in the 48-slot cryovial box 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.

10. Dispose of collection tube with gel matrix and red blood cells at the bottom of the tube according to your site's guidelines for disposing of biomedical waste.

Serum Separator (Gold-Top) Blood Collection Tube (5 mL) for Serum x 1

Step 1

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

Step 2

- Collect blood in (1) 5 mL Gold-Top tube, allowing blood to flow for 10 seconds and ensure blood flow has stopped.

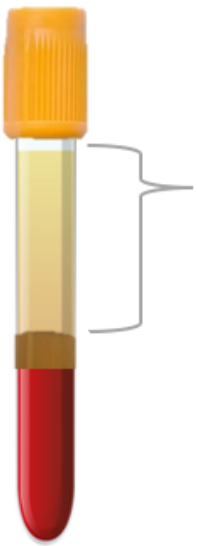
Step 3

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

Step 4

- Allow blood to clot at room temperature by placing it upright in a vertical position in a tube rack for 30 minutes.

Step 5



- Within 2 hours of blood draw, centrifuge samples at 2000 x g at 4°C for 10 minutes.

Step 6

- Using a clean pipette, aliquot 1.5 mL of serum from SST tube to pre-labeled red-cap serum cryovial.
- If residual aliquot is created in pre-labeled blue-cap serum cryovial, document specimen number and volume on sample form.
- Store serum aliquots upright at -80°C until shipment to NCRAD.

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

7.5 EDTA (Purple-Top) Blood Collection Tube (10 mL) for Plasma and Buffy Coat x 2

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

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

1. Set centrifuge to 4°C to pre-chill before use.

2. Place completed PTID Label and pre-printed “PLASMA” Collection Tube Labels on the Purple-Top EDTA tubes. Place pre-printed “PLASMA” Cryovial Labels on the (6) 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 Labels on the (2) 2 mL cryovials with gray lids.
3. Using a blood collection set and a holder, collect blood into the **(2) EDTA (Purple- Top) Blood Collection Tubes (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 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 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 ‘Blood Sample and Shipment Notification Form’ (Appendix C). Do not attempt to draw an additional EDTA tube at this time. Process blood obtained in existing EDTA tube.

5. **CRITICAL STEP: Immediately after blood collection, gently invert/mix (180 degree turns) the EDTA tubes 8-10 times.**

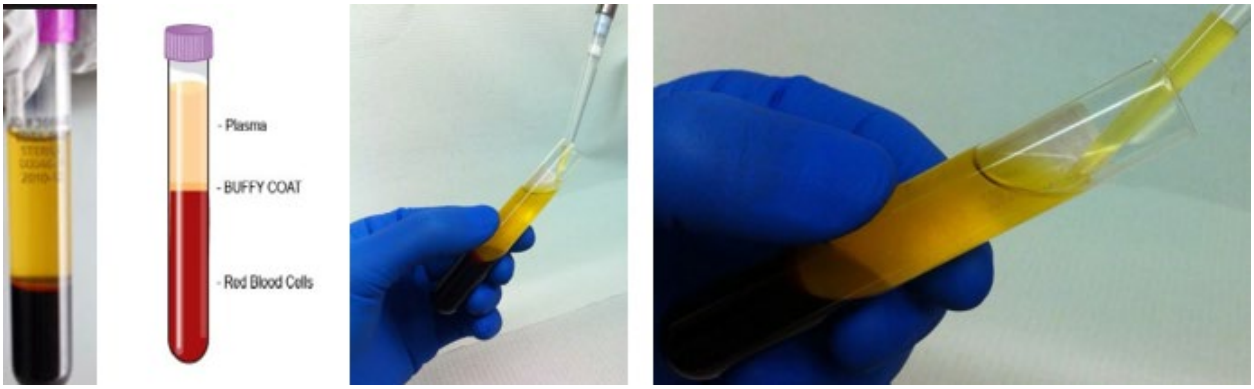
6. **CRITICAL STEP: Immediately after inverting the EDTA tubes, place them on wet ice until centrifugation begins.**
   a. **If remote draw, place tubes on 4°C ice pack until you reach the lab for processing.**

7. Centrifuge balanced tubes for 10 minutes at 2000 rcf (x g) 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 B to calculate RPM.)**

- Equivalent rpm for spin at 2000 x g
- While centrifuging, remember to record all times, temperatures and spin rates on the Blood Sample and Shipment Notification Form.
- Record original volume drawn for each tube in spaces provided on the **Blood Sample Shipment and Notification Form (Appendix C).**
- Plasma samples need to be spun, aliquoted, and placed in the freezer within 2 hours from the time of collection. **If remote draw, place tubes on 4°C ice pack until you reach the lab for processing.**
- Record time aliquoted on the Biological Sample Shipment and Notification Form (Appendix C).

8. 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 buffy coat and packed red blood cells at the bottom of the tube (see below). Transfer plasma from both Purple-Top EDTA tubes into the 15mL conical tube. Mix the plasma by gently inverting the conical tube 3 times.

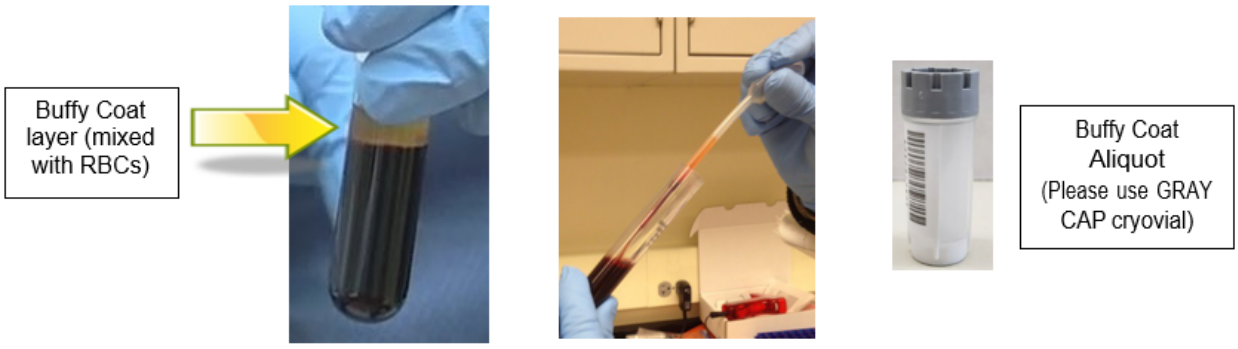
9. Using a pipette, transfer plasma from the 15 mL conical tube into the pre-labeled cryovials labeled "PLASMA" (total vials = up to 6 with 1.5 mL each). Each EDTA tube should yield, on average, 4-5 mL of plasma. Be sure to only place **plasma** in cryovials with purple-caps and labeled with "PLASMA" labels. Take caution not to disturb the red blood cells at the bottom of the tube. If there is extra plasma left, use extra cryovial provided (blue-cap) for another <1.5 mL aliquot of plasma per residual aliquot. **If residual aliquot (<1.5 ml) is created, document the specimen number and volume on the Biological Sample and Shipment Notification Form (Appendix C).**



NOTE: When pipetting plasma from the plasma tubes 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.

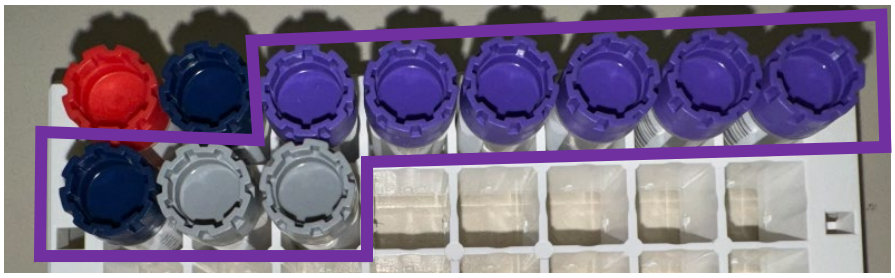
10. Place the labeled cryovials in the cryovial box and place on pelleted dry ice. Transfer to **-80°C Freezer when possible**. Store all samples at **-80°C until shipped** to NCRAD on pelleted dry ice. Record time aliquots placed in freezer and storage temperature of freezer on Biological Sample Shipment and Notification Form (Appendix C).

11. After plasma has been removed from each EDTA (Purple-Top) Blood Collection Tube (10 mL), aliquot buffy coat layer (in the top layer of cells mixed with RBCs - see figure below) into labeled cryovial with gray-cap using a clean pipette. The buffy coat aliquot is expected to have a reddish color from the RBCs. Be sure to place buffy coats into cryovials with the gray-caps and “BUFFY COAT” cryovial labels.



12. Dispose of tubes with red blood cell pellet according to your site’s guidelines for disposing of biomedical waste.

13. Place the labeled cryovials in the 48-slot cryovial box 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 volumes and last four digits of specimen barcode on Blood Sample and Shipment Notification Form (Appendix C).



Plasma Aliquots (up to 7 possible) and Buffy Coat Aliquots (2)

EDTA (Purple-Top) Blood Collection Tube (10 mL) for Plasma and Buffy Coat x 2

Step 1

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

Step 2

- Collect blood in (2) 10 mL Purple-Top tube, allowing blood to flow for 10 seconds and ensure blood flow has stopped.

Step 3

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

Step 4

- Immediately after inverting the EDTA tubes, place them on wet ice until centrifugation begins.
- Within 2 hours of blood draw, centrifuge samples at 2000 x g at 4°C for 10 minutes.

Step 5

- Using a clean pipette, transfer plasma from both 10 mL EDTA tubes into the 15 mL conical tube.
- Mix the plasma by gently inverting the conical tube 3 times.

Step 6

- Using a clean pipette, aliquot 1.5 mL of plasma from the 15 mL conical to pre-labeled purple-cap plasma cryovials.
- If residual aliquot is created in pre-labeled blue-cap plasma cryovial, document specimen number and volume on sample form.
- Store plasma aliquots upright at -80°C until shipment to NCRAD.

Step 7

- Using a clean pipette, transfer each buffy coat layer from EDTA tubes to pre-labeled gray-cap buffy coat cryovials (do not pool buffy coats).
- Store buffy coat aliquots upright at -80°C until shipment to NCRAD.

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

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.

If a blood redraw is not possible, attempt to collect a saliva sample to obtain DNA. 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 'Blood Sample and Shipment Notification Form' within the "Notes" section.
        ii. Complete the 'Blood 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 Frozen Packaging and Shipping Instructions (Blood)

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.

SHIP ALL FROZEN SAMPLES MONDAY - WEDNESDAY ONLY (MONDAY – TUESDAY FOR INTERNATIONAL SITES)!
BE AWARE OF HOLIDAYS!!
BE AWARE OF INCIPIENT INCLEMENT WEATHER THAT MAY DELAY SHIPMENT/DELIVERY OF SAMPLES

Sample Type	Processing/ Aliquoting	Tubes to NCRAD	Ship
Whole blood (Gold-Top SST) for isolation of serum	1.5 mL serum aliquot per 2.0 mL cryovial (red-cap) Residual volume placed in 2.0 mL cryovials (blue-cap)	**Up to 2**	**Frozen**
Whole blood (Purple-Top EDTA) for isolation of plasma & buffy coat (for DNA extraction)	1.5 mL plasma aliquot per 2.0 mL cryovial (purple-cap) Residual volume placed in 2.0 mL cryovials (blue-cap)	**Up to 7**	**Frozen**
	1.0 mL buffy coat aliquot per 2.0 mL cryovial (gray-cap)	**Up to 2**	**Frozen**

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.

Large Frozen Shipper:

** 45 lbs of dry ice pellets

AND

- Fits up to 8 x 48-slot cryoboxes

Small Frozen Shipper:

**10 lbs of dry ice pellets

AND

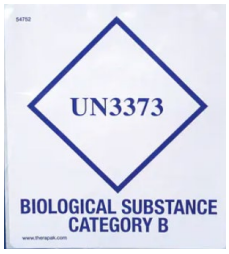
- Fits up to 2 x 48-slot cryoboxes

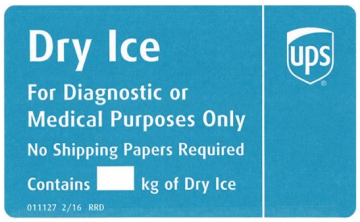
Specimens being shipped to NCRAD should be considered as Category B UN3373 specimens and as such must be tripled packaged and compliant with IATA Packing Instructions 650. *See the Latest Edition of the IATA Regulations for complete documentation.*

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 (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 (within the cryovial box containing the frozen cryovials) 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





9.1 Frozen Packaging Instructions

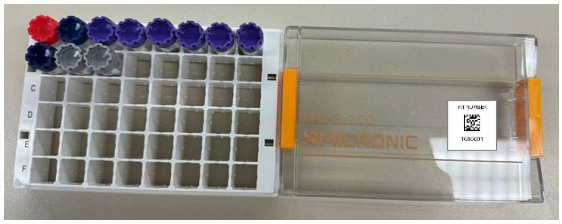
1. On the day of scheduled pick-up, begin packaging specimens on pelleted dry ice **~1 hour before UPS arrives**. Hold samples in -80°C freezer until it is time to package the specimens on pelleted dry ice for shipment. If storage in a -80°C freezer until UPS pick-up is not possible, package shipments no more than 4 hours before the expected pick-up time.
    1. **Important Note:** If shipping samples same day of collection, place samples upright on pelleted dry ice for 2 hours before shipment to ensure samples are completely frozen.

2. Notify NCRAD **IN ADVANCE** of shipment by emailing NCRAD coordinators

at: alzstudy@iu.edu.

1. Attach/include the following to/in the email:
    a. Completed Blood Sample and Shipment Notification Form to the email notification. (See Appendix C for an example of the NCRAD sample form)
    b. Shipment tracking number.
2. 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 frozen labeled aliquots of serum, plasma and buffy coat from the same participant in the cryovial cryobox.
    1. Each cryobox will hold approximately 11 cryovial samples. Place serum, plasma and buffy coat within one cryobox (2 serum, 7 plasma, 2 buffy coat) per participant blood draw (see below):



    2. Cryoboxes should contain all of the specimens from the same participant, per time point.
    3. **Batch shipping should be performed every 3 months or when specimens from 8 participants accumulates, whichever is sooner.**

4. Label the outside of the cryoboxes with the kit number label.

5. Place 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.
    1. See below: Cryobox with serum, plasma, and buffy coat aliquots in biohazard bag with absorbent sheet.

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

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

8. Fully cover the cryoboxes with approximately 2 inches of pelleted dry ice.

9. The inner Styrofoam shipping container must contain approximately 30-45 lbs. (or 21kg) of pelleted dry ice. The pelleted dry ice should fill the inner box entirely to ensure the frozen state of the specimens.

Full Shipping Container with Batched Samples and Dry Ice

10. Replace the lid on the Styrofoam carton. Place the completed Blood Sample and Shipment Notification Forms (Appendix C) in the package on top of the Styrofoam lid for each participant with samples included in the shipment, and close and seal the outer cardboard shipping carton with packing tape.

11. Complete the UPS Dry Ice Label:
    1. Net weight of pelleted dry ice in kg (must match amount on the airbill)
    2. Do not cover any part of this label with other stickers, including pre-printed address labels.

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

12. Apply all provided warning labels (UN3373, Blue UPS Dry Ice, and Fragile Label) and the pre-printed UPS return label to the outside of package, taking care not to overlap labels.

13. Specimens should be sent to the below address via UPS Next Day Air. Frozen shipments should be sent **Monday through Wednesday (Monday through Tuesday for Canadian and other international sites)** to avoid shipping delays on Thursday or Friday. UPS does not replenish pelleted dry ice if shipments are delayed or held over during the weekend.

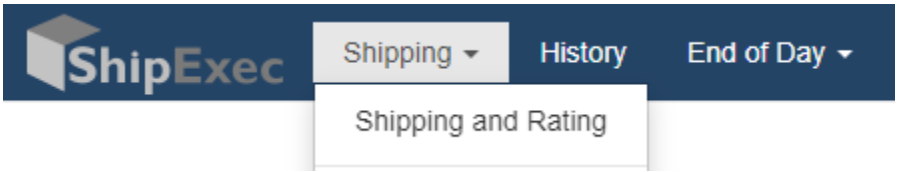
NCRAD
351 West 10th Street TK-217
Indianapolis, IN 46202
Phone: 1-800-526-2839

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

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 pelleted dry ice to avoid thawing in the shipment process.

9.2 Frozen Shipping Instructions

1. Log into the ShipExec™ Thin Client at ShipExec™ Thin Client.
    a. If a new user or contact needs access, please reach out to your study contact for access.



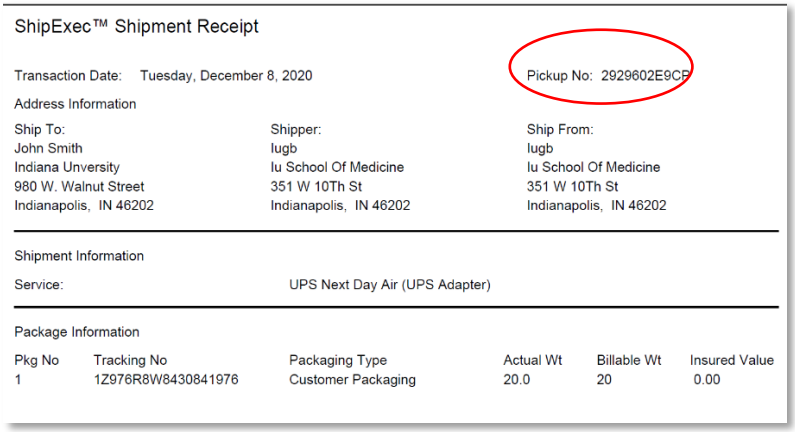
2. Click “Shipping” at the top of the page and select “Shipping and Rating.”
3. Select your study from the “Study Group” drop down on the right side of the main screen. Choosing your study will automatically filter the address book to addresses within your study.
4. Click on the magnifying glass icon in the “Ship From” section to search for your shipping address.

5. bottom right of the screen to re-search for the correct information.
6. Enter Package Information:
   a. 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 re-enter these values.
   b. 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.
   b. Enter the earliest pickup time and latest pickup time in 24-hr format.
      i. Users must schedule pickup **minimum** 1 hour before “Earliest Time Ready.”
         1. “Earliest Time Ready” has to be after current time of day even if scheduling pickup for later date.
      ii. Users will get an error if attempting to schedule pick-up after institution’s closing time.
   c. Give a name & phone number of someone who the UPS driver can call if having issues finding the package.
   d. Give the Floor and Room Number (if needed) where this package needs to be picked up from to be as descriptive as possible.
      i. Room number field is free text, Floor field is numerical only.
   e. Click Save.
8. Click on “Ship” button in the bottom right corner when ready to ship the package.
   a. If you receive an error relating to the pickup request, try again leaving the “Pickup Request” details blank. Call 1-800-PICK-UPS to manually set up a pick-up instead.
9. 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 under the "Action" column.
10. Fold airbill, and place inside plastic UPS sleeve.
11. Peel the back off of the UPS sleeve and stick the sleeve to the package.
12. If "Pickup Request" information was entered, 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.

Note:

- The "Pickup No." is the reference number to your specific pickup request in case there are any issues with your package being picked up by UPS.
- Check Pickup Progress by going to UPS.com, click on the Shipping, select Schedule a Pickup, and look on the right side of screen to click on "Pickup Progress". Enter the Pickup No. listed on the receipt into PRN field and submit.



ShipExec™ Shipment Receipt

Transaction Date: Tuesday, December 8, 2020

Pickup No: 2929602E9CF

Address Information

Ship To:	Shipper:	Ship From:
John Smith	Iugb	Iugb
Indiana Unversity	Iu School Of Medicine	Iu School Of Medicine
980 W. Walnut Street	351 W 10Th St	351 W 10Th St
Indianapolis, IN 46202	Indianapolis, IN 46202	Indianapolis, IN 46202

Shipment Information

Service: UPS Next Day Air (UPS Adapter)

Package Information

Pkg No	Tracking No	Packaging Type	Actual Wt	Billable Wt	Insured Value
1	1Z976R8W8430841976	Customer Packaging	20.0	20	0.00

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 participant 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 DNA extraction	**Oragene Saliva Collection Tube (OG-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 **Saliva Sample and Shipment Notification Form (see Appendix D).** Submit a copy to NCRAD with a reason provided for the omission.

Participants should not ingest anything for **30 minutes before providing a saliva sample.** If participant has ingested any substance, wait for 30 minutes until saliva sample is collected.

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

10.3 Specimen Collection Kits, Shipping Kits, and Supplies

Saliva collection kits and shipping supplies will be provided by the NCRAD. These materials include items listed below. PTID and Collection Tube Labels will also be provided by NCRAD. Collection Tube labels are pre-printed with the study name, specimen number, specimen type, and kit number. 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 necessary supplies to collect samples at each participant visit. 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. Please store all kits at room temperature until use.

Saliva Collection Kit

Quantity	ACAD Saliva Collection Kit Components
1	Oragene Saliva Collection Kit
1	Pre-printed Specimen Label
3	Pre-printed Kit Number Label
1	Label for handwritten PTID
1	Small Saliva Biohazard Bag with absorbent sheet
1	Resealable Kit Bag

Saliva Shipping Kit

Quantity	ACAD Saliva Batch Shipping Kit Components
1	Saliva Shipping Box (holds 36 saliva specimens)
1	Large Biohazard Bag
1	250mL Absorbent Sheet
1	UPS Airbill Sleeve
1	Human Exempt Specimen Label
1	UPS ClinPak
1	Resealable Kit Bag

Quantity	ACAD REMOTE Saliva Shipping Kit Components
1	Large bubble mailer/envelope
1	Small bubble mailer
1	Human Exempt Specimen Label
1	USPS Return Shipping Label
1	Resealable Kit Bag

Individual Supplies

Quantities	Items Available upon request within the NCRAD kit module.
By Request	Oragene Saliva Collection Kit
By Request	PTID Label
By Request	Small Saliva Biohazard Bag with absorbent sheet
By Request	Large Biohazard Bag
By Request	250mL Absorbent Sheet
By Request	Saliva Shipping Box (holds 36 saliva specimens)
By Request	Human Exempt Specimen Label
By Request	UPS ClinPak
By Request	UPS Airbill Sleeve
By Request	USPS Return Shipping Label
By Request	Large bubble mailer/envelope
By Request	Small bubble mailer

10.3.2 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 on hand to avoid running out prior to a scheduled study visit. In addition, keep in mind when kits on hand expire so you are prepared for study visits. Please go to https://redcap.link/acadU19 and follow the prompts to request the desired kits and/or extra supplies.
Please allow **THREE** weeks for kit orders to be processed and delivered. Due to ongoing supply limitations, we ask that you please only order as many kits and extra supplies that you will be able to use in the next 30 days. Doing so allows us to fulfill as many kit requests as possible without depleting stock for other kit requests in our queue. If we are not able to fulfill any part of your request due to supplies being out of stock, we will reach out about those individually.

10.4 Saliva Collection and Processing Procedures

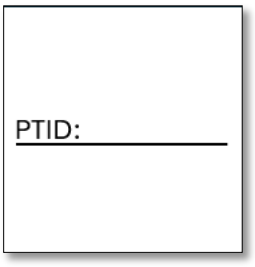
Important Note: In order to ensure the highest quality samples are collected, processed, and stored, it is essential to follow the specific collection, processing, and shipment procedures detailed in the following pages. Please read the following instructions before collecting any specimens. **A minimum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

10.4.1 Labeling Samples

Label Type Summary:

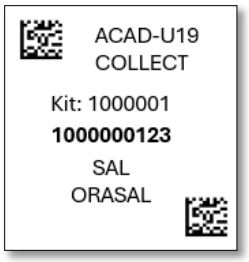
1. PTID Label
2. Kit Number Label
3. Specimen Label

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



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

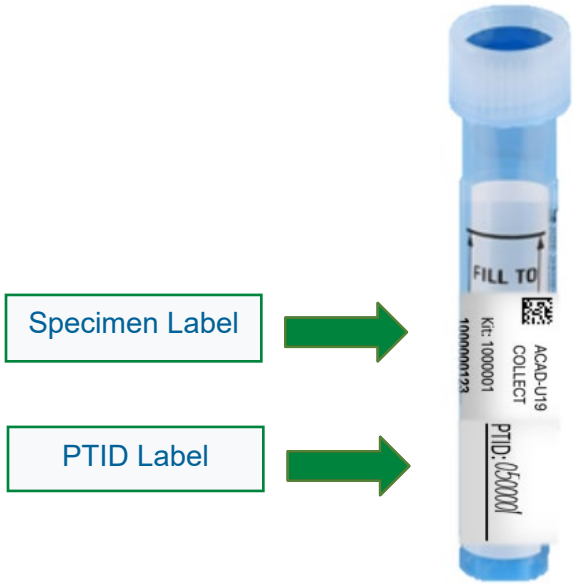
The **Kit Number Labels** do not indicate a specimen type but are affixed on the Saliva Sample and Shipment Notification Forms (Appendix D).



Place one **Specimen Label** on the saliva collection tube. The second, matching Specimen Label should be affixed to the participant's corresponding **Saliva 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.



Labeled Saliva Collection 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 2D barcodes on the top left-hand and bottom right-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.

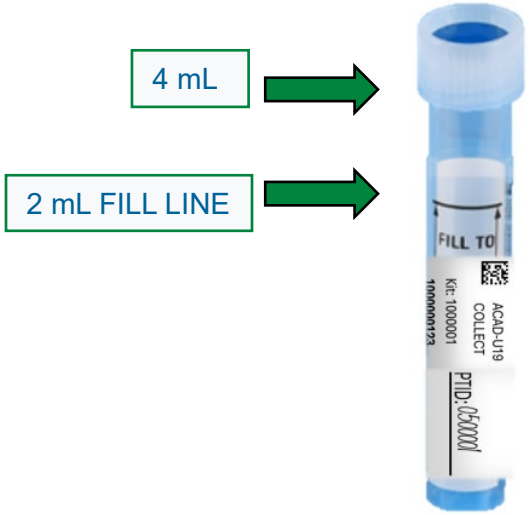
Saliva Tube Labeling

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 and Shipment Notification Form (see Appendix D).**



10.4.4 Saliva Collection Procedure

Saliva Collection for Extraction of DNA: Oragene Collection Tube (4.0 mL)

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

Oragene DNA Collection Kit (OG-500)

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 participant finds it difficult to produce a sample, instruct them to relax and rub their cheeks gently for 30 seconds to generate saliva.
   Some other helpful hints to increase saliva output:
   - Hydrate before collection. Drink at least one large glass of water prior to collection – must be done at least 30 minutes prior to collection (be mindful to explain they should not eat/drink 30 minutes before giving the sample).
   - Smelling appealing aromas, such as citrus fruits, can help with saliva production.
   - Telling participant to take their time filling the tube. Most participants take just a few minutes to complete, but those with dry mouth might need to take longer and should not feel rushed.
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 **Saliva Sample and Shipment Notification Form (see Appendix D).** Place sample into the provided biohazard bag with absorbent sheet. Peel the protective wrapping off to seal the bag. Roll packaging around the tube.

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

bubble mailer for remote draws.

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 Ambient Packaging and Shipping Instructions (Saliva)

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.

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

Packing and Labeling Guidelines:

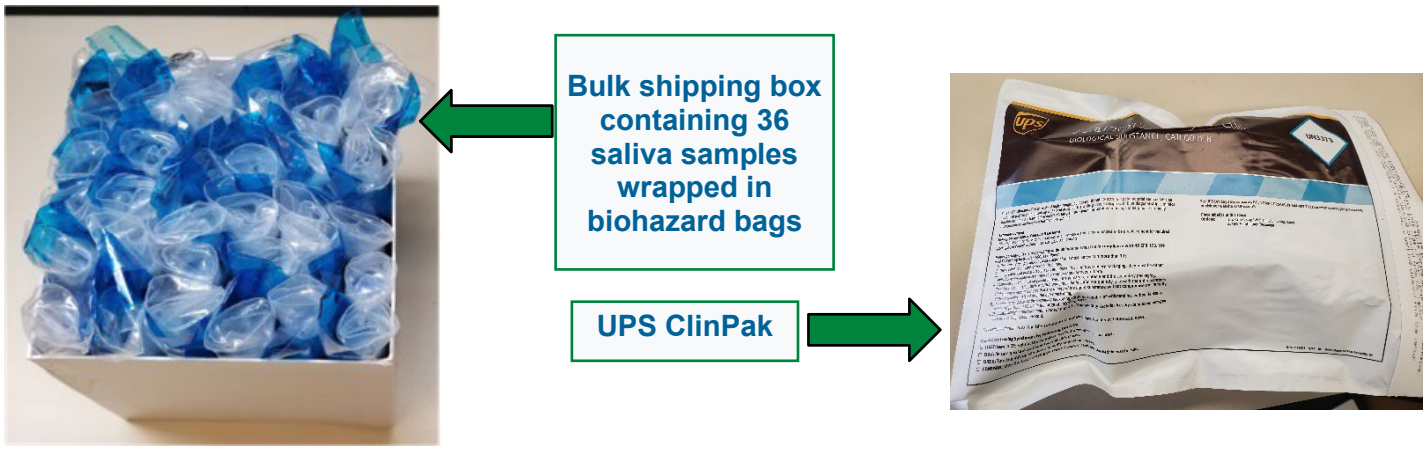
- The primary receptacle (saliva tube) must be leak-proof and in total must not contain more than 4ml of fluid.
- The secondary packaging (bulk shipping box and biohazard bag) must be leak-proof and, if multiple saliva tubes are placed in a single secondary packaging, they must be either individually 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"

DO NOT SHIP SALIVA IN SAME CONTAINER AS BLOOD AS THE SALIVA SHOULD BE AT AMBIENT TEMPERATURE AND NOT FROZEN.

Sample Type	Tube Type	Tubes to NCRAD	Volume	Ship
Saliva for DNA extraction	Oragene Saliva Collection Tube (OG-500)	1	2.0 mL of Saliva collected in each 4.0 mL tube	Ambient

10.5.1 Ambient Packaging Instructions

1. Notify NCRAD of shipment by emailing NCRAD coordinators at: alzstudy@iu.edu.
    a. Attach/include the following to/in the email:
        i. Completed Saliva Sample and Shipment Notification Form to the email notification. (See Appendix D for an example of the NCRAD sample form)
        ii. Shipment tracking number.
    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.
2. Place the completed Saliva Sample and Shipment Notification Form(s) (Appendix D) in the ClinPak (bubble mailer if remote draw).

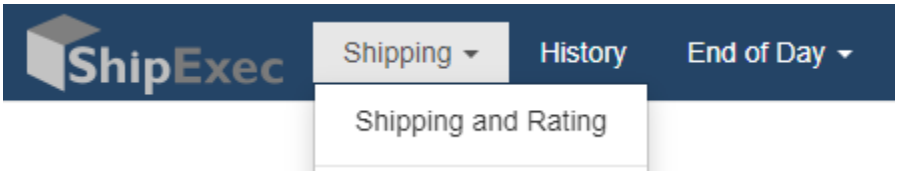


3. Apply all provided warning labels and UPS Airbill (pre-printed USPS Return Shipping Label for remote draws) to the outside of package, taking care not to overlap labels.
4. Use UPS tracking to ensure the delivery occurs as scheduled and is received by NCRAD.
    a. **Note**: The USPS shipping labels provided in Saliva Remote Shipping Kits cannot be tracked.

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.

10.5.2 Ambient Shipping Instructions

1. Log into the ShipExec™ Thin Client at ShipExec™ Thin Client.
    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 addresses within your study.
4. Click on the magnifying glass icon in the “Ship From” section to search for your shipping address.

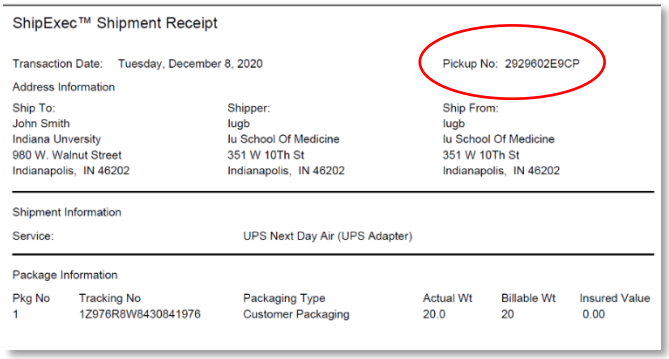
    a. Search by Company (site), Contact (name), or Address 1 (first line of your site’s street address). Click Search.
    b. Click Select to the left of the correct contact information.
5. Verify that both the shipping information AND study reference are correct for this shipment.
    a. If wrong study 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. 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.
        i. Users must schedule pickup **minimum** 1 hour before “Earliest Time Ready.”
            1. “Earliest Time Ready” has to be after current time of day even if scheduling pickup for later date.
        ii. Users will get an error if attempting to schedule pick-up after institution’s closing time.
    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) where this package needs to be picked up from to be as descriptive as possible.
        i. Room number field is free text, Floor field is numerical only.
    d. Click Save.
8. Click on “Ship” button in the bottom right corner when ready to ship the package.
    a. If you receive an error relating to the pickup request, try again leaving the “Pickup Request” details blank. Call 1-800-PICK-UPS to manually set up a pick-up instead.
9. 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 under the “Action” column.
10. Fold airbill, and place inside plastic UPS sleeve.
11. Peel the back off of the UPS sleeve and stick the sleeve to the package.
12. If “Pickup Request” information was entered, 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.

Note:

- The “Pickup No:” is the reference number to your specific pickup request in case there are any issues with your package being picked up by UPS.
- Check Pickup Progress by going to UPS.com, click on the Shipping, select Schedule a Pickup, and look on the right side of screen to click on “Pickup Progress”. Enter in the Pickup No. listed on receipt into PRN field and submit.



ShipExec™ Shipment Receipt

Transaction Date: Tuesday, December 8, 2020

Pickup No: 2929602E9CP

Address Information

Ship To:	Shipper:	Ship From:
John Smith	lugb	lugb
Indiana Unversity	Iu School Of Medicine	Iu School Of Medicine
980 W. Walnut Street	351 W 10Th St	351 W 10Th St
Indianapolis, IN 46202	Indianapolis, IN 46202	Indianapolis, IN 46202

Shipment Information

Service: UPS Next Day Air (UPS Adapter)

Package Information

Pkg No	Tracking No	Packaging Type	Actual Wt	Billable Wt	Insured Value
1	1Z976R8W8430841976	Customer Packaging	20.0	20	0.00

11.0 International Shipping Instructions

1. All international shipments will utilize the same packing requirements as specified in Section 9.0 and Section 10.5 (Frozen and Ambient Shipping Instructions).

2. Two components are necessary for international shipments:
    a. International UPS return airbill.
    b. International Commercial Invoice

3. Follow ShipExec™ Frozen and Ambient Shipping Instructions, **steps 1 – 7**, specified in Section 9.2 and Section 10.5.2.**:**
    a. Once you click 'Ship', the following documents will automatically be created/downloaded:
        i. UPS Package Label
        ii. UPS Commercial Invoice
        iii. ShipExec™ Return Shipment Receipt

4. Open the UPS Commercial Invoice:
    a. Ensure all information is correct.
    b. Fill in the harmonization code (see below example):

Units	U/M	Description of Goods/Part No.	Harm.Code	C/T/O	Unit Value	Total Value
1	PC	Biological Specimens	3002.12.00.90	CA	150	150

        i. Human Serum, Plasma and Buffy Coat: 3002.12.00.90

        i. <u>OR</u>

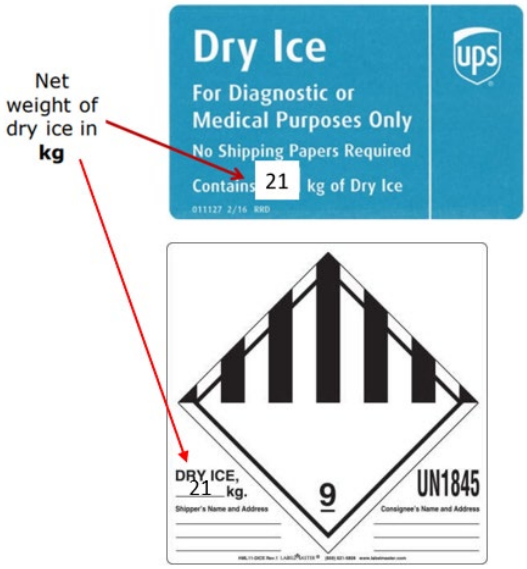
        ii. Human Saliva: 3002.90.90
    c. Enter the following in 'Additional Comments' section:
        i. Reason for export: Medical Research. Samples are for laboratory research purposes only and are not for use in live human nor animal research. Samples are non-dangerous, non-toxic, and non-infectious. Samples not intended for human nor animal consumption. This shipment does not contain animal products or byproducts. I declare that the information mentioned above is true and correct to the best of my knowledge.

5. Print, sign and date **<u>3 copies</u>** of the UPS Commercial Invoice. Fold in half.
    a. Use blue pen only.

6. Print 1 copy of UPS Package Label (airbill). Fold in half.

7. Place airbill on top of 3 completed copies of the commercial invoice. Place papers inside an airbill sleeve and adhere to the shipping box.

8. Important Reminder: Ensure all warning labels are adhered to package and are not covered.
    a. If dry ice Label is covered by other stickers and/or not completed, the shipping carrier will reject/return your package!



i. **Additional Resources:**
    1. UPS International Customer Service Center: 1-800-782-7892
    2. Commercial Invoice How-to Guide

Example Commercial Invoice - International

INVOICE

Page 1

FROM

Tax ID/VAT No.:

Contact Name: [redacted]

[redacted]

Toronto, ON M5T1R8
CA
Phone: [redacted]

Shipment ID: [redacted]

Invoice No.: [redacted]
Date: 12/22/2022
PO No.: ACAD
Terms of Sale(Incoterm):
Reason for Export: P

SHIP TO

Tax ID/VAT No.:
Contact Name: [redacted]

[redacted]

Indianapolis
IN-46202
US
Phone: [redacted]

SOLD TO INFORMATION

Tax ID/VAT No.:
Contact Name: [redacted]

[redacted]

Indianapolis
IN-46202
US
Phone: [redacted]

Units	U/M	Description of Goods/Part No.	Harm.Code	C/T/O	Unit Value	Total Value
1	PC	Biological Specimens	3002.12.00.90	CA	150	150

Additional Comments:
Reason for export: Medical Research. Samples are for laboratory research purposes only and are not for use in live human nor animal research. Samples are non-dangerous, non-toxic, and non-infectious. Samples not intended for human nor animal consumption. This shipment does not contain animal products or byproducts. I declare that the information mentioned above is true and correct to the best of my knowledge.

Declaration Statement:
The exporter of the products covered by this document declares that except where otherwise clearly indicated these products are of EEA preferential origin.

Shipper: Jane Doe Date: 1/5/2023

Invoice Line Total:	150.00
Discount/Rebate:	0.00
Invoice Sub-Total:	150.00
Freight:	0.00
Insurance:	0.00
Other:	0.00
Total Invoice Amount:	150.00 USD
Total Number of Packages:	1
Total Weight:	50 LBS

These items are controlled by the U.S. Government and authorized for export only to country of ultimate destination for use by the ultimate consignee or end-user(s) herein identified. They may not be resold, transferred or otherwise disposed of, to any other country or to any person other than the authorized ultimate consignee or end-user(s), either in their original form or after being incorporated into items, without first obtaining approval from the U.S. government or as authorized by U.S. law and regulations.

12.0 Data Queries and 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.

Low DNA Yield: Request a redraw. If blood redraw is not possible, attempt to redraw saliva sample to obtain DNA.

13.0 Appendices List

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

Appendix B: Rate of Centrifuge Worksheet

Please complete and return this form by email to the NCRAD Project Manager if you have any questions regarding sample processing. The correct RPM will be sent back to you. You can also use online calculators like this one - https://www.sigmaaldrich.com/CA/en/support/calculators-and-apps/g-force-calculator

For this, you will need:
RPM
Radius of rotor – Distance from center to middle of bucket

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 C: Blood Sample and Shipment Notification Form

Appendix C

Site ID: _____ **Participant ID:** _____

Blood Sample and Shipment Notification Form

Please email this form prior to the date of shipment.

To: Zoë McManus **Email:** alzstudy@iu.edu and zdpotter@iu.edu **Phone:** 1-800-526-2839

General Information: _____ **UPS tracking #:** _____

From: _____ **Date:** _____

Phone: _____ **Email:** _____

Study: ☑ ACAD U19 ☐ ADRC ADRC PT ID: _____ (if applicable) ☐ Co-Enrolled in a study other than ADRC

GUID: _____

Sex: M F Year of Birth: _____

Visit (circle number): 1 2 3 4 5

Visit (circle letter): a b c d e

Kit #: KIT LABEL/BARCODE

Blood Collection:

1.Date Drawn: _____ [MMDDYY]	2.Time of Draw: _____ [HHMM]
3.Last date subject ate: _____ [MMDDYY]	4.Last time subject ate: _____ [HHMM]

Blood Processing:

Serum (Gold-Top) Tube (5 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 serum aliquots created (red-cap):	_____
If applicable, volume of residual serum aliquot (less than 1.5 mL in blue cap):	_____ mL
If applicable, specimen number of residual serum aliquot (last four digits):	_ _ _ _
Original blood volume drawn (1 x 5 mL SST collection tube):	_____ mL
Time aliquots placed in freezer:	_____ [HHMM]
Storage temperature in freezer:	_____ °C
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 (purple-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):	_ _ _ _
Original blood volume drawn (2 x 10 mL EDTA collection tube):	EDTA #1: _____ mL EDTA #2: _____ mL
Time aliquots placed in freezer:	_____ [HHMM]
Storage temperature in freezer:	_____ °C
Buffy coat aliquot specimen numbers (last four digits):	Buffy Coat #1: _ _ _ _ Buffy Coat #2: _ _ _ _
Buffy coat volumes (~1.0 mL in gray-cap):	Buffy Coat #1: _____ mL Buffy Coat #2: _____ mL
Notes:	

E.g., hemolysis, blood is coagulated, thick or cloudy plasma, issues with buffy coat collection - please specify, etc.

Version (3.2024)

Appendix D: Saliva Sample and Shipment Notification Form

Appendix D

Site ID: _____ Participant ID: _____

Saliva Sample and Shipment Notification Form

Please email this form prior to the date of shipment.

To: Zoë McManus Email: alzstudy@iu.edu and zdpotter@iu.edu Phone: 1-800-526-2839

General Information: UPS tracking #: _____

From: _____ Date: _____

Phone: _____ Email: _____

Study: ACAD U19 GUID: _____ Specimen Label: KIT LABEL/BARCODE

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:

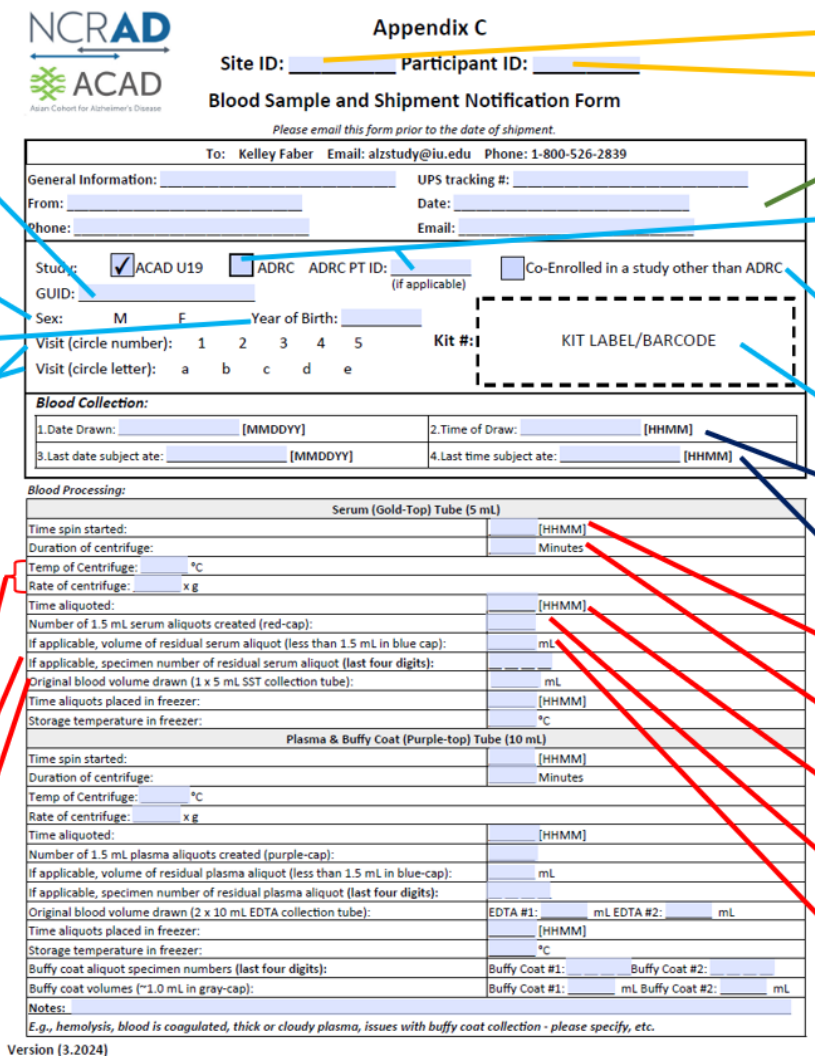
Saliva Volume: _____ mL

Notes:

E.g., incomplete sample, subject ate, drank, smoked, and/or chewed gum 30 minutes or less before giving saliva sample

Version (3.2024)

Appendix E: ACAD Blood Form Guide (Page 1)



NCRAD ACAD

Asian Cohort for Alzheimer's Disease

Appendix C

Site ID: _____ **Participant ID:** _____

Blood Sample and Shipment Notification Form

Please email this form prior to the date of shipment.

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

General Information: _____ UPS tracking #: _____

From: _____ Date: _____

Phone: _____ Email: _____

Study: ☑ ACAD U19 ☐ ADRC ADRC PT ID: _____ (if applicable) ☐ Co-Enrolled in a study other than ADRC

GUID: _____

Sex: M F Year of Birth: _____

Visit (circle number): 1 2 3 4 5 Kit #: KIT LABEL/BARCODE

Visit (circle letter): a b c d e

Blood Collection:

1.Date Drawn: _____ [MMDDYY]	2.Time of Draw: _____ [HHMM]
3.Last date subject ate: _____ [MMDDYY]	4.Last time subject ate: _____ [HHMM]

Blood Processing:

Serum (Gold-Top) Tube (5 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 serum aliquots created (red-cap):	
If applicable, volume of residual serum aliquot (less than 1.5 mL in blue cap):	mL
If applicable, specimen number of residual serum aliquot **(last four digits):**	
Original blood volume drawn (1 x 5 mL SST collection tube):	mL
Time aliquots placed in freezer:	[HHMM]
Storage temperature in freezer:	°C
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 (purple-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):**	
Original blood volume drawn (2 x 10 mL EDTA collection tube):	EDTA #1: _____ mL EDTA #2: _____ mL
Time aliquots placed in freezer:	[HHMM]
Storage temperature in freezer:	°C
Buffy coat aliquot specimen numbers **(last four digits):**	Buffy Coat #1: _____ Buffy Coat #2: _____
Buffy coat volumes (~1.0 mL in gray-cap):	Buffy Coat #1: _____ mL Buffy Coat #2: _____ mL

Notes:

E.g., hemolysis, blood is coagulated, thick or cloudy plasma, issues with buffy coat collection - please specify, etc.

Version (3.2024)

Enter GUID here. (Section 4.0 of MOP)

Check box next to the Participant's Sex (M = Male, F = Female)

Enter the participant's Year of Birth

Circle Visit Number
1 = Year 1 (newly enrolled)
2 = Year 2
3 = Year 3
etc.

Circle Visit Letter
a = First visit of the year
b = Second visit of the year
c = Third visit of the year
etc.

Enter temperature of centrifugation (i.e., 4°C) and rate of centrifugation (i.e., 2000 x g)

Enter the last 4-digits of the residual serum aliquot (if applicable)

Enter the original blood volume drawn in each SST (Gold-Top) Collection Tube (5mL) in mL.

Site ID = 3-digit Site Number

Participant ID = 5-digit Participant Number

Coordinator Contact Information and Sample Tracking Information

If the participant is co-enrolled in the ADRC study, please check the "ADRC" box and fill in the ADRC Patient ID in the "ADRC PT ID" field.

If the ACAD participant is co-enrolled in a study other than ADRC, please check this box.

Place Kit Number label here (Section 7.1 of MOP)

Enter time and date of blood collection in HHMM format.

Enter last date and time participant ate in HHMM format.

Enter time centrifugation started in HHMM format.

Enter duration of centrifugation in minutes (i.e., 10 minutes)

Enter the time the samples were aliquoted in HHMM format.

Enter the number of 1.5 mL serum aliquots that were created.

Enter the volume in mL of the residual serum aliquot (if applicable)

Appendix E: ACAD Blood Form Guide (Page 2)

Appendix C

Site ID: _____ **Participant ID:** _____

Blood Sample and Shipment Notification Form

Please email this form prior to the date of shipment.

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

General Information: _____ UPS tracking #: _____

From: _____ Date: _____

Phone: _____ Email: _____

Study: ☑ ACAD U19 ☐ ADRC ADRC PT ID: _____ (if applicable) ☐ Co-Enrolled in a study other than ADRC

GUID: _____

Sex: M F Year of Birth: _____

Visit (circle number): 1 2 3 4 5 Kit #: KIT LABEL/BARCODE

Visit (circle letter): a b c d e

Blood Collection:

1.Date Drawn: _____ [MMDDYY]	2.Time of Draw: _____ [HHMM]
3.Last date subject ate: _____ [MMDDYY]	4.Last time subject ate: _____ [HHMM]

Blood Processing:

Serum (Gold-Top) Tube (5 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 serum aliquots created (red-cap):	
If applicable, volume of residual serum aliquot (less than 1.5 mL in blue cap):	mL
If applicable, specimen number of residual serum aliquot **(last four digits):**	
Original blood volume drawn (1 x 5 mL SST collection tube):	mL
Time aliquots placed in freezer:	[HHMM]
Storage temperature in freezer:	°C
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 (purple-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):**	
Original blood volume drawn (2 x 10 mL EDTA collection tube):	EDTA #1: mL EDTA #2: mL
Time aliquots placed in freezer:	[HHMM]
Storage temperature in freezer:	°C
Buffy coat aliquot specimen numbers **(last four digits):**	Buffy Coat #1: Buffy Coat #2:
Buffy coat volumes (~1.0 mL in gray-cap):	Buffy Coat #1: mL Buffy Coat #2: mL
Notes:	

E.g., hemolysis, blood is coagulated, thick or cloudy plasma, issues with buffy coat collection - please specify, etc.

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Enter the time the aliquots were placed in the freezer in HHMM format.

Enter the temperature of the freezer the samples are stored in (i.e., -80°C).

Enter the last 4-digits of the buffy coat aliquots (the barcode is etched on the cryovial).

Enter the volume for Buffy Coat #1 and #2, corresponding with the barcodes in the field above.

Buffy Coat #1 was created from EDTA #1 and Buffy Coat #2 was created from EDTA #1.

Enter the original blood volume drawn in each EDTA (Purple-Top) Collection Tube (10mL) in mL.

Enter any non-conformance details here that NCRAD should make note of.