



# **Alzheimer's Biomarker Consortium – Down Syndrome**

in collaboration with

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

Blood-Based Biospecimen Training Slides  
Version 3.2



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# NCRAD Contact Information

## Questions?

**Zoë Potter, BA, CCRP, Study Coordinator**

Phone: (317) 278-9086

Email: [zdpotter@iu.edu](mailto:zdpotter@iu.edu)

## **General NCRAD Contact Information**

Phone: 1-800-526-2839

Email: [alzstudy@iu.edu](mailto:alzstudy@iu.edu)

Website: [www.ncrad.org](http://www.ncrad.org)

ABC-DS Study Specific Webpage: [NCRAD - The ABC-DS Active Study Page](#)



# IU Path Lab Contact Information

- **Shipping Address:**

IU Path Lab

350 W. 11th Street

Indianapolis, IN 46202

5<sup>th</sup> Floor, Rm 5013

- **Contact Information:**

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**Volume questions and any questions related to testing:**

Evan Salat - [esalat@IUHEALTH.ORG](mailto:esalat@IUHEALTH.ORG)

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Julie Ross - [jross20@IUHealth.org](mailto:jross20@IUHealth.org)



# UNTHSC Contact Information

- **Shipping Address:**

3420 Darcy Street

Fort Worth, TX 76107

- **Contact:**

Tori Conger, ITR Lab Manager- [Tori.Como@unthsc.edu](mailto:Tori.Como@unthsc.edu)



# **NCRAD Kit Request Module**

<https://kits.iu.edu/ABC-DS>



# ABC-DS Kit Request Module

**NCRAD**  
ABC-DS Kit Request System

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.

Please enter your email address here to receive a confirmation email after completing the survey:   
\* must provide value

ABC-DS Site:   
\* must provide value

024 - USA: University of Pittsburgh  
ATTN: Cathy Wolfe  
University of Pittsburgh  
3501 Forbes Ave  
Oxford Bldg, Rm 713  
Pittsburgh, PA 15213  
Phone: 412-235-5412  
Email: wolfec@upmc.edu

Is the contact name above correct?  Yes  No \* must provide value [reset](#)

Is the shipping address above correct?  Yes  No \* must provide value [reset](#)

Is the e-mail address above correct?  Yes  No \* must provide value [reset](#)

If possible, only order what you will need in the next month

- Enter your email to receive a confirmation email after you submit your kit request.
- Choose your site from the drop-down list.
- The coordinator name and contact information will appear.
- Verify that this information is accurate. Correct if necessary.

# ABC-DS Kit Request Module

Order NaHep tube for karyotyping separate from Ambient Kit under "Extra Supplies"

ABC-DS Ambient Blood Shipping Kit Qty  Do you also need a NaHep tube? Order under "Extra Supplies"

MOM's Substudy Frozen Blood Shipping Kit Qty

Blood Supplemental Supply Kit Qty

ABC-DS MOM's Substudy Blood Supplemental Kit Qty

22G CSF Supplemental Supply Kit Qty

24G CSF Supplemental Supply Kit Qty

22G Lumbar Puncture Tray Kit Qty

24G Lumbar Puncture Tray Kit Qty

Frozen CSF Shipping Supply Kit Qty

Do you need Extra Supplies?  Yes  No  
\* must provide value

Our standard shipping time for all orders is 3 weeks.  
We can ship this kit request by: **06-01-2023**  
If you need any supplies in this order prior to **06-01-2023**, you must contact the NCRAD coordinator for this study: [zdpotter@iu.edu](mailto:zdpotter@iu.edu).

Comments

Each ABC-DS MOM's Substudy Blood Supplemental Kit Contains (10612):  
4: EDTA (Lavender-Top) Blood Collection Tube (10 mL) - C7001  
4: Serum Separator (Gold-Top) Blood Collection Tube (5 mL) - C7002

- Indicate the quantity needed of each kit
  - Once selected, kit components of the chosen kit will appear at the bottom of the screen
- You can order extra supplies individually by selecting "Yes" here.
- We will return requests within 3 weeks from the order date.
  - If you need any supplies expedited, please contact the NCRAD Coordinator via email.
- Click "Submit" to turn in your request.
- \*\*Note: You can order more than one type of kit in a single kit request



# ABC-DS Kit List

- **Main Study**

- Blood Kits:

- ABC-DS DS Participant Blood Kit
    - ABC-DS Sibling Control Blood Kit
    - ABC-DS Clinical Labs Kit
    - ABC-DS Frozen Shipping Supply Kit – *set of shipping kits for UNTHSC and NCRAD*
    - ABC-DS Ambient Blood Shipping Supply Kit
    - Blood Supplemental Kit

- CSF Kits:

- CSF Supplemental Supply Kit
    - Lumbar Puncture Trays
    - CSF Shipping Supply Kit

- **MOM's Substudy**

- Blood Kits:

- ABC-DS MOM's Substudy Blood Kit
    - MOM's Substudy Frozen Blood Shipping Kit
    - ABC-DS MOM's Substudy Blood Supplemental Kit

- 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 for scheduled participants.
- Be sure to check your supplies and order additional materials before you run out or supplies expire so you are prepared for study visits.
- Allow a minimum of **3 weeks** for your order 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.

# Main Study



# Collection Schedules

NCRAD, UNTHSC, and IU Path Lab (Clinical Labs)



# NCRAD & UNTHSC Blood Based Collection Schedule:

## DS Participants and Sibling Controls

Blood Collection – to be sent to UNTHSC and/or NCRAD

	Serum	Plasma	DNA	RNA	Karyotyping <sub>1</sub>
All visits	X	X	X	X	X
SHIP TO:	NCRAD & UNTHSC	NCRAD & UNTHSC	NCRAD	NCRAD	NCRAD

<sub>1</sub> DS Participants only (if needed)

# Clinical Labs Blood Collection Schedule:

## DS Participants ONLY

### Blood Collection – to be sent to IU Path Lab

	Orange-Top Serum Tube	Gold-Top Serum Tube	3 mL EDTA Tube	
	Free T4, Thyroid, Triiodothyronine, TSH, Vit B12, ATA Preparation	Vit D, BMP, Lytes, Lipid Preparation	CBC Preparation	A1C Preparation
Cycle 1	X	X	X	X
Cycle 2	X	X	X	X
SHIP TO:	IU Path Lab	IU Path Lab	IU Path Lab	IU Path Lab

# **Re-draw Instructions and Timeframes**



# Re-draw Instructions and Timeframes

- Sample Collection-Blood eCRF is a log form. Select '*Add a new record*' to enter a record. Enter one record per Date of Collection and specify samples collected. At least one sample type must be marked as collected on this date to successfully submit the form.
- If a re-draw is necessary and occurs BETWEEN TWO VISITS, add a new record in the visit PRIOR to the re-draw timeframe, making sure to include the re-draw date of collection and Kit Number. If a sample was missed during a regularly scheduled visit, but a sample was collected PRIOR to NEXT scheduled visit, enter in the EDC as a re-draw. Also, provide reason for re-draw in the comments section.
- For ABC-DS, the re-draw timeframe is as follows:
  - For all visits, the re-draw timeframe will be up to 3 months prior and 3 months after the expected visit date.




# **NCRAD and UNTHSC Specimen Labels**



Provided by NCRAD



# Three Label Types

Kit Number  
  
454937

Kit Number  
Labels

 ABCDS  
0042851857  
BUFFYCOAT  
Kit #: 454937 

Collection and  
Aliquot Tube  
Labels

BDS ID:  
\_\_\_\_\_


Site and BDS ID  
Labels

# Kit Number Labels



- Used to track patient samples and provide quality assurance – Will be placed on the following locations :

1. Blood Sample and Shipment Notification Forms
2. Outside cryobox that houses aliquot tubes during storage and shipment
3. Placed on NaHep tubes for karyotyping
  1. Extra kit number label provided in DS

 **Appendix B** Biospecimen Collection, Processing, and Shipment Manual

PT ID: \_\_\_\_\_ Site ID: \_\_\_\_\_  
Cycle Visit (Circle One): 1 2 3 4

**Sample Collection - Blood & Shipment Notification Form**  
*Please email or fax the form on or prior to the date of shipment.*

To: NCRAD Email: alzstudy@iu.edu Phone: 1-800-526-2839  
To: UNTHSC Email: Tori.Como@unthsc.edu Phone: 1-817-735-2638

**General Information:**

From: \_\_\_\_\_ Date: \_\_\_\_\_  
Phone: \_\_\_\_\_ Email: \_\_\_\_\_


PT previously enrolled in (circle one):  ADDS  NIAD  N/A-new PT

NIAD/ADDS Legacy ID (if applicable): \_\_\_\_\_ Kit #: \_\_\_\_\_

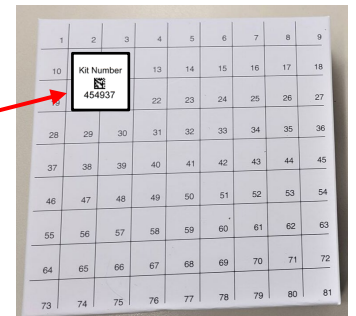
Arm:  DS Participant  Sibling Control

Sex:  M  F Year of Birth: \_\_\_\_\_

Shipment Tracking #: \_\_\_\_\_

**Kit #:** Kit Number  
  
454937 **KIT BARCODE**

Field Draw?:  Yes  No



# Collection and Aliquot Tube Labels

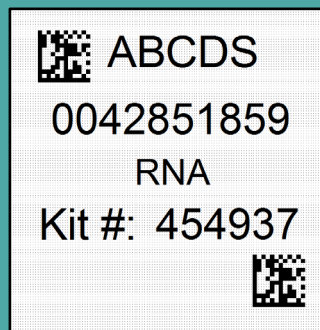


- Collection and Aliquot Tube labels have 4 components:
  - 10-digit specimen number (assigned by NCRAD)
  - Study name
  - Specimen type
  - Kit number (assigned by NCRAD)
    - Unique to subject AND visit
- Will be placed on the following locations :
  - All collection and aliquot tubes for UNTHSC and NCRAD

**Reminder:**

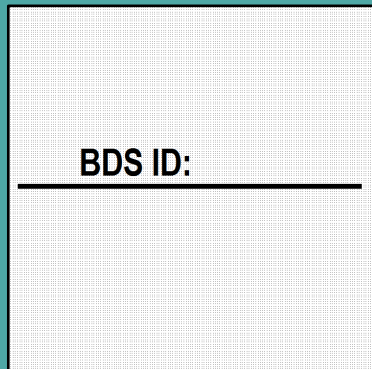
**These labels are NOT included in Clinical Lab kits and NOT placed on NaHep tubes for karyotyping**

# Collection and Aliquot Tube Labels (cont.)



- Labels to be placed on ALL collection and aliquot tubes
  - 5ml Serum Separator (Gold-Top) Blood Collection Tube (x2)
    - Serum aliquots (color-coded red strip)
  - 10ml EDTA (Lavender-Top) Blood Collection Tube (x2)
    - Plasma aliquots (color-coded purple strip)
    - Buffy coat aliquot
  - 2.5ml PAXgene™ Blood Collection Tube (x1)

# Site and BDS ID Labels

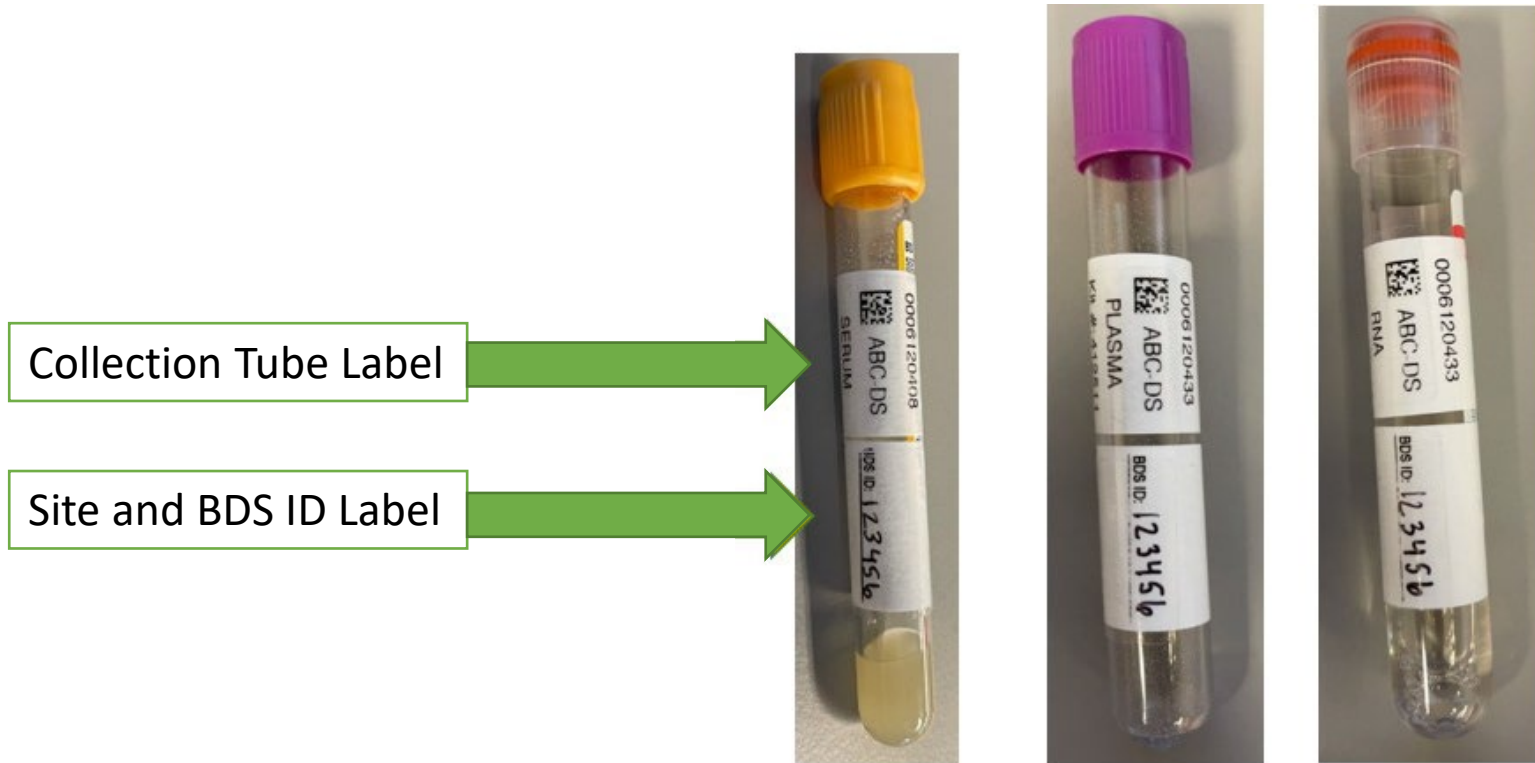


- Subjects will be identified by their Site and BDS ID (PT ID)
- Sites will be responsible for handwriting this onto the provided labels
  - Must use fine point permanent marker
- Will be placed on the following locations :
  - All Collection Tubes
    - Serum Separator (Gold-Top) Blood Collection Tube (5 mL) x2
    - NaHep (Green-Top) Blood Collection Tube (4 mL) x1
    - EDTA (Lavender-Top) Blood Collection Tube (10 mL) x2
    - PAXgene™ Blood Collection Tube (2.5 mL) for RNA x 1

**Note:**

**Each NaHep tube that is ordered will come with a Site and BDS ID Label**

# SST, EDTA, and RNA Collection Tube Labels:



Collection Tube Label

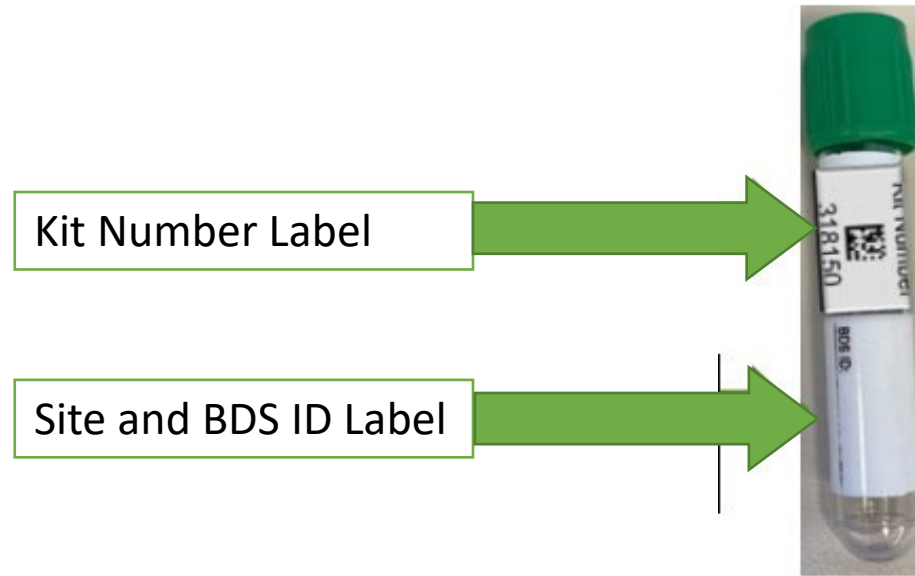
Site and BDS ID Label

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

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

PAXgene™ Blood  
Collection Tube  
(2.5 ml)

# NaHep Tube Labels for Karyotyping DS Participants:

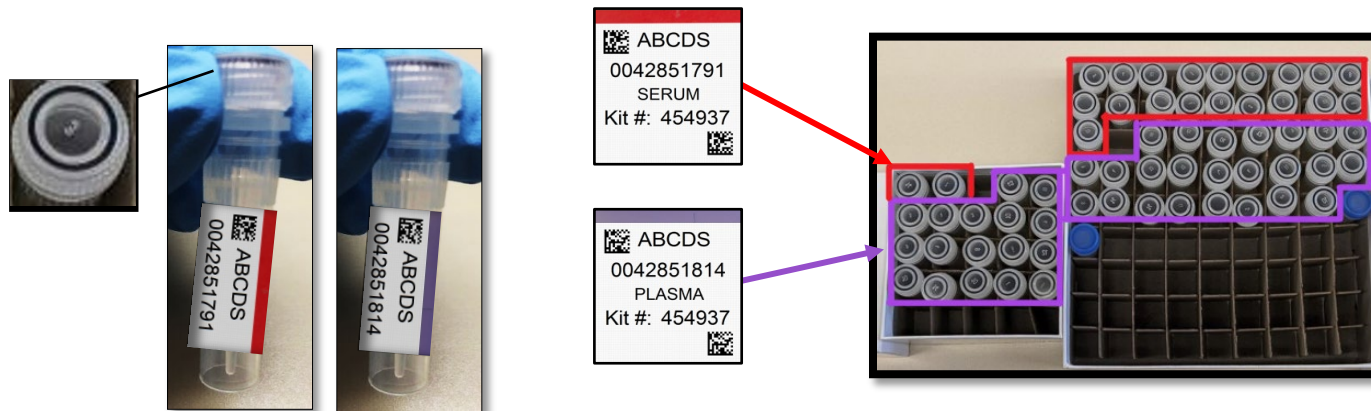


NaHep Blood  
Collection Tube  
(4 ml)



# Clear Cap Cryovials Serum and Plasma

- Aliquot Tube Labels for Plasma and Serum are color-coded to replace cap stickers. Cap stickers were causing issues with robotic freezer storage.



# IU Pathology Laboratory Specimen Labels

Provided by NCRAD



# One Label Type

BDS ID:

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DOB: 01/01/

---

Site BDS ID and DOB Labels

# Site BDS ID and DOB Labels

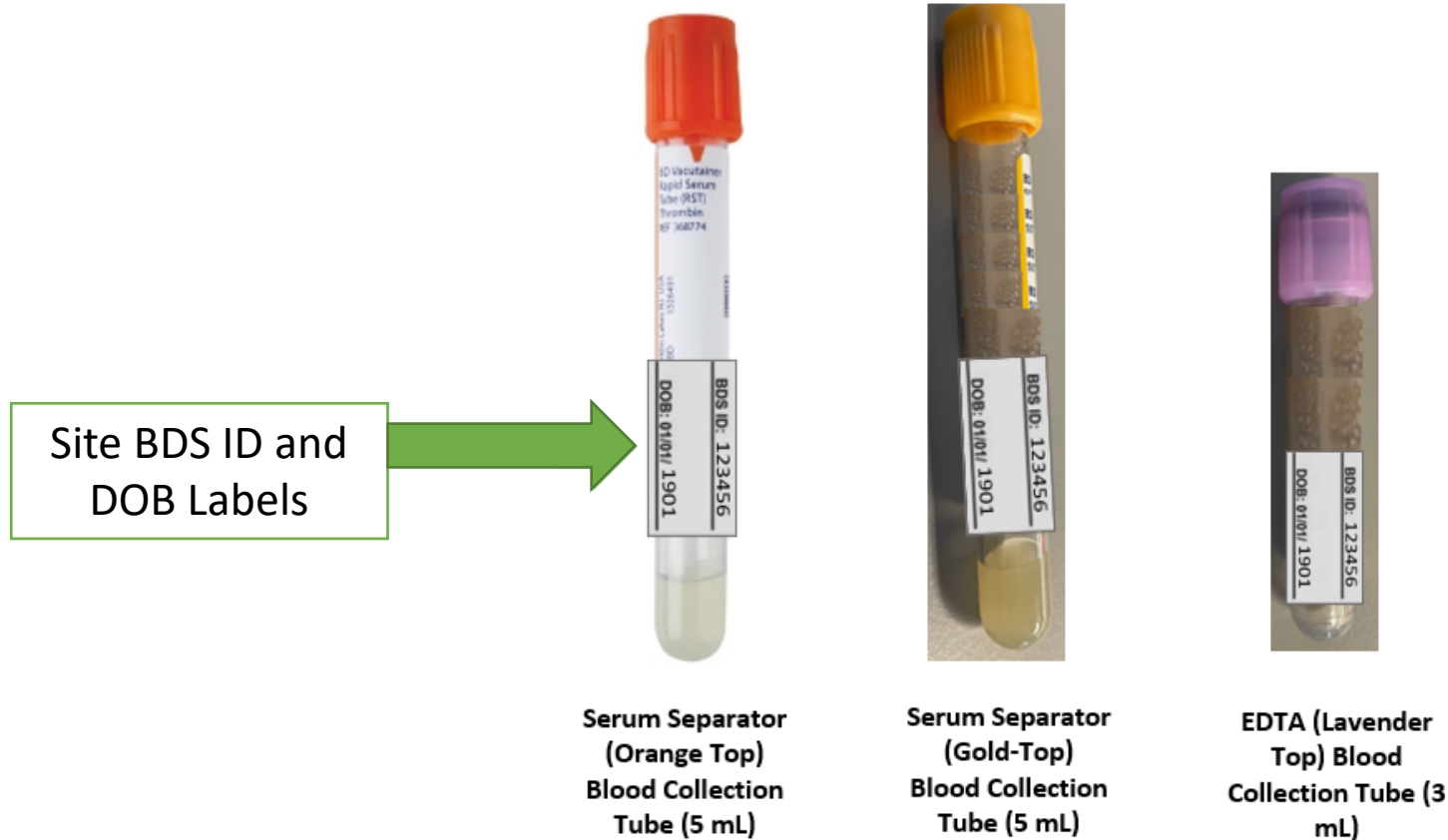
BDS ID:
DOB: 01/01/

**Important Note:**

DOB is required in the system to register the sample. You can use the participant's true DOB or a generic DOB. Either way, the DOB on the req form **MUST** match the DOB on the Site BDS ID and DOB Label.

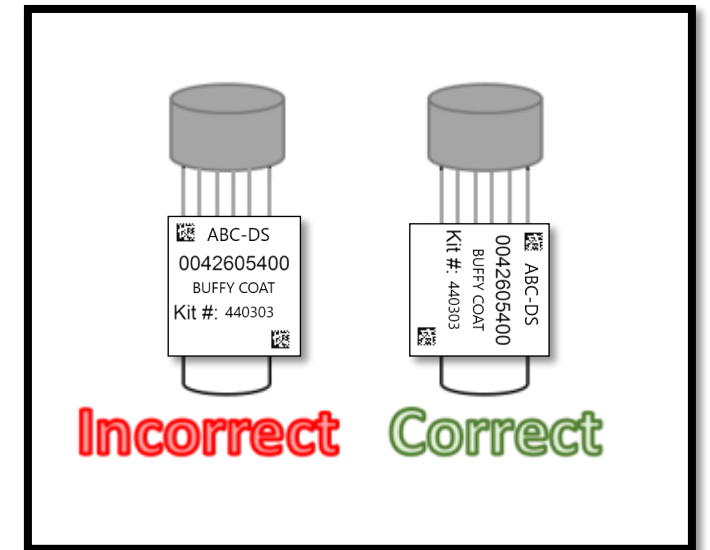
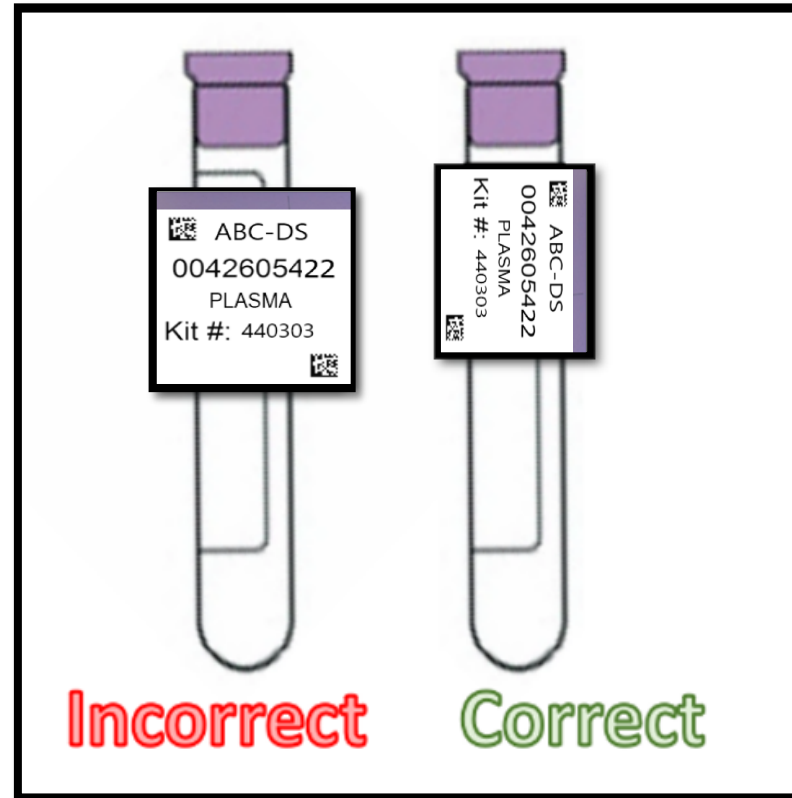
- Subjects will be identified by their Site BDS ID (PT ID) and DOB Labels
- Sites will be responsible for handwriting this onto the provided labels
  - Must use fine point permanent marker
- Will be placed on the following locations :
  - All Collection Tubes
    - Serum Separator (Orange-Top) Blood Collection Tube (5 mL) for Serum x 1
    - Serum Separator (Gold-Top) Blood Collection Tube (5 mL) for Serum x 1
    - EDTA (Lavender-Top) Blood Collection Tube (3 mL) x 1

# SST and EDTA Collection Tube Labels:



# Properly Labeling Biologic Samples:

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



# Handling/Processing Study Specimens



# Site Required Equipment

## BLOOD COLLECTION/SAFETY EQUIPMENT

- 1) Personal Protective Equipment:
  - 1) lab coat, nitrile/latex gloves, safety glasses
- 2) Tourniquet
- 3) Alcohol Prep Pad
- 4) Gauze Pad
- 5) Bandage
- 6) Butterfly needles (21 gauge) and hub
- 7) Microcentrifuge tube rack
- 8) Sharps bin and lid

## PROCESSING/STORAGE EQUIPMENT

- 1) For NCRAD/UNTHSC: Centrifuge capable of  $\geq 2000 \times g$  with refrigeration to  $4^{\circ}\text{C}$
- 2) For IU Path Lab: Centrifuge capable of  $1300 \times g$  with refrigeration to  $4^{\circ}\text{C}$
- 3)  $-80^{\circ}\text{C}$  Freezer
- 4) 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. There are 2 options for blood draw order:**

# Draw Order – Option 1 (PREFERRED)

Research collection tubes drawn done on Day 1 and Clinical Labs drawn on Day 2:

Research collection (Day 1):

- 1. Serum Separator (Gold-Top) Blood Collection Tube (5 mL) for Serum x 2
- 2. Sodium Heparin (Green-Top) Blood Collection Tube (4 mL) for Karyotyping (DS Participants only, as needed)
- 3. EDTA (Lavender-Top) Blood Collection Tube (10 mL) for DNA and Plasma x 2
- 4. PAXgene™ Blood Collection Tube (2.5 mL) for RNA

Clinical labs collection (Day 2):

- ❖ 1. Serum Separator (Orange-Top) Blood Collection Tube (5 mL) for Serum x 1
- ❖ 2. Serum Separator (Gold-Top) Blood Collection Tube (5 mL) for Serum x 1
- ❖ 3. EDTA (Lavender-Top) Blood Collection Tube (3ml) for hematology

# Draw Order – Option 2

## Collection – Research and Clinical Labs on same day/visit:





- 1. Serum Separator (Gold-Top) Blood Collection Tube (5 mL) for Serum x 2 (NCRAD)
- ❖ 2. Serum Separator (Orange-Top) Blood Collection Tube (5 mL) for Serum x 1 (IU Path Lab)
- ❖ 3. Serum Separator (Gold-Top) Blood Collection Tube (5 mL) for Serum x 1 (IU Path Lab)
- 4. Sodium Heparin (Green-Top) Blood Collection Tube (4 mL) for Karyotyping (DS Participants only, as needed) (NCRAD)
- 5. EDTA (Lavender-Top) Blood Collection Tube (10 mL) for DNA and Plasma x 2 (NCRAD)
- ❖ 6. EDTA (Lavender-Top) Blood Collection Tube (3 mL) for hematology (IU Path Lab)
- 7. PAXgene™ Blood Collection Tube (2.5 mL) for RNA x 1 (NCRAD)

# NCRAD and UNTHSC Sample Collection and Processing



# NCRAD & UNTHSC Research Blood Collection

## DS Participants and Sibling Controls

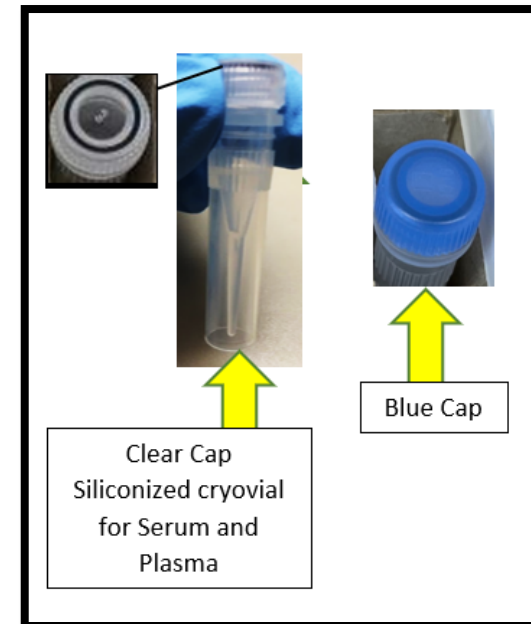
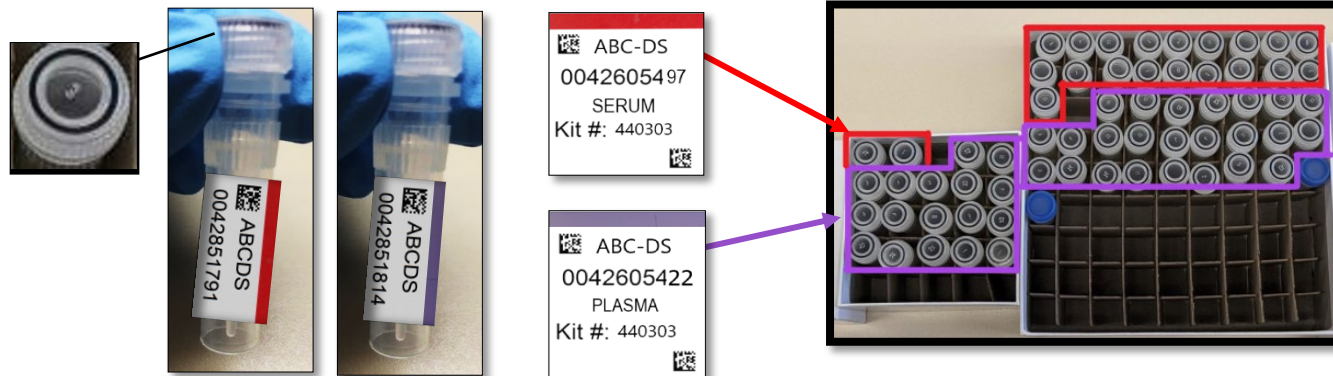
Tube Type	Number of Tubes Drawn	Tube Image
1. Serum Separator (Gold-Top) Blood Collection Tube (5 mL)	X 2	
2. Sodium Heparin (Green-Top) Blood Collection tube (4 mL) *	X 1	
3. EDTA (Lavender-Top) Blood Collection Tube (10 mL)	X 2	
4. PAXgene™ Blood Collection Tube (2.5 mL)	X 1	

\*DS participants only

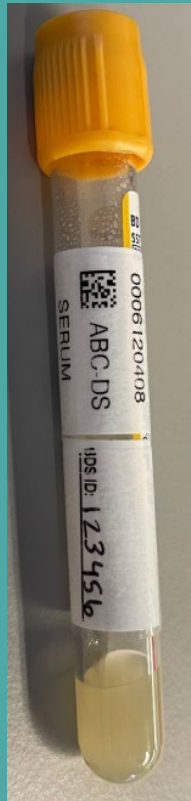
# Aliquot Cap & Label Colors

Color Coding	Sample Type
Clear Cap / Red Strip on Label	<b>Serum and Serum Residual (&lt;0.25 mL)</b> (Document Specimen Number and Volume of Residual Aliquot on Sample Form)
Clear Cap / Purple Strip on label	<b>Plasma and Plasma Residual (&lt;0.25 mL)</b> (Document Specimen Number and Volume of Residual Aliquot on Sample Form)
Blue Cap	<b>Buffy Coat</b>

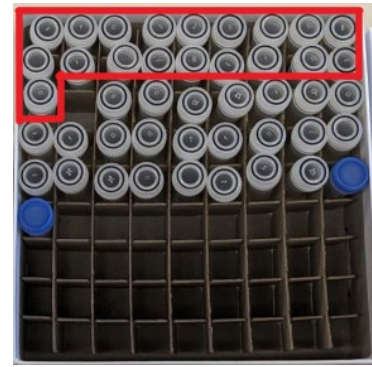
- Important Note:** Aliquot Tube Labels for Plasma and Serum are color-coded to replace color coded cap stickers. Cap stickers were causing issues with robotic freezer storage.



# Serum Collection



Close up view of clear cap 0.5 mL Cryovial

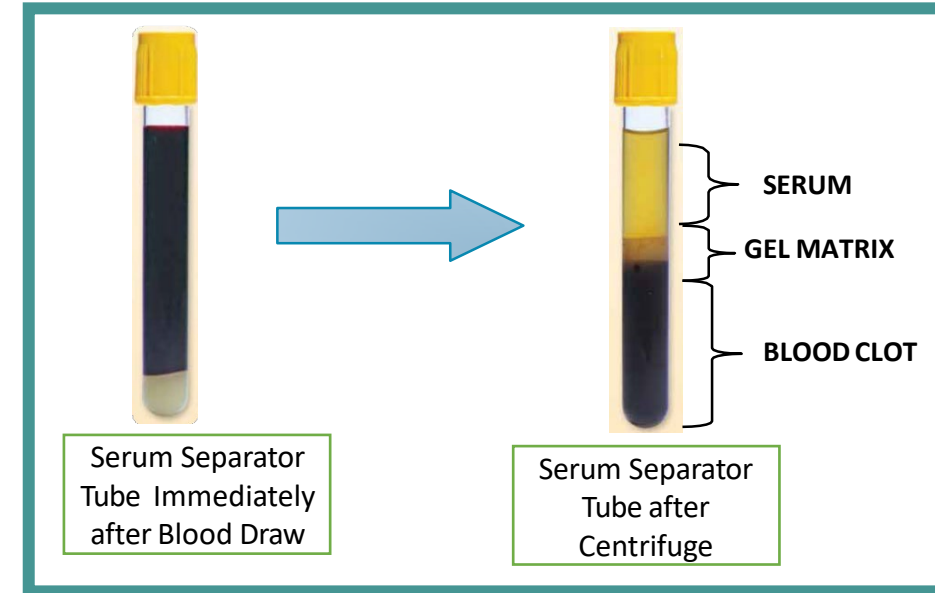


81 cell cryobox with 0.5 mL cryovials – sent to NCRAD



25 cell cryobox with 0.5 mL cryovials – sent to UNTHSC

- 2 x Serum Separator (Gold-Top) Blood Collection Tube (5 mL)
  - Create up to (19) 0.25 mL serum aliquots to be shipped to NCRAD
  - Create up to (2) 0.25 mL serum aliquots to be shipped to UNTHSC
  - If residual aliquot created, document specimen number and volume on sample form



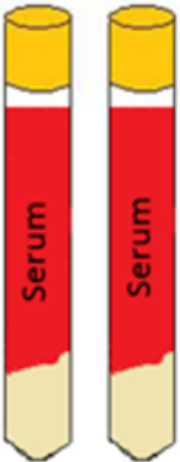
# Serum Preparation (5 ml Gold-Top Tube) X 2



Step One



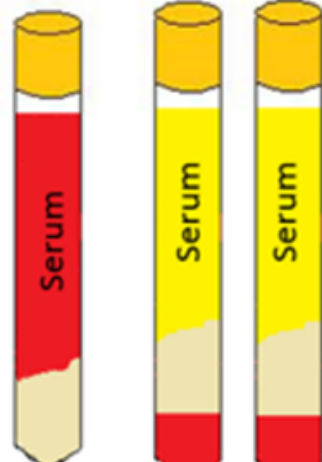
Step Two



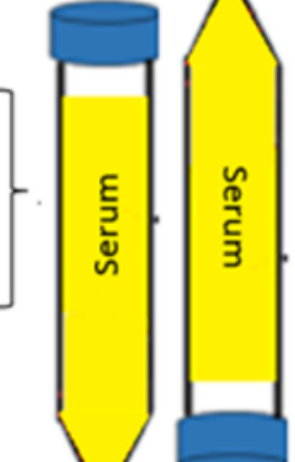
Step Three



Step Four



Step Five



Step Six



Up to 19 sent to NCRAD

Up to 2 sent to UNTHSC

- Store tubes at room temperature.
- Place completed Site and BDS ID Label and Collection and Aliquot "SERUM" Tube Labels on 5 mL Gold-Top tubes prior to blood draw.
- Place pre-printed Aliquot "SERUM" Tube Labels with color-coded red strip on the (21) 0.5 mL cryovial tubes with clear caps prior to blood draw.

- Collect blood in (2) 5 mL Gold-Top tubes allowing blood to flow for 10 seconds and ensure blood flow has stopped.

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

- Allow blood to clot for 30 minutes.
- Within 2 hours of blood draw, centrifuge samples at 2000 x g at 4°C for 10 minutes.

- Using a clean transfer pipette, transfer Serum from both 5 mL Gold-Top tubes to the 15 mL conical tube.
- Mix the 15 mL conical tube gently by inverting 3-4 times.

- Aliquot 0.25 mL into each labeled cryovial tube.
- If a residual aliquot is created, document specimen number on Sample Notification Form.
- Store serum aliquots at -80°C until shipment.

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



# If field draw,

- Allow blood to clot at room temperature before placing on wet ice, upright on rack and transferring to lab for further processing. Record if field draw and time it took to process samples on sample form for NCRAD and UNTHSC. Please check “Yes” box on sample form ([Appendix B](#)) if field-draw and make note on [Appendix F](#). If processing takes longer than 2 hours, please make note on both forms.

# NaHep Collection (for karyotyping)



Drawn for DS Participants at Baseline ONLY AS NEEDED

Used to obtain karyotype for full or partial trisomy 21.

## Important Note:

If karyotyping has been done for the participant, please check “Yes” on the Biological Sample and Shipment Notification Form (Appendix B).

- 1 x Sodium Heparin (Green-Top) Blood Collection tube (4 mL)
  - This tube is to be shipped to NCRAD ambient on the day of collection via overnight delivery without further processing at collection site.

Fill out BDS ID and NaHep volume on Constitutional (Blood) Test Requisition Form (Appendix E) and send with sample. These samples should only be collected Monday-Thursday. Please DO NOT collect these samples on Fridays.

- **If field draw,** keep sample at room temperature until shipping.



# NaHep Collection (for karyotyping)



Drawn for DS Participants at Baseline ONLY AS NEEDED  
Used to obtain karyotype for full or partial trisomy 21.

### Important Note:

If karyotyping has been done for the participant, please check "Yes" on the Biological Sample and Shipment Notification Form (Appendix B).

## • Trisomy 21 Results:

- Results from karyotyping will be uploaded to the ABC-DS EDC site at ATRI by the NCRAD study coordinator 7-10 days after receipt into the laboratory.
- You can find the results in your site folder: Docs → Site Topics → Choose Site Folder.
- To set notifications so you know when a report has been uploaded, first go to the "Docs" tab, then click "Manage Notifications" to the right of the search bar.

Biospecimen Collection, Processing, and Shipment Manual

**NCRAD**

Appendix B

**ABC-DS**

PT ID: \_\_\_\_\_ Site ID: \_\_\_\_\_  
Cycle Visit (Circle One): 1 2 3 4

**Sample Collection - Blood & Shipment Notification Form**  
*Please email or fax the form on or prior to the date of shipment.*

To: NCRAD Email: alzstudy@iu.edu Phone: 1-800-526-2839	
To: UNTHSC Email: Tori.Como@unthsc.edu Phone: 1-817-735-2638	

**General Information:**

From: \_\_\_\_\_ Date: \_\_\_\_\_  
Phone: \_\_\_\_\_ Email: \_\_\_\_\_

PT previously enrolled in (circle one): ADDS NIAD N/A-new PT

NIAD/ADDS Legacy ID (if applicable): \_\_\_\_\_ Kit #: \_\_\_\_\_

Arm:  DS Participant  Sibling Control

Sex:  M  F Year of Birth: \_\_\_\_\_

Shipment Tracking #: \_\_\_\_\_ Field Draw?:  Yes  No

**Blood Collection:**

1. Date Drawn: [YYYYMMDD] 2. Time of Draw (24 hour clock): [HHMM]

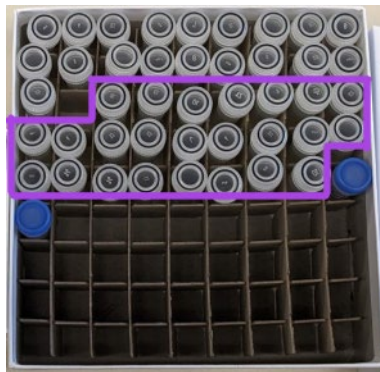
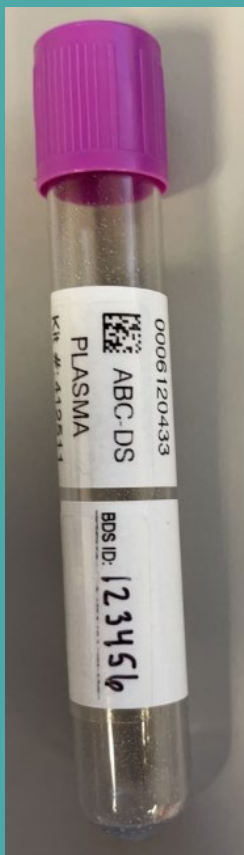
3. Last time subject ate (Date): [YYYYMMDD] 4. Last time subject ate (24 hour clock): [HHMM]

**Blood Processing:**

RNA PAXgene™ Tube Original volume drawn (1x2.5mL RNA PAXgene™ tube): _____ mL Time placed in freezer: [HHMM]	NaHep Tube for karyotyping (if not drawn, enter N/A by mL) Original volume drawn (1x4 mL NaHep tube): _____ mL
Plasma (EDTA/Lavender Top Tube) Time spin started (24 hour clock): [HHMM]	Has karyotyping ever been completed? <input type="checkbox"/> Yes <input type="checkbox"/> No
Duration of centrifuge: _____	Serum (Serum Separator/Gold Top Tube)



# Plasma Collection



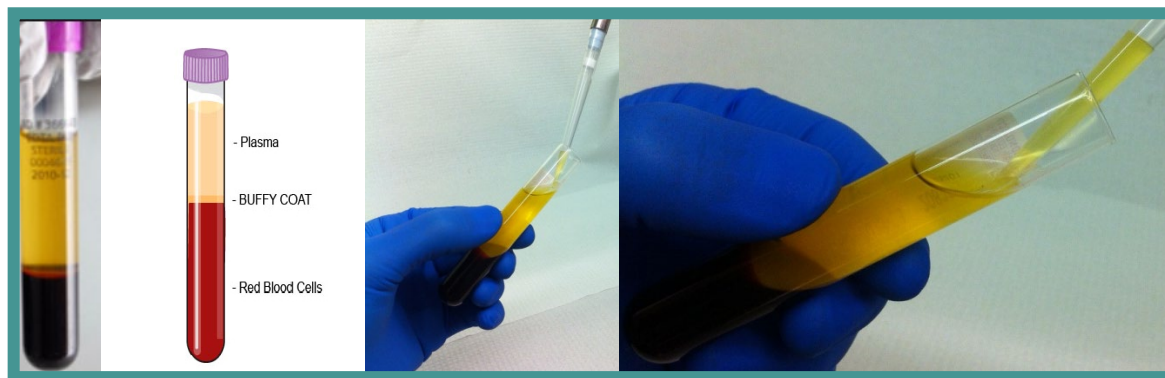
81 cell cryobox with 0.5 mL cryovials – sent to NCRAD



25 cell cryobox with 0.5 mL cryovials – sent to UNTHSC

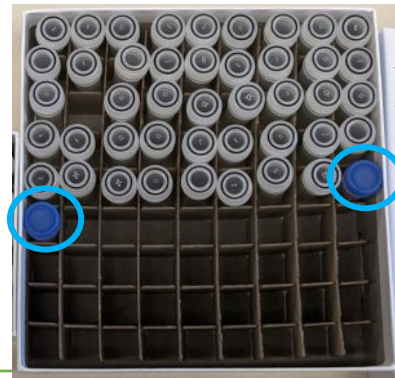
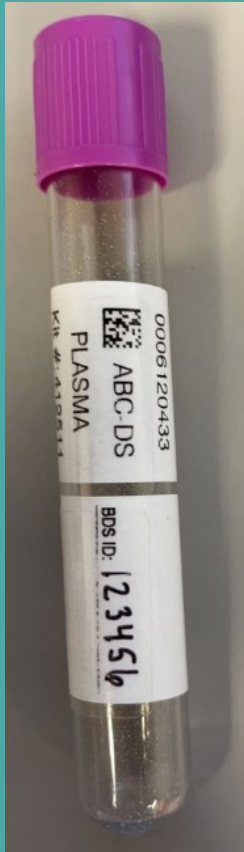
- 2 x EDTA (Lavender-Top) Blood Collection Tube (10 mL)
  - Create up to (24) 0.25 mL plasma aliquots to be shipped to NCRAD
  - Create up to (17) 0.25 mL plasma aliquots to be shipped to UNTHSC
  - If residual aliquot created, document specimen number and volume on sample form

Close up view of clear cap 0.5 mL Cryovial



**NOTE: When pipetting plasma from the plasma tube 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.**

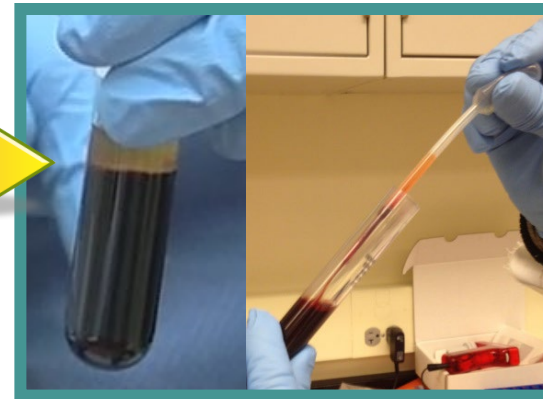
# Buffy Coat Collection



81 cell cryobox with 2.0 mL cryovials – sent to NCRAD

- 2 x EDTA (Lavender-Top) Blood Collection Tube (10 mL)
  - **Create up to (2) 0.25 mL buffy coat aliquots to be shipped to NCRAD**
    - Expected to have a reddish color from the RBCs.
    - Be sure to only place the buffy coat from one EDTA tube into each cryovial

Buffy Coat layer (mixed with RBCs)



Buffy Coat Aliquot (Please use BLUE CAP cryovial)

# Important Note: APOE

A SNP fingerprint is also obtained from every DNA sample, to be compared longitudinally across study visits to identify any subject/sample mix-ups. Apolipoprotein E (*APOE*) genotype is generated in-house as part of this fingerprint assay.



# Plasma and Buffy Coat Preparation (10 mL Lavender-Top Tube) x 2



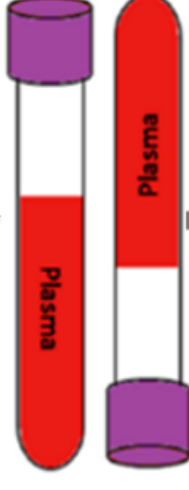
## Step One



## Step Two



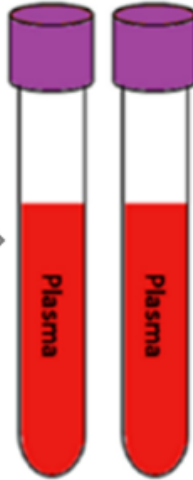
## Step Three



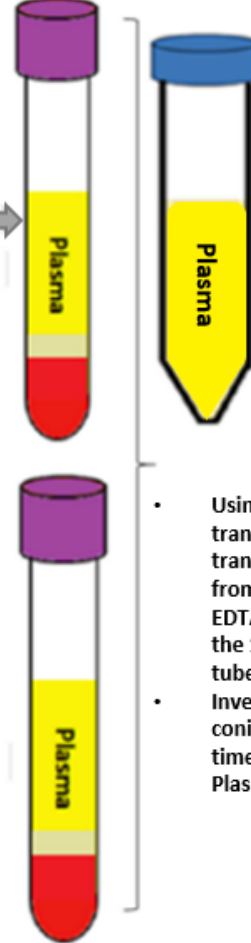
## Step Four



## Step Five



## Step Six



## Step Seven

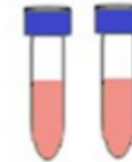


Up to 24 sent to NCRAD

Up to 17 sent to UNTHSC

- Aliquot 0.25 mL into each labeled cryovial tube.
- If a residual aliquot is created, document specimen number on Sample Notification Form.
- Store Plasma aliquots at -80°C until shipment.

## Step Eight



- Using a clean pipette tip aliquot buffy coat layer (may have residual plasma and RBCs) into labeled cryovials with blue cap.
- Store Buffy Coat aliquots at -80°C until shipment.



- Store tubes at room temperature.
- Place completed Site and BDS ID Label and Collection and Aliquot "PLASMA" Tube Labels on 10 mL Lavender-Top tubes prior to blood draw.
- Place pre-printed Aliquot "PLASMA" Tube Labels with color-coded purple strip on the (41) 0.5 mL cryovial tubes with clear caps prior to blood draw.
- Place pre-printed Aliquot "BUFFY COAT" Tube Labels on the (2) blue cap cryovials prior to blood draw.

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

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

- Place thoroughly mixed tubes on wet ice until centrifugation begins.

- Preferably within 30 minutes of blood draw, centrifuge samples at 2000 x g at 4°C for 10 minutes.
- Samples need to be spun, aliquoted, and in the freezer within 2 hours from the time of collection.

- Using a clean transfer pipette, transfer Plasma from both 10 mL EDTA tubes to the 15 mL conical tube.
- Invert 15 mL conical tube 3 times to mix the Plasma.



Appendix B



PT ID: \_\_\_\_\_ Site ID: \_\_\_\_\_  
Cycle Visit (Circle One): 1 2 3 4

Sample Collection - Blood & Shipment Notification Form

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

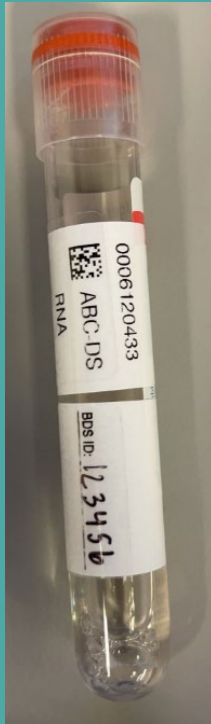
To: NCRAD		Email: alzstudy@iu.edu		Phone: 1-800-526-2839	
To: UNTHSC		Email: Tori.Como@unthsc.edu		Phone: 1-817-735-2638	
<b>General Information:</b>					
From: _____			Date: _____		
Phone: _____			Email: _____		
PT previously enrolled in (circle one): ADDS NIAD N/A-new PT					
NIAD/ADDS Legacy ID (if applicable): _____			Kit #: _____		
Arm: <input type="checkbox"/> DS Participant <input type="checkbox"/> Sibling Control			<div style="border: 1px solid black; padding: 5px; text-align: center;"> </div>		
Sex: <input type="checkbox"/> M <input type="checkbox"/> F Year of Birth: _____					
Shipment Tracking #: _____					
Field Draw?: <input type="checkbox"/> Yes <input type="checkbox"/> No					
<b>Blood Collection:</b>					
1. Date Drawn: _____ [YYYYMMDD]			2. Time of Draw (24 hour clock): _____ [HHMM]		
3. Last time subject ate (Date): _____ [YYYYMMDD]			4. Last time subject ate (24 hour clock): _____ [HHMM]		
<b>Blood Processing:</b>					
<b>RNA PAXgene™ Tube</b>			<b>NaHep Tube for karyotyping (if not drawn, enter N/A by mL)</b>		
Original volume drawn (1x2.5mL RNA PAXgene™ tube): _____ mL			Original volume drawn (1x4 mL NaHep tube): _____ mL		
Time placed in freezer: _____ [HHMM]			Has karyotyping ever been completed? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>Plasma (EDTA/Lavender Top Tube)</b>			<b>Serum (Serum Separator/Gold Top Tube)</b>		
Time spin started (24 hour clock): _____ [HHMM]			Time spin started (24 hour clock) (30 minutes after draw time): _____ [HHMM]		
Duration of centrifuge: _____ [minutes]			Duration of centrifuge: _____ [minutes]		
Temp of centrifuge: _____ °C Rate of centrifuge: _____ x g			Temp of centrifuge: _____ °C Rate of centrifuge: _____ x g		
Original volume drawn (2x10 mL EDTA tube): EDTA #1: _____ mL EDTA #2: _____ mL			Original volume drawn (2x5 mL Serum tube): _____ mL		
Time aliquoted: _____ [HHMM]			Time aliquoted: _____ [HHMM]		
Number of 0.25 mL plasma aliquots created (35-40 total) (Silicized cryovial): _____ x 0.25 mL			Number of 0.25 mL serum aliquots created (16-20 total) (Silicized cryovial): _____ x 0.25 mL		
Number of 0.25 mL plasma aliquots sent to UNTHSC: _____			Number of 0.25 mL serum aliquots sent to UNTHSC: _____		
Number of 0.25 mL plasma aliquots sent to NCRAD: _____			Number of 0.25 mL serum aliquots sent to NCRAD: _____		
If applicable, volume of residual plasma aliquot (less than 0.25 mL) (Silicized cryovial): _____ mL			If applicable, volume of residual serum aliquot (less than 0.25 mL) (Silicized cryovial): _____ mL		
If applicable, specimen number of residual aliquot (last four digits): _____			If applicable, specimen number of residual aliquot (last four digits): _____		
Time aliquots placed in freezer (24 hour clock): _____ [HHMM]			Time aliquots placed in freezer (24 hour clock): _____ [HHMM]		
Storage temperature of freezer: _____ °C			Storage temperature of freezer: _____ °C		
Buffy coat #1 (last four digits): _____ Buffy Coat #1 volume: _____ mL			Buffy coat #1 (last four digits): _____ Buffy Coat #1 volume: _____ mL		
Buffy coat #2 (last four digits): _____ Buffy Coat #2 volume: _____ mL			Buffy coat #2 (last four digits): _____ Buffy Coat #2 volume: _____ mL		
Notes: _____					

If field draw,

- Keep the samples on wet ice until you reach your destination. Record if field draw on sample form for NCRAD and UNTHSC. Please check "Yes" box on sample form (Appendix B) if field-draw and make note on Appendix F.

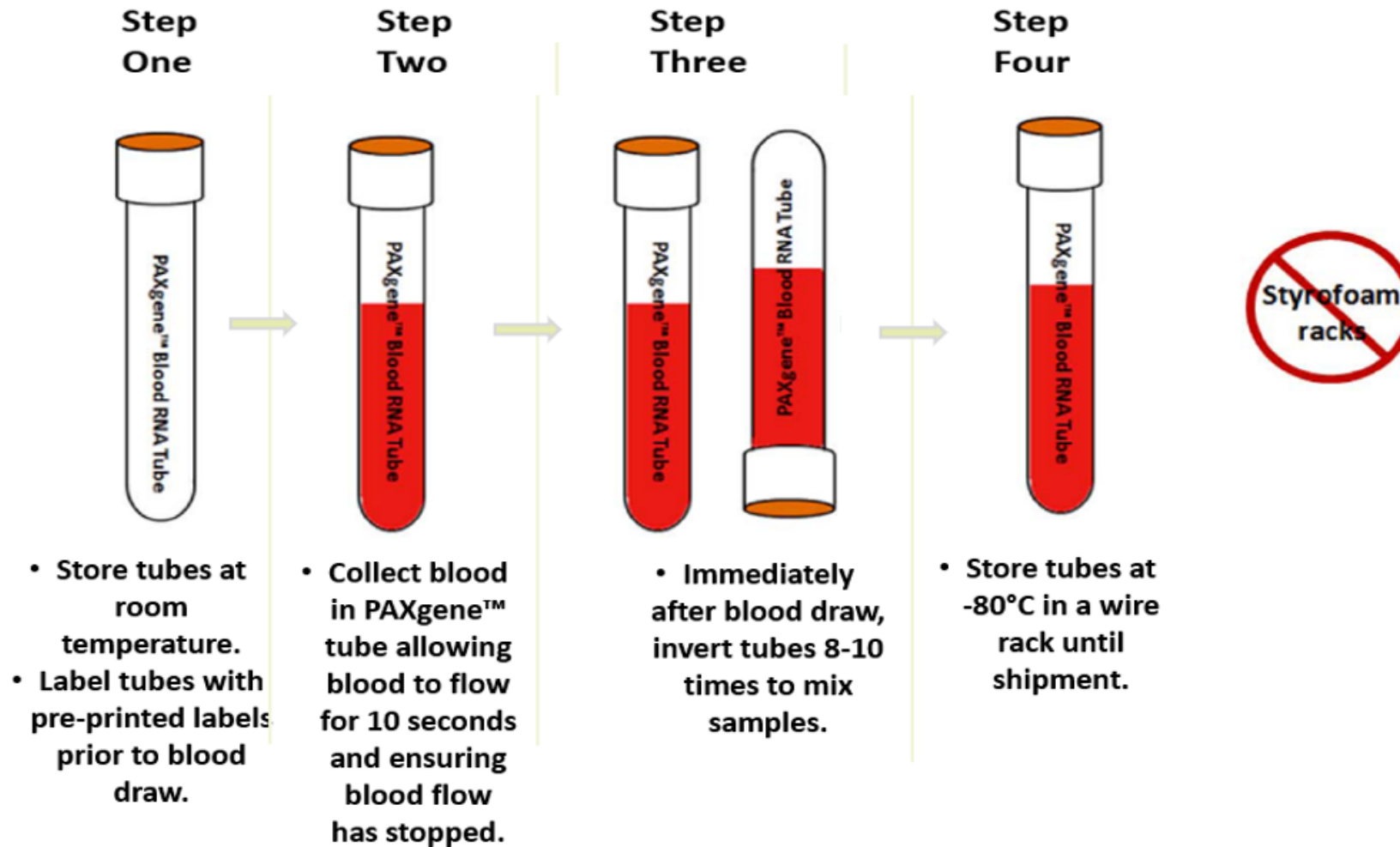


# RNA Collection



- 1 x PAXgene™ Blood Collection Tube (2.5 mL)
  - **This tube is to be shipped to NCRAD frozen, without further processing at the collection site.**
  - **If this happens to be the only tube collected at a visit, a serum discard tube is required to be drawn ahead of the PAXgene™ tube.**

# RNA Preparation (2.5mL PAXgene™ Tube) x 1



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



Appendix B



PT ID: \_\_\_\_\_ Site ID: \_\_\_\_\_

Cycle Visit (Circle One): 1 2 3 4

**Sample Collection - Blood & Shipment Notification Form**

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

To: NCRAD		Email: alzstudy@iu.edu		Phone: 1-800-526-2839	
To: UNTHSC		Email: Tori.Como@unthsc.edu		Phone: 1-817-735-2638	
<b>General Information:</b>					
From: _____			Date: _____		
Phone: _____			Email: _____		
PT previously enrolled in (circle one): ADDS NIAD N/A-new PT					
NIAD/ADD5 Legacy ID (if applicable): _____					KIT #: _____
Arm: <input type="checkbox"/> DS Participant <input type="checkbox"/> Sibling Control		<div style="border: 1px solid black; padding: 5px; display: inline-block;">KIT BARCODE</div>			
Sex: <input type="checkbox"/> M <input type="checkbox"/> F Year of Birth: _____					
Shipment Tracking #: _____					
Field Draw?: <input type="checkbox"/> Yes <input type="checkbox"/> No					
<b>Blood Collection:</b>					
1. Date Drawn: _____ [YYYYMMDD]			2. Time of Draw (24 hour clock): _____ [HHMM]		
3. Last time subject ate (Date): _____ [YYYYMMDD]			4. Last time subject ate (24 hour clock): _____ [HHMM]		
<b>Blood Processing:</b>					
<b>RNA PAXgene™ Tube</b>			<b>NaHep Tube for karyotyping (if not drawn, enter N/A by mL)</b>		
Original volume drawn (1x2.5mL RNA PAXgene™ tube): _____ mL		Time placed in freezer: _____ [HHMM]	Original volume drawn (1x4 mL NaHep tube): _____ mL		
<b>Plasma (EDTA/Lavender Top Tube)</b>					
Time spin started (24 hour clock): _____ [HHMM]		Has karyotyping ever been completed? <input type="checkbox"/> Yes <input type="checkbox"/> No			
<b>Serum (Serum Separator/Gold Top Tube)</b>					
Duration of centrifuge: _____ [minutes]		Time spin started (24 hour clock) (30 minutes after draw time): _____ [HHMM]		Duration of centrifuge: _____ [minutes]	
Temp of centrifuge: _____ °C		Rate of centrifuge: _____ x g		Temp of centrifuge: _____ °C	
Original volume drawn (2x10 mL EDTA tube): EDTA #1: _____ mL EDTA #2: _____ mL		Rate of centrifuge: _____ x g		Original volume drawn (2x5 mL Serum tube): _____ mL	
Time aliquoted: _____ [HHMM]		Original volume drawn (2x5 mL Serum tube): _____ mL		Time aliquoted: _____ [HHMM]	
Number of 0.25 mL plasma aliquots created (35-40 total) (Siliconized cryovial): _____ x 0.25 mL		Number of 0.25 mL plasma aliquots sent to UNTHSC: _____		Number of 0.25 mL plasma aliquots sent to NCRAD: _____	
If applicable, volume of residual plasma aliquot (less than 0.25 mL) (Siliconized cryovial): _____ mL		Number of 0.25 mL serum aliquots sent to UNTHSC: _____		Number of 0.25 mL serum aliquots sent to NCRAD: _____	
If applicable, specimen number of residual aliquot (last four digits): _____		If applicable, volume of residual serum aliquot (less than 0.25 mL) (Siliconized cryovial): _____ mL		If applicable, specimen number of residual aliquot (last four digits): _____	
Time aliquots placed in freezer (24 hour clock): _____ [HHMM]		Time aliquots placed in freezer (24 hour clock): _____ [HHMM]		Storage temperature of freezer: _____ °C	
Storage temperature of freezer: _____ °C		Buffy coat #1 (last four digits): _____ Buffy Coat #1 volume: _____ mL		Buffy coat #2 (last four digits): _____ Buffy Coat #2 volume: _____ mL	
Notes:					

# If field draw,

- **If field-draw**, transfer tube upright in a **WIRE** rack at room temperature until storage in a **-80°C freezer**. Complete remainder of the Biological Sample and Shipment Notification Form (Appendix B) . Please check “Yes” box on sample form (Appendix B) if field-draw and make note on Appendix F.

# Important Note

**UNTHSC samples take priority!**

**If equal to or less than 2 serum aliquots are created, only send to UNTHSC.**

**If equal to or less than 17 plasma aliquots are created, only send to UNTHSC.**






TO UNTHSC: 25-cell  
cryobox to contain Plasma  
and Serum aliquots

# IU Path Lab (Clinical Labs) Sample Collection and Processing



# IU Path Lab Research Blood Collection

## DS Participants ONLY

Tube Type	Number of Tubes Drawn	Tube Image
1. Serum Separator (Orange-Top) Blood Collection Tube (5 mL)	X 1	
2. Serum Separator (Gold-Top) Blood Collection Tube (5 mL)	X 1	
3. EDTA (Lavender-Top) Blood Collection Tube (3 mL)	X 1	

# Aliquot Cap Colors

Cap Color	Sample Type
Clear Cap	Serum (<1.0 mL)
Red Cap	Serum (<1.0 mL)

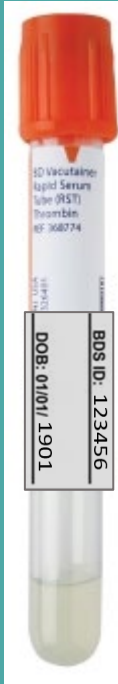


Clear Cap



Red Cap

# Serum Collection



25 cell cryobox with 1.0 mL cryovials – sent to IU Path Lab

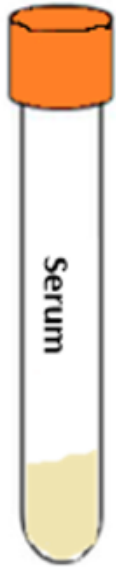
- 1 x Serum Separator (Orange-Top) Blood Collection Tube (5 mL)
  - Create up to (2) 1.0 mL serum aliquots to be shipped to IU Path Lab



# Free T4, Thyroid, Triiodothyronine, TSH, Vit B12, ATA Preparation (1 X 5 ml Orange Top Tubes)



Step One



- Store tubes at room temperature.
- Label tubes with pre-printed subject labels prior to blood draw.

Step Two



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

Step Three



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

Step Four



- Within 60 minutes of blood draw, centrifuge samples at 1300 x g at 4°C for 10 minutes.

Step Five



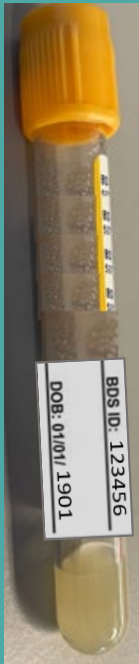
- Label clear cap cryovial tubes with preprinted labels.
- Aliquot 1.0ml of serum into each cryovial tube.
- Store serum aliquots in refrigerator until shipment.

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

# CRITICAL STEP:

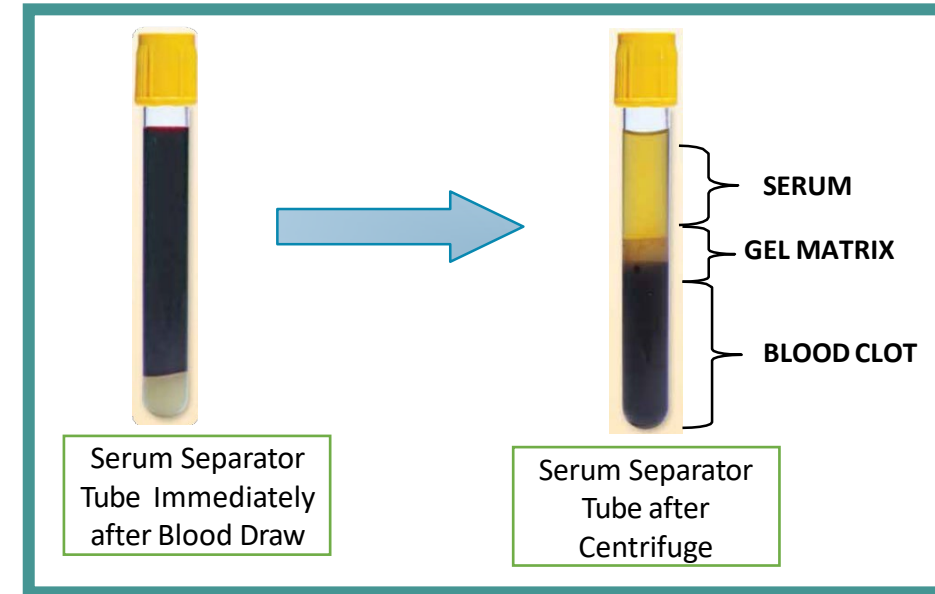
1. For best results, serum samples should be spun within 1 hour from the time of collection.
2. **EXCEPTION:** If field-draw, processing must be completed within 2 hours from time of collection. Place tube on rack in upright position during transfer to lab with cold packs until able to process. Please note on the IU Path Lab form ([Appendix D](#)) that it is a field-draw and the time it takes to process the samples.

# Serum Collection



25 cell cryobox with 1.0 mL cryovials – sent to IU Path Lab

- 1 x Serum Separator (Gold-Top) Blood Collection Tube (5 mL)
  - Create up to (2) 1.0 mL serum aliquots to be shipped to IU Path Lab



# Vit D, BMP, Lytes and Lipid Preparation (1 X 5 ml Gold Top Tube)



Step One



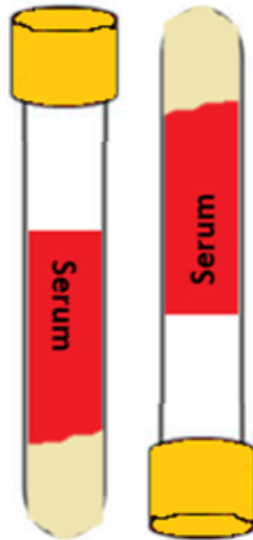
- Store tubes at room temperature.
- Label tubes with pre-printed subject labels prior to blood draw.

Step Two



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

Step Three



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

Step Four



- Allow blood to clot for 30 minutes.
- Within 60 minutes of blood draw, centrifuge samples at 1300 x g at 4°C for 10 minutes.

Step Five



- Label red cap cryovial tubes with preprinted labels.
- Aliquot 1.0ml of serum into each cryovial tube.
- Store serum aliquots in refrigerator until shipment.

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

# CRITICAL STEP:

1. Allow blood to clot at room temperature by placing it upright in a vertical position in a tube rack for 30 minutes. For best results, serum samples should be spun within 1 hour from the time of collection.
2. **EXCEPTION:** If field-draw, processing must be completed within 2 hours from time of collection. Place tube on rack in vertical position during transfer to lab with cold packs until able to process. Please note on the IU Path Lab form (Appendix D) that it is a field-draw and the time it takes to process the samples.

## NOTICE:

The SST (gold-top) tube requires clotting (Vit D, BMP, Lytes, Lipid Preparation).

The SST (orange-top) tube DOES NOT require clotting.

# Whole Blood Collection for CBC and A1C



- 1 x EDTA (Lavender-Top) Blood Collection Tube (3 mL)
  - **This tube is to be shipped to IU Path Lab refrigerated on the day of collection, without further processing at the collection site.**

# CBC and A1C Preparation (1 x 3ml EDTA Purple Top Tube)



Step One



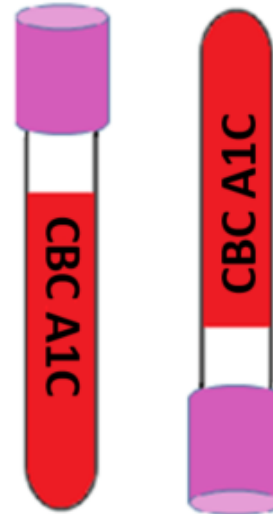
- Store tubes at room temperature.
- Label tubes prior to blood draw.

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 whole blood tube in refrigerator until shipment.

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





# Accessing Clinical Lab Results:

- Clinical lab results will be available through the IU Health Lifepoint application. To access site specific participant results, study personnel must complete an “Access Request –Lifepoint, IU Non-Employee Form” ([link](#)) and submit directly to IU Health. Social Security Number can be documented as “n/a” if the form is signed off on by the Field Site Lead in place of Manager. IU Health will send log-in information to you directly. The ABC-DS Admin Core will not need copies of these set up documents; however, please inform us who from your site will be designated to access the Lifepoint portal.
- Biospecimen Collection, Processing, and Shipment Manual
- 67 Version (4.2022)
- The ‘group data’ for all participants will be sent directly from the IU Health Path Lab to LONI, for purposes of analysis. (Site and participant IDs will be removed and new ID assigned per ABC-DS protocol.)
- **\*Please check the portal for results ASAP in case a test fails and a re-draw is in order. Saturday deliveries: If issues arise with the specimens, the IU Path Lab will perform the tests offline. The following Monday, after review and corrections, results will be posted.**

# Incomplete and 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 UNTHSC and NCRAD. See page 11 of the manual for re-draw instructions.



# 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 UNTHSC and NCRAD
    - i. Indicate blood draw difficulties at the bottom of the 'Biological Sample and Shipment Notification Form' within the "Notes" section.
    - ii. Complete the 'Biological Sample and Shipment Notification Form' with tube volume approximations and number of aliquots created.
  - c. Contact a NCRAD coordinator and alert them of the challenging blood draw
  - d. If samples are hemolyzed (see right), please do not send.
2. *If the biospecimens at a scheduled visit **are not** collected:*
  - a. Contact the ABC-DS Monitor and a NCRAD coordinator to alert them of the challenging blood draw or circumstances as to why biospecimens were not collected.
  - b. Schedule participant for a longitudinal visit.
    - i. If samples were unable to be drawn, please draw the Sodium Heparin (Green-Top) Tube for Karyotyping during the next visit (as needed).



(photo: A.H. – U of Wisconsin)

# Packing and Shipping Samples



# **NCRAD and UNTHSC Sample Shipping**

# NCRAD and UNTHSC Blood Sample Shipment Summary

Sample Type	Processing/ Aliquoting	Tubes to NCRAD	Tubes to UNTHSC	Ship
Whole blood for isolation of serum	0.25 mL serum aliquot per 0.5 mL cryovial (clear cap)	19	2	Frozen
Whole blood for Karyotyping	N/A	1	0	Ambient
Whole blood for isolation of plasma & buffy coat (for DNA extraction)	0.25 mL plasma aliquot per 0.5 mL cryovial (clear cap)	24	17	Frozen
	1 mL buffy coat aliquot per 2.0 mL cryovial (BLUE CAP)	2	0	Frozen
Whole blood for RNA extraction	N/A	1	0	Frozen

# **Frozen Shipping**

Serum, Plasma, Buffy Coat and RNA

# Notify NCRAD and UNTHSC When Samples Ship:

1. **Notify NCRAD of shipment** by emailing NCRAD coordinators at: [alzstudy@iu.edu](mailto:alzstudy@iu.edu)

➤ Attach the following to the email:

- Completed Biological Sample and Shipment Notification Form ([Appendix B](#) – also found on the [NCRAD ABC-DS study page](#)).
- If email is unavailable, please call NCRAD and do not ship until you've contacted and notified NCRAD coordinators about the shipment in advance.
- Please include the tracking number in the body of the email.
- Place physical copy of the filled out Biological Sample and Shipment Notification (Appendix B) in your shipment.

2. **Notify UNTHSC of shipment** by emailing UNTHSC Lab Manager at: [Tori.Como@unthsc.edu](mailto:Tori.Como@unthsc.edu)

➤ Attach the following to the email:

- Completed UNTHSC Intake Form ([Appendix F](#) – also found on the [NCRAD ABC-DS study page](#)) and the UNTHSC Import Batch Form ([Appendix G](#)):
  - Aliquot barcodes need to be listed on the UNTHSC Import Batch Form ([Appendix G](#)). NCRAD will send an Excel file with all aliquot barcodes included in each kit when kit supplies are shipped.
- If email is unavailable, please call UNTHSC and do not ship until you've contacted and notified UNTHSC Lab Manager about the shipment in advance.
- Please include the tracking number in the body of the email.
- Place physical copy of the UNTHSC Intake Form (Appendix F) and UNTHSC Import Batch Form (Appendix G) in your shipment.



# Frozen Shipment Packaging:

Place all frozen labeled aliquots of serum, plasma and buffy coat in the cryovial cryoboxes.



Place kit number label(s) on cryoboxes



**FOR NCRAD:** Place up to 19 serum, 24 plasma, and 2 buffy coat cryovials per participant visit inside 81 cell cryobox. Put the RNA tube inside the bubble wrap sleeve, seal, and place inside large biohazard bag along with the 81 cell cryobox to ship to NCRAD frozen. Seal biohazard bag according to the instructions on the bag.

**FOR UNTHSC:** Place up to 2 serum and 17 plasma cryovials per participant visit inside 25 cell cryobox. Place 25 cell cryobox inside the small biohazard bag with absorbent sheet. Seal biohazard bag according to the instructions on the bag.

# Batch Shipping

- FOR **NCRAD** - Batch shipping should be performed every 3 months **or** when specimens from 5 participants accumulates, whichever is sooner. Up to 5 81-slot cryoboxes can fit in the shipper provided with dry ice included.
- FOR **UNTHSC** – Batch shipping should be performed every 3 months **or** when specimens from 5 participants accumulate, whichever is sooner. Up to 5 25-slot cryoboxes can fit in the shipper provided with dry ice included.

# Frozen Shipment Packaging

- Place 2-3 inches of dry ice in the bottom of the Styrofoam shipping container, then insert the cryoboxes laying upright.
- 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.
- Fill shipper to the top with dry ice!

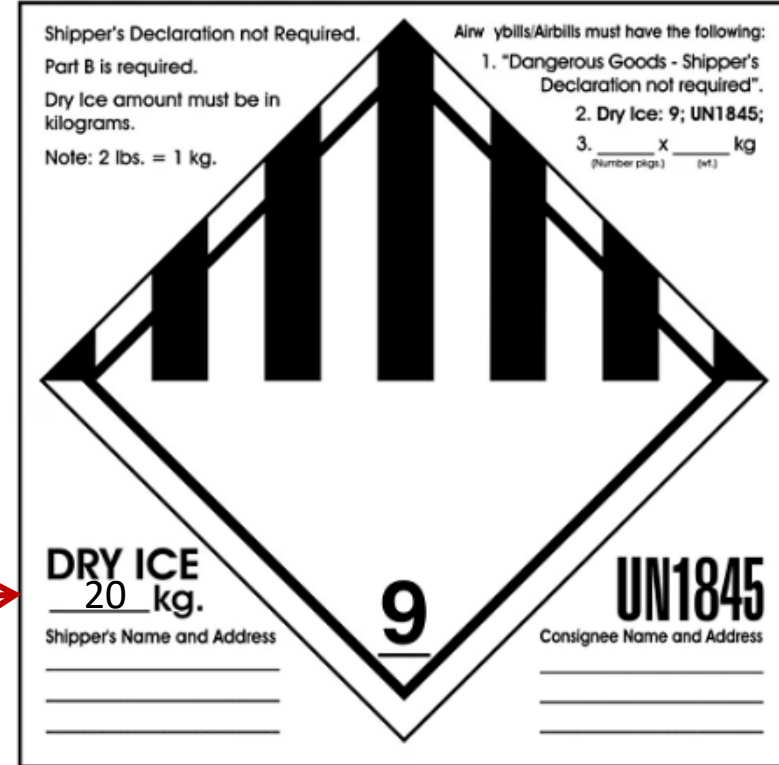


# Frozen Shipping Dry Ice Requirements

**Failure to do the following will result in shipping carrier rejecting/returning your package!**

1. Net weight of dry ice in kg (must match amount on the airbill)!
2. Dry Ice label should not be covered with other stickers and must be completed (see right)!

Net weight of dry ice in **kg**



Shipper's Declaration not Required. Part B is required. Dry Ice amount must be in kilograms. Note: 2 lbs. = 1 kg.

Airbills/Airbills must have the following:

1. "Dangerous Goods - Shipper's Declaration not required".
2. Dry Ice: 9; UN1845;
3. \_\_\_\_\_ x \_\_\_\_\_ kg  
(Number pgs.) (wt.)

**DRY ICE**  
20 kg.

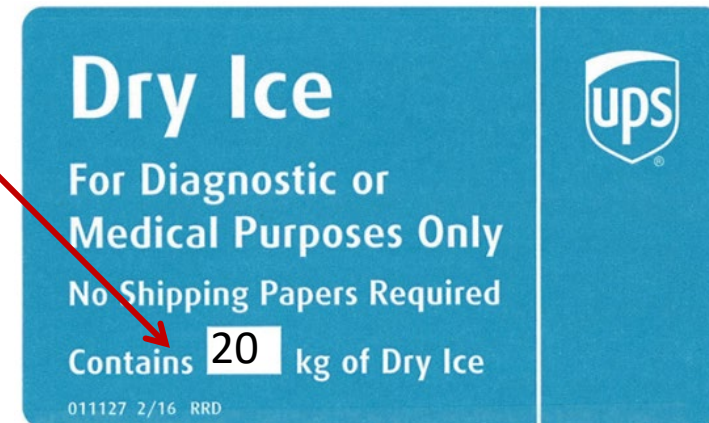
Shipper's Name and Address \_\_\_\_\_

**9**

**UN1845**

Consignee Name and Address \_\_\_\_\_

FedEx Dry Ice Sticker



**Dry Ice**

For Diagnostic or Medical Purposes Only

No Shipping Papers Required

Contains **20** kg of Dry Ice

011127 2/16 RRD

**ups**

UPS Dry Ice Sticker (UW-Madison Only)

# Critical Frozen Shipping Instructions

1. On the day of scheduled pick-up, begin packaging specimens on dry ice at least 1 hour before UPS/FedEx arrives. Hold samples in -80°C freezer until it is time to package the specimens on dry ice for shipment to NCRAD.

2. Frozen samples should be shipped via FedEx Priority Overnight (via UPS Next Day Air for UW-Madison)

3. Frozen shipments should be sent Monday through Wednesday ONLY to avoid shipping delays on Thursday or Friday.

**BE AWARE OF HOLIDAYS and current weather conditions!**

FedEx does not replenish dry ice if shipments are delayed or held over during the weekend.

4. Remember to complete the requisition forms and include a copy in your shipment: Biological Sample and Shipment Notification (Appendix B) for NCRAD and UNTHSC Intake Form (Appendix F) and UNTHSC Import Batch Form (Appendix G) for UNTHSC.

# **Creating Airbills/Scheduling Pickups**

Frozen Shipments

# Creating Airbills/Scheduling Pickups

**1. Complete the FedEx return airbill (if UW-Madison, follow UPS instructions provided at site) with the following information:**

- Section 1, “From”: fill in your name, address, phone number, and Site FedEx Account Number.
- Section 2, “Your Internal Billing Reference”: add any additional information required by your site.
- Section 6, “Special Handling and Delivery Signature Options”: under “Does this shipment contain dangerous goods?” check the boxes for “Yes, Shipper’s Declaration not required” and “Dry Ice”. Enter the number of packages (1) x the net weight of dry ice in kg.
- Section 7, “Payment”, check sender and bill transportation costs to your site’s study FedEx account number.

**2. Complete the Class 9 UN 1845 Dry Ice label (black and white diamond) with the following information:**

- Your name and return address
- Net weight of dry ice in kg (must match amount on the airbill)
- Consignee name and address:

**NCRAD**

IU School of Medicine  
351 West 10th Street  
TK-217  
Indianapolis, IN 46202  
Phone: 1-800-526-2839

**UNTHSC**

ATTN: Tori Conger  
3420 Darcy Street  
Fort Worth, TX 76107  
Phone: 817-735-2638

- Do not cover any part of this label with other stickers, including pre-printed address labels.

**3. Apply all provided warning labels and the completed FedEx return airbill to the outside of package, taking care not to overlap labels.**

# **Ambient Shipping**

Sodium Heparin (Green-Top) Blood  
Collection Tube (4 mL) for karyotyping



# Notify NCRAD When NaHep Tube Ships:

1. Notify NCRAD of shipment by emailing NCRAD coordinators at: [alzstudy@iu.edu](mailto:alzstudy@iu.edu)
  - Attach the following to the email:
    - Complete and attach the Constitutional (Blood) Test Requisition Form to the email. (See [Appendix E](#) for an example of the 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.
    - Please include the tracking number in the body of the email.
    - Place physical copy of the filled out Constitutional (Blood) Test Requisition Form (Appendix E) inside the biohazard bag.

## Reminder:

Drawn for DS Participants at Baseline ONLY AS NEEDED

Used to obtain karyotype for full or partial trisomy 21.

**If karyotyping has been done for the participant, please check "Yes" on the Biological Sample and Shipment Notification Form (Appendix B).**

Biospecimen Collection, Processing, and Shipment Manual

**NCRAD**

Appendix B

PT ID: \_\_\_\_\_ Site ID: \_\_\_\_\_

Cycle Visit (Circle One): 1 2 3 4

**Sample Collection - Blood & Shipment Notification Form**

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

To: NCRAD	Email: alzstudy@iu.edu	Phone: 1-800-526-2839
To: UNTHSC	Email: Tori.Como@unthsc.edu	Phone: 1-817-735-2638

General Information:

From: \_\_\_\_\_ Date: \_\_\_\_\_

Phone: \_\_\_\_\_ Email: \_\_\_\_\_

PT previously enrolled in (circle one): ADDS NIAD N/A-new PT

NIAD/ADDS Legacy ID (if applicable): \_\_\_\_\_ Kit #: \_\_\_\_\_

Arm:  DS Participant  Sibling Control

Sex:  M  F Year of Birth: \_\_\_\_\_

Shipment Tracking #: \_\_\_\_\_ Field Draw?:  Yes  No

**Blood Collection:**

1. Date Drawn: [YYYYMMDD] 2. Time of Draw (24 hour clock): [HHMM]

3. Last time subject ate (Date): [YYYYMMDD] 4. Last time subject ate (24 hour clock): [HHMM]

**Blood Processing:**

RNA PAXgene™ Tube	NaHep Tube for karyotyping (if not drawn, enter N/A by mL)
Original volume drawn (1x2.5mL RNA PAXgene™ tube): _____ mL Time placed in freezer: [HHMM]	Original volume drawn (1x4 mL NaHep tube): _____ mL

**Plasma (EDTA/Lavender Top Tube)**

Time spin started (24 hour clock): [HHMM]

Duration of centrifuge: [minutes]

Has karyotyping ever been completed?  Yes  No

**Serum (Serum Separator/Cold Top Tube)**

Time spin started (24 hour clock) (30 minutes after): \_\_\_\_\_

# Ambient Shipment Packaging:



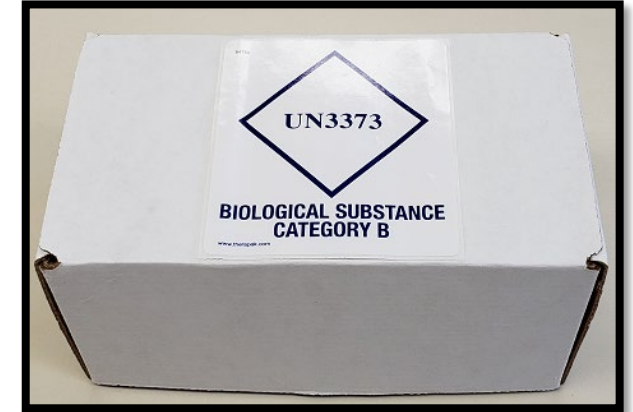
NaHep Sample



Absorbent Pad



Biohazard Bag



- Place the filled and sealed sodium heparin (green-top) tube within the slots in the absorbent pad provided, and place into the plastic biohazard bag with absorbent sheet.
- Place the filled out Constitutional (Blood) Test Requisition Form (Appendix E) inside the biohazard bag as well.
- Remove as much air as possible from the plastic biohazard bag and ensure the Kit Number Label and BDS ID Label are placed on the tube before sealing the bag according to the directions printed on the bag.

- Place the sealed biohazard bag inside the cooler and place the refrigerant pack into the cooler on top of the filled biohazard bag.
- Place the lid onto the cooler.
- Place the cooler in the provided small IATA Shipping Box.

- Close 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 Clinical Pak. Seal the Clinical Pak.
- Place return airbill on the sealed Clinical Pak.

# Creating Airbills/Scheduling Pickups

1. Be sure to complete the return airbill with the following information:
  1. Section 1, “From”: fill in the date, your name, and phone number.
  2. Section 2, “Your Internal Billing Reference”: add any additional information required by your site.
2. NaHep tubes should be sent ambient to the below address via FedEx Priority Overnight (via UPS Next Day Air for UW-Madison) **Monday through Thursday ONLY!!!**

**ABC-DS at NCRAD**  
IU School of Medicine  
351 West 10th Street  
TK-217  
Indianapolis, IN 46202  
Phone: 1-800-526-2839

3. Use tracking to ensure the delivery occurs as scheduled and is received by NCRAD.

# Critical Ambient Shipping Instructions

Sodium Heparin (Green-Top) Blood Collection Tube (1 x 4 mL)

**1. Ambient specimens should be shipped to NCRAD via FedEx Priority Overnight (via UPS Next Day Air for UW-Madison) ON DAY OF BLOOD DRAW!**

**2. Ambient shipments should be sent Monday through Thursday ONLY! Do NOT draw blood on Fridays!**

**BE AWARE OF HOLIDAYS and current weather conditions!**

**3. Include no more than one tube per shipping container and only include tube from one participant.**

**4. Place physical copy of the filled out Constitutional (Blood) Test Requisition Form (Appendix E) inside the biohazard bag.**

# **International Shipments**



# University of Cambridge: Forwarding Samples to UNTHSC from NCRAD

- All international shipments will utilize the same packing requirements as specified in Section 8.1 (Frozen Shipping Instructions).
- UNTHSC will not be receiving international shipments.
  - International sites will receive a fluorescent label that reads “ABC-DS: Forward to UNTHSC” to adhere to the outside of the shipping container with samples to be forwarded to UNTHSC by NCRAD.
  - When NCRAD receives a shipment from Cambridge with this fluorescent sticker, the lab will replenish the dry ice WITHOUT taking inventory and ship the frozen samples to UNTHSC.
  - **SHIP ON MONDAYS ONLY TO AVOID DELAYS**

# Two components are necessary for international shipments:

1. International return airbill
2. International Commercial Invoice

## Ship samples to NCRAD's lab:

### **NCRAD**

IU School of Medicine

351 West 10<sup>th</sup> Street

TK-217

Indianapolis, IN 46202

Phone: 1-800-526-2839

**If shipping via World Courier, skip these directions.**

# Creating Airbills/Scheduling Pickups

- Two components are necessary for international shipments:
  - International FedEx return airbill
  - International Commercial Invoice
- NCRAD will provide an International FedEx return airbill to all International sites. However, these international sites are welcome to utilize the FedEx electronic system.
  - Be sure to complete the FedEx return airbill with the following information:
    - Section 1, From: Enter the date and your name, phone number, complete address, and FedEx account number.
    - Section 2, To: This information will be preprinted with NCRAD's return address and phone number.
    - Section 3, Shipment information: This information does NOT replace a Commercial Invoice that is required for these shipments. Total Packages, Weight, and box dimensions are required. Be consistent between this International FedEx return airbill and the International Commercial Invoice.
      - Do not declare the value of the shipment to be over \$2,500. This would require additional paperwork (a Shipper's Export Declaration form).
    - Section 4, Express Package Services: Please check FedEx Intl. Priority for both Frozen and Ambient Shipments. (Pictured)

4 Express Package Service

FedEx Intl. Priority     FedEx Intl. First  
Available to select localities.

\_\_\_\_\_     FedEx Intl. Economy  
FedEx Envelope and FedEx Pak.  
rates not available.

Packages up to 150 lbs. / 68 kg.  
For packages over 100 lbs. / 45 kg, use the  
FedEx Expanded Service Int. Air Waybill.



# Creating Airbills/Scheduling Pickups (cont.)

5. Section 5, Packaging: Please select “Other” for Frozen Shipments and “FedEx Pak” for Ambient Shipments.
6. Section 6, Special Handling: Please leave blank.
7. Section 7 and 8, Payment: Check Sender and bill transportation costs to your site’s study FedEx account number. Duties and Taxes will also be billed to the sender. If your site requests information to be included as reference, please complete Section 8.
8. Section 9, Required Signature: This section must be signed by the sender or department representative.

# Creating Airbills/Scheduling Pickups (cont.)

- a. International Commercial Invoice (See [Appendix C](#) – fillable online PDF [here](#))
  - i. The International Commercial Invoice must be completed and placed with the International return airbill.
    - 1. Include **ONE** original and **THREE** copies of this completed form with the FedEx return airbill.
  - i. Complete “Shipped From” with your name, address, and any additional contact information.
  - i. Complete “Shipped To, Consignee” with the NCRAD shipping address:

**NCRAD**

IU School of Medicine  
351 West 10<sup>th</sup> Street  
TK-217  
Indianapolis, IN 46202  
Phone: 1-800-526-2839

- iv. Complete Number of Packages and Shipping weight to match the information recorded within the International FedEx return airbill.
- 7. Immediately below the shipping weight is a section asking for the Country of Origin, Description of Goods, Quantity, Unit Price, and Total Price. Please be as detailed as possible within this section (example pictured below).

# Creating Airbills/Scheduling Pickups (cont.)

- a. International Commercial Invoice (See [Appendix C](#) – fillable online PDF [here](#))
  - i. The International Commercial Invoice must be completed and placed with the International return airbill.
    - 1. Include **ONE** original and **THREE** copies of this completed form with the FedEx return airbill.
  - ii. Complete “Shipped From” with your name, address, and any additional contact information.
  - iii. Complete “Shipped To, Consignee” with the NCRAD shipping address:

**NCRAD**  
IU School of Medicine  
351 West 10<sup>th</sup> Street  
TK-217  
Indianapolis, IN 46202  
Phone: 1-800-526-2839

- iv. Complete Number of Packages and Shipping weight to match the information recorded within the International FedEx return airbill.
- v. Immediately below the shipping weight is a section asking for the Country of Origin, Description of Goods, Quantity, Unit Price, and Total Price. Please be as detailed as possible within this section (example pictured below).

COUNTRY OF ORIGIN & PROVINCE, IF CANADA PAYS D'ORIGINE ET PROVINCE, SI CANADA	DESCRIPTION OF GOODS DESCRIPTION DES MARCHANDISES	QUANTITY QUANTITE	UNIT PRICE PRIX UNITAIRE	TOTAL PRICE PRIX TOTAL
Canada, Vancouver	Non-Infectious, non-contagious, human Plasma and Buffy Coat sample	1 Box (11 Aliquots)	100.00	100.00

# Creating Airbills/Scheduling Pickups (cont.)

vi. Tally the Total Price within the last column for all goods included in shipment and record appropriately.

1. Reminder: the total price/value of the shipment should not exceed \$2,500.

vii. Complete the final section with your signature.

viii. Specimens should be sent to the below address via FedEx Priority Overnight. Ambient FedEx shipments should be sent Monday through Thursday. Frozen FedEx Shipments should only be sent Monday through Wednesday.

ix. Use FedEx tracking to ensure the delivery occurs as scheduled and is received by NCRAD.

**Clinical Labs**  
**Sample Shipping**  
Samples to IU Path Lab

# IU Path Lab Blood Sample Shipment Summary

## DS Participants ONLY

Sample Type	Tube Type	Processing/ Aliquoting	Tubes to IU Path Lab	Ship
Whole blood for isolation of serum	Serum Separator (Orange-Top) Blood Collection Tube (5 mL)	N/A	N/A	N/A
	SERUM: 2.0 mL cryovials	1.0 mL serum aliquot per 2.0mL cryovial (CLEAR CAP)	2	Refrigerated
	Serum Separator (Gold-Top) Blood Collection Tube (5 mL)	N/A	N/A	N/A
	SERUM: 2.0 mL cryovials	1.0 mL serum aliquot per 2.0mL cryovial (RED CAP)	2	Refrigerated
Whole Blood for CBC Preparation	EDTA (Lavender-Top) Blood Collection Tube (3 mL)	N/A	1	Refrigerated
Whole Blood for A1C Preparation				

If a sample is not obtained at a particular visit, this should be recorded in the notes section of the **IU Path Lab form** ([Appendix D](#)). Submit a copy to IU Path Lab with a reason provided for the omission.

# **Refrigerated Shipping**

Serum and EDTA Tube (3 mL)

# Notify IU Path Lab When Samples Ship:

1. Notify the IU Pathology Lab of shipment by emailing IU Path Lab study contacts at: [kcleary@IUHealth.org](mailto:kcleary@IUHealth.org), [PJordan@IUHealth.org](mailto:PJordan@IUHealth.org), [rball3@IUHEALTH.ORG](mailto:rball3@IUHEALTH.ORG), AND [jminch1@iuhealth.org](mailto:jminch1@iuhealth.org).
  - a. Attach the following to the email:
    - i. Completed IU Path Lab Requisition Form ([Appendix D](#)).
    - ii. If email is unavailable please call IU Path Lab and do not ship until you've contacted and notified IU Path Lab study contacts about the shipment in advance.
    - iii. Please include the tracking number in the body of the email.
    - iv. Place physical copy of the filled out IU Path Lab Req Form (Appendix D).

## Friday Blood Draws:

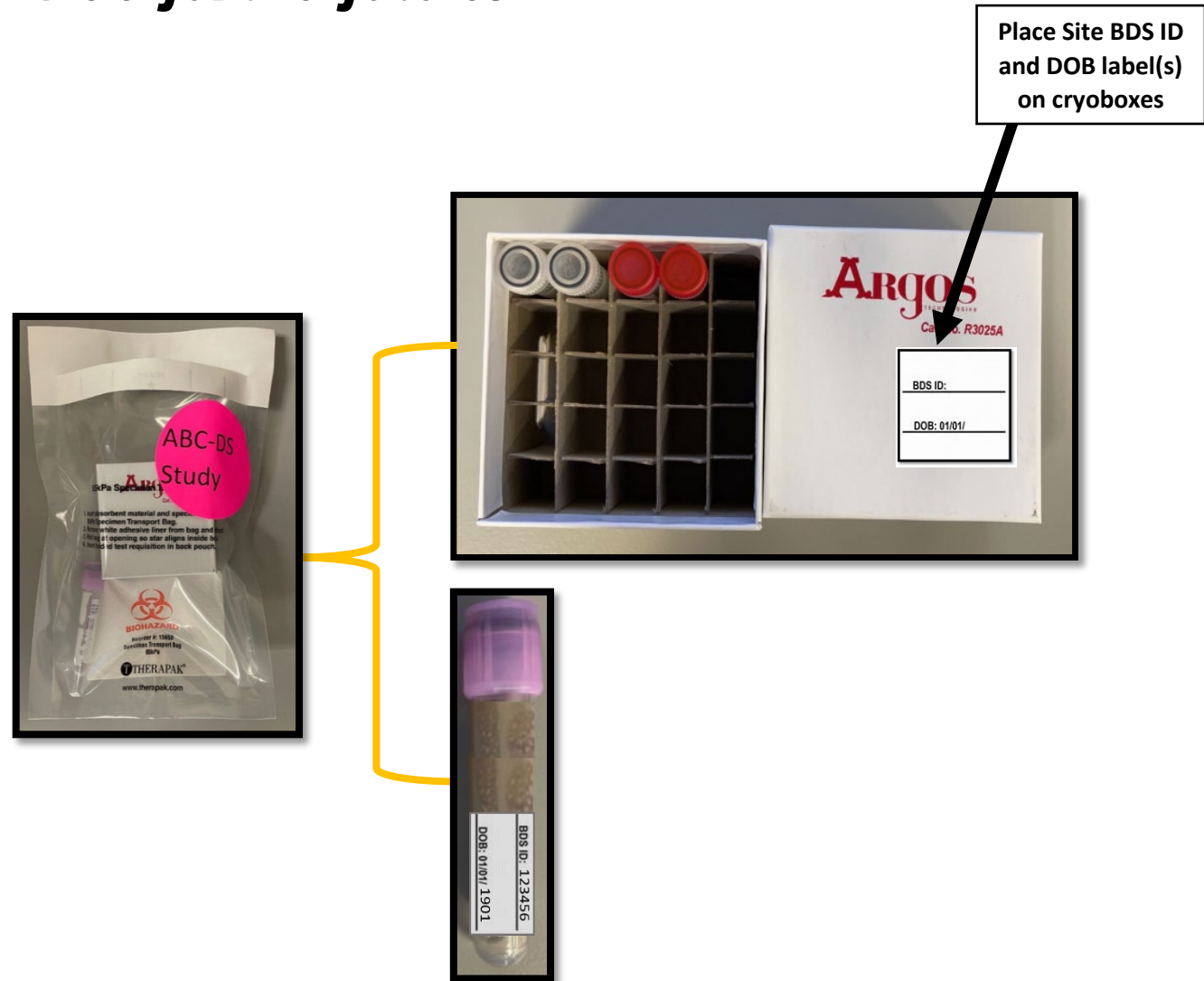
The IU Path Lab building is locked on the weekend, therefore one of the staff members will have to let the delivery driver in to complete delivery. Make sure the IU Path Lab is properly notified of the shipment and carefully track the package in transit.



# Refrigerated Shipment Packaging:

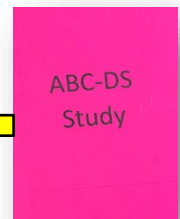
Place all refrigerated labeled aliquots of serum in the cryovial cryoboxes.

- Place up to 4 serum cryovials per participant visit inside 25 cell cryobox. Put the EDTA (3 mL) tube inside the bubble wrap sleeve, seal, and place inside the biohazard bag along with the 25 cell cryobox. Seal according to the instructions on the bag.
- **Ensure fluorescent round sticker is on biohazard bag.**



# Refrigerated Shipment Packaging (cont.):

- Place biohazard bag within X-Small Insulated shipper with 2 cold packs and put lid on cooler.
  - **CRITICAL STEP:** Store Cold Packs in refrigerator, ~4°C, 24 hours before use.
- **Place X-Small Insulated shipper within brown corrugated box and include air pouches.**
- **Place fluorescent rectangular sticker on outside of brown corrugated box.**
- Include original copy of the IU Path Lab Req Form (Appendix D).
- Seal the outer cardboard shipping carton with packing tape.
- Apply all provided warning labels and the provided UPS Next Day Air return airbill (pre-printed and included in the kit) on the outside of the package. Do not overlap labels.



# Airbills/Scheduling Pickups

1. Apply all provided warning labels and the **UPS Next Day Air** return airbill (pre-printed and included in the kit) on the outside of the package. *Do not overlap labels!*
  1. Ensure the large rectangular fluorescent sticker is on the outside of the brown corrugated box.
  2. Specimens should be sent to the below address via UPS Next Day Air. Refrigerated shipments should be sent **Monday through Friday (see next slide for important instructions when shipping on a Friday)**.

ABC-DS Study at IU Path Lab  
IU Health Pathology  
Laboratory  
350 W. 11th Street  
5th Floor, Rm 5013  
Indianapolis, IN 46202

2. Schedule a pick-up using the following link: [Schedule a Pickup | UPS - United States](#). You will need to provide the tracking number found on the pre-printed airbill and UPS account number.
3. Use tracking to ensure the delivery occurs as scheduled and is received by the IU Path Lab.

# Critical Refrigerated Shipping Instructions

1. Refrigerated shipments should be sent Monday through Friday to the IU Path Lab.

2. It is vital to properly notify the IU Path Lab team of sample shipment, especially when shipping on Fridays! The IU Path Lab building is locked on the weekend, therefore one of the staff members will have to let the delivery driver in to complete delivery. Ensure the IU Path Lab requisition form is properly completed and the tubes properly labeled to avoid verification issues and delayed results.

3. Refrigerated samples should be shipped via UPS Next Day Air (pre-printed airbills provided).

4. The DOB on the IU Path Lab Req form needs to match the DOB on the Site BDS ID and DOB Label.

DOB is required in the system to register the sample. You can use the participant's true DOB or a generic DOB (e.g., 01/01/1950). Either way, the DOB on the req form HAS TO match the DOB on the Site BDS ID and DOB Label.

5. Place physical copy of the filled out IU Path Lab Req Form (Appendix D).

# Accessing Karyotype Results and Clinical Lab Results



# Accessing Karyotype Results and Clinical Lab Results

- **Results from karyotyping** will be uploaded to the ABC-DS EDC site at ATRI by the NCRAD study coordinator 7-10 days after receipt into the laboratory. You can find the results in your site folder: Docs → Site Topics → Choose Site Folder. To set notifications so you know when a report has been uploaded, first go to the "Docs" tab, then click "Manage Notifications" to the right of the search bar. Select a notification for 'file added' or other choices shown.
- **Clinical lab results** will be available through the [IU Health Lifepoint](#) application. To access site specific participant results, study personnel must complete an "Access Request –Lifepoint, IU Non-Employee Form" ([link](#)) and submit directly to IU Health. Social Security Number can be documented as "n/a" if the form is signed off on by the Field Site Lead in place of Manager. IU Health will send log-in information to you directly. The ABC-DS Admin Core will not need copies of these set up documents; however, please inform us who from your site will be designated to access the Lifepoint portal.
- The 'group data' for all participants will be sent from the IU Health Path Lab to LONI, for purposes of analysis. (Site and participant IDs will be removed and new ID assigned per ABC-DS protocol.)
- **\*Please check the portal for results ASAP in case a test fails and a re-draw is in order. Saturday deliveries: If issues arise with the specimens, the IU Path Lab will perform the tests offline. The following Monday, after review and corrections, results will be posted.**

# **Addendum 1**

# **MOM's Substudy**



# Collection Schedules

UNTHSC





# UNTHSC Blood Based Collection Schedule:

## Parent Participants

Blood Collection – to be sent to UNTHSC

	Serum	Plasma	DNA
All visits	X	X	X
SHIP TO:	UNTHSC	UNTHSC	UNTHSC


\*Collection will be at 1 time-point for all parents.

# UNTHSC Specimen Labels



Provided by NCRAD



# Three Label Types

Kit Number  
  
450604

Kit Number  
Labels

 DSMOM  
0042718846  
BUFFYCOAT  
Kit #: 450604 

Collection and  
Aliquot Tube  
Labels

BDS ID:  
\_\_\_\_\_

Site and BDS ID  
Labels

# Kit Number Labels



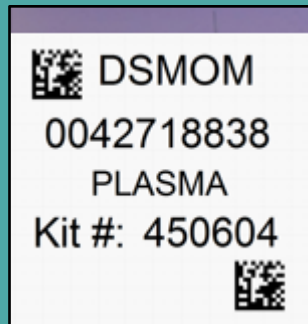
- Used to track patient samples and provide quality assurance – Will be placed on the following locations :
  1. Outside cryobox that houses aliquot tubes during storage and shipment

# Collection and Aliquot Tube Labels



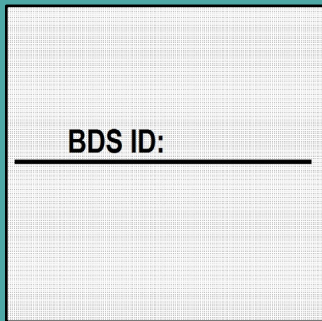
- Collection and Aliquot Tube labels have 4 components:
  - 10-digit specimen number (assigned by NCRAD)
  - Study name
  - Specimen type
  - Kit number (assigned by NCRAD)
    - Unique to subject AND visit
- Will be placed on the following locations :
  - All collection and aliquot tubes for UNTHSC

# Collection and Aliquot Tube Labels (cont.)



- Labels to be placed on ALL collection and aliquot tubes
  - 5ml Serum Separator (Gold-Top) Blood Collection Tube (x1)
    - Serum aliquots (color-coded red strip)
  - 10ml EDTA (Lavender-Top) Blood Collection Tube (x1)
    - Plasma aliquots (color-coded purple strip)
    - Buffy coat aliquot

# Site and BDS ID Labels



A rectangular label template with a horizontal line. Above the line, the text "BDS ID:" is printed. The label is intended for handwritten identification of subjects and collection tubes.

- Subjects will be identified by their Site and BDS ID (PT ID)
- Sites will be responsible for handwriting this onto the provided labels
  - Must use fine point permanent marker
- Will be placed on the following locations:
  - All Collection Tubes
    - Serum Separator (Gold-Top) Blood Collection Tube (5 mL) x1
    - EDTA (Lavender-Top) Blood Collection Tube (10 mL) x1

# SST and EDTA Collection Tube Labels:

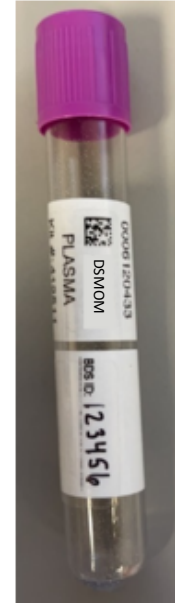
Collection Tube Label



Site and BDS ID Label



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

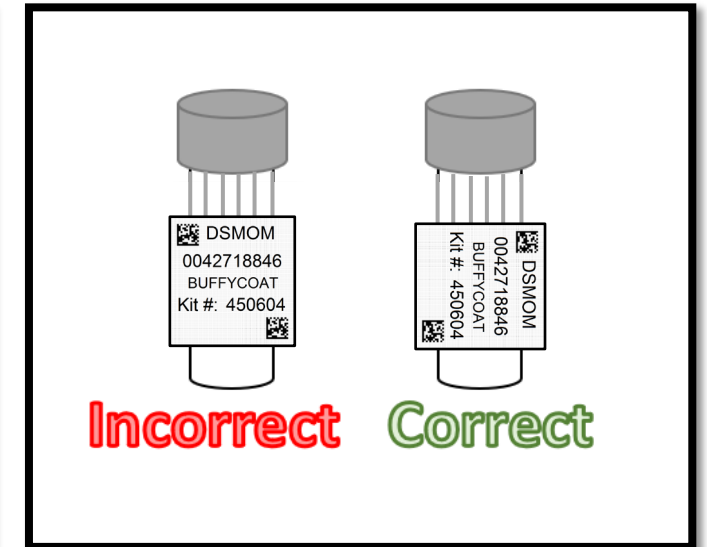
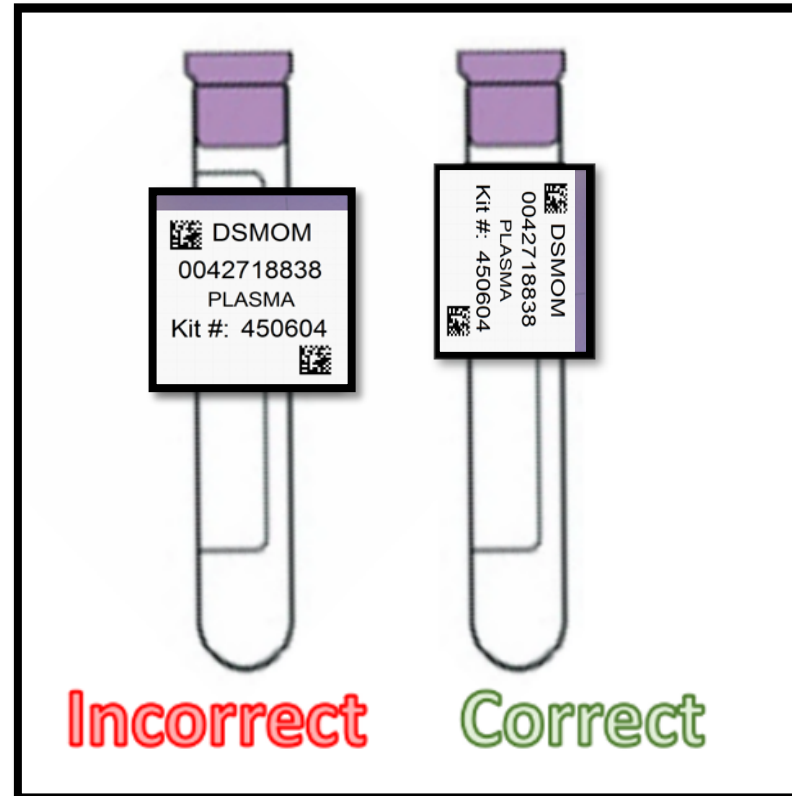


EDTA (Lavender-Top)  
Blood Collection Tube  
(10 mL)



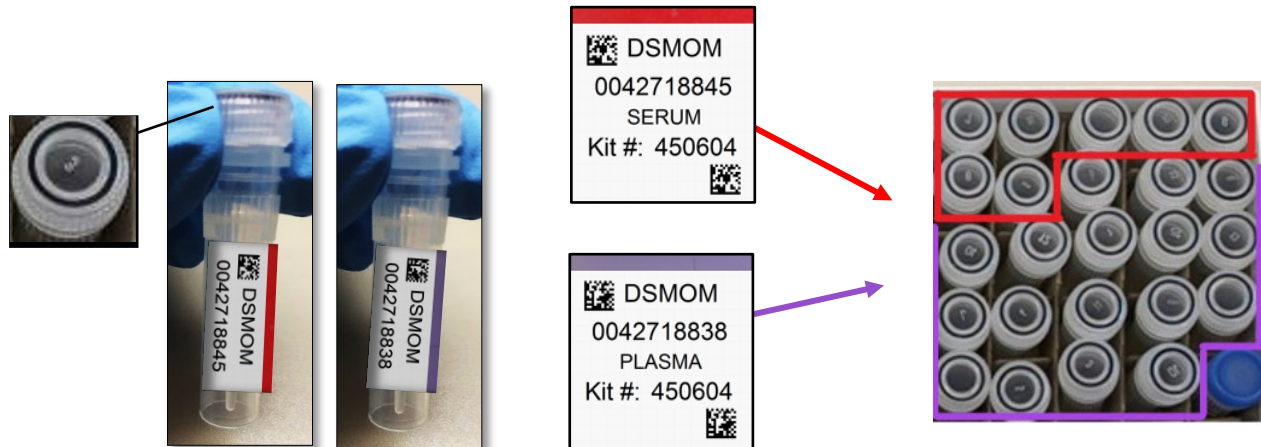
# Properly Labeling Biologic Samples:

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



# Clear Cap Cryovials Serum and Plasma

- Aliquot Tube Labels for Plasma and Serum are color-coded.



# Handling/Processing Study Specimens



# Site Required Equipment

## BLOOD COLLECTION/SAFETY EQUIPMENT

- 1) Personal Protective Equipment:
  - 1) lab coat, nitrile/latex gloves, safety glasses
- 2) Tourniquet
- 3) Alcohol Prep Pad
- 4) Gauze Pad
- 5) Bandage
- 6) Butterfly needles (21 gauge) and hub
- 7) Microcentrifuge tube rack
- 8) Sharps bin and lid

## PROCESSING/STORAGE EQUIPMENT

- 1) For UNTHSC: Centrifuge capable of  $\geq 2000 \times g$  with refrigeration to 4°C
- 2) -80 ° C Freezer
- 3) Wet Ice Bucket



# UNTHSC

# Sample Collection and Processing



# UNTHSC Substudy Blood Collection

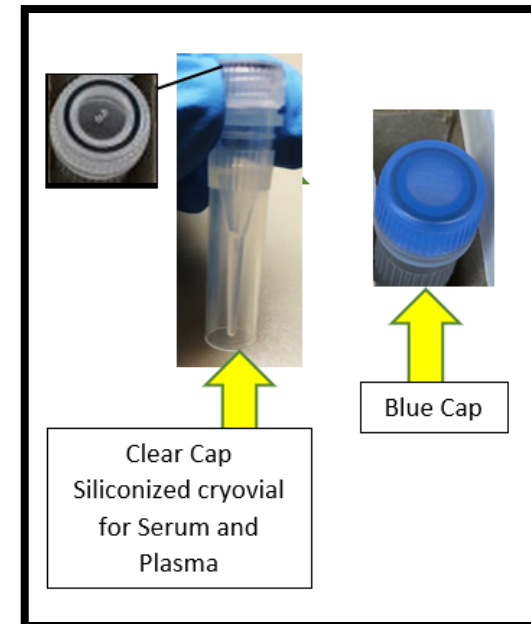
## Parent Participants

Tube Type	Number of Tubes Drawn	Tube Image
1. Serum Separator (Gold-Top) Blood Collection Tube (5 mL)	X 1	
2. EDTA (Lavender-Top) Blood Collection Tube (10 mL)	X 1	

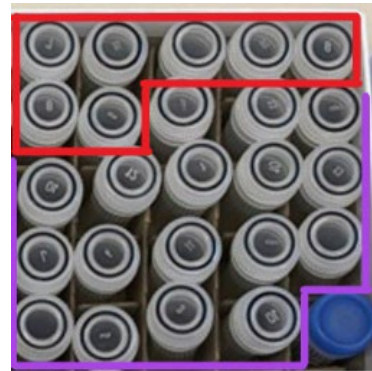
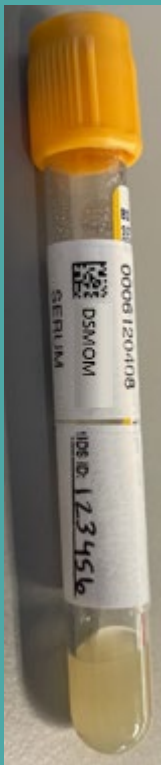
# Aliquot Cap & Label Colors

Color Coding	Sample Type
Clear Cap / Red Strip on Label	<b>Serum and Serum Residual (&lt;0.25 mL)</b> (Document Specimen Number and Volume of Residual Aliquot on Sample Form)
Clear Cap / Purple Strip on label	<b>Plasma and Plasma Residual (&lt;0.25 mL)</b> (Document Specimen Number and Volume of Residual Aliquot on Sample Form)
Blue Cap	<b>Buffy Coat</b>

- Important Note:** Aliquot Tube Labels for Plasma and Serum are color-coded to replace color coded cap stickers. Cap stickers were causing issues with robotic freezer storage.



# Serum Collection

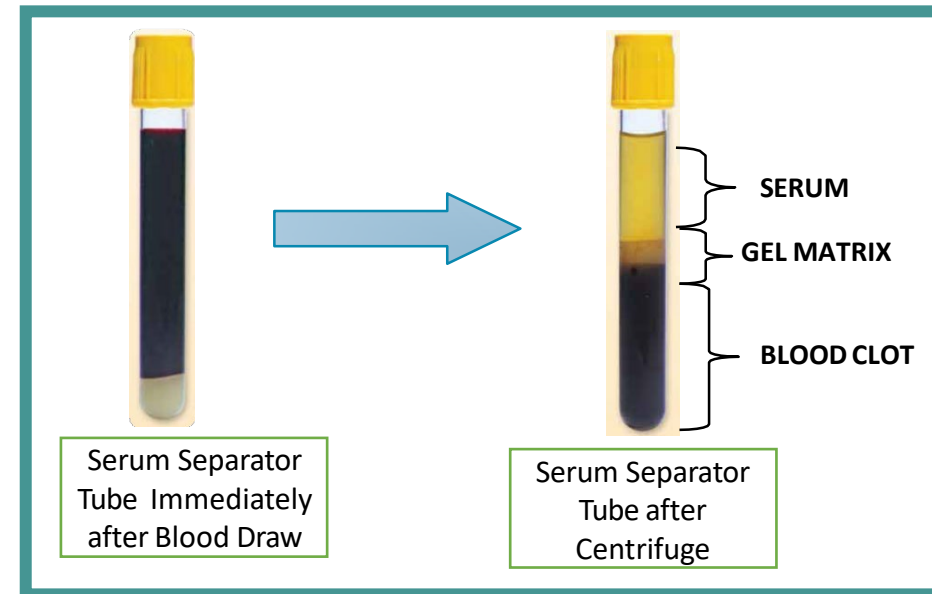


25 cell cryobox with 0.5 mL cryovials – sent to UNTHSC



Close up view of clear cap 0.5 mL Cryovial

- 1 x Serum Separator (Gold-Top) Blood Collection Tube (5 mL)
  - Create up to (7) 0.25 mL serum aliquots to be shipped to UNTHSC
  - If residual aliquot created, document specimen number and volume on Appendix F.

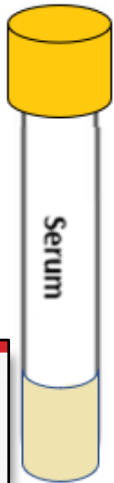




# Serum Preparation (5mL Gold-Top Tube) x 1



Step One



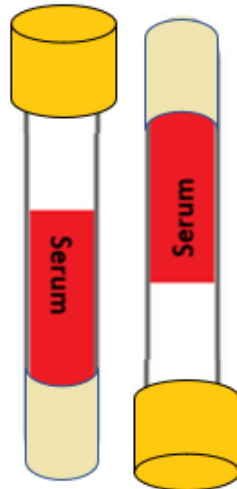
- Store tube at room temperature.
- Place completed Site and BDS ID Label and Collection and Aliquot "SERUM" Tube Labels on 5 mL Gold-Top tube prior to blood draw
- Place pre-printed Aliquot "SERUM" Tube Labels with color-coded red strip on the (7) 0.5 mL siliconized cryovial tubes with clear caps prior to blood draw.

Step Two



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

Step Three



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

Step Four



- Allow blood to clot for 30 minutes.
- Within 2 hours of blood draw, centrifuge samples at 2000 x g at 4°C for 10 minutes.

Step Five



- Aliquot 0.25 mL into each labeled cryovial tube.
- If a residual aliquot is created, document specimen number on UNTHSC Intake Form (Appendix F).
- Store serum aliquots at -80°C until shipment.



Up to 7 sent to UNTHSC

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

# If field draw,

- Allow blood to clot at room temperature before placing on wet ice, upright on rack and transferring to lab for further processing. Please make note on **Appendix F** if field draw. Record time it took to process samples on sample form for UNTHSC. If processing takes longer than 2 hours, please make note on form.

UNTHSC Contact Information

Lab Contact: Tori Conger

Phone number: 817-735-2638

Email Address: [tori.como@unthsc.edu](mailto:tori.como@unthsc.edu)

Lab Fax Number: 817-735-2051

Secondary Lab Contact: David Julovich

Phone Number: 817-735-0334

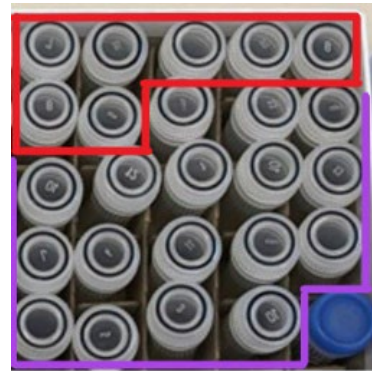
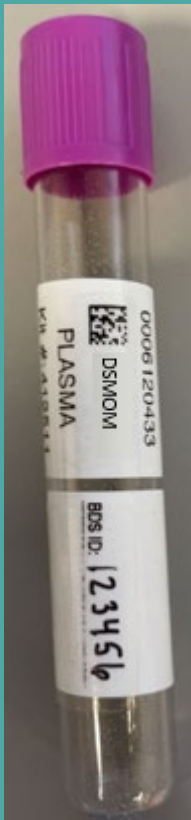
Email Address: [david.julovich@unthsc.edu](mailto:david.julovich@unthsc.edu)

Lab Fax Number: 817-735-2051

Notes to Lab

This was a field draw. Processing took 2.5 hours.

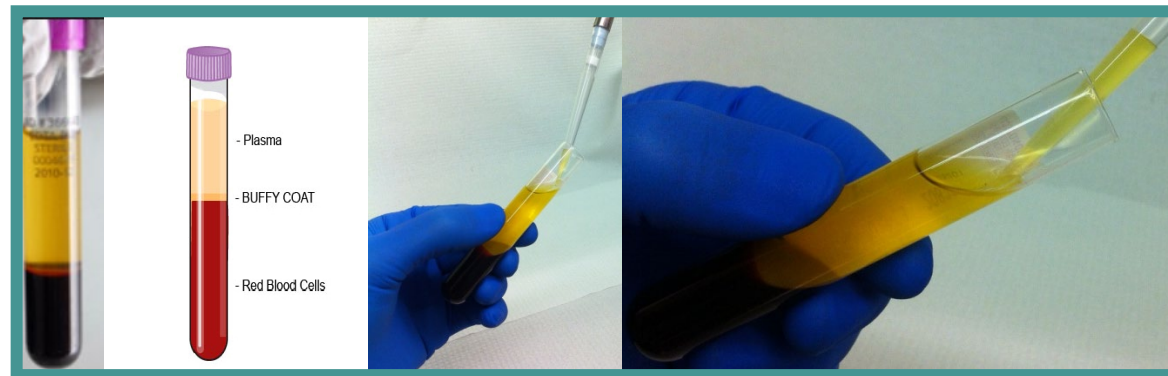
# Plasma Collection



25 cell cryobox with 0.5 mL cryovials – sent to UNTHSC

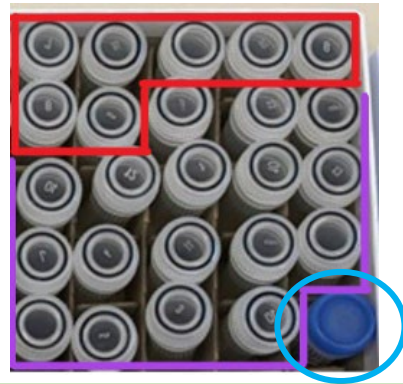
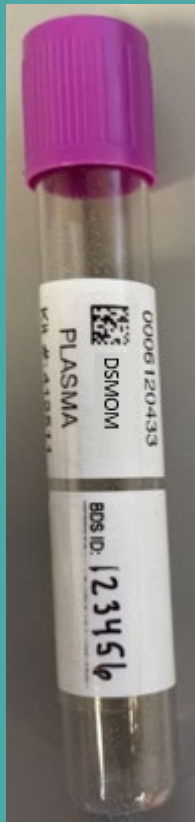
- 1 x EDTA (Lavender-Top) Blood Collection Tube (10 mL)
  - Create up to (17) 0.25 mL plasma aliquots to be shipped to UNTHSC
  - If residual aliquot created, document specimen number and volume on Appendix F.

Close up view of clear cap 0.5 mL Cryovial



**NOTE:** When pipetting plasma from the plasma tube 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.

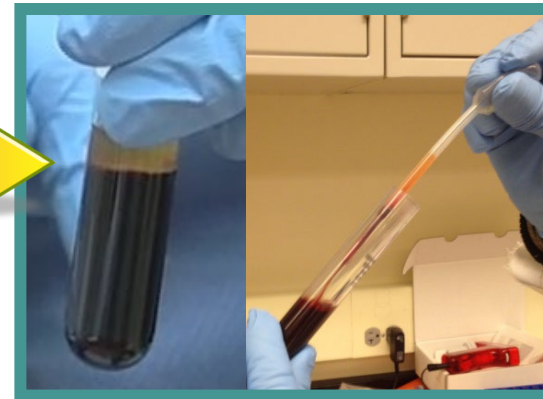
# Buffy Coat Collection



25 cell cryobox with 0.5 mL cryovials – sent to UNTHSC

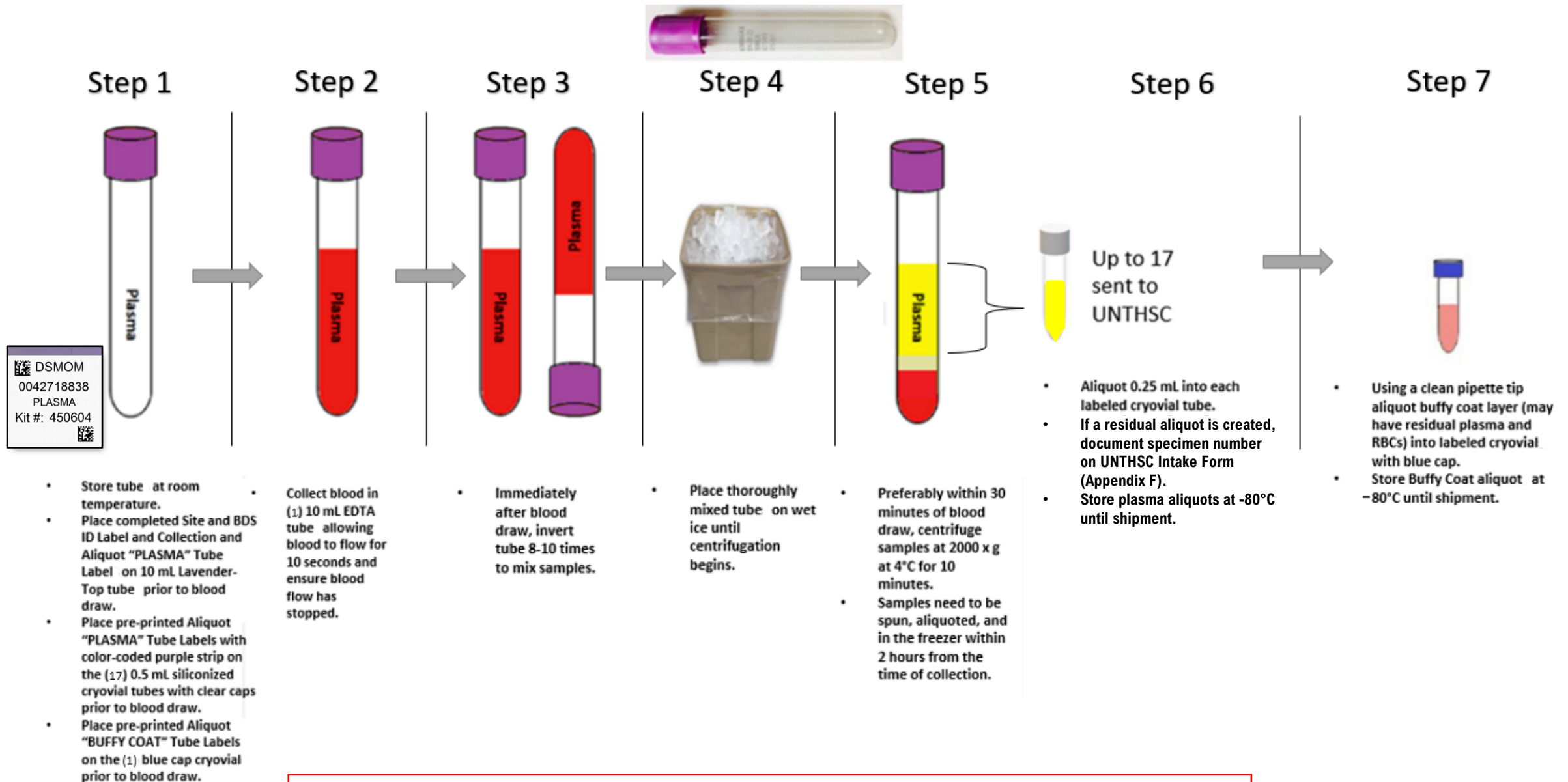
- 1 x EDTA (Lavender-Top) Blood Collection Tube (10 mL)
  - **Create up to (1) 0.25 mL buffy coat aliquot to be shipped to UNTHSC**
    - Expected to have a reddish color from the RBCs.

Buffy Coat layer (mixed with RBCs)



Buffy Coat Aliquot (Please use BLUE CAP cryovial)

# Plasma and Buffy Coat Preparation (10 mL Lavender-Top Tube) x1



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

# If field draw,

- **Keep the samples on wet ice until you reach your destination. Record if field draw on sample form for UNTHSC (Appendix F).**

UNTHSC Contact Information

Lab Contact: Tori Conger

Phone number: 817-735-2638

Email Address: [tori.como@unthsc.edu](mailto:tori.como@unthsc.edu)

Lab Fax Number: 817-735-2051

Secondary Lab Contact: David Julovich

Phone Number: 817-735-0334

Email Address: [david.julovich@unthsc.edu](mailto:david.julovich@unthsc.edu)

Lab Fax Number: 817-735-2051

Notes to Lab This was a field draw.

# **Packing and Shipping Substudy Samples to UNTHSC**



# UNTHSC Substudy Blood Sample Shipment Summary

Sample Type	Processing/ Aliquoting	Tubes to UNTHSC	Ship
<b>Whole blood for isolation of serum</b>	0.25 mL serum aliquot per 0.5 mL cryovial (clear cap)	7	Frozen
<b>Whole blood for isolation of plasma &amp; buffy coat (for DNA extraction)</b>	0.25 mL plasma aliquot per 0.5 mL cryovial (clear cap)	17	Frozen
	1 mL buffy coat aliquot per 2.0 mL cryovial (BLUE CAP)	1	



# **Frozen Shipping**

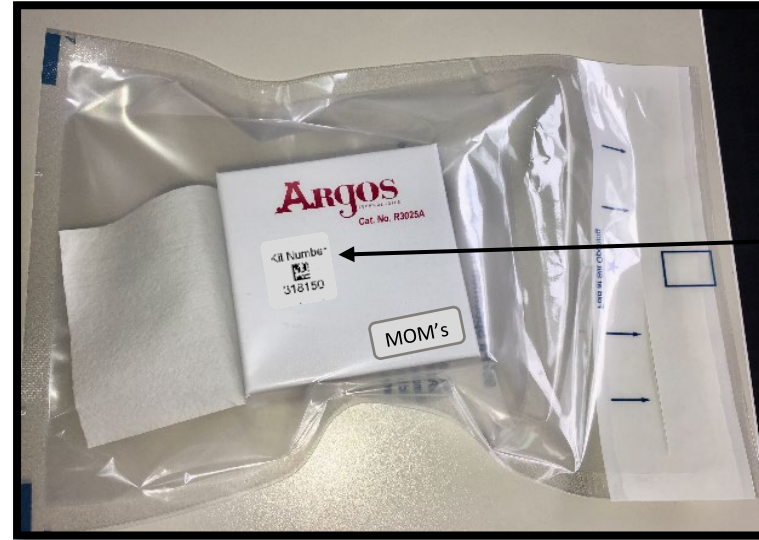
Serum, Plasma, and Buffy Coat

# Notify UNTHSC When Samples Ship:

1. **Notify UNTHSC of shipment** by emailing UNTHSC Lab Manager at: [Tori.Como@unthsc.edu](mailto:Tori.Como@unthsc.edu)
  - Attach the following to the email:
    - Completed UNTHSC Intake Form ([Appendix F](#) – also found on the [NCRAD ABC-DS study page](#)) and the UNTHSC Import Batch Form ([Appendix G](#)):
      - Aliquot barcodes need to be listed on the UNTHSC Import Batch Form ([Appendix G](#)). NCRAD will send an Excel file with all aliquot barcodes included in each kit when kit supplies are shipped.
    - If email is unavailable, please call UNTHSC and do not ship until you've contacted and notified UNTHSC Lab Manager about the shipment in advance.
    - Please include the tracking number in the body of the email.
    - Place physical copy of the UNTHSC Intake Form (Appendix F) and UNTHSC Import Batch Form (Appendix G) in your shipment.

# Frozen Shipment Packaging:

Place all frozen labeled aliquots of serum, plasma and buffy coat in the cryovial cryoboxes.



Place kit number label(s) on cryoboxes

**FOR UNTHSC:** Place up to 7 serum, 17 plasma, and 1 buffy coat cryovials per participant visit inside 25 cell cryobox. Place 25 cell cryobox inside the small biohazard bag with absorbent sheet. Seal biohazard bag according to the instructions on the bag.

# Batch Shipping

- FOR **UNTHSC** – Batch shipping should be performed every 3 months **or** when specimens from 5 participants accumulate, whichever is sooner. Up to 5 25-slot cryoboxes can fit in the shipper provided with dry ice included.

# Frozen Shipment Packaging

- Place 2-3 inches of dry ice in the bottom of the Styrofoam shipping container, then insert the cryoboxes laying upright.
- 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.
- Fill shipper to the top with dry ice!

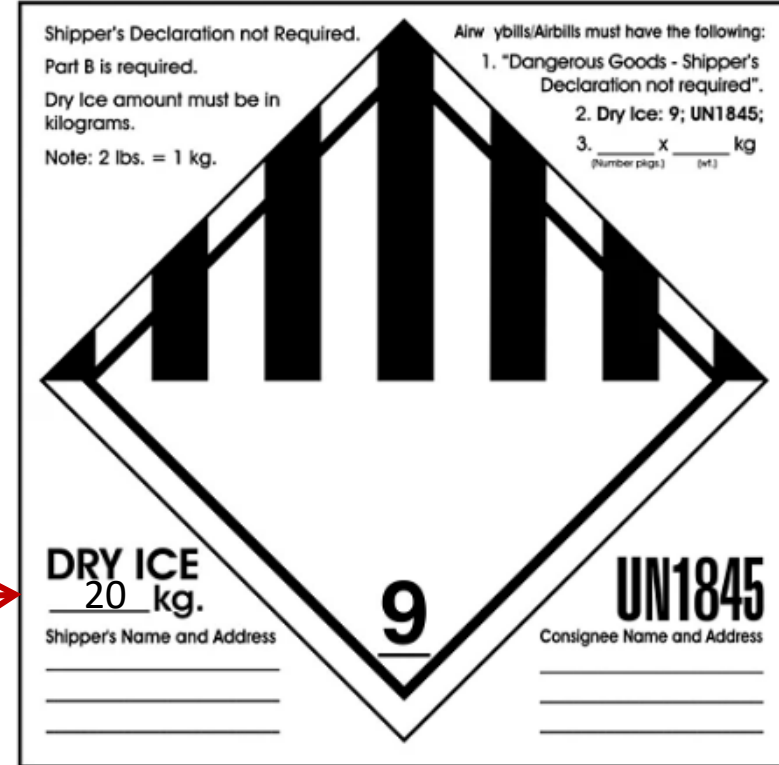


# Frozen Shipping Dry Ice Requirements

**Failure to do the following will result in shipping carrier rejecting/returning your package!**

1. Net weight of dry ice in kg (must match amount on the airbill)!
2. Dry Ice label should not be covered with other stickers and must be completed (see right)!

Net weight of dry ice in **kg**



Shipper's Declaration not Required. Part B is required. Dry Ice amount must be in kilograms. Note: 2 lbs. = 1 kg.

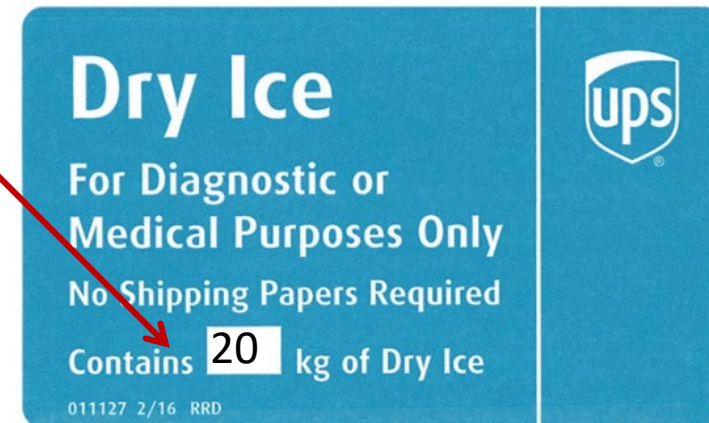
Airbills/Airbills must have the following:  
1. "Dangerous Goods - Shipper's Declaration not required".  
2. Dry Ice: 9; UN1845;  
3. \_\_\_\_\_ x \_\_\_\_\_ kg  
(Number pgs.) (wt.)

**DRY ICE**  
20 kg.  
Shipper's Name and Address  
\_\_\_\_\_  
\_\_\_\_\_

**9**

**UN1845**  
Consignee Name and Address  
\_\_\_\_\_  
\_\_\_\_\_

FedEx Dry Ice Sticker



**Dry Ice**

For Diagnostic or Medical Purposes Only  
No Shipping Papers Required  
Contains **20** kg of Dry Ice

011127 2/16 RRD

**ups**

UPS Dry Ice Sticker (UW-Madison Only)

# Critical Frozen Shipping Instructions

1. On the day of scheduled pick-up, begin packaging specimens on dry ice at least 1 hour before UPS/FedEx arrives. Hold samples in -80°C freezer until it is time to package the specimens on dry ice for shipment to UNTHSC.

2. Frozen samples should be shipped via FedEx Priority Overnight (via UPS Next Day Air for UW-Madison)

3. Frozen shipments should be sent Monday through Wednesday ONLY to avoid shipping delays on Thursday or Friday.

**BE AWARE OF HOLIDAYS and current weather conditions!**

FedEx does not replenish dry ice if shipments are delayed or held over during the weekend.

4. Remember to complete the requisition forms and include a copy in your shipment: UNTHSC Intake Form (Appendix F) and UNTHSC Import Batch Form (Appendix G) for UNTHSC.

# **Creating Airbills/Scheduling Pickups**

Frozen Shipments



# Creating Airbills/Scheduling Pickups

**1. Complete the FedEx return airbill (if UW-Madison, follow UPS instructions provided at site) with the following information:**

- Section 1, “From”: fill in your name, address, phone number, and Site FedEx Account Number.
- Section 2, “Your Internal Billing Reference”: add any additional information required by your site.
- Section 6, “Special Handling and Delivery Signature Options”: under “Does this shipment contain dangerous goods?” check the boxes for “Yes, Shipper’s Declaration not required” and “Dry Ice”. Enter the number of packages (1) x the net weight of dry ice in kg.
- Section 7, “Payment”, check sender and bill transportation costs to your site’s study FedEx account number.

**2. Complete the Class 9 UN 1845 Dry Ice label (black and white diamond) with the following information:**

- Your name and return address
- Net weight of dry ice in kg (must match amount on the airbill)
- Consignee name and address:

**UNTHSC**  
ATTN: Tori Conger  
3420 Darcy Street  
Fort Worth, TX 76107  
Phone: 817-735-2638

- Do not cover any part of this label with other stickers, including pre-printed address labels.


**3. Apply all provided warning labels and the completed FedEx return airbill to the outside of package, taking care not to overlap labels.**

# Sample Forms




# **NCRAD Forms**

# Appendix B: Biological Sample and Shipment Notification Form ([link](#))



**NCRAD**



Biospecimen Collection, Processing, and Shipment Manual

**Appendix B**

PT ID: \_\_\_\_\_ Site ID: \_\_\_\_\_

Cycle Visit (Circle One): 1 2 3 4

### Sample Collection - Blood & Shipment Notification Form

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

To: NCRAD	Email: alzstudy@iu.edu	Phone: 1-800-526-2039
To: UNTHSC	Email: Tori.Como@unthsc.edu	Phone: 1-817-735-2638

*General Information:*

From: \_\_\_\_\_ Date: \_\_\_\_\_

Phone: \_\_\_\_\_ Email: \_\_\_\_\_

PT previously enrolled in (circle one): ADDS NIAD N/A-new PT

NIAD/ADDS Legacy ID (if applicable): \_\_\_\_\_ Kit #: \_\_\_\_\_

Arm:  DS Participant  Sibling Control

Sex:  M  F Year of Birth: \_\_\_\_\_

Shipment Tracking #: \_\_\_\_\_

KIT BARCODE

Field Draw?:  Yes  No

*Blood Collection:*

1. Date Drawn: \_\_\_\_\_ [YYYYMMDD] 2. Time of Draw (24 hour clock): \_\_\_\_\_ [HHMM]

3. Last time subject ate (Date): \_\_\_\_\_ [YYYYMMDD] 4. Last time subject ate (24 hour clock): \_\_\_\_\_ [HHMM]

*Blood Processing:*

RNA PAXgene™ Tube	NaHep Tube for karyotyping (if not drawn, enter N/A by mL)
Original volume drawn (1x2.5mL RNA PAXgene™ tube): _____ mL Time placed in freezer: _____ [HHMM]	Original volume drawn (1x4 mL NaHep tube): _____ mL
<b>Plasma (EDTA/Lavender Top Tube)</b>	Has karyotyping ever been completed? <input type="checkbox"/> Yes <input type="checkbox"/> No
Time spin started (24 hour clock): _____ [HHMM]	<b>Serum (Serum Separator/Gold Top Tube)</b>
Duration of centrifuge: _____ [minutes]	Time spin started (24 hour clock) (30 minutes after draw time): _____ [HHMM]
Temp of centrifuge: _____ °C Rate of centrifuge: _____ x g	Duration of centrifuge: _____ [minutes]
Original volume drawn (2x10 mL EDTA tube): EDTA #1: _____ mL EDTA #2: _____ mL	Temp of centrifuge: _____ °C Rate of centrifuge: _____ x g
Time aliquoted: _____ [HHMM]	Original volume drawn (2x5 mL Serum tube): _____ mL
Number of 0.25 mL plasma aliquots created (35-40 total) (Siliconized cryovial): _____ x 0.25 mL	Time aliquoted: _____ [HHMM]
<b>Number of 0.25 mL plasma aliquots sent to UNTHSC:</b> _____ <b>Number of 0.25 mL plasma aliquots sent to NCRAD:</b> _____	Number of 0.25 mL serum aliquots created (16-20 total) (Siliconized cryovial): _____ x 0.25 mL
If applicable, volume of residual plasma aliquot (less than 0.25 mL) (Siliconized cryovial): _____ mL	Number of 0.25 mL serum aliquots sent to UNTHSC: _____
If applicable, specimen number of residual aliquot (last four digits): _____	If applicable, volume of residual serum aliquot (less than 0.25 mL) (Siliconized cryovial): _____ mL
Time aliquots placed in freezer (24 hour clock): _____ [HHMM]	If applicable, specimen number of residual aliquot (last four digits): _____
Storage temperature of freezer: _____ °C	Time aliquots placed in freezer (24 hour clock): _____ [HHMM]
Buffy coat #1 (last four digits): _____ Buffy Coat #1 volume: _____ mL	Storage temperature of freezer: _____ °C
Buffy coat #2 (last four digits): _____ Buffy Coat #2 volume: _____ mL	

Notes: \_\_\_\_\_


Version 10.2021

## Note:

Please ensure forms are filled out in their entirety. Complete during the participant study visit as samples are processed to guarantee accuracy.

**Form for Main Study ONLY!**

# Appendix E: Constitutional (Blood) Test Requisition Form ([link](#))

CONSTITUTIONAL (BLOOD) TEST REQUISITION FORM	
 <b>Cytogenetic Laboratories</b> Indiana University School of Medicine 975 W. Walnut, IB 350, Indianapolis, IN 46202 317/274-2243 (Office) 317/278-1616 (Fax)	<i>Patient Laboratory Label</i>
	CAP#: 16789-30    CLIA#: 15D0647198
<b>1) PHYSICIAN(S):</b>	<b>FOR LABORATORY USE ONLY:</b>
Ordering Physician: <u>Kelley Faber, MS, CCRC</u> Address: <u>MMGE HS 4007</u>  City: <u>Indianapolis</u> State: <u>IN</u> Zip: <u>46202</u> Phone: <u>317-274-7360</u> Fax: _____  Primary Physician: <u>Zoë Potter</u> Address: <u>MMGE HS 4000H</u> City: <u>Indianapolis</u> State: <u>IN</u> Zip: <u>46202</u> Phone: <u>317-278-9086</u> Fax: _____	Date Received: ____/____/____ Time Received: ____:____ am/pm Received By: _____  <input type="checkbox"/> BL  <input type="checkbox"/> CMA <input type="checkbox"/> MO <input type="checkbox"/> C-banding <input type="checkbox"/> Q-banding <input type="checkbox"/> NOR-staining Handling Charge x _____ <input type="checkbox"/> Handling <b>ONLY</b> Lab Comment(s): Vacs: ____ green ____ purple; Other _____
<b>2) PATIENT INFORMATION:</b>	
ABC-DS BDS ID: _____    Original volume drawn (1x4 mL NaHep tube): _____ mL	
<b>4) REFERRING DIAGNOSES ( please check all that apply ):</b>	
<input type="checkbox"/> Ambiguous Genitalia <input type="checkbox"/> Dysmorphic Features <input type="checkbox"/> Seizures <input type="checkbox"/> Family History of Chromosome Abnormality <input type="checkbox"/> Autism Spectrum Disorder <input type="checkbox"/> Failure to Thrive <input type="checkbox"/> Short Stature <input type="checkbox"/> Congenital Heart Defect <input type="checkbox"/> Hypotonia <input checked="" type="checkbox"/> Other <u>ABC-DS Study</u> (Please provide name, DOB, MRN) <input type="checkbox"/> Developmental Delay <input type="checkbox"/> Multiple Congenital Anomalies <input checked="" type="checkbox"/> Down Syndrome <input type="checkbox"/> Recurrent Pregnancy Loss <input type="checkbox"/> ICD-10 Code: _____	
<b>5) REQUESTED TESTING:</b>	
<input checked="" type="checkbox"/> Standard Chromosome Analysis/Karyotype -- 1 Sodium Heparin Tube (Dark Green-top); 3 mL (infants), 7 mL (adults) <input type="checkbox"/> Rapid Chromosome Analysis/Karyotype: -- Preliminary result in 48-72 hours -- 1 Sodium Heparin Tube (Dark Green-top); 3 mL (infants) <input type="checkbox"/> Peripheral Blood or Skin Biopsy for Fanconi Anemia Breakage Study using DEB -- 2 Sodium Heparin Tubes (Dark Green-top); 7-12 mL <input type="checkbox"/> Standard Chromosome Analysis with Reflex to Microarray (CMA): -- Reflexes if karyotype is normal -- 1 EDTA Tube (Purple-top); minimum 1 mL -- 1 Sodium Heparin Tube (Dark Green-top); 3 mL (infants), 7 mL (adults) <input type="checkbox"/> Fluorescence In Situ (FISH) Analysis (Select Probe below) -- 1 Sodium Heparin Tube (Dark Green-top); 2 mL	
<input type="checkbox"/> Aneuploidy FISH Full Panel (13, 18, 21, X/Y) <input type="checkbox"/> Aneuploidy FISH 13/21 Only <input type="checkbox"/> Aneuploidy FISH 18/X/Y Only -- Results in 24-72 hours -- 1 Sodium Heparin Tube (Dark Green-top); 2 mL, minimum 1 mL <input type="checkbox"/> Constitutional Chromosomal Microarray (CMA) - Peripheral Blood is preferred. <b>Two tubes of blood are required:</b> -- 1 EDTA Tube (Purple-top); minimum 1 mL -- 1 Sodium Heparin Tube (Dark Green-top); minimum 1 mL Buccal Swabs are also accepted (contact lab for collection kit). <input type="checkbox"/> Parent/Family Member Studies as Follow-up to CMA (Test performed based on recommendations in proband's CMA report) -- 1 Sodium Heparin Tube (Dark Green-top); 2 mL <b>Please provide previous patient information (Name, MRN, DOB)</b>	
<b>6) MICRODELETION FISH ANALYSIS REQUESTED:</b>	
<input type="checkbox"/> Angelman <input type="checkbox"/> Kallman <input type="checkbox"/> Smith-Magenis <input type="checkbox"/> Williams <input type="checkbox"/> Cri-Du Chat <input type="checkbox"/> Miller-Dieker <input type="checkbox"/> SRY <input type="checkbox"/> Wolf-Hirschhorn <input type="checkbox"/> DiGeorge (VCFS) <input type="checkbox"/> Prader-Willi <input type="checkbox"/> STS	

## Note:

Please ensure forms are filled out in their entirety.  
 Complete during the participant study visit as samples are processed to guarantee accuracy.

**Form for Karyotyping ONLY!**

# **UNTHSC Forms**

# Appendix F: UNTHSC Intake Form

([link](#))

**\*Click link to view all pages\***

I have created a PowerPoint guide on how to fill out this form. Please contact [zdpotter@iu.edu](mailto:zdpotter@iu.edu) to receive the guide!

## Note:

Please ensure forms are filled out in their entirety. Complete during the participant study visit as samples are processed to guarantee accuracy.

[Form for Main Study AND MOM's Substudy!](#)

## UNTHSC Sample Shipping Process

We appreciate your time and dedication to this project; with that, we want to ensure the best scenario for your samples upon arrival and best possible test results.

Our testing is a highly automated process requiring a good deal of preparation prior to any testing. In order for the Institute for Translational Research Laboratory to be prepared for the upcoming shipment of your samples, we ask that you answer a few questions regarding your samples as this will prevent any delay in obtaining your results.

**\*\*\*MINIMUM VOLUME REQUIREMENT\*\*\* 500ul of sample for MSD and 500ul of sample for Quanterix. Please discuss this with our lab personnel.**

Please be sure to include:

- An excel file with the 5 columns listed below:
  - Unique Sample ID (Each sample is uniquely identified)- **required**
  - Unique TubeID/Barcode-**required**
  - Visit # (unique timepoint for each sample in the study)-**required for multiple visits**
  - Date of Collection- if applicable
  - Notes for sample (i.e. hemolyzed etc)- if applicable

Unique Sample ID	Unique Tube ID/Barcode	Visit Number	Date of Collection	Notes for Samples

- Indicate sample type(s) to be sent
  - Plasma
  - Serum
  - Other \_\_\_\_\_
- Number of samples per sample type \_\_\_\_\_
- Volume of each sample (please add notes for any low volume samples).
  - Please note, any sample we declare as **unusable will be discarded**.






# **IU Path Lab Forms**

# Appendix D: IU Path Lab Req Form

## [IU Path Lab Portal Access Instructions](#)

 <b>Indiana University Health</b>		<b>Study/Research Lab Orders</b>	IU Health Pathology Laboratory 350 W. 11th Street, Rm 5013 Indianapolis, IN 46202 317.491.6000 or 800.433.0740 Fax: 317.491.6001	
Patient Name: BDS, _____		DOB 1/1/	Date/Time of Collection	
<input type="checkbox"/> M <input type="checkbox"/> F	MRN Number	PI: Brad Christian		
<b>Client Code:</b>				
<b>Attention IUHPL: Add Cycle to Cerner Comment</b>				
Test Code		Test Name	Select Cycle	
7598	x	1,25 Dihydroxyvitamin D	Cycle 1	Cycle 2
7462	x	Anti-Thyroglobulin Antibody QN	Cycle 1	Cycle 2
6917	x	Basic Metabolic Panel	Cycle 1	Cycle 2
127	x	CBC with Diff	Cycle 1	Cycle 2
6318	x	Hemoglobin A1C HPLC Bld QN	Cycle 1	Cycle 2
6039	x	Lipid Panel SerPI QN	Cycle 1	Cycle 2
6940	x	T4 Free Direct SerPI QN	Cycle 1	Cycle 2
7699	x	Thyroid Peroxidase Ab	Cycle 1	Cycle 2
7430	x	Triiodothyronine Ser QN (T3 Total)	Cycle 1	Cycle 2
7339	x	TSH 3rd Generation SerPI QN	Cycle 1	Cycle 2
6691	x	Vitamin B12 SerPI QN	Cycle 1	Cycle 2

### Note:

Please ensure forms are filled out in their entirety. Complete during the participant study visit as samples are processed to guarantee accuracy.

**Form for Main Study Clinical Labs ONLY!**

# NCRAD Website



# NCRAD ABC-DS Study Page


[NCRAD - The ABC-DS Active Study Page](#)



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[Home](#)
[About NCRAD](#)
[Information For Families](#)
[Biospecimens & Data](#)
[Banking with NCRAD](#)
[Tools for Active Studies](#)

## The ABC-DS Active Study Page



Welcome ABC-DS Study staff, coordinators and PIs. This section encompasses study specific tools and videos for your reference. If you have any questions, comments, or new ideas, please contact NCRAD by email or phone 317-274-7546 or 800-526-2839.

BANK SAMPLES

with NCRAD

SAMPLE TYPES

we Bank

### Specimen Collection Overview

#### Main Study Blood Collection – to be sent to NCRAD & UNTHSC

	RNA	Serum	Plasma	DNA	Karyotyping,
All Visits	✓	✓	✓	✓	✓
Ship to:	NCRAD	NCRAD & UNTHSC	NCRAD & UNTHSC	NCRAD	NCRAD

DS Participants only (if needed)

#### Main Study Blood Collection – to be sent to IU Path Lab (Clinical Labs)

	Orange-Top Serum Tube	Gold-Top Serum Tube	3 mL EDTA Tube	
	Free T4, Thyroid, Triiodothyronine, TSH, Vit B12, ATA Preparation	Vit D, BMP, Lytes, Lipid Preparation	CBC Preparation	A1C Preparation
Cycle 1	✓	✓	✓	✓
Cycle 2	✓	✓	✓	✓
Ship to:	IU Path Lab	IU Path Lab	IU Path Lab	IU Path Lab

#### MOM's Substudy Blood Collection – to be sent to UNTHSC

	Serum	Plasma	DNA
All visits	✓	✓	✓
Ship to:	UNTHSC	UNTHSC	UNTHSC

\*Collection will be at 1 time-point for all parents.

### Download Documents

- [Manual of Procedures](#)
- [Training Slides](#)
- [Appendix B: NCRAD Sample Form](#)
- [Appendix D: IU Path Lab Portal Access Instructions](#)
- [Appendix E: Karyotyping Req Form](#)
- [Appendix F: UNTHSC Intake Form](#)
- [Appendix G: UNTHSC Import Batch Form](#)
- [Lumbar Puncture Manual of Procedures](#)

### Additional Resources

- [Kit Request System](#)
- [Friday Blood Draws](#)
- [Shipping Address](#)
- [Holiday Closures](#)
- [Biomarker Assay Laboratory](#)

### Questions/Comments

**Email:** [alzstudy@iu.edu](mailto:alzstudy@iu.edu)  
**Phone:** 800-526-2839

### Study Resources

- Kit Request Module
- Biological Sample and Shipment Notification Forms
- Manual of Procedures
- Study Related Video Tutorials
- Training Slides

# NCRAD Website: Helpful Pages

[NCRAD - The ABC-DS Active Study Page](#)

[https://ncrad.org/holiday\\_closures.html](https://ncrad.org/holiday_closures.html)

## Holiday Closures

Date	Holiday
January 1	New Year's Day
3 <sup>rd</sup> Monday in January	Martin Luther King, Jr Day
4 <sup>th</sup> Monday in May	Memorial Day
June 19	Juneteenth (observed)
July 4	Independence Day (observed)
1 <sup>st</sup> Monday in September	Labor Day
4 <sup>th</sup> Thursday in November	Thanksgiving
4 <sup>th</sup> Friday in November	Friday after Thanksgiving
December 25	Christmas

[https://ncrad.org/shipping\\_address.html](https://ncrad.org/shipping_address.html)

## Shipping Address

NCRAD  
Indiana University School of Medicine  
351 W. 10th St TK-217  
Indianapolis, IN 46202

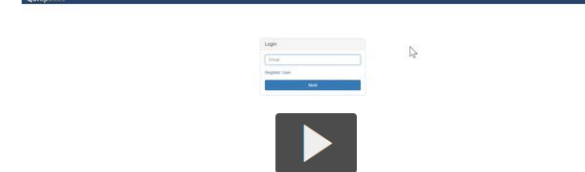
## UPS Shipping Resources

To generate air waybills and schedule UPS pickups for shipments to NCRAD, please visit the UPS ShipExec™ Thin Client website.

For instructions on how to use the UPS ShipExec™ Thin Client website, please refer to the NCRAD UPS ShipExec™ Thin Client Guide.

## Navigating UPS ShipExec™

To request edited captions for the deaf/HOH, see <https://kb.iu.edu/d/adad>

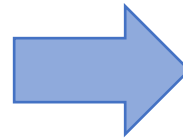


# Noncomformance Issues



# Nonconformance Issues

Sample aliquots and collection tubes frozen at an angle/inverted



**Recommendation:**

Place aliquots in cryoboxes/tube rack in freezer *upright* until shipment

Fields left blank on Blood Sample and Shipment Notification Form

Last time subject ate often left blank/unknown

Incorrect data reported on Sample and Shipment Notification Forms

Reason for partial draw not noted on sample form



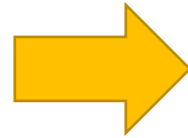
**Recommendation:** Complete Sample Notification forms during the participant study visit as samples are processed.

# Nonconformance Issues

All frozen samples for a participant not sent within one shipment box

Aliquots arriving to NCRAD without labels

Sample forms not scanned to NCRAD the day before shipment



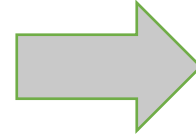
**Recommendation:**

Ship Samples to NCRAD utilizing the Notification Form, by PTID. Do not throw away labels until samples are packed and shipped.



# Nonconformance Issues

Multiple low volume aliquots



**Recommendation:**

Lay out cryovials in a row and aliquot in order until sample is depleted

