

Alzheimer's Disease in Down Syndrome

Alzheimer's Disease in Down Syndrome (ADDS)

in collaboration with

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

Blood-Based Biospecimen Training Slides

Contact Information

Questions?

Please contact NCRAD Coordinators at:

• Phone: 1-800-526-2839

• E-mail: alzstudy@iu.edu

Website: <u>www.ncrad.org</u>



Training Overview:

- Blood-Based Collection Schedule
- Kit Request Module
- Specimen Labels
- Handling/Processing Study Specimens
- Sample Shipping
- NCRAD Website
- Questions?

ADDS Blood Based Collection Schedule:

	Baseline (1A)	3-Month (1B)	16-Month (2A)	19-Month (2B)	32-Month (3A)	35-Month (3B)
Serum		X		X		X
DNA		Χ		Χ		X
Plasma		X		X		X

Kit Request Module

http://kits.iu.edu/adds-niad



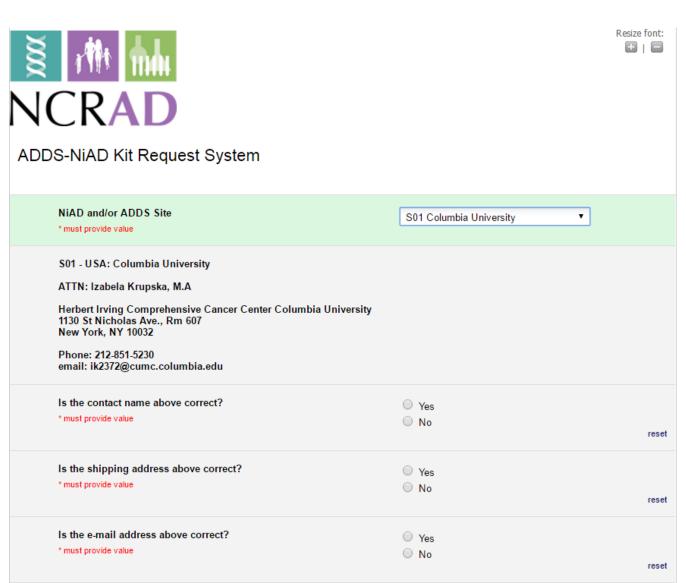
Kit Request Module

 An initial stock of kits will be delivered prior to the designated site specific start date.

- Kits and individual supplies are available to order:
 - ADDS Blood Kit
 - ADDS Frozen Blood Shipping Supply Kit
 - Blood Supplemental Kit
 - CSF Supplemental Supply Kit
 - Lumbar Puncture Trays
 - Frozen CSF Shipping Supply Kit

NCRAD Kit Request Module

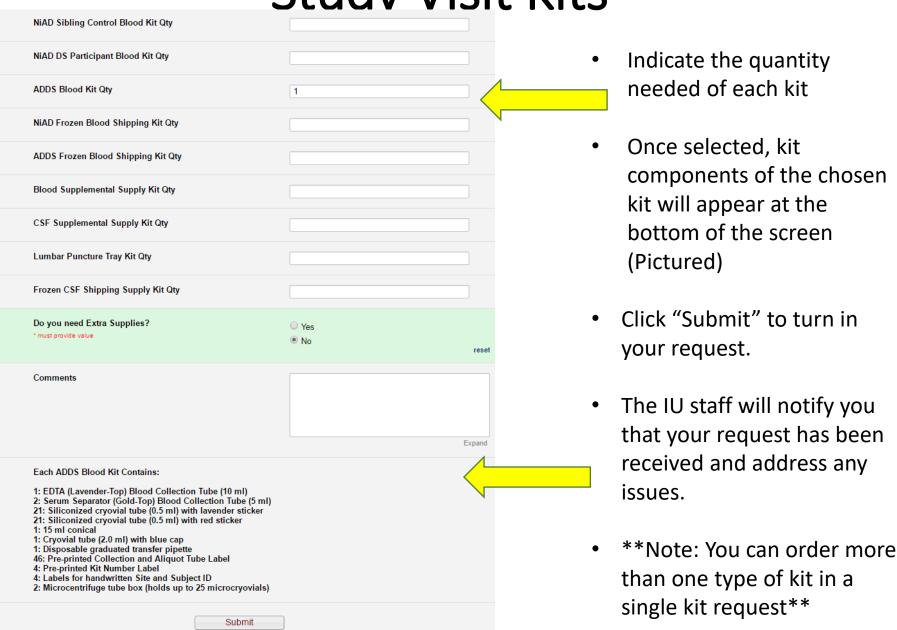
- 1. Choose your site from the drop down list
- 2. The coordinator name and contact information will appear
- 3. Verify that this information is accurate, correct if necessary



ADDS and NiAD Kits Available

NiAD Sibling Control Blood Kit Qty		
NiAD DS Participant Blood Kit Qty		
ADDS Blood Kit Qty		
NiAD Frozen Blood Shipping Kit Qty		
ADDS Frozen Blood Shipping Kit Qty		
Blood Supplemental Supply Kit Qty		
CSF Supplemental Supply Kit Qty		
Lumbar Puncture Tray Kit Qty		
Frozen CSF Shipping Supply Kit Qty		
Do you need Extra Supplies? * must provide value		○ Yes ○ No
Comments		Expand
	Submit	

Study Visit Kits



Specimen Labels



Label Type Summary

- 1. Kit Number Labels
- 2. Site and Subject ID Labels
- 3. Collection and Aliquot Tube Labels
 - Differ by specimen type

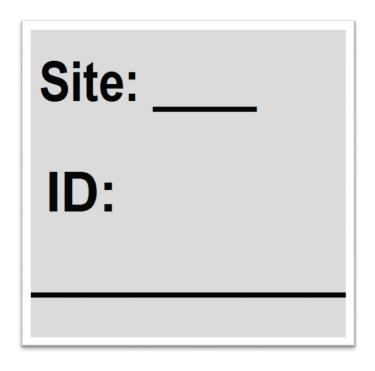
Kit Number Labels



Provided by NCRAD in the kits

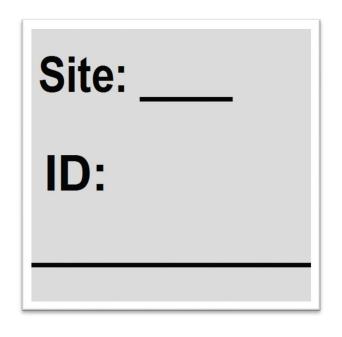
- Used to track patient samples and provide quality assurance
- Will be placed on the following locations:
 - Biological Sample and Shipment Notification Form
 - 2. Outside cryobox that houses aliquot tubes during storage and shipment

Site and Subject ID Label



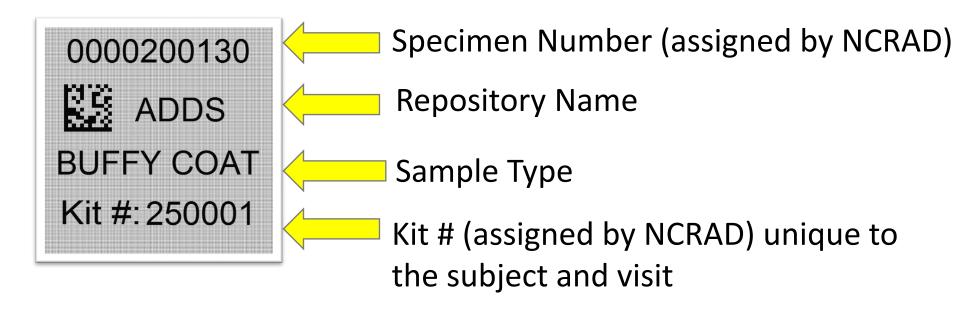
- Subjects will be identified by their site ID and subject ID
- The subject ID may only be available shortly before the visit
- Sites will be responsible for handwriting this onto the provided labels
 - Must use fine point permanent marker
 - Each site will receive 4 markers in initial kit supply

Site and Subject ID Label Cont.



- Write information on label prior to adhering to tube
- Label will be placed on all collection tubes
 - (2) Serum Separator (Gold-Top) Blood Collection Tube (5 ml)
 - EDTA (Lavender-Top) Blood Collection Tube (10 ml)
- Kits will include one extra label

Collection and Aliquot Tube Labels



Collection and Aliquot Tube Labels- Blood

0000200128

ADDS

PLASMA

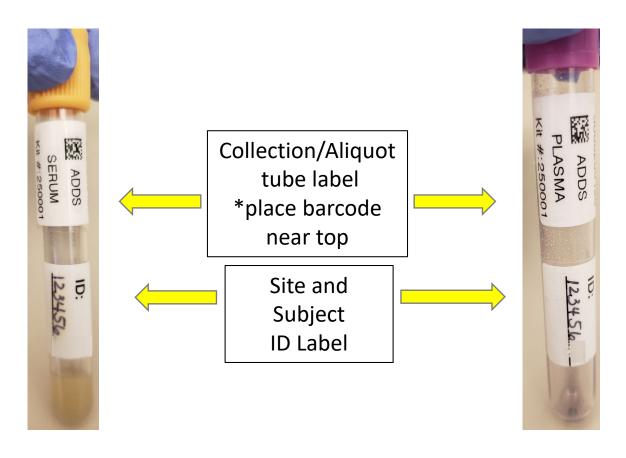
Kit #: 250001



0000200129
ADDS
SERUM
Kit #: 250001

- Labels to be placed on ALL collection and aliquot tubes
 - 1. Serum Separator (Gold-Top) Blood Collection Tube (x2)
 - Serum aliquots
 - 2. EDTA (Lavender-Top) Blood Collection Tube (x1)
 - Plasma aliquots
 - Buffy coat aliquot

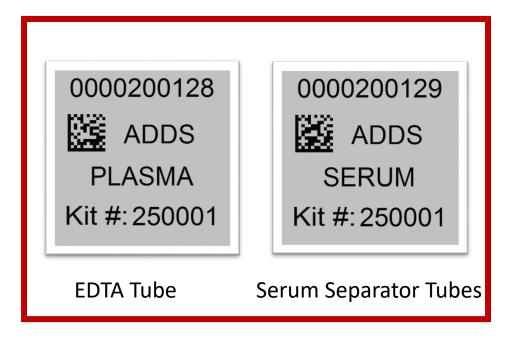
Collection Tubes – Blood



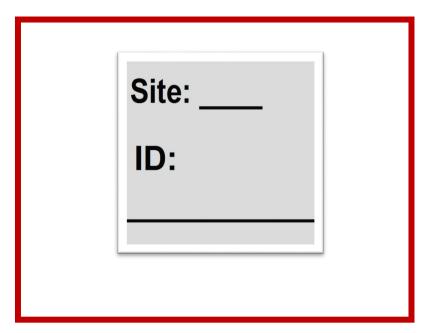
Serum Separator (Gold-Top) Blood Collection Tube (5 ml) EDTA (Lavender-Top)
Blood Collection Tube
(10 ml)

Collection Tubes - Blood

Label 1: Collection Tube Label

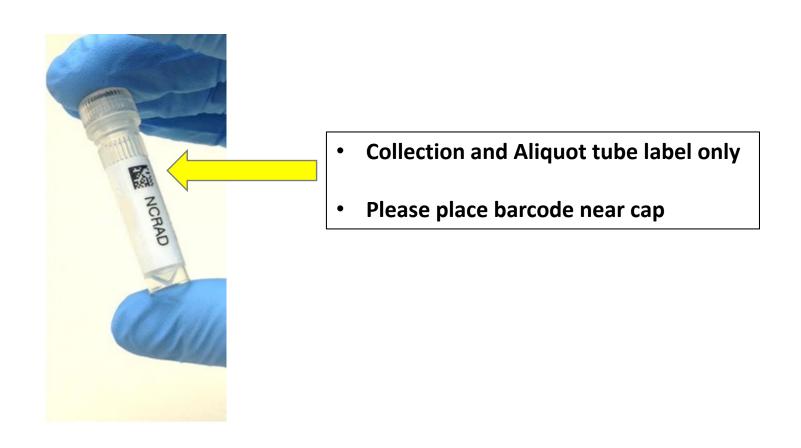


Label 2: Site and ID Label



- All collection tubes will have two labels
 - The Collection Tube Labels
 - The handwritten Site and Subject ID Label

Aliquot Tube Labels – Serum, Plasma and Buffy Coat



NCRAD Kit Request Module: When It Must be Used

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

- To order, sites will use the Indiana University online kit ordering module: http://kits.iu.edu/adds-niad
- Allow a minimum of 2 weeks for your order to be processed and delivered.

Handling/Processing Study Specimens



Site Required Equipment

Blood Collection/Safety Equipment

- 1. PPE
 - Lab Coat, Safety Glasses
- 2. Tourniquet
- 3. Alcohol Prep Pad
- 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
- Wet Ice Bucket

Draw Order

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. Draw blood in the following order:

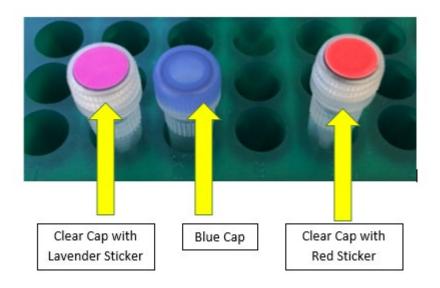
- 1. Serum Separator (Gold-Top) Blood Collection Tube (5 ml) for Serum x 2
- 2. EDTA (Lavender-Top) Blood Collection Tube (10 ml) for DNA and Plasma

Sample Collection - Blood

	Tube Type	Number of Tubes Drawn	Tube Image
1.	Serum Separator (Gold-Top) Blood Collection Tube (5 ml)	x2	B C S S
2.	EDTA (Lavender-Top) Blood Collection Tube (10 ml)	x1	1366643 IRAQ23 IRAQ23 IRAQ23 IRAQ23 IRAQ3

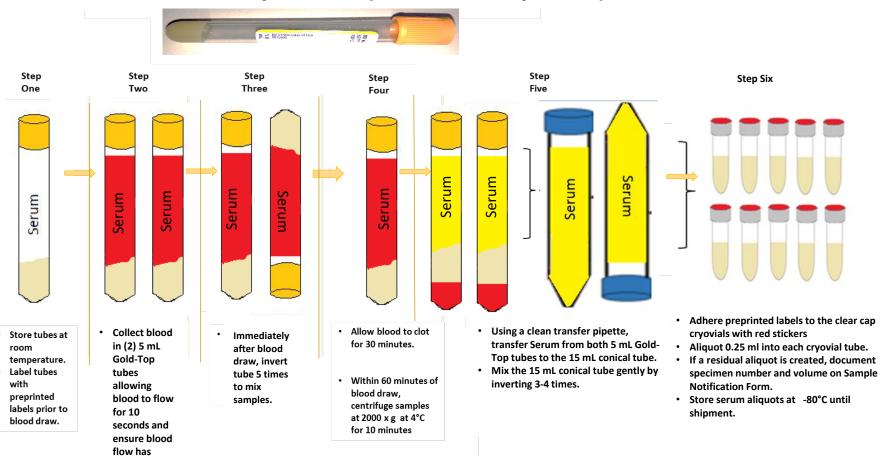
Aliquot Cap Colors

Cap Color	Sample Type
Clear Cap with	Plasma and Plasma Residual (<0.25 ml)
Lavendar Sticker	(Document Specimen Number of Residual Aliquot on Sample Form)
Clear Cap with Red	Serum and Serum Residual (<0.25 ml)
Sticker	(Document Specimen Number of Residual Aliquot on Sample Form)
Blue	Buffy Coat

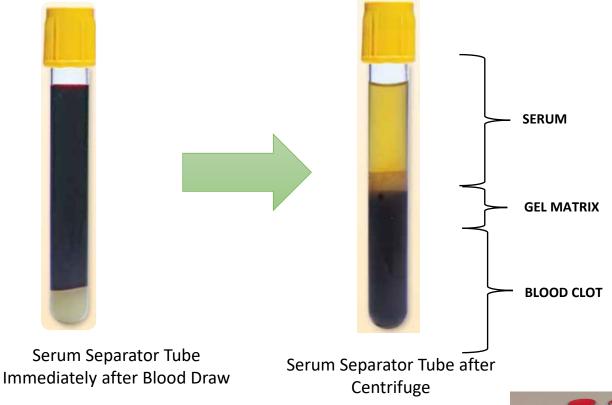


Serum Preparation (5 ml Gold-Top Tube)

stopped.



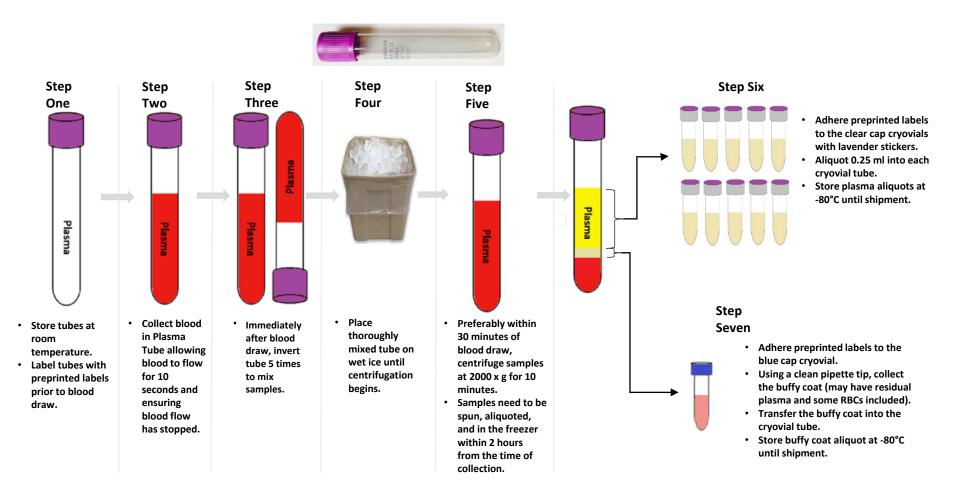
Serum Separator Tube (Serum Collection)



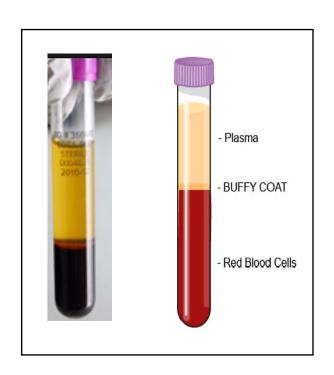
Create 16 to 21 aliquots of 0.25ml; if residual aliquot created, document specimen number and volume on sample form

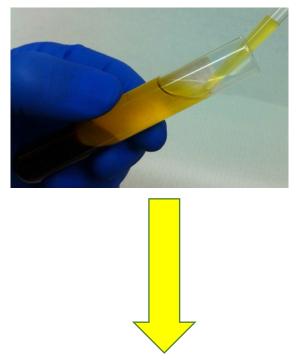


Plasma and Buffy Coat Preparation (10ml Lavender-Top Tube)



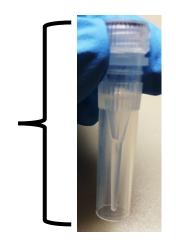
EDTA Tube (Plasma Collection)





Create 16 to 21 aliquots of 0.25ml; if residual aliquot created, document specimen number and volume on sample form





EDTA Tube (Buffy Coat Collection)





Important Note:

Buffy Coat aliquots will be distinguished from the plasma aliquots through a blue cap.

Sample Shipping



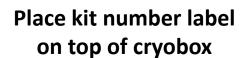
Blood Sample Shipment Summary

Sample Type	ADDS	Processing/ Aliquoting	Tubes to NCRAD	Ship
Whole blood (Gold- Top SST) for isolation of serum		0.25 ml serum aliquots per 0.5 ml siliconized cryovial (clear caps with RED stickers)	16-21	Frozen
Whole blood (lavender-Top EDTA) for isolation of plasma & buffy coat (for DNA extraction)	Yes	0.25 ml plasma aliquots per 0.5 ml siliconized cryovial (clear caps with lavender stickers)	16-21	Frozen
	Yes	1 ml buffy coat aliquot per 2.0 ml cryovial (BLUE cap)	1	Frozen

Frozen Sample Shipping

- Ship Monday-Wednesday Only
 - Serum, Plasma and Buffy Coat
- Hold packaged samples in a -80°C freezer until pickup.
- Batch Samples together
 - 10 cryoboxes (5 participant biospecimens visits per shipment)
 - Batch shipping should be performed quarterly or as a full shipment of specimens accumulates, whichever is sooner.

Frozen Shipping – Cryoboxes





One cryobox to contain Serum aliquots, one per subject.

One cryobox to contain Plasma and Buffy Coat aliquots, one per subject.



Place both cryoboxes into one Biohazard Bag.

Shipping Frozen Samples

- Schedule FedEx
- Send Biological Sample and Shipment Notification Form to IU (US) <u>ahead of</u> <u>shipment</u>
 - *Email: alzstudy@iu.edu* or
 - Fax: 317-321-2003

Frozen Shipping – Dry Ice Requirements

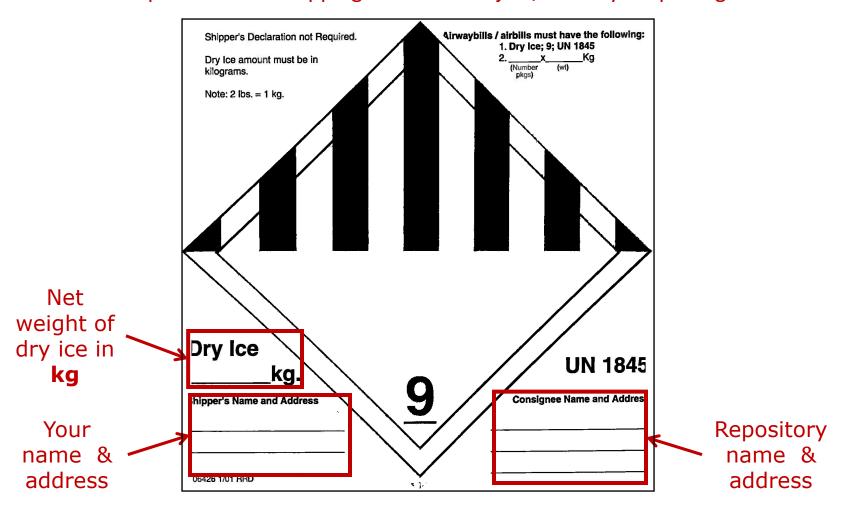


 Fully cover the cryoboxes with about 2 inches of dry ice in the provided shipper.

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

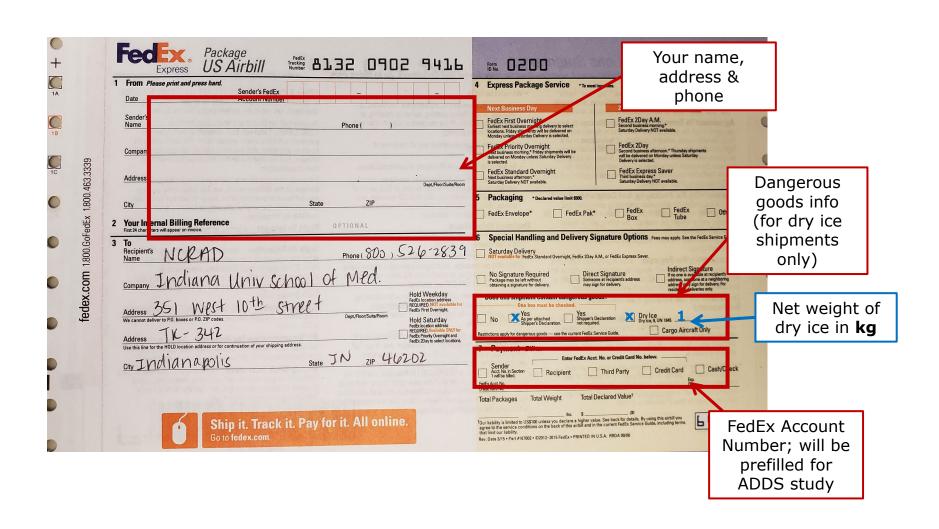
Frozen Shipping – Dry Ice Requirements

Class 9 Dry Ice label should not be covered with other stickers and must be completed or the shipping carrier will reject/return your package!



Frozen Shipping - Fedex Airbill

Airbill must be completed or the shipping carrier will reject/return your package!



Biological Sample and Shipment Notification Forms

- A copy of the sample form must be emailed or faxed 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>
- Fax: 317-321-2003



Biological Sample Notification Form- Blood



Biospecimen Collection, Processing, and Shipment Manual

Appendix B

ADDS
Alzheimer 's disease in Down Syndrome

Subject ID:	Site ID:	MGH InitID:
Date: / /	Cycl	e Visit: 1A 1B 2A 2B 3A 3B

Biological Sample and Shipment Notification Form

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

To: Kelley Faber Ema	il: alzstudy@iu.edu	FAX: 317-321-2003	Phone: 1-800-526-2839	
General Information:	ii: aizstudy@iu.edu	PAX. 317-321-2003	111011e. 1-000-320-2033	
From:		Date:		
Phone: Study: ADDS DS Participant Sex: M F Year of Birth: FedEx tracking #:		Kit #:	KIT BARCODE	
redex tracking #:				
Blood Collection:				
1. Date Drawn: [YYYYMMDD]		2. Time of Draw (24 h	our clock):	<u>[MN</u>
Last time subject ate (Date):	YMMDD]	4. Last time subject at	e (24 hour clock):	[HHMM]
5. Was the EDTA tube placed on ice immediately after in	verting tube 5 times u	ntil centrifugation began?	Yes No	
Blood Processing:				
Plasma (EDTA/Lavender Top Tube)		Serum	(Serum Separator/Gold Top Tub	e)
Time spin started (24 hour clock):	[HHMM]	. Time spin started (draw time):	(24 hour clock) (30 minutes after	[MMM]
Duration of centrifuge:	[minutes	Duration of centrif	uge:	minutes
Temp of centrifuge:°C	ge: x g	Temp of centrifuge	e:°C • Rate of centrif	fuge: x g
Original volume drawn (1x10 mL EDTA tube):	mL	Original volume drawn	(2x5 mL Serum tube):	mL
Time aliquoted:	[HHMM]	Time aliquoted:		[HHMM]
Number of 0.25 mL plasma aliquots created (16-20 total) (Siliconized cryovial):	x 0.25 mL	Number of 0.25 mL sero (Siliconized cryovial):	um aliquots created (16-20 total)	x 0.25 mL
. If applicable, volume of residual plasma aliquot (less than 0.25 mL) (Siliconized cryovial):	mL	. If applicable, volui than 0.25 mL) (Sili	ne of residual serum aliquot (less conized cryovial):	mL
If applicable, specimen number of residual aliquot (Last four digits):		If applicable, specimen (Last four digits):	number of residual aliquot	
Time aliquots placed in freezer (24 hour clock):	[HHMM]	Time aliquots place	ed in freezer (24 hour clock):	[HHMM]
Storage temperature of freezer:	°c	Storage temperate	ure of freezer:	°c
Buffy coat aliquot created (one per EDTA tube) (Blue cap cryovial):	mL	Note: Bulleted iter	ms not entered into eCRF.	
Notes:				

Blood collected for:

- Serum
- Plasma
- Buffy Coat

Version 03.2020

NCRAD Website Helpful Pages



- https://ncrad.org/holiday_closures.html
- https://ncrad.org/friday blood draws.html

What to do for Friday Blood Draws

NCRAD is not open for business on Saturday or Sunday; therefore, we ask that no samples be shipped on a Friday. We cannot guarantee the conditions in which the samples will be held by the shipping courier over the weekend. It is important to have plans in place for each type of sample to be held over the weekend prior to shipping. Please refer to the table below for how to handle samples drawn on a Friday.

When possible, please only ship frozen samples on Monday-Wednesday. There is always the potential for an unexpected shipping courier delay and by shipping Monday through Wednesday there should be enough time to receive the samples before the weekend.

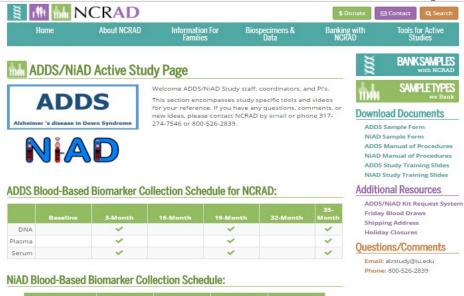
Sample Type	Tube Type	Product	Shipment Method	Friday Draw Instructions
Whole Blood	Sodium Heparin	PBMC	Ambient	DO NOT DRAW ON FRIDAY. Must be drawn on Monday – Thursday.
Whole Blood	EDTA Tube	DNA Only	Ambient	Do NOT refrigerate. Please keep sample at room temperature until the specimen can be shipped via next day delivery methods the following Monday.



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://www.ncrad.org/resource adds niad.html

ADDS/NiAD Active Study Page



**

**

NiAD Blood-Based Biomarker Collection Schedule for Sibling Controls:

**No Blood Based Biomarkers are collected at the 48-month visit.

	Baseline	16-Month	32-Month	48-Month
DNA	~			
Plasma	~			

* DNA from the 16-Month Visit (University of Pittsburgh ONLY) will not be shipped to NCRAD

Study Resources

Plasma

but maintained at the site.

Kit Request Module	
Study Specific Sample Notification Forms	
ADDS/NiAD Manual of Procedures	
Study Related Video Tutorials	
ADDS/NiAD Training Slides	

Contact Information

Questions?

Please contact NCRAD Coordinators at:

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

• E-mail: <u>alzstudy@iu.edu</u>

Website: www.ncrad.org

