

Asian Cohort for Alzheimer's Disease

in collaboration with

The National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD)



Contact Information

Questions?

Please contact NCRAD Coordinators at:

Phone: 1-800-526-2839 or 317-274-7546

• E-mail: <u>alzstudy@iu.edu</u> or <u>wilmesk@iu.edu</u>

• Website: www.ncrad.org





Training Overview

- Blood Collection
 - Blood Collection Schedule
 - Kit Request Module
 - Specimen Labels
 - Handling/Processing Study Specimens
 - Sample Shipping

If not able to collect blood samples for a participant, Saliva can be collected for DNA extraction

- Saliva Collection
 - Saliva Collection Schedule
 - Specimen Labels
 - Handling/Processing Study Specimens
 - Sample Shipping
- NCRAD Website
- Questions?



ACAD Blood-Based Biomarker Collection Schedule

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

Kit Request Module

https://kits.iu.edu/acad





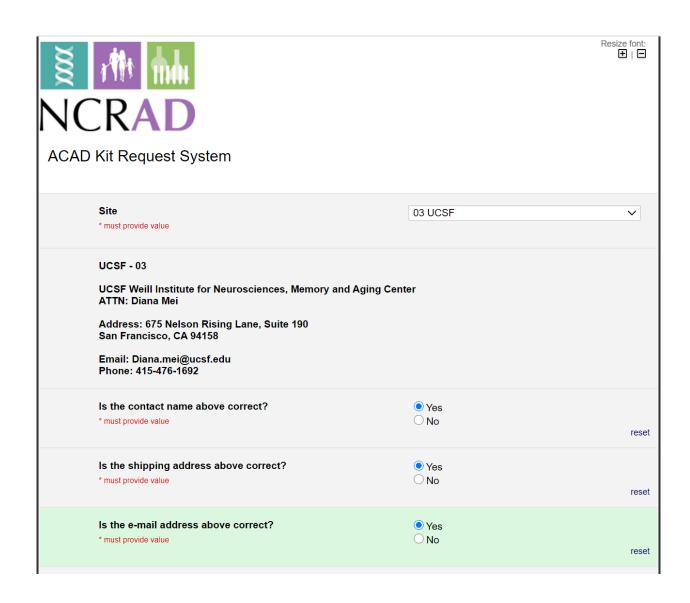
Kit Request Module

- An initial stock of kits will be delivered prior to the designated site-specific start date.
- Kits and individual supplies are available to order:
 - ACAD Blood-Based Kit
 - ACAD Blood-Based Supplemental Supply Kit
 - ACAD Frozen Blood Shipping Supply Kit
 - ACAD Saliva Collection Kit
 - ACAD Saliva Shipping Supply Kit



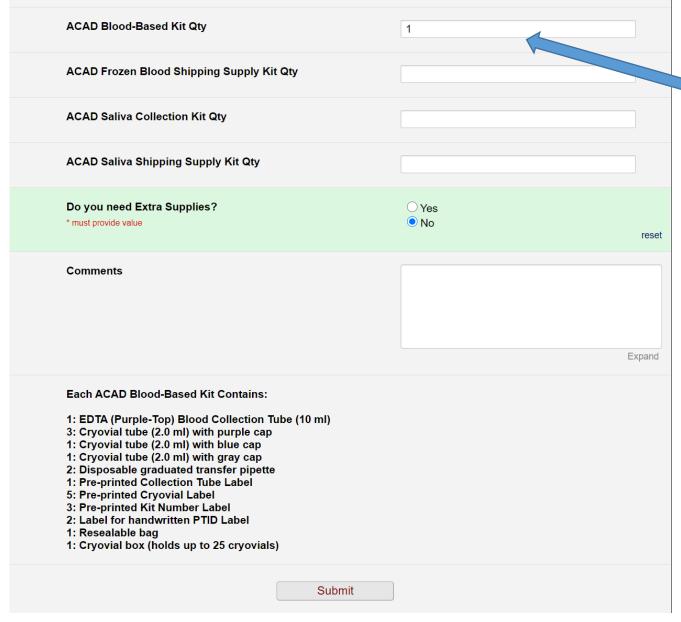
NCRAD Kit Request Module

- 1. Choose your site from the drop-down list
- 2. The coordinator name and contact information will appear
- 3. Verify that this information is accurate, correct if necessary





Study Visit Kits



- Indicate the quantity needed of each kit
- Once selected, kit components of the chosen kit will appear at the bottom of the screen (Pictured)
- Click "Submit" to turn in your request.
- The IU staff will notify you that your request has been received and address any issues.
- **Note: You can order more than one type of kit in a single kit request



NCRAD Kit Request Module: When It Must be Used

 Each site will be responsible for ordering kits (labels included) and maintaining supplies on site for scheduled participants

 To order, sites will use the Indiana University online kit ordering module: https://kits.iu.edu/acad

 Allow a minimum of 2 weeks for your order to be processed and delivered.



Blood Specimen Labels

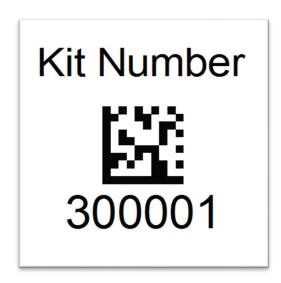




Label Type Summary

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

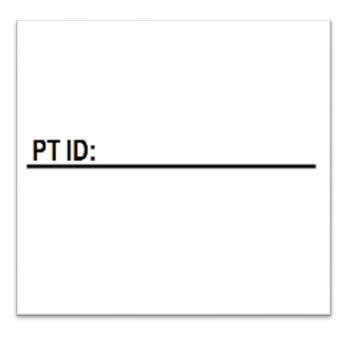
Kit Number Labels



Provided by NCRAD in the kits

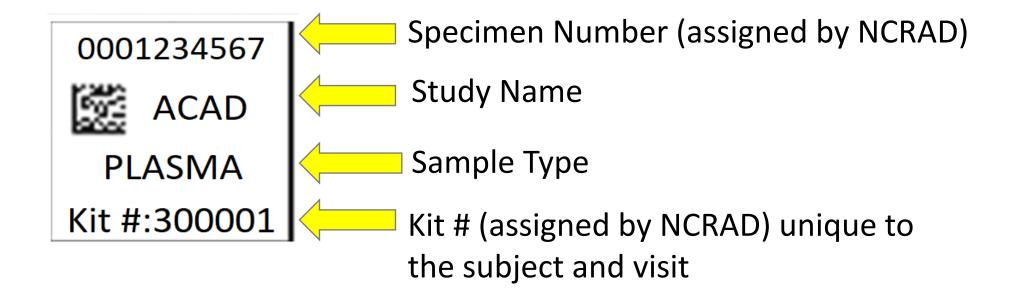
- Used to track patient samples and provide quality assurance
- Will be placed on the following locations:
 - Biological Sample and Shipment Notification Form
 - 2. Outside cryobox that houses aliquot tubes during storage and shipment

PTID Label



- Subjects will be identified by their PTID.
- The PTID may only be available shortly before the visit
- Sites will be responsible for handwriting this onto the provided labels
 - Must use fine point permanent marker
 - Each site will receive 4 markers in initial kit supply
- Write information on label prior to adhering to tube
- Label will be placed on all collection tubes
 - EDTA (Lavender-Top) Blood Collection Tube (10 ml) for DNA and Plasma
- Kits will include one extra label

Collection Tube Labels



Placed on all collection tubes

Cryovial Label

ACAD

Plasma

Kit: 300001

ACAD

Buffy Coat

Kit: 300001

- Only one label to be placed on each cryovial
 - Plasma
 - From EDTA tube
 - Buffy Coat
 - From EDTA tube

Blood Collection Tube

Label 1: Collection Tube Label

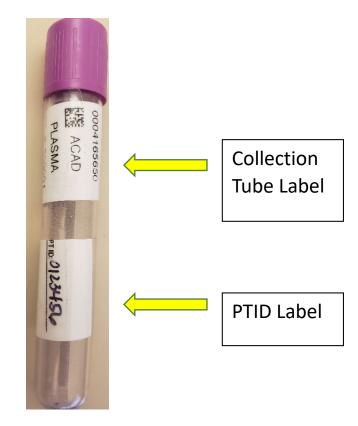


Label 2: PTID Label



All collection tubes will have 2 labels:

- The handwritten PTID label
- The Collection Tube Label

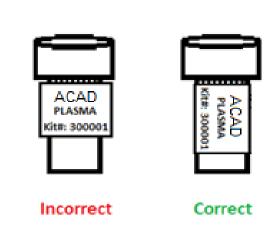


EDTA (Purple-Top) Blood Collection Tube (10 ml)

Labeling NCRAD Cryovials

Please...

- Label all collection and aliquot tubes <u>before</u> cooling, collecting, processing or freezing samples.
- Label only <u>1</u> subject's tubes at a time to avoid mix-ups.
- Wrap the label around the tube <u>horizontally</u>. Label position is important for <u>all</u> tube types.
- Make sure the label is completely adhered by rolling between your fingers.





Handling/Processing Study Blood Specimens



Site Required Equipment

Blood Collection/Safety Equipment

- 1. Personal Protective Equipment (PPE)
 - Lab Coat, Safety Glasses
- 2. Tourniquet
- 3. Alcohol Prep Pad
- 4. Gauze Pad
- 5. Butterfly Needles
- 6. Bandage
- 7. Sharps Bin and Lid

Processing/Storage Equipment

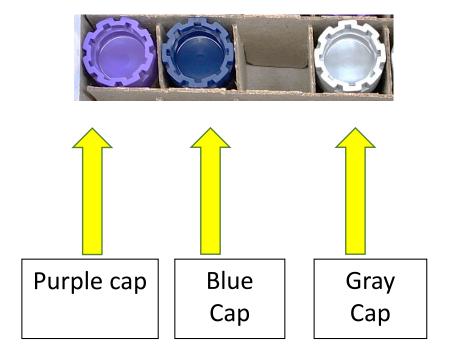
- Centrifuge capable of ≥2000 rcf with refrigeration to 4°C
- 2. -80°C Freezer
- 3. Wet Ice Bucket

Sample Collection - Blood

Tube Type	Number of Tubes Drawn	Tube Image
EDTA (Lavender-Top) Blood Collection Tube (10 ml) for Plasma	x 1	13 366643 ILA (KC), A 12 3616 IL 57 363 IL 57

NCRAD Cryovial Cap Colors

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



Plasma Collection



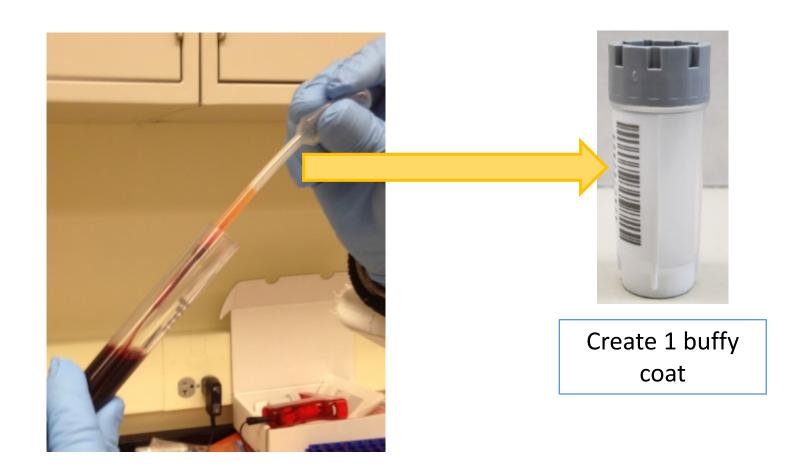




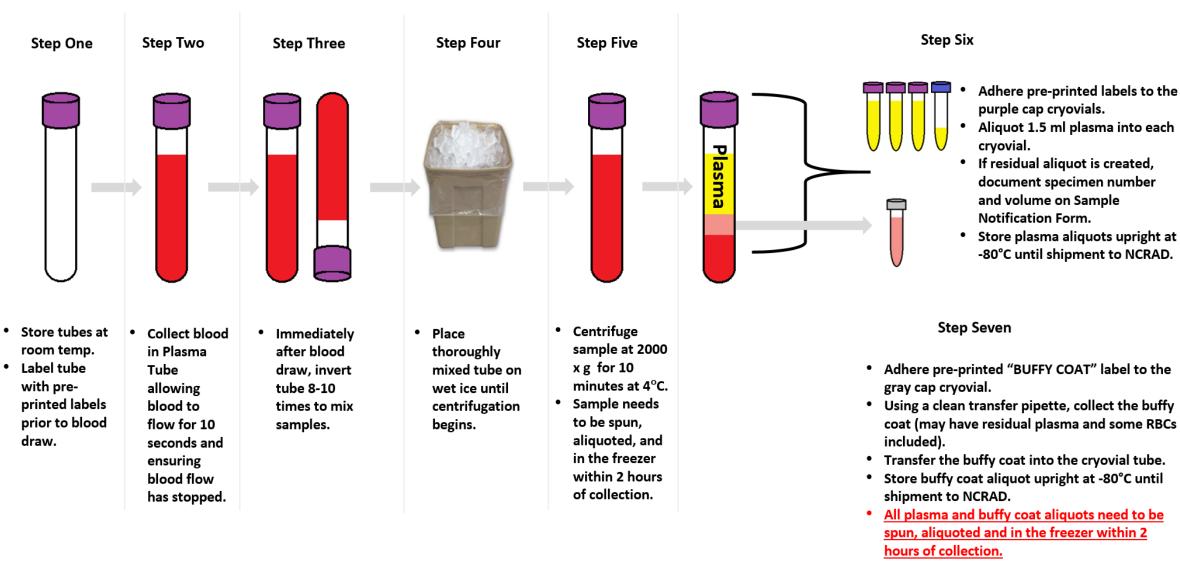
Plasma Aliquots (up to 4 possible) and Buffy Coat (1)

Buffy Coat Collection





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



Blood Sample Shipping



Blood Sample Shipment Summary

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

Frozen Sample Shipping

Ship Monday-Wednesday Only

- Plasma and Buffy Coat
 - Hold packaged samples in a -80°C freezer until pickup.
- Batch Samples together
 - 8 Cryoboxes
 - Batch shipping should be performed every 3 months or as a full shipment of specimens accumulates, whichever is sooner.

Frozen Blood Shipping - Cryoboxes



One cryobox to contain Plasma and Buffy Coat Aliquots



Place kit number label on each cryobox

Frozen Shipping – Dry Ice Requirements

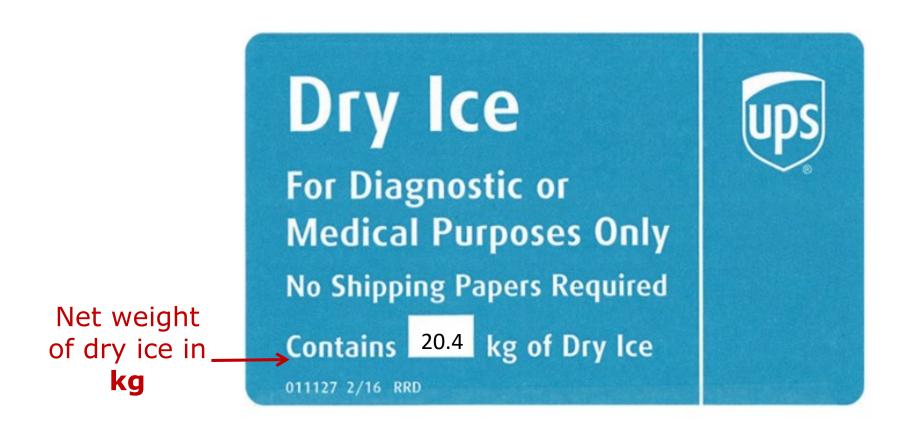


 Fully cover the cryoboxes with about 2 inches of dry ice in the provided shipper.

 Each Styrofoam shipper must contain about 45 lbs (20 kg) of dry ice.

Frozen Shipping – Dry Ice Requirements

Dry Ice label should not be covered with other stickers and must be completed or the shipping carrier will reject/return your package!



Shipping Frozen Samples

- Schedule UPS pickup
- Send Biological Sample and Shipment Notification Form to IU <u>ahead of shipment</u>
 - Email: alzstudy@iu.edu

Blood Sample and Shipment Notification Forms

- A copy of the sample form *must* be emailed to NCRAD prior to the date of sample arrival.
- Please include sample forms in all shipments of frozen and ambient samples.
- Email: <u>alzstudy@iu.edu</u>



Blood Sample and Shipment Notification Form

NCRAD	Appendix C				
ACAD Asian Cohort for Alzheimer's Disease Site ID: Participant ID: Blood Sample and Shipment Notification Form Please email or fax this from prior to the date of shipment.					
To: Kelley Faber Email: <u>alzstud</u> y	<u>y@iu.edu</u> FAX: 317-321-2003 Ph	none: 1-800-526-2	1839		
General Information:	UPS tracking #:				
From:	Date:				
Phone:	Email:				
Study: ACAD GUID:	Kit #:	WIT BARCONE			
Visit (circle one): V01 V02	Visit (circle one): V01 V02				
Sex: M F Year of Birth:					
Jex. Total or birding					
Blood Collection:					
Blood Collection: 1. Date Drawn: [[MMDDYY] 2. Time of Draw: MMDDYY] 4. Last time subject	t ate:	[HHMM]		
Blood Collection: 1. Date Drawn: [I		t ate:			
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Blood Collection: 1. Date Drawn: [I 3. Last time subject ate: [I Blood Processing: Plasma & Buffy Coat (Purple-top) Tube (10 ml Time spin started: Duration of centrifuge: *C Rate of centrifuge: Temp of Centrifuge: *C Rate of centrifuge: Time aliquoted: Number of 1.5 mL plasma aliquots created (lavende if applicable, volume of residual plasma aliquot (les if applicable, specimen number of residual plasma: Buffy coat last four digits of specimen number: Buffy coat volume: Original blood volume drawn: Time aliquots placed in freezer:	MMDDYY) 4. Last time subject L) e: x g er cap): ss than 1.5 mL in blue cap);	[HHMM] HHMMM Minutes (HHMMM) mL mL mL [HHMM]		
Blood Collection: 1. Date Drawn: [1] 3. Last time subject ate: [1] Blood Processing: Plasma & Buffy Coat (Purple-top) Tube (10 ml Time spin started: Duration of centrifuge: Temp of Centrifuge: "C Rate of centrifuge Time aliquoted: Number of 1.5 mL plasma aliquots created (lavende If applicable, volume of residual plasma aliquot (les If applicable, specimen number of residual plasma: Buffy coat last four digits of specimen number: Buffy coat volume: Original blood volume drawn: Time aliquots placed in freezer: Storage temperature in freezer:	MMDDYY) 4. Last time subject L) e: x g er cap): ss than 1.5 mL in blue cap);	[HHMM] HHMMM Minutes (HHMMM) mL mL mL [HHMM]		

Blood collected for:

- Plasma
- DNA

Version (2.2021)

Saliva Sample Collection

If not able to collect blood samples for a participant, Saliva can be collected for DNA extraction



ACAD Saliva-Based Biomarker Collection Schedule

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

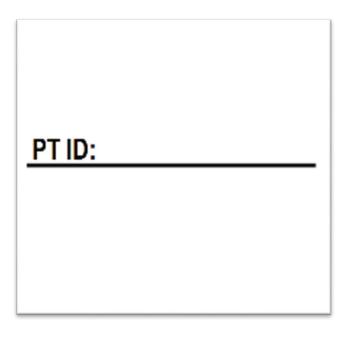
Saliva Specimen Labels



Label Type Summary

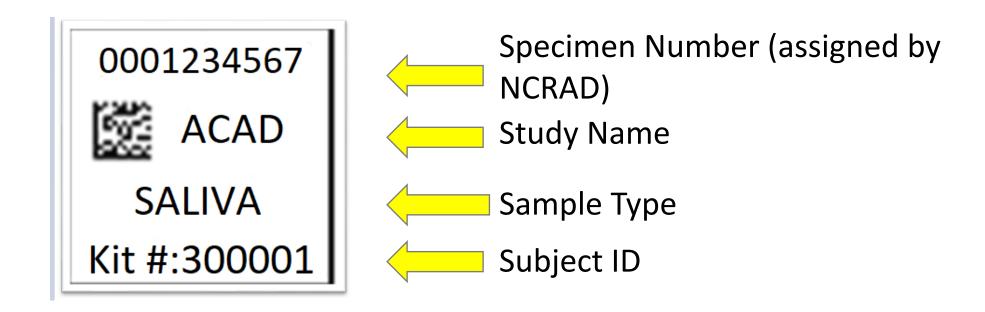
- 1. PTID Label
- 2. Specimen Label

PTID Label



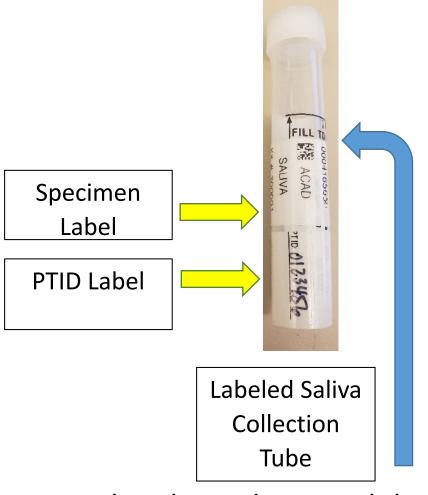
- Subjects will be identified by their PTID.
- The PTID may only be available shortly before the visit
- Sites will be responsible for handwriting this onto the provided labels
 - Must use fine point permanent marker
 - Each site will receive 4 markers in initial kit supply
- Write information on label prior to adhering to tube
- Label will be placed on all collection tubes
 - Saliva Collection Tube
- Kits will include one extra label

Saliva Specimen Labels

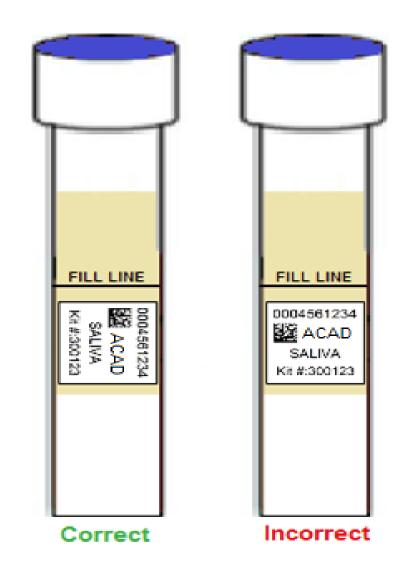


One Specimen Label for each saliva collection tube. The second, matching Specimen Label should be affixed to the participant's corresponding Biological Sample and Shipment Notification Form.

Saliva Collection Tube



- Place barcode toward the tube cap
 AND below the "Fill To" line.
- Place labels before sample collection



Saliva Sample Collection



NCRAD Saliva Collection Instructions

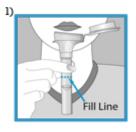
Preparation for saliva collection:

- Remember: Do NOT remove plastic film from the lid.
- Subject should not eat, drink, smoke, chew gum or brush teeth for 30 minutes prior to giving sample.
- Subject does NOT need to rinse their mouth prior to giving the sample.
- Before spitting, subject should relax and rub their cheeks gently for 30 seconds to create saliva.
- Most people take between 2 and 5 minutes to deliver a saliva sample.

NCRAD Saliva Collection Instructions

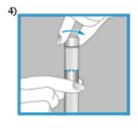
Collection:

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.

4



Pick up the small cap for the tube. Use the small cap to close the tube tightly. Discard the funnel.

2



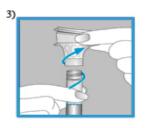
After collection, hold the tube upright.

5



Shake the capped tube for 5 seconds.
Complete the Biological Sample and
Shipment Notification Form Place sample
into the provided biohazard bag. Peel the
protective wrapping off to seal the bag. Roll
packaging around the tube.

3



Unscrew the funnel from the tube.

Place sample into the provided Bulk Saliva Shipping Box.

Video of Saliva Collection Procedure:

To review a video of the saliva collection procedure, please visit:

http://www.dnagenotek.com/ROW/support/ciOG500.html

Saliva Sample Shipping



Saliva Sample Shipping







Collect saliva, ensure properly closed and place in biohazard bag.





UPS ClinPak

Place the sealed biohazard bag, with the saliva tube sealed separately inside, into the bulk shipping box (contains 36 saliva samples)

Saliva Sample Shipping (cont'd)

- Ensure all ambient, labeled saliva samples are appropriately packaged.
- Place the completed Saliva Sample and Shipment Notification Forms in the UPS ClinPak.
- Apply all provided warning labels and the printed UPS return label to the outside of the package, taking care not to overlap labels.
- Use UPS tracking to ensure delivery occurs.

Saliva Sample and Shipment Notification Forms

- A copy of the sample forms must be emailed or faxed to NCRAD prior to the date of sample arrival.
- Please include all sample forms within UPS ClinPak
- A web-based version will be an option soon.
- Email: alzstudy@iu.edu



Saliva Sample and Shipment Notification Form

NCRAD	Appendix D			
ACAD Asian Cohort for Alzheimer's Disease Site ID: Participant ID: Saliva Sample and Shipment Notification Form Please email or fax this from prior to the date of shipment.				
To: Kelley Faber Email: alzstudy@ic	u.edu FAX: 317-321-2	003 Phone: 1-800-	526-2839	
General Information: UPS tracking #:				
From:	Date:			
Phone:	Email:			
Study: ACAD GUID: Visit(circle one): V01 V02	Specimen Label:	Specimen L	abel	
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:				
	Sal	iva Volume:	ml	
Notes:				

Version (02.2021

NCRAD Website

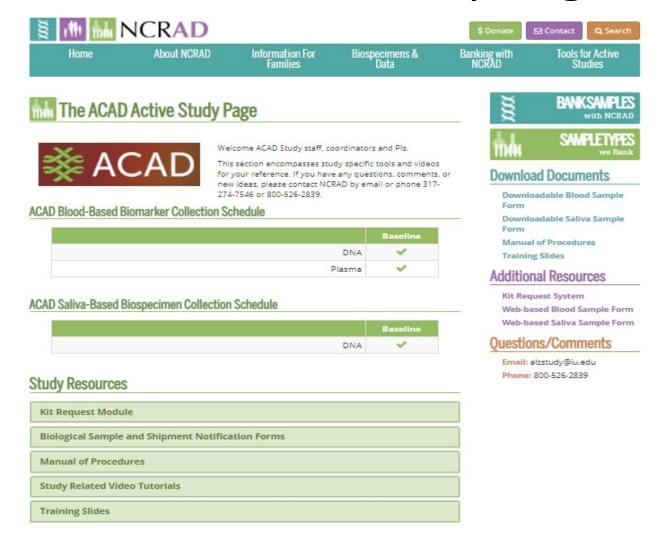
Holiday Closures

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

https://ncrad.org/holiday_closures.html



ACAD Active Study Page



https://www.ncrad.org/resource/acad.html

Contact Information

• Questions?

Please contact NCRAD Coordinators at:

Phone: 1-800-526-2839 or 317-274-7546

• E-mail: <u>alzstudy@iu.edu</u>; <u>wilmesk@iu.edu</u>

• Website: www.ncrad.org

