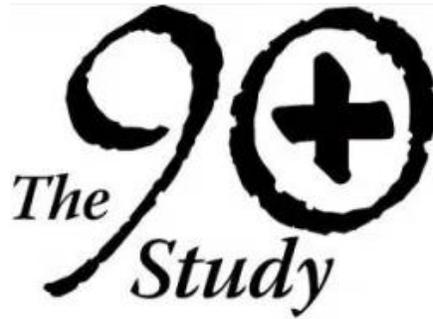


90+ Study Manual of Procedures Update: Version 06.2025

| Section | Change |
|-------------------------------|--|
| Document Footer | The version date was updated for this amendment. |
| Throughout | Updated colors, logos, and other updated changes to format. Minor changes made to phrasing and wording. No alterations to procedures were made unless listed here. |
| 5.2 Kit Supply to Study Sites | Addition of information: Please allow THREE weeks for kit orders to be processed and delivered. |
| 3.3 | Juneteenth and Winter Break holiday added |
| 7.1 | New label examples added |
| | |



in collaboration with

**National Centralized Repository for Alzheimer's
Disease and Related Dementias**



**Biospecimen Collection, Processing, and Shipment
Manual of Procedures**

Version 06.2025

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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 |
| NCRAD | National Centralized Repository for Alzheimer's Disease and Related Dementias |
| PHI | Protected Health Information |
| UPS | United Parcel Service |

2.0 Purpose

The collection of blood-based biofluids is an important part of the 90+ Study. The purpose of this manual is to provide study staff (PIs, study coordinators, phlebotomists) at the study site with instructions for collection and submission of blood-based biological samples for 90+ 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:

- 10ml Whole Blood EDTA tube (2)

OR

- Saliva (for DNA extraction), if not able to collect blood samples ([see Section 9.0](#))

This manual includes instructions for collection of blood, 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 90+ protocol.

3.0 NCRAD information

3.1 NCRAD Contacts

Tatiana Foroud, PhD, Core Leader

Phone: 317-274-2218

Kelley Faber, MS, CCRC, Project Manager

Phone: 317-274-7360

Email: kelfaber@iu.edu

Jeanine Marshall, MPH, CCRP Study Coordinator

Phone: 317-278-8460

Email: jldatzma@iu.edu

General NCRAD Contact Information

Phone: 1-800-526-2839 or 317-278-8413

Email: alzstudy@iu.edu

Website: www.ncrad.org

90+ Study Specific Webpage:

https://ncrad.org/resource_90plus.html

Sample Shipment Mailing address

NCRAD

Indiana University School of Medicine

351 West 10th Street, TK-217

Indianapolis, IN 46202

Phone: 1-800-526-2839

3.2 NCRAD Hours of Operation

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

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

For packaging and shipment details of ambient samples, please refer to [Section 9.5](#) of this protocol.

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

3.3 NCRAD 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 |
| June 19 | Juneteenth |
| 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 |
| December 26-31 | Winter Break |

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.

- 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 Laboratory Collection

4.1 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 (21 gauge) and hub
- Microcentrifuge tube rack
- Sharps bin and lid

4.2 Biospecimens Sent to NCRAD

For packaging and shipment details of ambient samples, please refer to [Section 9.5](#) of this protocol. Guidelines for the processing and timing of sample collection are listed in the tables below.

4.2.1 Biospecimen Collection Schedule

| | Baseline |
|--------------------------------|----------|
| Two 10ml Whole Blood EDTA tube | X |

Whole blood is collected in one type of tube (purple top 10 ml EDTA tube) for shipment to NCRAD. These tubes are shipped ambient 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 participant should be kept on file by the site investigator.

4.2.2 Blood Collection

| Sample Type | Tube Type | Number of Tubes Supplied in Kit | Aliquot Volume | Tubes Sent to NCRAD | Ship |
|--------------------------------|---|---------------------------------|----------------|---------------------|---------|
| Whole blood for DNA extraction | EDTA (Purple-Top) Blood Collection Tube (10 ml) | 2 | N/A | 2 | 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 A](#)). Submit a copy to NCRAD with a reason provided for the omission.

5.0 Specimen Collection Kits, Shipping Kits, and Supplies

NCRAD will provide: 1) Blood sample collection kits for research specimens to be stored at NCRAD and the Ambient Blood Shipment Supply Kit and 2) clinical lab supplies (with the exception of equipment supplies listed in [Section 4.1](#)). The provided materials include blood tubes, partially completed shipping labels to send materials to NCRAD and ambient shipping kits. Kit Number Labels, PTID Labels, and Collection Tube Labels will all be provided by NCRAD. Collection Tube 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 6.1](#).

5.1 NCRAD 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. Please keep kit contents in original bag provided by NCRAD so supplies are not mixed together.*

Blood Kit

| Quantity | Blood Kit Components |
|----------|---|
| 2 | EDTA (purple-top) blood collection tube (10 ml) |
| 2 | Preprinted Collection Tube and Aliquot Labels |
| 3 | Preprinted Kit Number Label |
| 3 | Label for handwritten PTID |

NCRAD Ambient Shipping Kit

| Quantity | NCRAD Ambient Shipping Kit Components |
|----------|---|
| 1 | Plastic biohazard bag with absorbent sheet |
| 1 | Small IATA shipping box with insulated cooler |
| 1 | Small refrigerant pack |
| 1 | UN3373 Biological Substance Category B label |
| 1 | List of contents card |
| 1 | UPS Airbill Sleeve |
| 1 | UPS Laboratory Pak |

Individual Supplies

| Quantities | Items Available upon request within the NCRAD kit module |
|------------|--|
| By Request | EDTA (Purple-Top) Blood Collection Tube (10 ml) |
| By Request | Label for handwritten PTID |
| By Request | UN3373 label |
| By Request | Biohazard label |
| By Request | PTID Labels |
| By Request | Plastic biohazard bag with absorbent sheet (small) |
| By Request | UPS Airbill Sleeve |

5.2 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/90+> 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 **THREE weeks** for kit orders to be processed and delivered.

6.0 Blood Collection Procedures

6.1 Labeling Samples

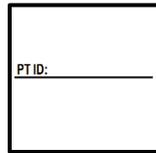
In order to ensure the highest quality samples are collected and stored, it is essential to follow the specific collection and shipment procedures detailed in the following pages. Please read the following instructions first before collecting any specimens. Have all your supplies and equipment out and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

6.1.1 Label Type Summary

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



The **Kit Number Labels** tie together all specimens collected from one participant at one visit. One label should be placed on the Blood Sample and Shipment Notification Form, and on each biohazard bags the blood tubes are in.



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



Place one **Collection Tube Label** on each blood collection tube.

Labeled EDTA (Purple-Top) Blood Collection Tube (10mL)

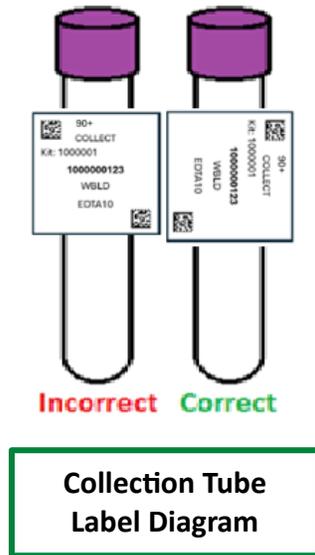


Each collection tube will contain two labels: the collection tube label and the PTID Label. Be sure to place labels in the same configuration consistently among tubes, with the barcoded label near the top of the tube and the handwritten PTID label near the bottom of the tube.

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

- Place Collection Tube Labels on **ALL** tubes **BEFORE** sample collection. This should help to ensure the label properly adheres to the tube before exposure to moisture or different temperatures.
- Using a fine point permanent marker, fill-in and place the PTID Labels on the collection tubes (EDTA) **BEFORE** sample collection. These labels are placed on collection tubes in addition to the Collection Tube Label.

- The Collection Tube Labels contain a 2D barcode on the left hand and bottom right-hand side of the label.
- Take a moment to ensure the label is completely adhered to each tube. It may be helpful to roll the tube between your fingers after applying the label. The following pictures show the correct position of the labels on the collection tubes and cryovials.



6.2 Whole Blood Collection with 10ml EDTA (Purple-Top) Blood Collection Tube (10 ml)

Whole Blood Collection: Two EDTA (Purple-Top) Blood Collection Tube (10 ml) (for processing of buffy coat aliquot for DNA).

1. Store empty EDTA tubes at room temperature, 64°F - 77°F (18 °C – 25 °C) before use. Check expiration dates on all collection tubes before visit.
2. Place completed PTID label and pre-printed Collection Tube Label on the (purple-top) EDTA tubes.
3. Using a blood collection set and a holder, collect blood into the **EDTA (Purple-Top) Blood Collection Tube (10 ml)** using your organization'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 the last collection tube.
 - d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

4. Allow at least 10 seconds for a complete blood draw to take place in each tube. **Ensure that the blood has stopped flowing into the tube before removing the tube from the holder.** The tube with its vacuum is designed to draw 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.
5. **CRITICAL STEP:** Immediately after blood collection, gently invert/mix (180 degree turns) each tube 8-10 times.
5. Ship the (purple top) EDTA blood collection tubes **ambient** to NCRAD the day of the participant visit if possible. For packaging and shipment details of ambient samples, please refer to [Section 9.5](#) of this protocol.
6. Complete Blood Sample and Shipment Notification Form ([Appendix A](#)).

DNA Preparation (10ml Purple Top Tube)



Step One



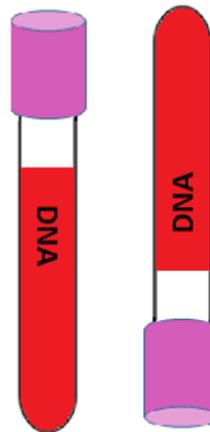
- Store tubes at room temperature.
- Label tubes prior to blood draw.

Step Two



- Collect blood in EDTA Tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



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

Step Four



- Store tubes ambient until shipment
- Send within three days of collection



7.0 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.

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:
 - 1.1. Document difficulties on the 'Biological Sample and Shipmen Notification Form' prior to submission to NCRAD
 - 1.1.1. Indicate blood draw difficulties at the bottom of the 'Biological Sample and Shipment Notification Form' within the "Notes" section.
 - 1.1.2. Complete the 'Biological Sample and Shipment Notification Form' with tube volume approximations.
 - 1.2. Contact a NCRAD coordinator and alert them of the challenging blood draw.
2. If the blood biospecimens at a scheduled visit **are not** collected:
 - 2.1. See Section 10.0 Saliva Collection for instructions on how to collect saliva samples.

8.0 Packaging and Shipping Instructions

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

In addition to tracking and reconciliation of samples, the condition and number of samples received are tracked by NCRAD for each sample type. Investigators and clinical coordinators for each project are responsible to ensure the requested amounts of each fluid are collected to the best of their ability.

8.1 Ambient Packaging Instructions

AMBIENT SAMPLES MUST BE SHIPPED MONDAY-THURSDAY ONLY!

Ambient EDTA (Purple-Top) Blood Collection Tube (10 ml) shipments should be considered as Category B UN3373 and as such must be tripled packaged and compliant

with the IATA Packing Instructions 650. *See the Latest Edition of the IATA Regulations for complete documentation.*

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

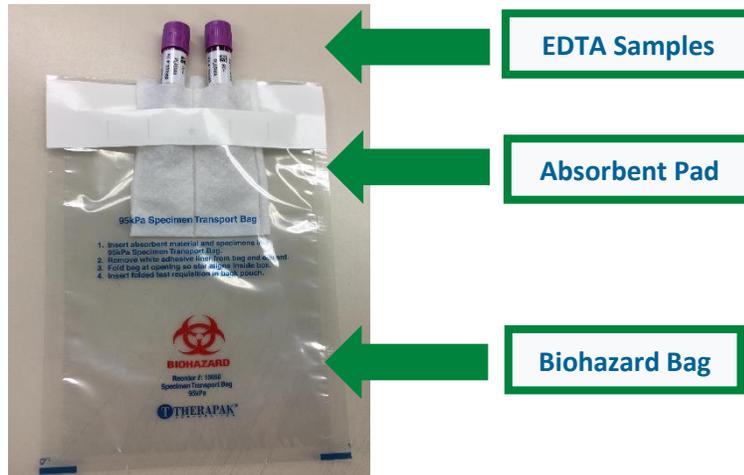
Ambient Shipping Packing and Labeling Guidelines

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

8.1.1 NCRAD Packaging Instructions—Ambient Shipments

1. Place refrigerant pack in the freezer 24 hours prior to shipment.
2. Notify NCRAD of shipment by emailing NCRAD coordinators at: alzstudy@iu.edu
 - a. Complete and attach the Biological Sample and Shipment Notification Form to the email. (See [Appendix A](#) for an example of the form)

- Place filled and labeled EDTA (purple-top) tubes in the biohazard bag with absorbent sheet provided. If absorbent tube sleeve included, place tubes in sleeve slots then place sleeve with tubes in the biohazard bag.

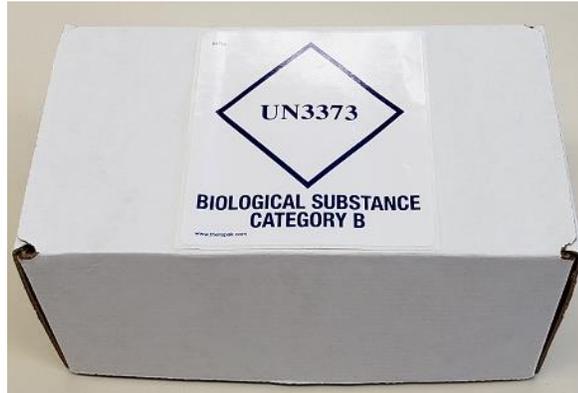


- Remove as much air as possible from the plastic biohazard bag and seal the bag according to the directions printed on the bag. Ensure the kit number label is on the biohazard bag.
- Place the refrigerant pack into the cooler on top of the filled biohazard bag.



- Place the lid onto the cooler.
- Place an extra copy of the Blood Sample and Shipment Notification Form on top of the cooler lid along with a completed list of contents card.
- Close the shipping box. Label the outside of the cardboard box with the enclosed UN3373 (Biological Substance Category B) label.

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



- Place UPS return airbill on the sealed UPS Laboratory Pak.
- Use UPS tracking to ensure the delivery occurs as scheduled and is received by NCRAD.

8.2 Ambient Shipping Instructions

- Log into the ShipExec Thin Client at kits.iu.edu/UPS.
 - If a new user or contact needs access, please reach out to your study contact for access.
- Click "Shipping" at the top of the page



- 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 this study.

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

Ship From

Company

Contact

Address 1

Address 2

Address 3

City

State/Province

Postal Code

Country/Territory

Phone

- Search by Company (site), Contact (name), or Address 1 (first line of your site’s street address). Click Search.
 - Click Select to the left of the correct contact information.
- Verify that both the shipping information AND study reference are correct for this shipment.
 - If wrong study contact or study reference, click Reset in the bottom right of the screen to research for the correct information.
 - Enter Package Information
 - Ambient shipments
 - Enter the total weight of your package in the “Weight” field and leave the “Dry Ice Weight” field empty.
 - Frozen shipments
 - Enter the total weight of your package in the “Weight” field.
 - Enter the dry ice weight in the “Dry Ice Weight” field.
 - If the “Dry Ice Weight” field is higher than the “Weight” field, you will receive an error message and need to reenter these values.
 - Click Ship in the bottom right of the page when complete.
 - If your site does not already have a daily UPS pickup, you can schedule one here.
 - Click the blue Pickup Request button. Enter the earliest pickup time and latest pickup time in 24-hr format.
 - Give a name & phone number of someone who the UPS driver can call if having issues finding the package.
 - Give the Floor and Room Number (if needed) to be as descriptive as possible where this package needs to be picked up from. Click Save.

8. Print the airbill that is automatically downloaded.
 - a. To reprint airbill, click History at the top left of the page.
 - i. Shipments created from the user that day will automatically populate. If shipments from a previous day need to be located, search by ship date.
 - ii. Locate the correct shipment, and click on the printer icon to the left of the tracking number under “Action” to reprint the airbill
 - iii. Click print icon on right side of the tracking number line.
9. Fold airbill, and place inside plastic UPS sleeve.
10. Peel the back off of the UPS sleeve, and stick the sleeve to the package. Ensure that sleeve does not cover any warning labels or overlap taped seams.

9.0 Saliva Collection

9.1 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 9.5](#). Guidelines for the timing of sample collection and storage of samples are detailed in the tables below.

9.2 Biospecimen Collection Chart

| Sample Type | Tube Type | Number of Tubes Supplied in Kit | Tubes to NCRAD | Volume | Ship |
|---|----------------------------------|---------------------------------|----------------|---|---------|
| Saliva for isolation for DNA extraction | Saliva Kit (DNA Genotek) OGR-500 | 1 | 1 | 2.0 ml of Saliva collected in one 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 A](#)). Submit a copy to NCRAD with a reason provided for the omission.

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

If the participant 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 A](#)).

9.3 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 9.5](#)

9.3.1 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.

90+ Saliva Kit

| Quantity | 90+ Saliva Collection Kit Components |
|----------|--------------------------------------|
| 1 | Oragene Saliva Collection Kit |
| 1 | Pre- printed Collection Tube Labels |
| 2 | Pre-printed Kit Number Label |
| 1 | Label for handwritten PTID |
| 1 | Small Saliva Biohazard Bag |
| 1 | Large Resealable Bag |
| 1 | Human Exempt Specimen Label |
| 1 | UPS ClinPak |

Individual Supplies

| Quantity | 90+ 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 | Human Exempt Specimen Label |
| By Request | UPS ClinPak |

9.3.2 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/90+> 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 **THREE weeks** for kit orders to be processed and delivered.

9.4 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.

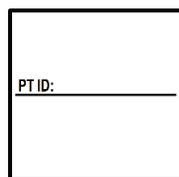
9.4.1 Labeling Samples

1. Kit Number Label
2. PTID Label
3. Collection Tube and Aliquot Label

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



The **Kit Number Labels** tie together all specimens collected from one participant at one visit. One label should be placed on the Blood Sample and Shipment Notification Form, and on each biohazard bags the blood tubes are in.



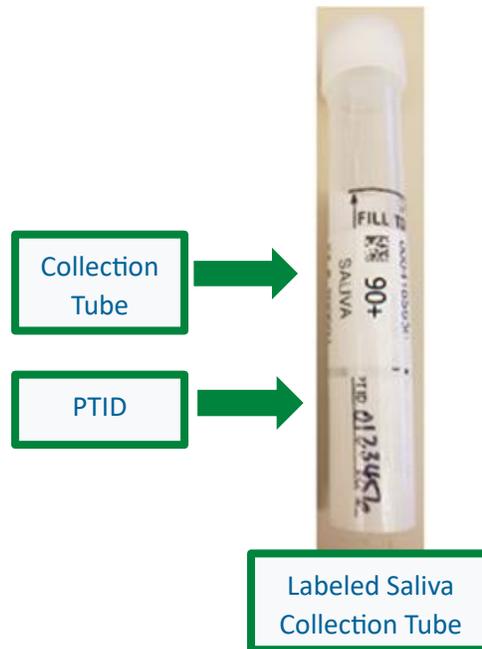
The **PTID Labels** are used to document the individual's unique PTID. Place one label on the saliva collection tube.



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

****Important Note****

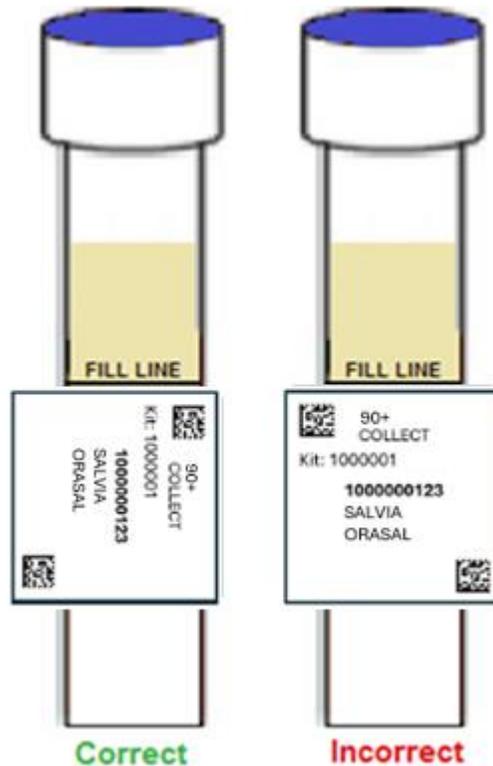
Each collection tube will contain two labels: the Collection Tube Label and the PTID Label. Be sure to place labels in the same configuration, with the Collection Tube Label near the top of the tube and the PTID label at the bottom of the tube.



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.
- Collection Tube 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



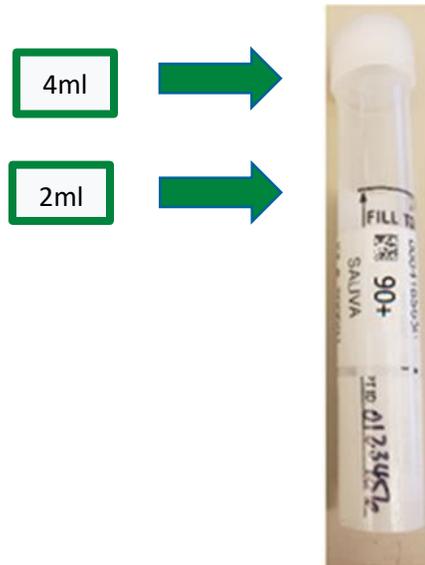
9.4.2 Saliva Collection Video

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

9.4.3 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



9.4.4 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 participant 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 A](#)). Place sample into the provided biohazard bag. Peel the protective wrapping off to seal the bag. Roll packaging around the tube.

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).

9.5 Packaging and Shipping Instructions

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.*

Ambient Shipping 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 (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. 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 A](#) 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. Ensure all ambient, labeled saliva samples, are appropriately packaged (see below).

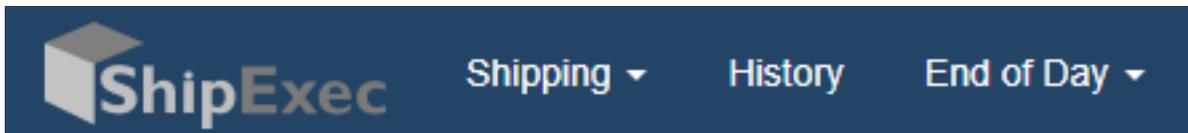


3. Place the completed Biological Sample and Shipment Notification Forms in the ClinPak.
4. Apply all provided warning labels and the pre-printed UPS return label to the outside of package, taking care not to overlap labels.
5. Use UPS tracking to ensure the delivery occurs as scheduled and is received 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.

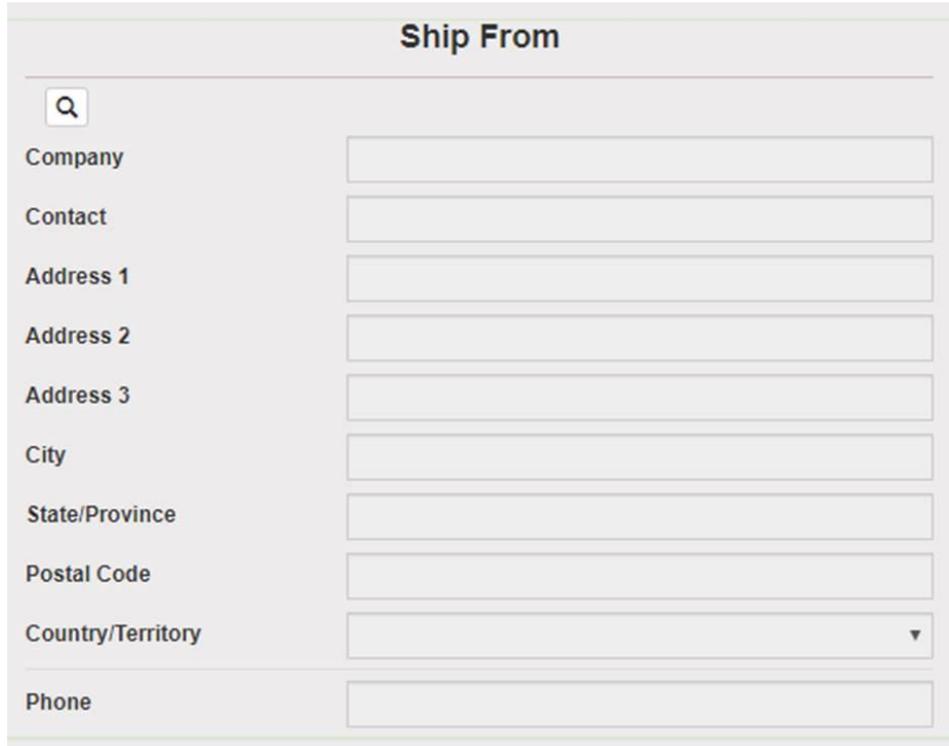
In addition to the tracking and reconciliation of samples, the condition and amount of samples received are recorded for each sample type. Investigators and clinical coordinators at each site are responsible for ensuring the requested amounts of each fluid are collected to the best of their ability and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

9.5.1 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.

10.0 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 study database compared to samples received and logged at NCRAD. Additional discrepancies may be sent directly to the site 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 study database.

11.0 Appendices List

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

Appendix A: Sample and Shipment Notification Form

NCRAD Biological Sample Form

90+ Study

Please complete this form when sending blood to NCRAD. The form can be completed on your computer and submitted electronically by an email attachment or can be completed by hand and faxed. Use the Tab key to move to the next field. The contact information for emailing or faxing the form is in the box below.

Please email or fax the form as soon as possible after the blood is drawn. NCRAD would like to receive this form before the blood arrives.

| | | |
|--|--------------------------|---|
| To: Kelley Faber | FAX: 1-317-321-2003 | Email: alzstudy@iu.edu |
| Phone: 1-800-526-2839 | Phone: 1-317-274-7546 | |
| From: _____ | Site: _____ | |
| Phone: _____ | Fax: _____ | |
| Email: _____ | Date: _____ | |
| Subject #: _____ | | |
| Sex: _____ | | |
| Sample Type Included in Shipment: | | |
| <input type="checkbox"/> Blood in Purple top EDTA Tube <input type="checkbox"/> Saliva in Oragene Collection Kit | | |
| Date sample collected: _____ | | |
| UPS tracking #: _____ | | |
| For internal NCRAD use only, do not complete. | | |
| Specimen Barcodes: | Volume(ml): Purple _____ | |
| | Volume(ml): Purple _____ | |
| | Volume(ml): Saliva _____ | |