ABC-DS
Alzheimer Biomarker Consortium-Down Syndrome

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 3.3

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

Training Overview: ABC-DS

- **Contact Information**
- **Kit Request Module**
- **Main Study**
  - Collection Schedules
  - Re-draw Instructions and Timeframes
  - Specimen Labels
  - Handling/Processing Study Specimens
  - Incomplete or Difficult Blood Draws
  - Packaging Sample Shipments
  - Accessing Karyotype Results and Clinical Lab Results
- **Sample Forms**
- **NCRAD Website**
- **Common Nonconformance Issues**
- **Questions?**

NCRAD

NCRAD Contact Information

Shipping Address:

Indiana University School of Medicine
351 West 10th Street
TK-217
Indianapolis, IN 46202
800-526-2839
alzstudy@iu.edu

Contact Information:

Zoë McManus, BA, CCRP, Study Coordinator

Phone: (317) 278-9086

Email: zdpotter@iu.edu

General NCRAD Contact Information

Phone: 1-800-526-2839

Email: alzstudy@iu.edu

Website: www.ncrad.org

ABC-DS Study Specific Webpage: NCRAD - The ABC-DS Active Study Page

UNTHSC Contact Information

- **Shipping Address:**

  3420 Darcy Street

  Fort Worth, TX 76107

- **Contact Information:**

  Tori Conger, ITR Lab Manager- Tori.Como@unthsc.edu

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IU Health Path Lab Contact Information

- **Shipping Address:**
  350 W. 11th Street
  5th Floor, Rm 5013
  Indianapolis, IN 46202
  317-491-6000

- **Contact Information:**
  DPLM PRS DL - dplmprs@iuhealth.org
  Carrie Robinson - crobinson13@iuhealth.org
  Katrina Prine - kprine@iuhealth.org
- **Volume questions and any questions related to testing**:
  Evan Salat - esalat@IUHEALTH.ORG
  Rustin Ball - rball3@IUHEALTH.ORG
  Julie Ross - jross20@IUHealth.org

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IU Cytogenetics Lab Contact Information

- **Shipping Address:**
  MMGE IU Genetic Testing Laboratories
  975 W. Walnut Street, IB 350
  Indianapolis, IN 46202
  317-274-2243

- **Contact Information:**
  iugtl@iu.edu

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NCRAD Kit Request Module

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

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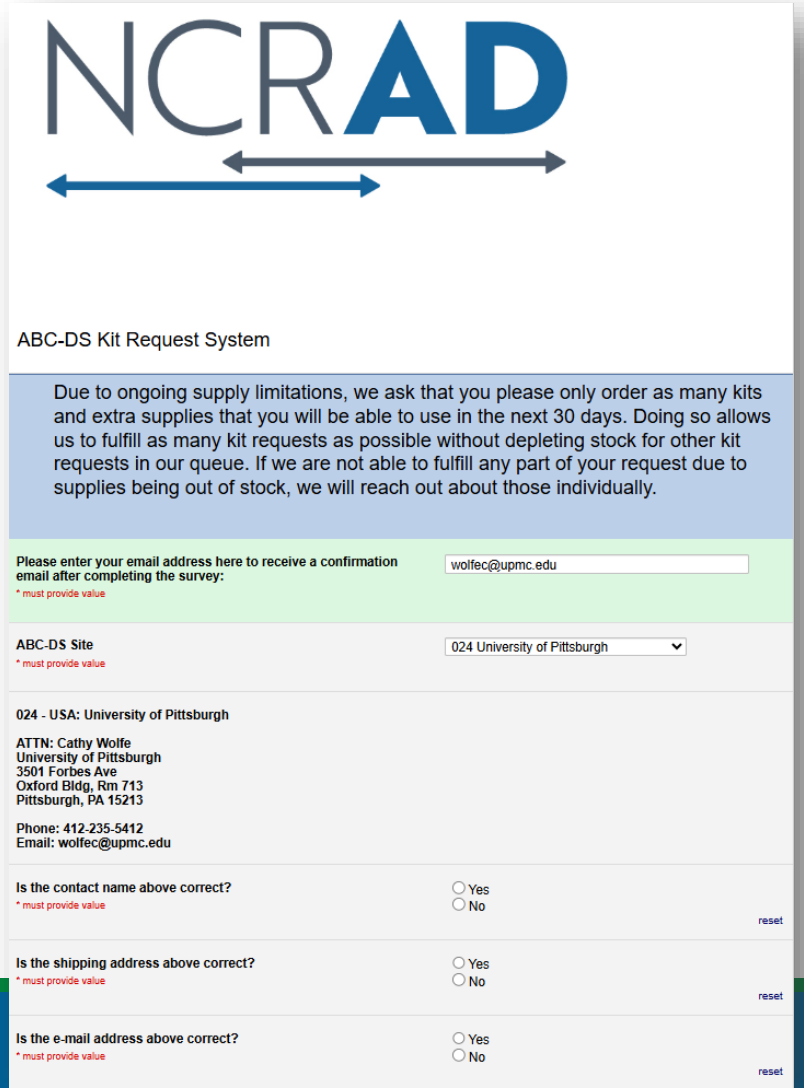
ABC-DS Kit Request Module

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



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: wolfec@upmc.edu

* must provide value

ABC-DS Site: 024 University of Pittsburgh

* 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 reset

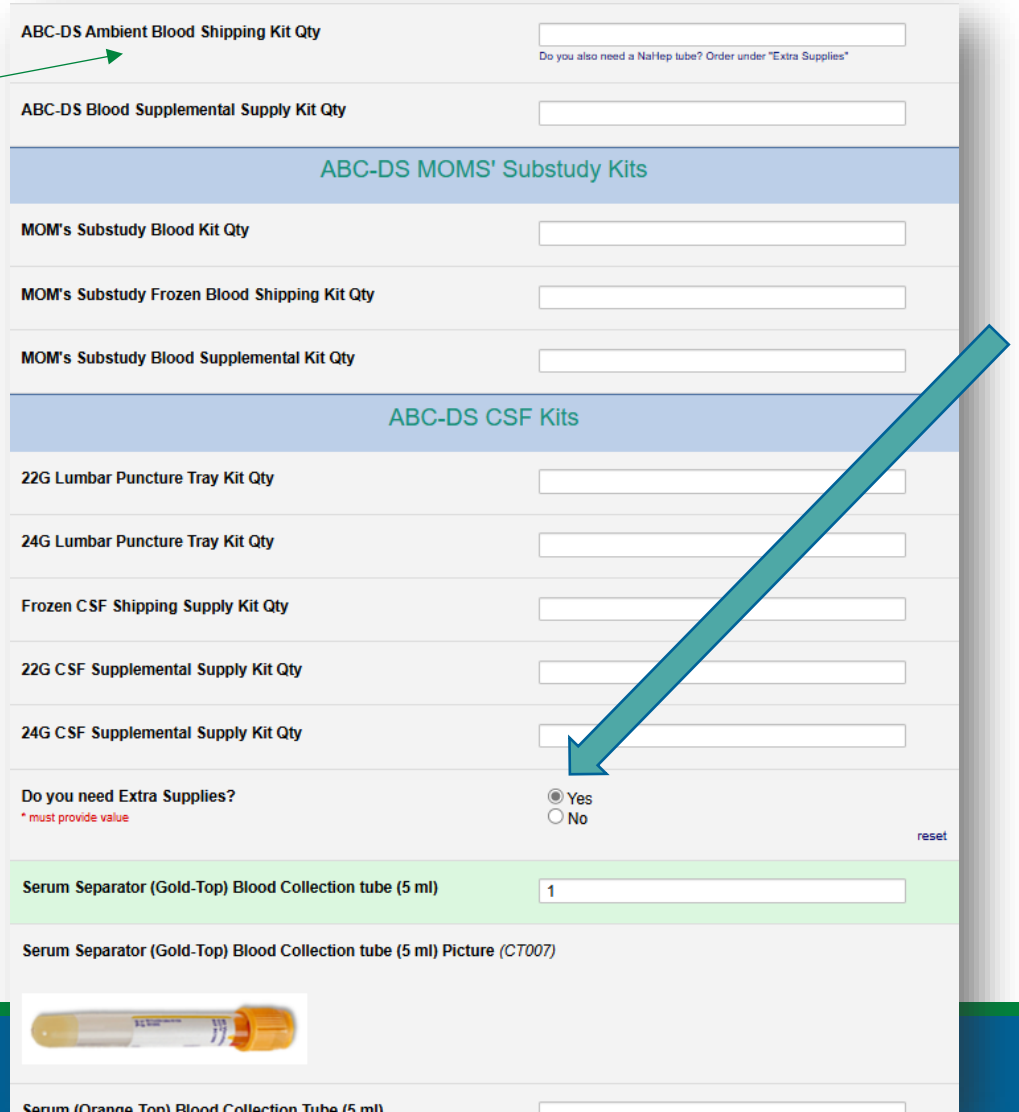
Is the shipping address above correct? Yes No reset

Is the e-mail address above correct? Yes No reset

- 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”



- 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

- 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

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- 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.

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Collection Schedules

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

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Alzheimer's Disease and Related Dementias

Blood-Based Collection Schedule:

DS Participants and Sibling Controls

Blood Collection – to be sent to UNTHSC, NCRAD, and IU Cyto Lab

	Serum	Karyotyping[1]	Plasma	DNA	RNA
All Visits	X	X	X	X	X
SHIP TO:	NCRAD & UNTHSC	IU Cyto Lab	NCRAD & UNTHSC	NCRAD	NCRAD

[1]DS Participants only (if needed) at Cycle 1 visit

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Clinical Labs Blood Collection Schedule:

DS Participants ONLY

Blood Collection – to be sent to IU Health 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 HEALTH PATH LAB	IU HEALTH PATH LAB	IU HEALTH PATH LAB	IU HEALTH PATH LAB

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Redraw Instructions and Timeframes

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Alzheimer's Disease and Related Dementias

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

National Centralized Repository for
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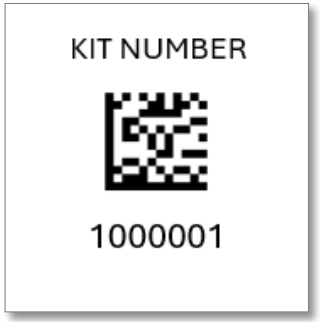
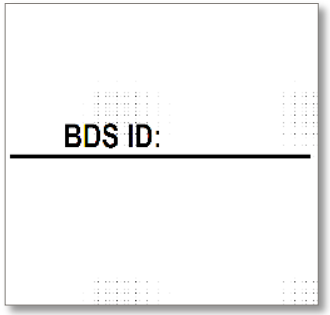
Four Label Types



Kit Number Labels

Collection Tube Labels



Site and BDS ID Labels

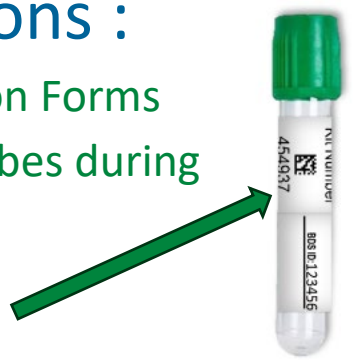
Aliquot Tube Labels

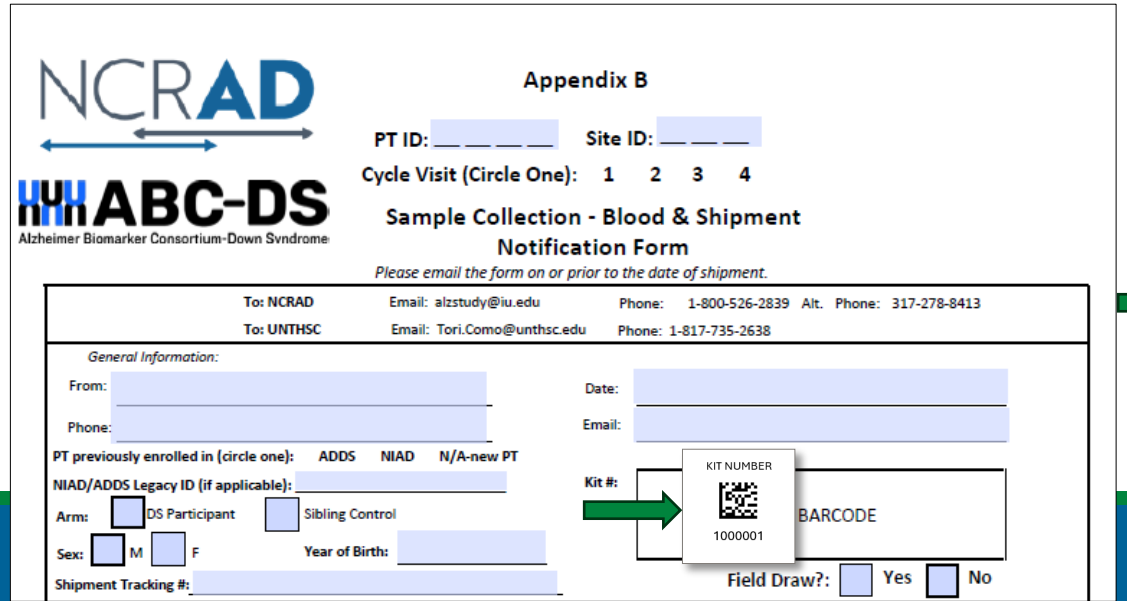
Kit Number Labels

KIT NUMBER

1000001

- 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





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Appendix B

PT ID: __ __ __ __ **Site ID:** __ __ __

Cycle Visit (Circle One): 1 2 3 4

Sample Collection - Blood & Shipment Notification Form

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

To: NCRAD Email: alzstudy@iu.edu Phone: 1-800-526-2839 Alt. Phone: 317-278-8413

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):

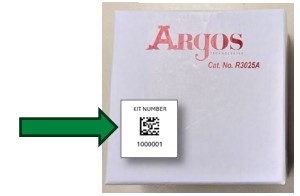
Arm: DS Participant Sibling Control

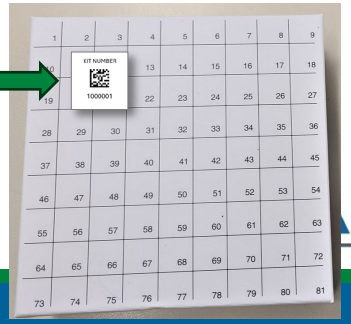
Sex: M F Year of Birth:

Shipment Tracking #:

Kit #: KIT NUMBER 1000001 BARCODE

Field Draw?: Yes No





Collection Tube Labels

- Collection Tube labels have 6 components:
  - Study name
  - COLLECT – Indicates the label is for the collection tube
  - Kit number (assigned by NCRAD)
    - Unique to participant AND visit
  - 10-digit specimen number (assigned by NCRAD)
  - Specimen type = WBLD
  - Collection tube type
- Will be placed on the following locations :
  - All Collection Tubes
    - 2 x Serum Separator (Gold-Top) Blood Collection Tube (5 mL)
    - 2 x EDTA (Purple-Top) Blood Collection Tube (10 mL)
    - 1 x PAXgeneTM Blood Collection Tube (2.5 mL)

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

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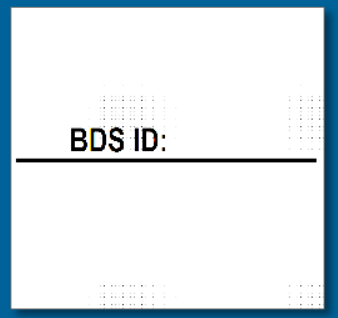
Site and BDS ID Labels



- 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

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Aliquot Tube Labels

- One label to be placed on each 0.5 mL cryovial:
  - **Serum**
    - From 5 mL SST (Gold-Top) Tubes
  - **Plasma**
    - From 10 mL EDTA Tubes
  - **Buffy Coat**
    - From 10 mL EDTA Tubes

Note: Aliquot Tube Labels will have “ALIQUOT” under the study name. Since moving to a new LIMS, the labels will no longer have a color-coded strip.

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SST, EDTA, and RNA Collection Tube Labels:

Serum Separator (Gold-Top) Blood Collection Tube (5 mL)	EDTA (Lavender-Top) Blood Collection Tube (10 mL)	PAXgene™ Blood Collection Tube (2.5 mL)
WBLD	*WBLD*	*WBLD*
SSTGLD	*EDTA10*	*RNA – PAX10*

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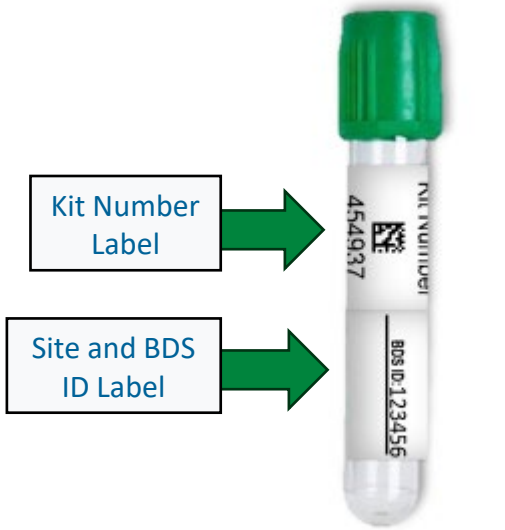
NaHep Tube Labels for Karyotyping DS Participants:



IU Pathology Laboratory Specimen Labels

Provided by NCRAD

National Centralized Repository for
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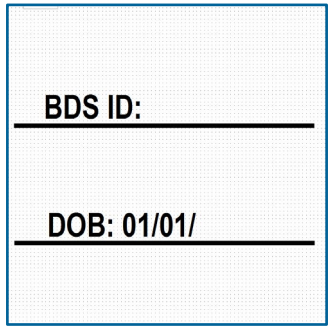
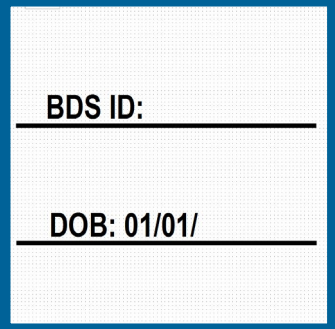
One Label Type



Site BDS ID and DOB Labels

Site BDS ID and DOB Labels



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

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SST and EDTA Collection Tube Labels:

Site BDS ID and DOB Labels

Serum Separator (Orange Top) Blood Collection Tube (5 mL)

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

EDTA (Lavender Top) Blood Collection Tube (3 mL)

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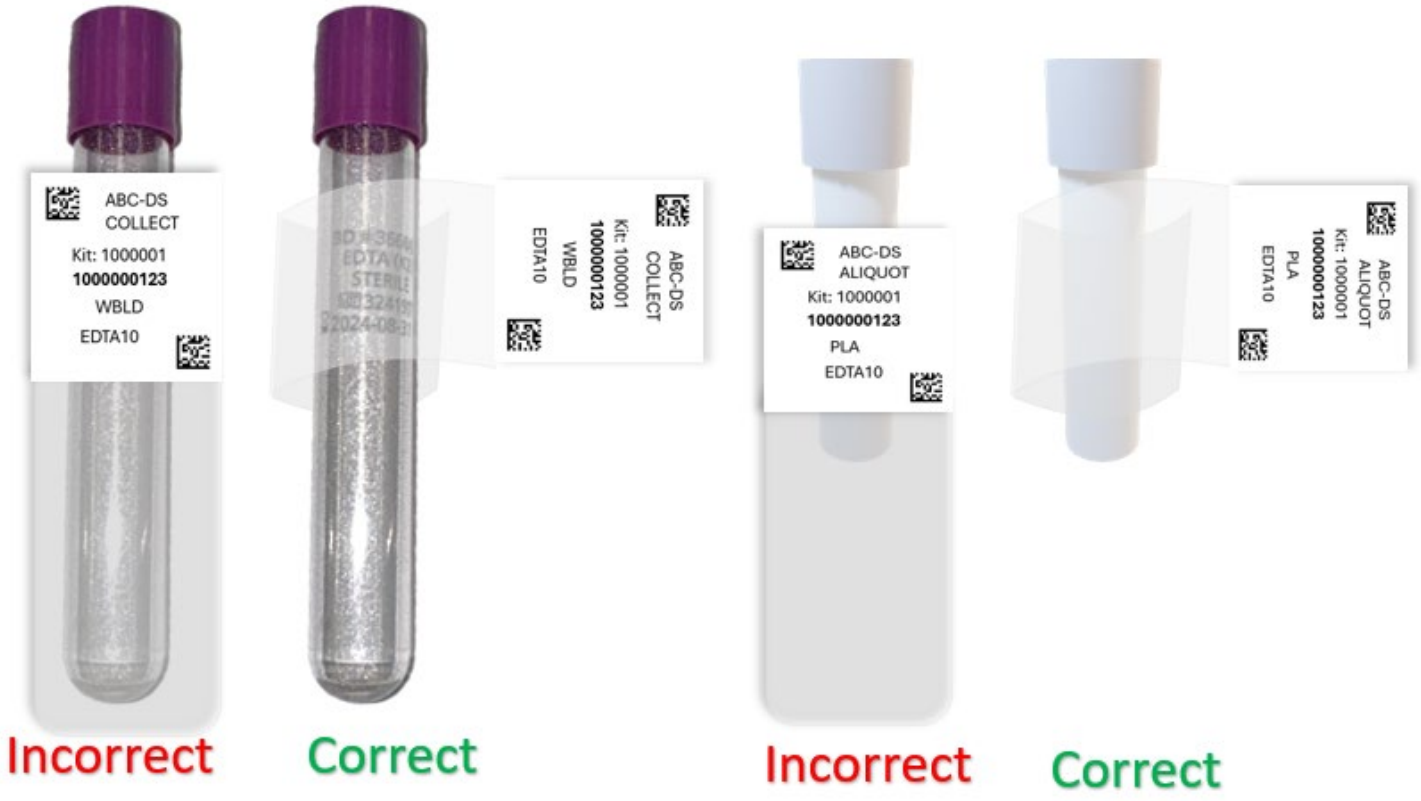
Properly Labeling Biologic Samples:

- 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

National Centralized Repository for
Alzheimer's Disease and Related Dementias

Site Required Equipment

BLOOD COLLECTION/SAFETY EQUIPMENT

- Personal Protective Equipment: lab coat, nitrile/latex gloves, safety glasses
- Tourniquet
- Alcohol Prep Pad
- Gauze Pad
- Bandage
- Butterfly needles (21 gauge) and hub
- Microcentrifuge tube rack
- Sharps bin and lid
- Wet Ice Bucket

PROCESSING/STORAGE EQUIPMENT

- For NCRAD/UNTHSC: Centrifuge capable of ≥ 2000 x g with refrigeration to 4°C
- For IU Health Path Lab: Centrifuge capable of 1300 x g with refrigeration to 4°C
- -80°C Freezer
- Wet Ice
- Pelleted dry ice

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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 the 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 Health Path Lab)
- 3. Serum Separator (Gold-Top) Blood Collection Tube (5 mL) for Serum x 1 (IU Health 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 Health Path Lab)
- 7. PAXgene™ Blood Collection Tube (2.5 mL) for RNA x 1 (NCRAD)

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NCRAD and UNTHSC
Sample Collection and Processing

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National Centralized Repository for
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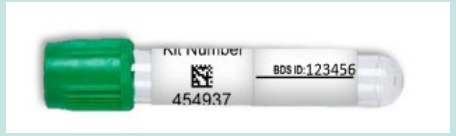
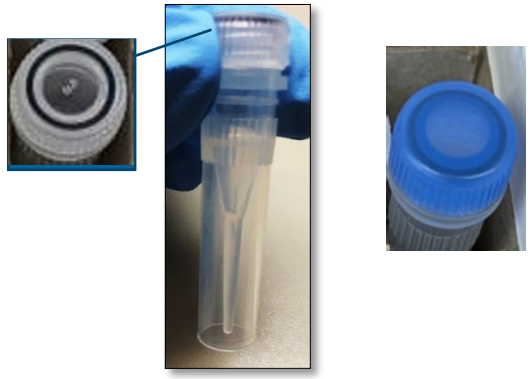
NCRAD & UNTHSC Research Blood Collection
DS Participants and Sibling Controls

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	

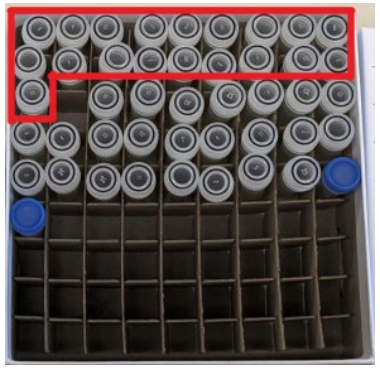
*DS participants only

Aliquot Cap & Label Colors

Color Coding	Sample Type
Clear-Cap	Serum
Clear-Cap	Plasma
Blue-Cap	Buffy Coat

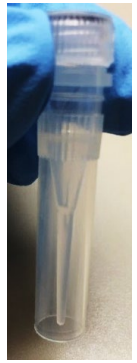


Serum Collection



81 cell cryobox with 0.5 mL cryovials – sent to NCRAD

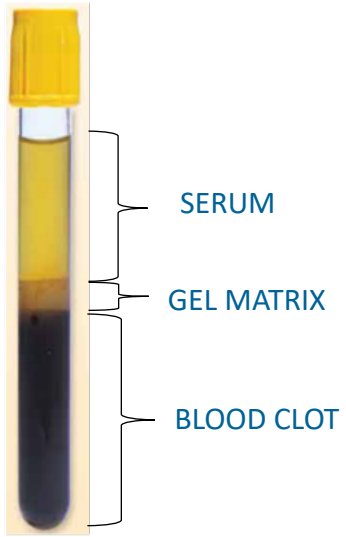
25 cell cryobox with 0.5 mL cryovials – sent to UNTHSC



Close up view of 0.5 mL Cryovial

- 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**

SST immediately after blood draw.



SST immediately following the centrifuge.

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Serum Separator (Gold-Top) Blood Collection Tube (5 mL) x 2

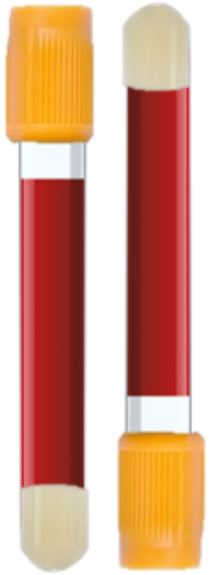
Step 1

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

Step 2

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

Step 3

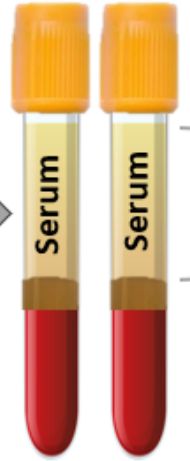


- Immediately after blood draw, invert tube 5 times to mix samples.

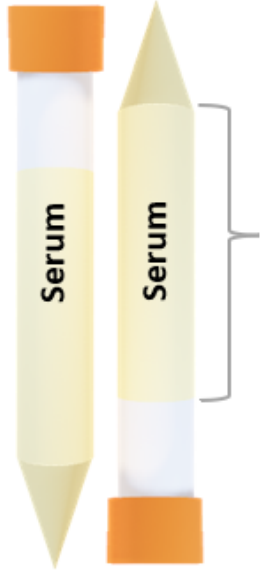
Step 4

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

Step 5



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



- Using a clean pipette, transfer serum from both 5 mL SST tubes into the 15 mL conical tube.
- Mix the serum by gently inverting the conical tube 3-4 times.

Step 6

Up to 19 sent to NCRAD

Up to 2 sent to UNTHSC

- Using a clean pipette, aliquot .25 mL of serum into each pre-labeled cryovial tube.
- If residual aliquot is created, document specimen number and volume on sample form.
- Store serum aliquots upright 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.

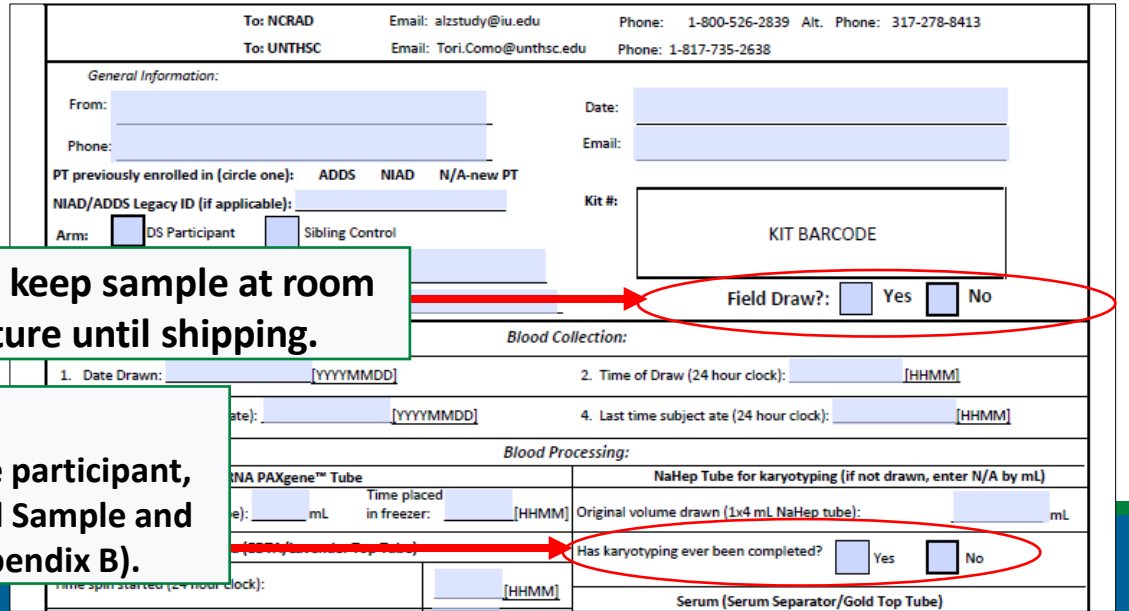
- 1 x Sodium Heparin (Green-Top) Blood Collection tube (4 mL)
  - **This tube is to be shipped to IU Cyto Lab ambient on the day of collection via overnight delivery without further processing at collection site.**

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.

NCRAD

NaHep Collection (for karyotyping)

- 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.


To: NCRAD Email: alzstudy@iu.edu Phone: 1-800-526-2839 Alt. Phone: 317-278-8413
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 #:

KIT BARCODE

Arm: DS Participant Sibling Control

Field Draw?: Yes No

Blood Collection:

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

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

Blood Processing:

NaHep Tube for karyotyping (if not drawn, enter N/A by mL)

Time placed in freezer: [HHMM] Original volume drawn (1x4 mL NaHep tube): mL

Has karyotyping ever been completed? Yes No

[HHMM]

Serum (Serum Separator/Gold Top Tube)

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

Important Note

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

NCRAD

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

Step 1

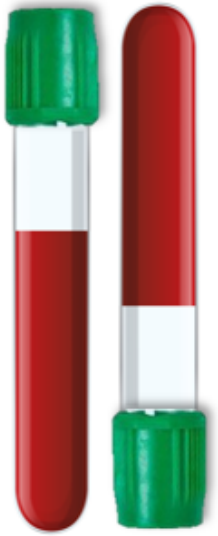
- Store tubes at room temperature.
- Label tubes with pre-printed Kit Number and BDS ID labels prior to blood draw.

Step 2

x1

- Collect blood in (1) 4 mL Sodium Heparin tube, allowing blood to flow for 10 seconds and ensure blood flow has stopped.

Step 3



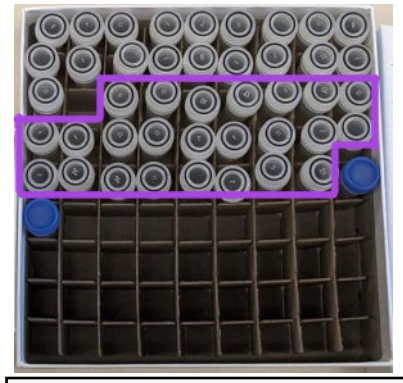
- Immediately after blood draw, invert tube 8-10 times to mix samples.

Step 4

- Store tube at room temperature until shipment.
- Ship ambient to the IU Cyto Lab on same day as blood draw.

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

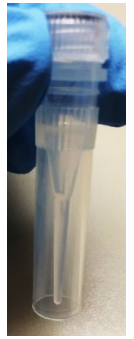
Plasma Collection



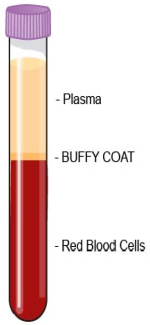
81 cell cryobox with 0.5 mL cryovials – sent to NCRAD

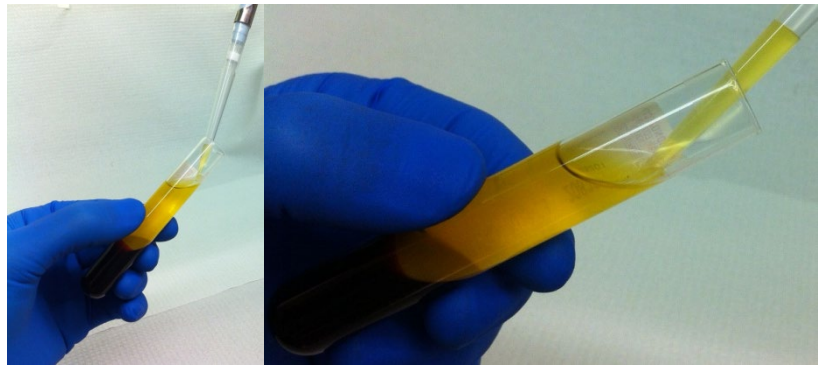
25 cell cryobox with 0.5 mL cryovials – sent to UNTHSC

- 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 0.5 mL Cryovial

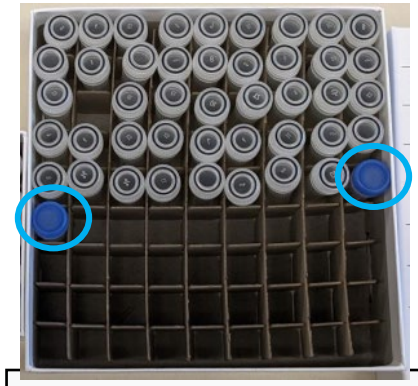




NOTE: When pipetting plasma from the plasma tube into the 15 mL conical tube, be very careful to pipette the plasma top layer only, leaving the buffy coat and the red blood cell layers untouched.

NCRAD

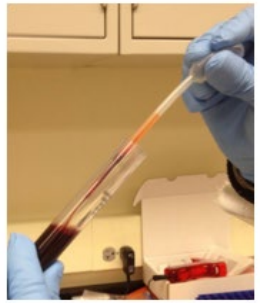
Buffy Coat Collection



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)

NCRAD

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.

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

Step 1

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

Step 2

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

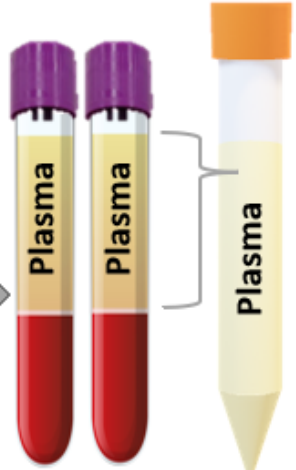
Step 3

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

Step 4

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

Step 5



- Within 30 minutes of blood collection, 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 pipette, transfer plasma from both 10 mL EDTA tubes into the 15 mL conical tube.
- Mix the plasma by gently inverting the conical tube 3 times.

Step 6

Up to 24 sent to NCRAD

Up to 17 sent to UNTHSC

- Using a clean pipette, aliquot .25 mL of plasma into each pre-labeled cryovial tube.
- If residual aliquot is created, document specimen number and volume on sample form.
- Store serum aliquots upright at -80°C until shipment.

Step 7

x2

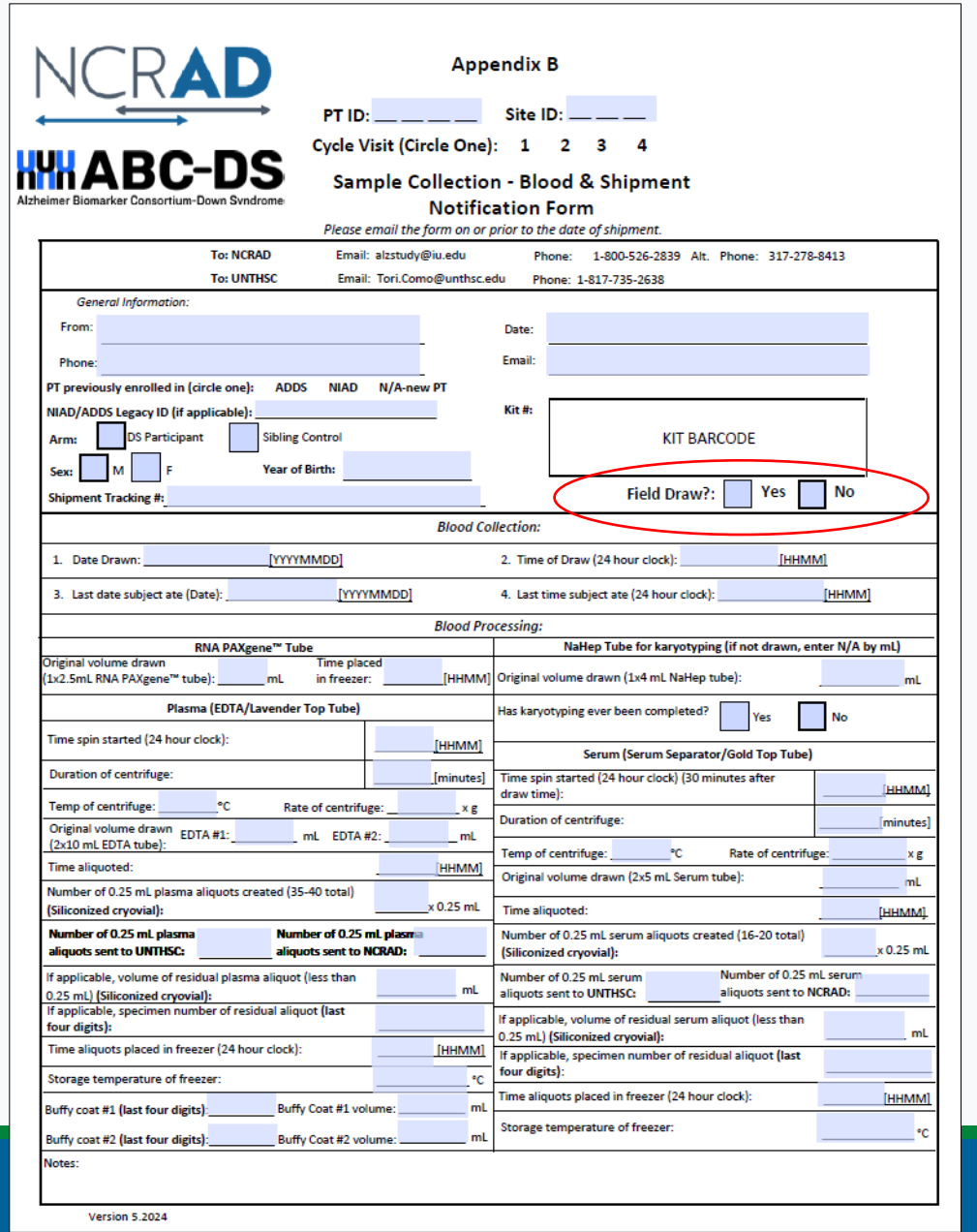
- Using a clean pipette, transfer each buffy coat layer (may have residual plasma and RBCs) from EDTA tubes to pre-labeled blue-cap buffy coat cryovials (do not pool buffy coats).
- Store buffy coat aliquots upright at -80°C until shipment to NCRAD.

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

NCRAD

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.



NCRAD

ABC-DS
Alzheimer Biomarker Consortium-Down Syndrome

Appendix B

PT ID: __ __ __ __ **Site ID:** __ __ __

Cycle Visit (Circle One): 1 2 3 4

Sample Collection - Blood & Shipment Notification Form

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

To: NCRAD Email: alzstudy@iu.edu Phone: 1-800-526-2839 Alt. Phone: 317-278-8413

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 #: KIT BARCODE

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 date 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]

Plasma (EDTA/Lavender Top Tube)

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

Duration of centrifuge: [minutes]

Temp of centrifuge: °C Rate of centrifuge: x g

Original volume drawn (2x10 mL EDTA tube): EDTA #1: mL EDTA #2: 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

If applicable, specimen number of residual aliquot **(last four digits):**

Time aliquots placed in freezer (24 hour clock): [HHMM]

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:

NaHep Tube for karyotyping (if not drawn, enter N/A by mL)

Original volume drawn (1x4 mL NaHep tube): mL

Has karyotyping ever been completed? Yes No

Serum (Serum Separator/Gold Top Tube)

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

Original volume drawn (2x5 mL Serum tube): mL

Time aliquoted: [HHMM]

Number of 0.25 mL serum aliquots created (16-20 total) **(Siliconized cryovial):** x 0.25 mL

Number of 0.25 mL serum aliquots sent to **UNTHSC:** Number of 0.25 mL serum aliquots sent to **NCRAD:**

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]

Storage temperature of freezer: °C

Version 5.2024

NCRAD

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.**

NCRAD

RNA Preparation (2.5 mL PAXgene™ Tube) x 1

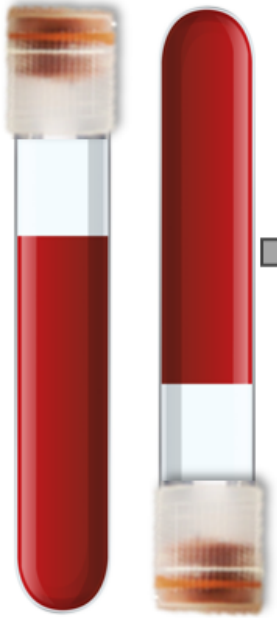
Step 1

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

Step 2

- Collect blood in PAXgene™ tube allowing blood to flow for at least 10 seconds and ensuring blood flow has stopped.

Step 3



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

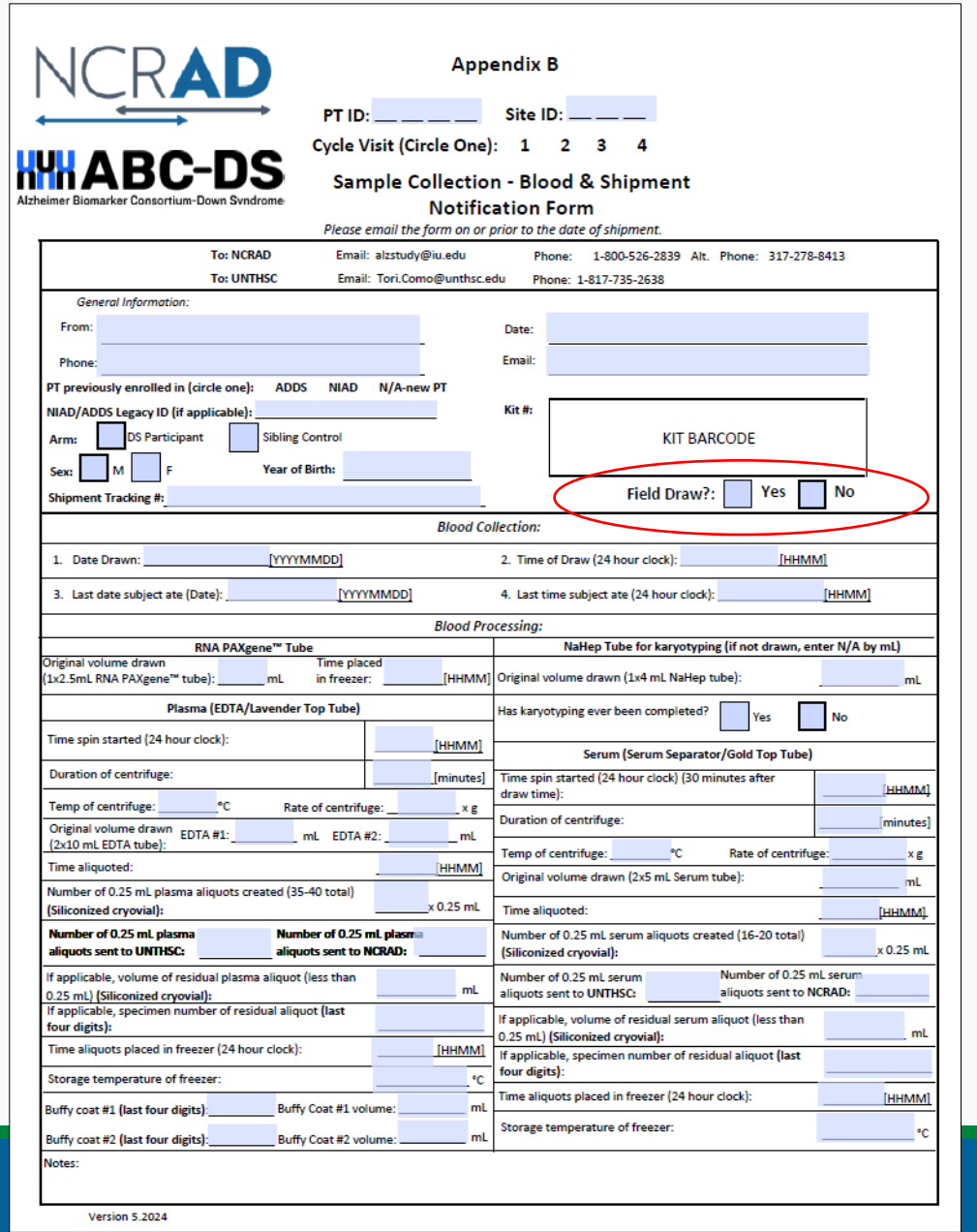
Step 4

- Store tube upright at -80°C until shipment to NCRAD.

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

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.**



NCRAD

ABC-DS
Alzheimer Biomarker Consortium-Down Syndrome

Appendix B

PT ID: __ __ __ __ **Site ID:** __ __ __

Cycle Visit (Circle One): 1 2 3 4

Sample Collection - Blood & Shipment Notification Form

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

To: NCRAD Email: alzstudy@iu.edu Phone: 1-800-526-2839 Alt. Phone: 317-278-8413

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 #:** KIT BARCODE

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 date 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]

Plasma (EDTA/Lavender Top Tube)

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

Duration of centrifuge: [minutes]

Temp of centrifuge: °C Rate of centrifuge: x g

Original volume drawn (2x10 mL EDTA tube): EDTA #1: mL EDTA #2: 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

If applicable, specimen number of residual aliquot **(last four digits):**

Time aliquots placed in freezer (24 hour clock): [HHMM]

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:

NaHep Tube for karyotyping (if not drawn, enter N/A by mL)

Original volume drawn (1x4 mL NaHep tube): mL

Has karyotyping ever been completed? Yes No

Serum (Serum Separator/Gold Top Tube)

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

Original volume drawn (2x5 mL Serum tube): mL

Time aliquoted: [HHMM]

Number of 0.25 mL serum aliquots created (16-20 total) **(Siliconized cryovial):** x 0.25 mL

Number of 0.25 mL serum aliquots sent to **UNTHSC:** Number of 0.25 mL serum aliquots sent to **NCRAD:**

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]

Storage temperature of freezer: °C

Version 5.2024

NCRAD

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.

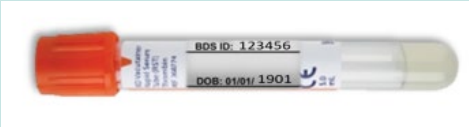
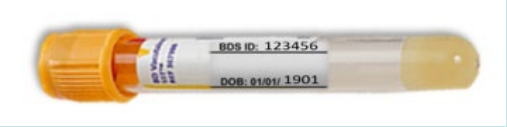
25-cell cryobox with Plasma and Serum aliquots – sent to UNTHSC

NCRAD

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

National Centralized Repository for
Alzheimer's Disease and Related Dementias

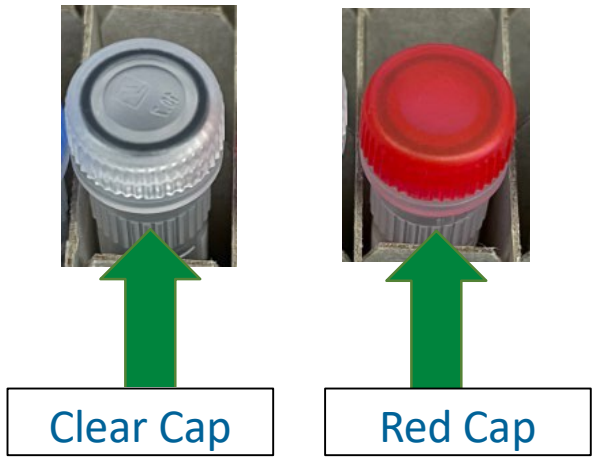
IU Health Path Lab Research Blood Collection
DS Participants ONLY

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	

NCRAD

Aliquot Cap Colors

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



Serum Collection

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

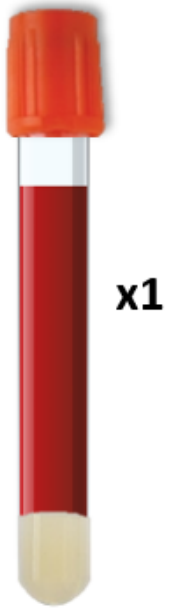
NCRAD

Free T4, Thyroid, Triiodothyronine, TSH, Vit B12, ATA Preparation (1 x 5 mL Orange-Top SST Tube)

Step 1

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

Step 2



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

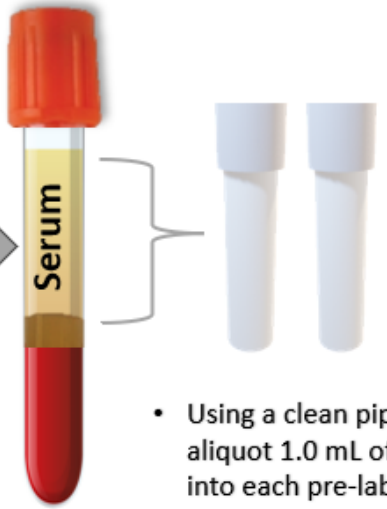
Step 3

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

Step 4

- Within 1 hour of blood draw, centrifuge tube for 10 minutes at 1300 x g at 4°C.

Step 5



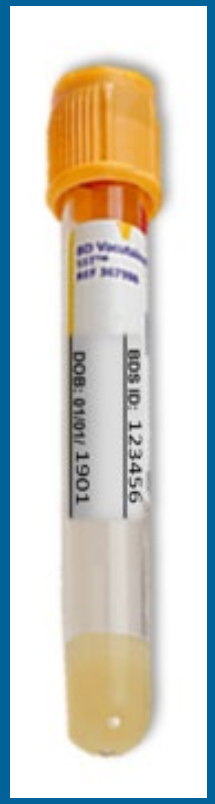
- Using a clean pipette, aliquot 1.0 mL of serum into each pre-labeled cryovial tube.
- Store serum aliquots upright in refrigerator until shipment to the IU Path Lab. **Ship same day as blood draw.**

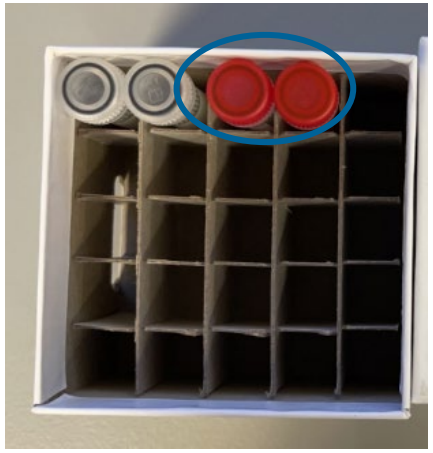
Important Note: Ensure all tubes are not expired prior to collection and processing of samples.

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 Health Path Lab form (Appendix D) that it is a field-draw and the time it takes to process the samples.

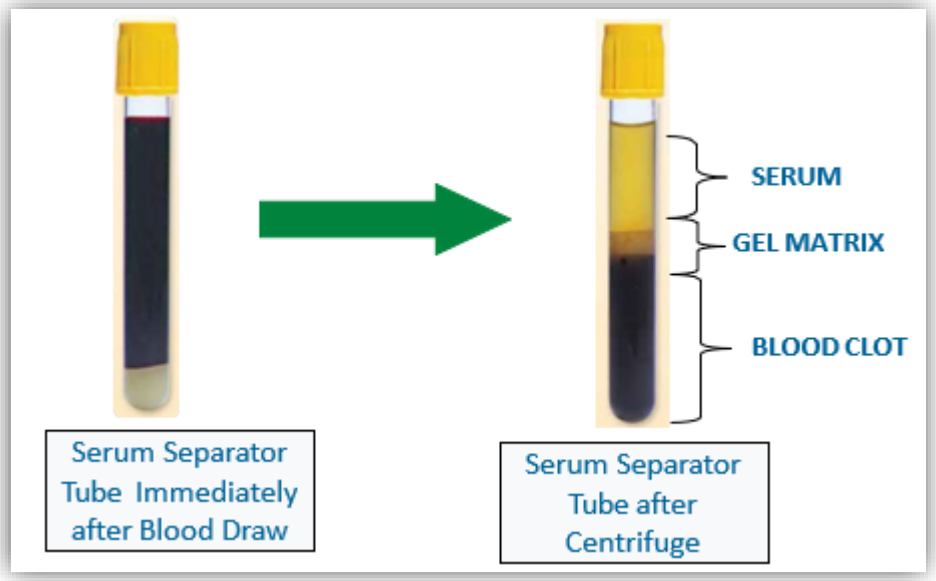
Serum Collection





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



NCRAD

Vit D, BMP, Lytes and Lipid Preparation (1 x 5 mL Gold-Top SST Tube)

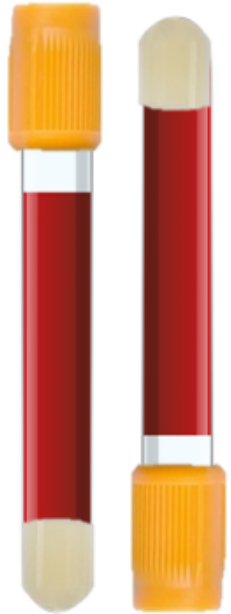
Step 1

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

Step 2

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

Step 3



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

Step 4

- **Allow blood to clot for 30 minutes**
- Within 1 hour of blood draw, centrifuge tube for 10 minutes at 1300 x g at 4°C.

Step 5

- Using a clean pipette, aliquot 1.0 mL of serum into each pre-labeled cryovial tube.
- Store serum aliquots upright in refrigerator until shipment to the IU Path Lab. **Ship same day as blood draw.**

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 Health 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.

NCRAD

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 Health Path Lab refrigerated on the day of collection, without further processing at the collection site.**

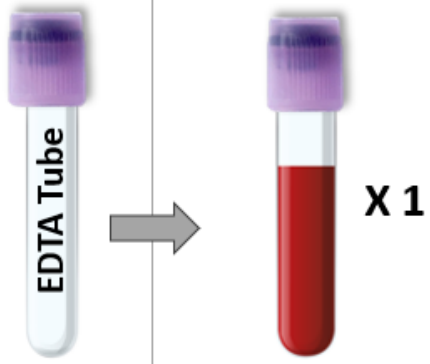
NCRAD

CBC and A1C Preparation (1 x 3 mL Lavender-Top Tube)

Step 1

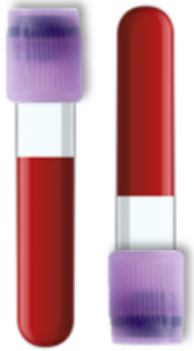
- Store tubes at room temperature.
- Label Collection Tube with pre-printed labels prior to blood draw.

Step 2



- Collect blood in (1) 3 mL Lavender-Top tube, allowing blood to flow for 10 seconds and ensure blood flow has stopped.

Step 3



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

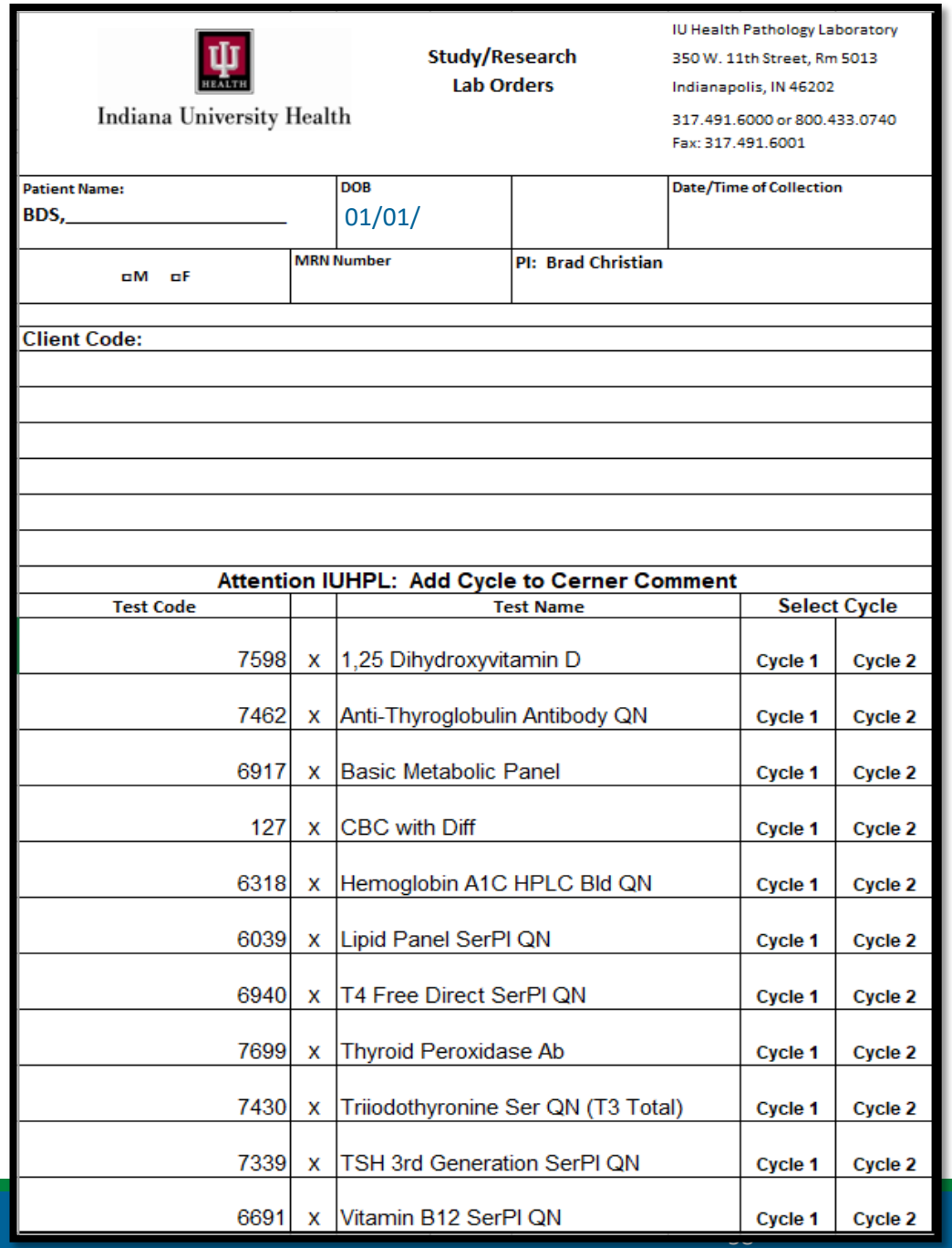
Step 4

- Store Whole Blood upright in refrigerator until shipment to the IU Path Lab. **Ship same day as blood draw.**

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

CRITICAL STEP:

1. Store EDTA (Lavender-Top) Blood Collection Tube (3 mL) in refrigerator until shipment.
2. If field draw, keep tube on cold packs during transfer to lab. Store tube in refrigerator until shipment. Please note on the IU Health Path Lab form (Appendix D) that it is a field-draw.



Indiana University Health

Study/Research Lab Orders

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 01/01/		Date/Time of Collection
▫M ▫F	MRN Number	PI: Brad Christian	

Client Code:

Attention IUHPL: Add Cycle to Cerner Comment

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 SerPl QN	Cycle 1	Cycle 2
6940	x	T4 Free Direct SerPl 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 SerPl QN	Cycle 1	Cycle 2
6691	x	Vitamin B12 SerPl QN	Cycle 1	Cycle 2

NCRAD

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.

NCRAD

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Alzheimer's Disease and Related Dementias

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.

(photo: A.H. – U of Wisconsin)

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).

NCRAD

Packing and Shipping Samples

NCRAD

National Centralized Repository for
Alzheimer's Disease and Related Dementias

NCRAD and UNTHSC Sample Shipping

National Centralized Repository for
Alzheimer's Disease and Related Dementias

NCRAD and UNTHSC Blood Sample Shipment Summary

Sample Type	Processing/ Aliquoting	Tubes to NCRAD	Tubes to UNTHSC	Tubes to IU Cyto Lab	Ship
Whole blood for isolation of serum	0.25 mL serum aliquot per 0.5 mL cryovial (Clear-Cap)	19	2	**N/A**	**Frozen**
Whole blood for Karyotyping	**N/A**	**0**	**0**	**1**	**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	**N/A**	**Frozen**
	1 mL buffy coat aliquot per 2.0 mL cryovial (Blue-Cap)	2	**0**	**N/A**	**Frozen**
Whole blood for RNA extraction	**N/A**	1	**0**	**N/A**	**Frozen**

NCRAD

Frozen Shipping

Serum, Plasma, Buffy Coat and RNA

NCRAD

National Centralized Repository for
Alzheimer's Disease and Related Dementias

Notify NCRAD and UNTHSC When Samples Ship:

1. Notify NCRAD in advance of shipment by emailing NCRAD coordinators at: alzstudy@iu.edu and zdpotter@iu.edu

➢ Attach the following to the email:

- Completed Blood 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 have contacted and notified NCRAD coordinators about the shipment in advance.
- Please include the tracking number in the body of the email.
  -
  - Notify UNTHSC in advance of shipment by emailing UNTHSC Lab Manager at: Tori.Como@unthsc.edu

➢ Attach the following to the email:

- Completed UNTHSC Intake Form (Appendix F) and the UNTHSC Import Batch Form (Appendix G – both forms found on the NCRAD ABC-DS study page):
  - BDS IDs (not the kit number) and specimen barcodes need to be scanned or pasted into the UNTHSC Import Batch Form (Appendix G). *NCRAD will send an Excel file with all specimen barcodes included in each kit when kit supplies are shipped.*
- If email is unavailable please call UNTHSC and do not ship until you have 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.

NCRAD

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.

Large Frozen Shipper:

** 45 lbs. of dry ice pellets

AND

Fits up to 5 x 81-slot cryoboxes
and 5 x 25-slot cryoboxes

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!

NCRAD

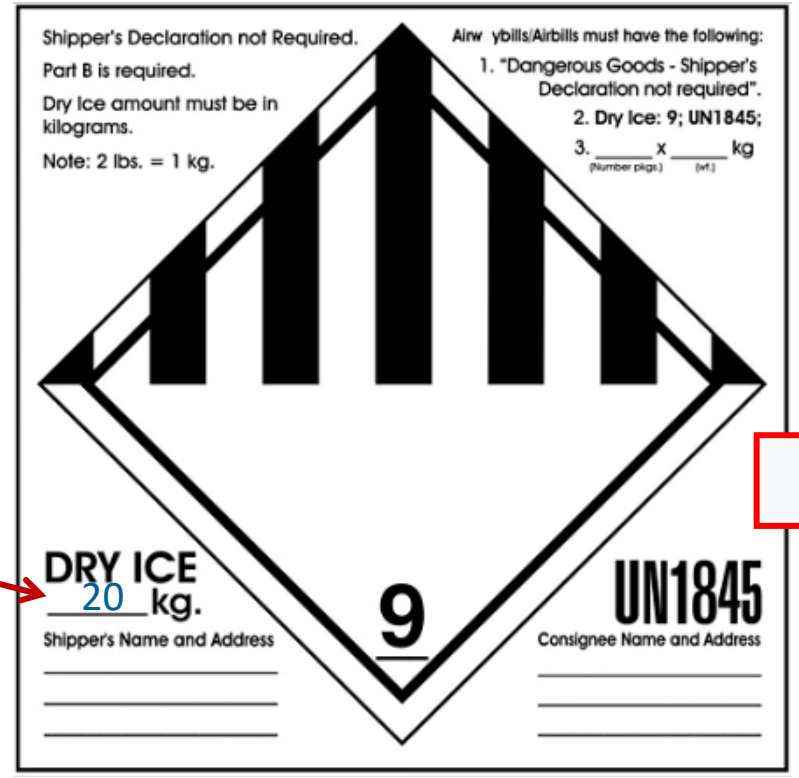
Frozen Shipping Dry Ice Requirements

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

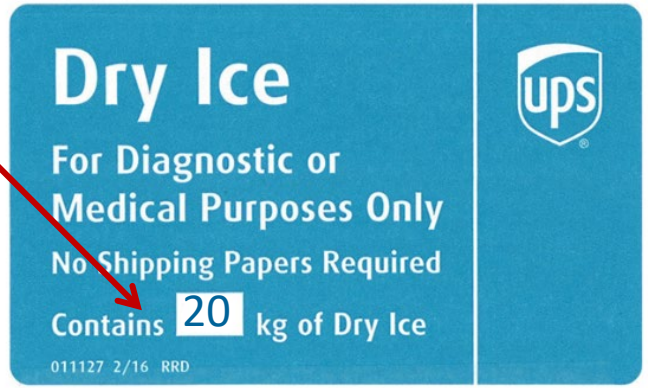
1.Net weight of dry ice in kg (must match amount on the airbill)!

2. Dry Ice label should not be covered with other stickers and must be completed (see right)!

Net weight of dry ice in **kg**



FedEx Dry Ice Sticker



UPS Dry Ice Sticker (UW-Madison Only)

NCRAD

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.

NCRAD

Creating Airbills/Scheduling Pickups

Frozen Shipments

NCRAD

National Centralized Repository for
Alzheimer's Disease and Related Dementias

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

NCRAD

Ambient Shipping

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

NCRAD

National Centralized Repository for
Alzheimer's Disease and Related Dementias

Notify IU Cyto Lab and NCRAD Coordinator When NaHep Tube Ships:

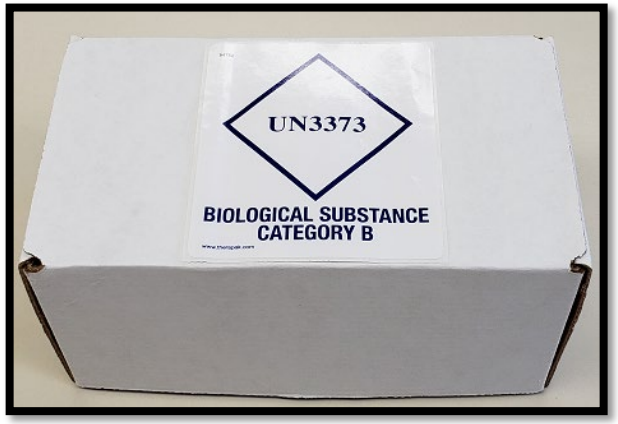
1. Notify the IU Cyto Lab of shipment by emailing the following: iugtl@iu.edu, alzstudy@iu.edu, and zdpotter@iu.edu.
    a. Complete and attach the Constitutional (Blood) Test Requisition Form to the email. (See Appendix E for an example of the form)

Ambient Shipment Packaging:

NaHep Sample

Absorbent Pad

Biohazard Bag



1. Place filled and labeled Sodium Heparin (green-top) tube within a slot 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.
2. 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.
3. Place the sealed biohazard bag inside the cooler and place the refrigerant pack into the cooler on top of the filled biohazard bag.
4. Place the lid onto the cooler.
5. Place the cooler in the provided small IATA Shipping Box.
6. Close shipping box. Label the outside of the cardboard box with the enclosed UN3373 (Biological Substance Category B) label.
7. Place the closed, labeled shipping box within a Clinical Pak. Seal the Clinical Pak.
8. Place return airbill on the sealed Clinical Pak.

NCRAD

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!!!**

IU Cytogenetics Laboratory

MMGE IU Genetic Testing Laboratories

975 W. Walnut Street, IB 350

Indianapolis, IN 46202

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

NCRAD

Critical Ambient Shipping Instructions

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

1. Ambient specimens should be shipped to IU Cyto Lab 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.

NCRAD

International Shipments

NCRAD

National Centralized Repository for
Alzheimer's Disease and Related Dementias

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

NCRAD

Necessary components are necessary for international shipments:

1. International Waybill
2. Receipt
3. International Commercial Invoice
4. Warning Labels

Ship samples to NCRAD's lab:

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

Visit DHL Guides and Tips for more helpful information.

NCRAD

Clinical Labs Sample Shipping

Samples to IU Health Path Lab

NCRAD

National Centralized Repository for
Alzheimer's Disease and Related Dementias

IU Health Path Lab Blood Sample Shipment Summary

DS Participants ONLY

Sample Type	Tube Type	Number of Tubes Supplied in Kit	Processing/ Aliquoting	Tubes to IU Health Path Lab	Ship
Whole blood for isolation of serum	**Serum Separator (Orange-Top) Blood Collection Tube (5 mL)**	**1**	**N/A**	**N/A**	**N/A**
	SERUM: 2.0 mL cryovials	2	1.0 mL serum aliquot per 2.0mL cryovial (Clear-Cap)	2	**Refrigerated**
	Serum Separator (Gold-Top) Blood Collection Tube (5 mL)	**1**	**N/A**	**N/A**	**N/A**
	SERUM: 2.0 mL cryovials	2	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)**	**1**	**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 Health Path Lab form (Appendix D).** Submit a copy to IU Health Path Lab with a reason provided for the omission.

Refrigerated Shipping

Serum and EDTA Tube (3 mL)

NCRAD

National Centralized Repository for
Alzheimer's Disease and Related Dementias

Notify IU Health Path Lab When Samples Ship:

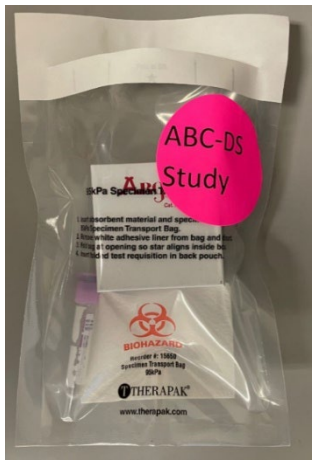
1. Notify the IU Pathology Lab of shipment by emailing IU Health Path Lab study contacts at: crobinson13@iuhealth.org, dplmprs@iuhealth.org, and kprine@iuhealth.org.
    a. Attach the following to the email:
        a. Completed IU Health Path Lab Requisition Form (Appendix D).
            1. Fill out the following on the form:
                a. ID in this format: last name = BDS (already printed on template)
                b. First name = the 7 numerals of the rest of the ABC-DS ID (e.g., 024007).
                c. Date of collection
                d. Male/Female
                e. 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.
                f. MRN: NCRAD will generate this.
        b. If email is unavailable please call IU Health Path Lab and do not ship until you have contacted and notified IU Health Path Lab study contacts about the shipment in advance.
        c. **Please include the tracking number in the body of the email.**
        d. **Place physical copy of the filled out IU Health Path Lab Req Form (Appendix D).**

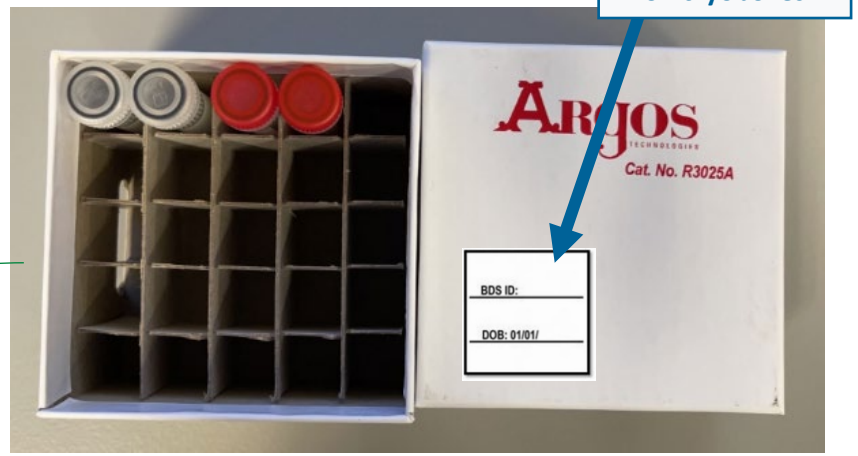
NCRAD

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 Health 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 Health 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 Health Path Lab.

NCRAD

Critical Refrigerated Shipping Instructions

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

2. It is vital to properly notify the IU Health Path Lab team of sample shipment, especially when shipping on Fridays! The IU Health 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 Health 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 Health 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 Health Path Lab Req Form (Appendix D).

NCRAD

Accessing Karyotype Results and Clinical Lab Results

NCRAD

National Centralized Repository for
Alzheimer's Disease and Related Dementias

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" and submit directly to IU Health @DPLM Lab IS Interface Support DL. 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 Health Path Lab will perform the tests offline. The following Monday, after review and corrections, results will be posted.

NCRAD

Sample Forms

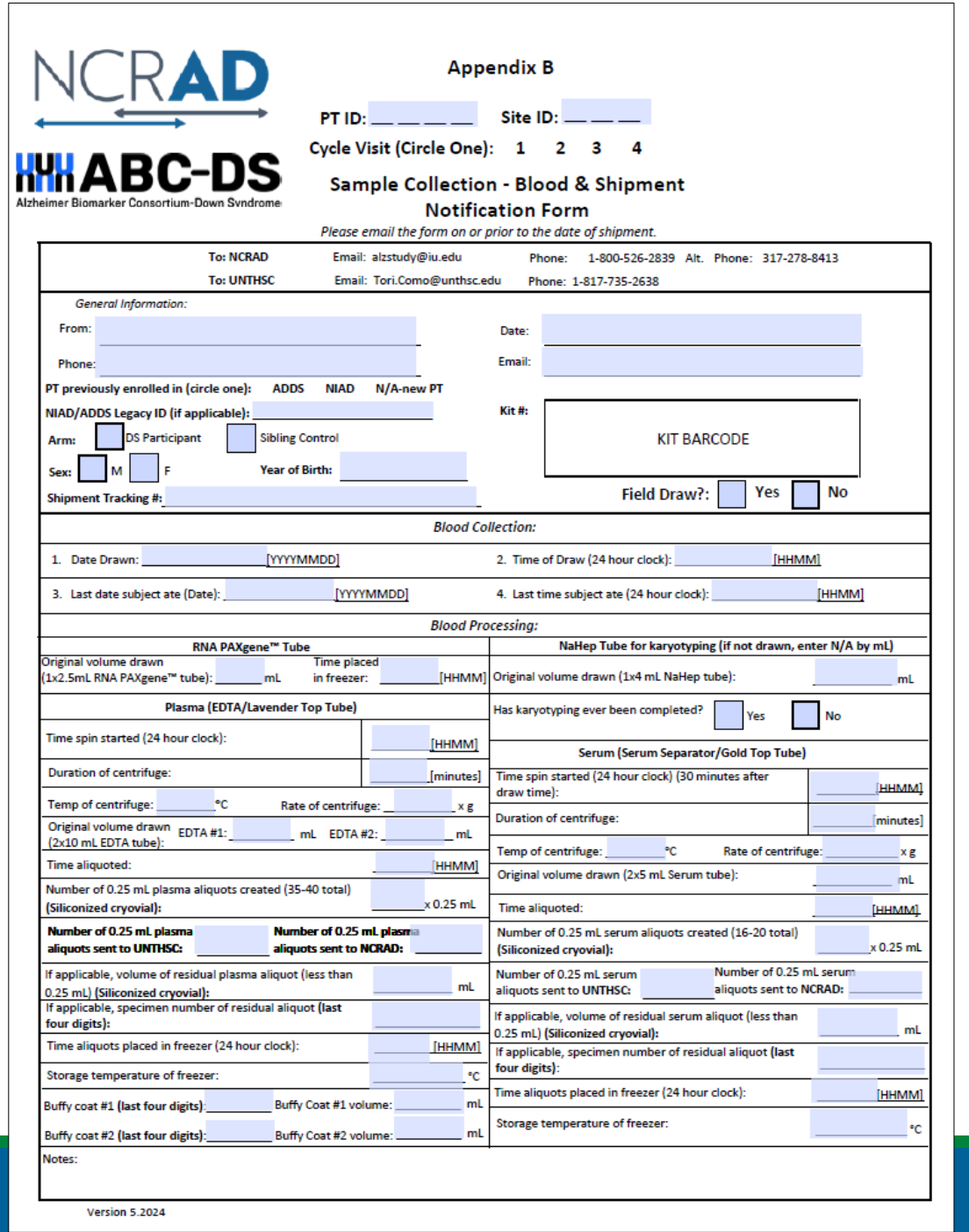
National Centralized Repository for
Alzheimer's Disease and Related Dementias

NCRAD Forms

National Centralized Repository for
Alzheimer's Disease and Related Dementias

Appendix B: Biological Sample and Shipment Notification Form

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



NCRAD

ABC-DS
Alzheimer Biomarker Consortium-Down Syndrome

Appendix B

PT ID: ___ ___ ___ ___ **Site ID:** ___ ___ ___

Cycle Visit (Circle One): 1 2 3 4

Sample Collection - Blood & Shipment Notification Form

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

To: NCRAD Email: alzstudy@iu.edu Phone: 1-800-526-2839 Alt. Phone: 317-278-8413

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 #: KIT BARCODE

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 date 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]

Plasma (EDTA/Lavender Top Tube)

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

Duration of centrifuge: [minutes]

Temp of centrifuge: °C Rate of centrifuge: x g

Original volume drawn (2x10 mL EDTA tube): EDTA #1: mL EDTA #2: 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

If applicable, specimen number of residual aliquot **(last four digits):**

Time aliquots placed in freezer (24 hour clock): [HHMM]

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:

NaHep Tube for karyotyping (if not drawn, enter N/A by mL)

Original volume drawn (1x4 mL NaHep tube): mL

Has karyotyping ever been completed? Yes No

Serum (Serum Separator/Gold Top Tube)

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

Original volume drawn (2x5 mL Serum tube): mL

Time aliquoted: [HHMM]

Number of 0.25 mL serum aliquots created (16-20 total) **(Siliconized cryovial):** x 0.25 mL

Number of 0.25 mL serum aliquots sent to **UNTHSC:** Number of 0.25 mL serum aliquots sent to **NCRAD:**

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):**

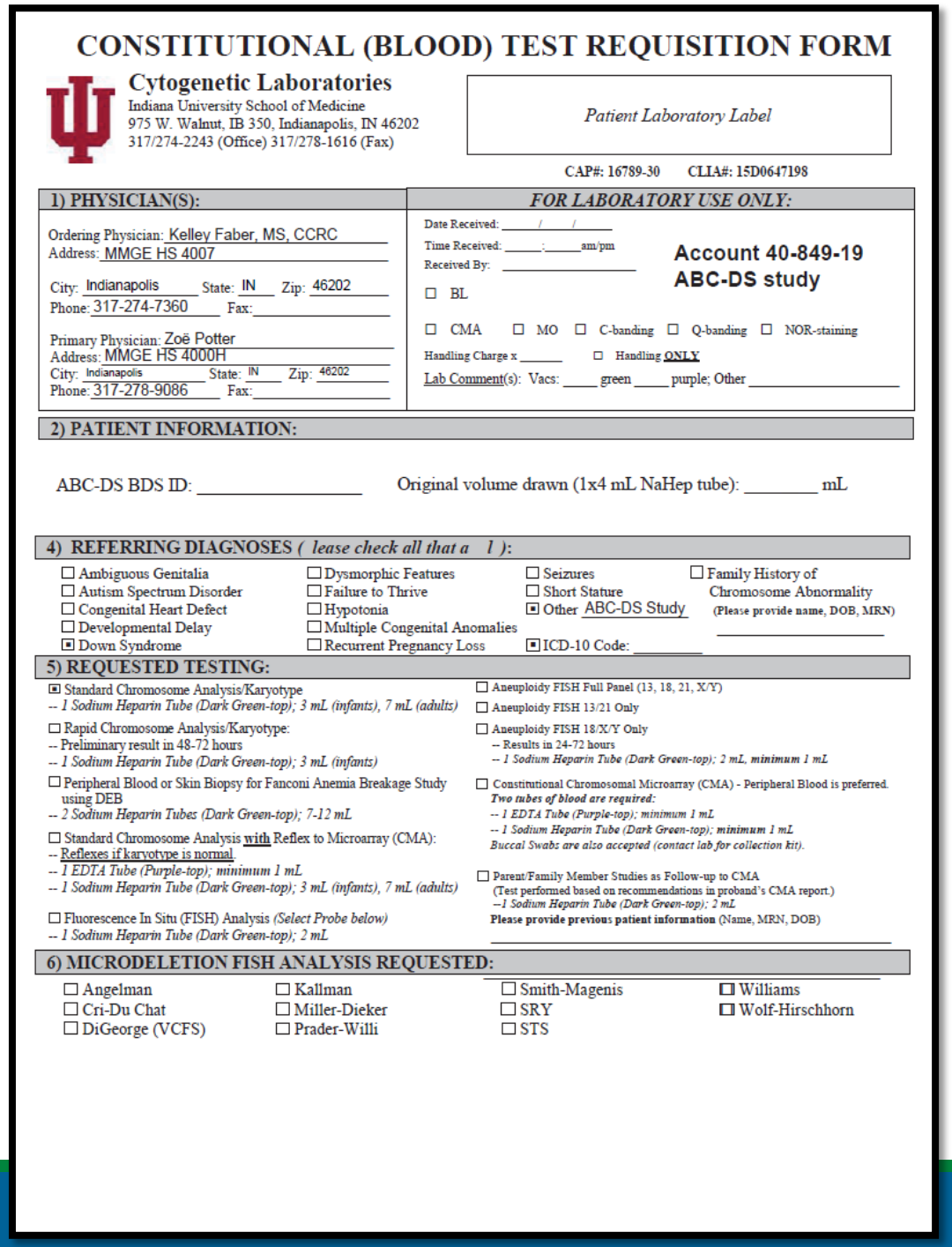
Time aliquots placed in freezer (24 hour clock): [HHMM]

Storage temperature of freezer: °C

Version 5.2024

Appendix E: Constitutional (Blood) Test Requisition Form

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!



CONSTITUTIONAL (BLOOD) TEST REQUISITION FORM

Cytogenetic Laboratories
Indiana University School of Medicine
975 W. Walnut, IB 350, Indianapolis, IN 46202
317/274-2243 (Office) 317/278-1616 (Fax)

Patient Laboratory Label

CAP#: 16789-30 CLIA#: 15D0647198

1) PHYSICIAN(S):

Ordering Physician: Kelley Faber, MS, CCRC
Address: MMGE HS 4007
City: Indianapolis State: IN Zip: 46202
Phone: 317-274-7360 Fax:

Primary Physician: Zoë Potter
Address: MMGE HS 4000H
City: Indianapolis State: IN Zip: 46202
Phone: 317-278-9086 Fax:

FOR LABORATORY USE ONLY:

Date Received: ___/___/___
Time Received: ___:___am/pm
Received By: ___

Account 40-849-19
ABC-DS study

☐ BL

☐ CMA ☐ MO ☐ C-banding ☐ Q-banding ☐ NOR-staining

Handling Charge x ___ ☐ Handling ONLY

Lab Comment(s): Vacs: ___ green ___ purple; Other ___

2) PATIENT INFORMATION:

ABC-DS BDS ID: _____ Original volume drawn (1x4 mL NaHep tube): _____ mL

4) REFERRING DIAGNOSES *(lease check all that a l):*

☐ Ambiguous Genitalia
☐ Autism Spectrum Disorder
☐ Congenital Heart Defect
☐ Developmental Delay
☒ Down Syndrome
☐ Dysmorphic Features
☐ Failure to Thrive
☐ Hypotonia
☐ Multiple Congenital Anomalies
☐ Recurrent Pregnancy Loss
☐ Seizures
☐ Short Stature
☒ Other ABC-DS Study
☒ ICD-10 Code: _____
☐ Family History of Chromosome Abnormality (Please provide name, DOB, MRN) _____

5) REQUESTED TESTING:

☒ Standard Chromosome Analysis/Karyotype
-- 1 Sodium Heparin Tube (Dark Green-top); 3 mL (infants), 7 mL (adults)

☐ Rapid Chromosome Analysis/Karyotype:
-- Preliminary result in 48-72 hours
-- 1 Sodium Heparin Tube (Dark Green-top); 3 mL (infants)

☐ Peripheral Blood or Skin Biopsy for Fanconi Anemia Breakage Study using DEB
-- 2 Sodium Heparin Tubes (Dark Green-top); 7-12 mL

☐ 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)

☐ Fluorescence In Situ (FISH) Analysis *(Select Probe below)*
-- 1 Sodium Heparin Tube (Dark Green-top); 2 mL

☐ Aneuploidy FISH Full Panel (13, 18, 21, X/Y)
☐ Aneuploidy FISH 13/21 Only
☐ Aneuploidy FISH 18/X/Y Only
-- Results in 24-72 hours
-- 1 Sodium Heparin Tube (Dark Green-top); 2 mL, minimum 1 mL

☐ Constitutional Chromosomal Microarray (CMA) - Peripheral Blood is preferred.
Two tubes of blood are required:
-- 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).

☐ 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
Please provide previous patient information (Name, MRN, DOB)
_____

6) MICRODELETION FISH ANALYSIS REQUESTED:

☐ Angelman
☐ Cri-Du Chat
☐ DiGeorge (VCFS)
☐ Kallman
☐ Miller-Dieker
☐ Prader-Willi
☐ Smith-Magenis
☐ SRY
☐ STS
☒ Williams
☒ Wolf-Hirschhorn

UNTHSC Forms

NCRAD

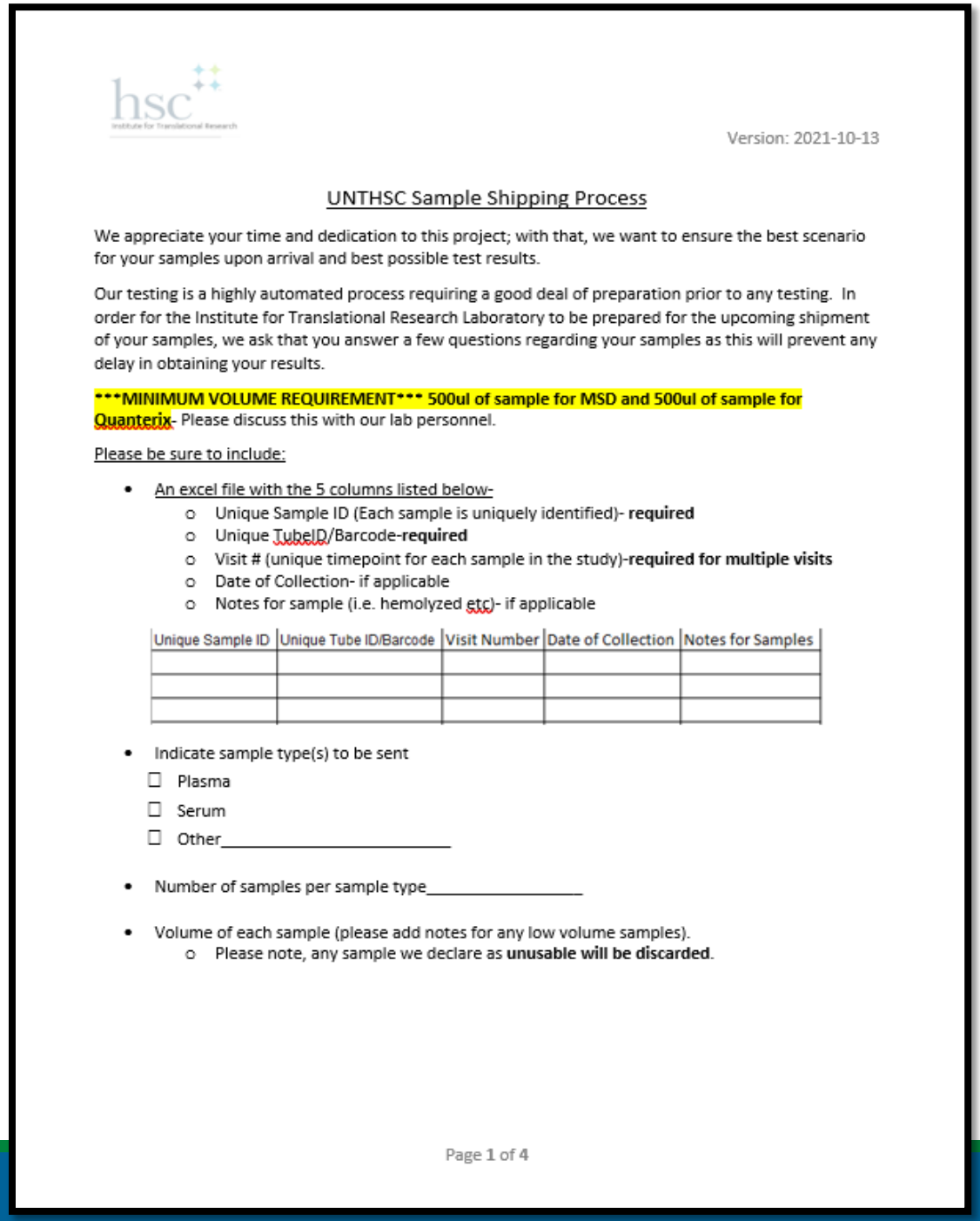
National Centralized Repository for
Alzheimer's Disease and Related Dementias

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 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.



hsc
Institute for Translational Research

Version: 2021-10-13

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**.

Page 1 of 4

Appendix G: UNTHSC Import Batch Form

Import Batch Format:

e. Outside ID = **Participant/BDS ID**

f. Outside Tube ID = **Barcode on Collection Tube and Aliquot Tube Labels provided by NCRAD**

ABC-DS
ALIQUOT
Kit: 1000001
1000000123
BC
EDTA10

g. Outside Notes = **e.g., lipemic, hemolyzed, low volume, went through a freeze thaw cycle etc.**

h. Outside Date = **Collection Date**

i. Tissue Type = **Plasma or Serum**

j. Visit Number = **1, 2, 3, 4 (only numeric values)**

OutsideId	OutsideTubeId	OutsideNotes	OutsideDate	TissueType	VisitNumber

Make sure the barcodes in the OutsideTubeId column are in TEXT format (not number) so leading zeros are not deleted

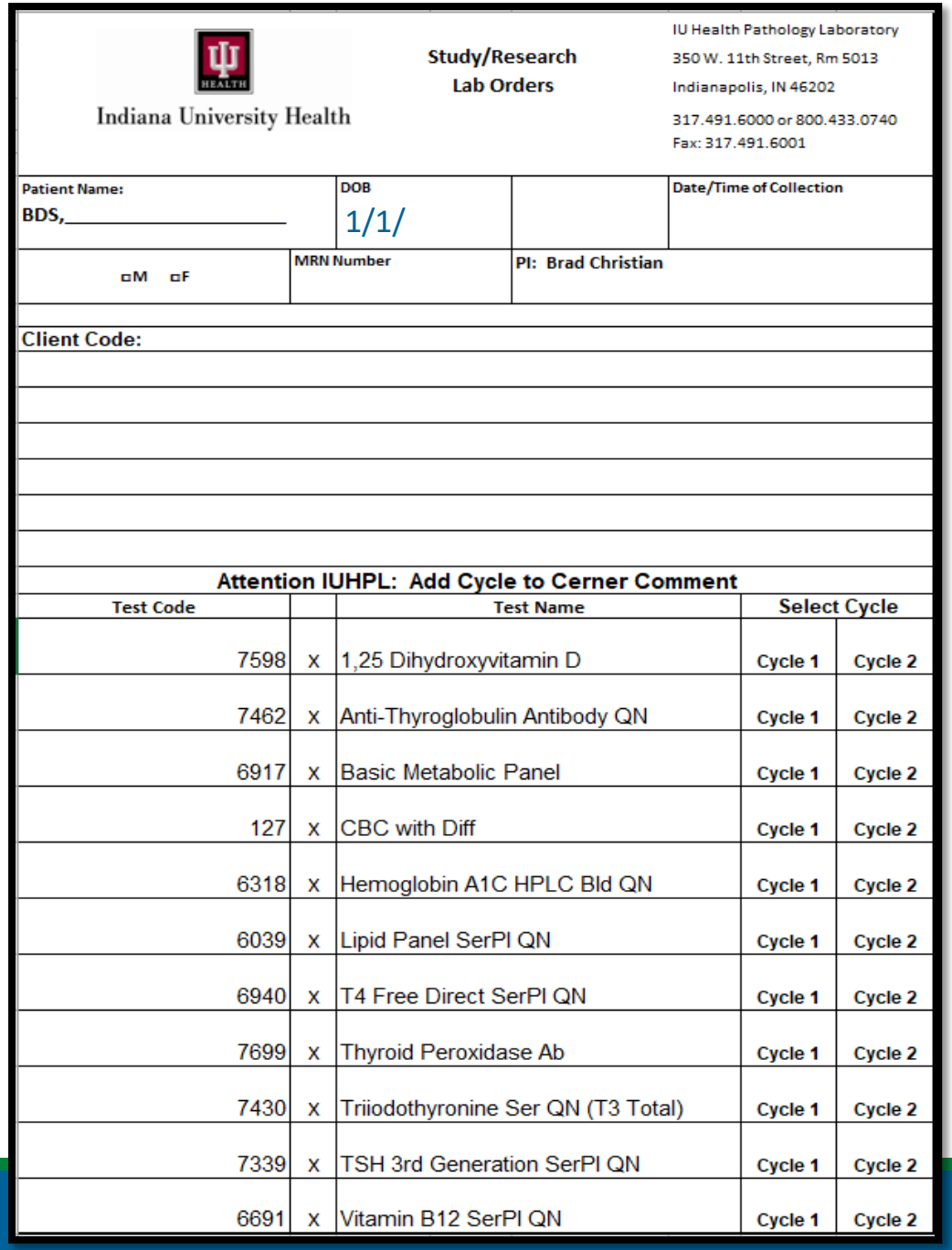
Send a separate Import Batch form for Serum and Plasma samples sent

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

OutsideId	OutsideTubeId	OutsideNotes	OutsideDate	TissueType	VisitNumber

IU Health Path Lab Forms

Appendix D: IU Health Path Lab Req Form



Indiana University Health

Study/Research Lab Orders

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
▫M ▫F	MRN Number	PI: Brad Christian	

Client Code:

Attention IUHPL: Add Cycle to Cerner Comment

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 SerPl QN	Cycle 1	Cycle 2
6940	x	T4 Free Direct SerPl 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 SerPl QN	Cycle 1	Cycle 2
6691	x	Vitamin B12 SerPl QN	Cycle 1	Cycle 2

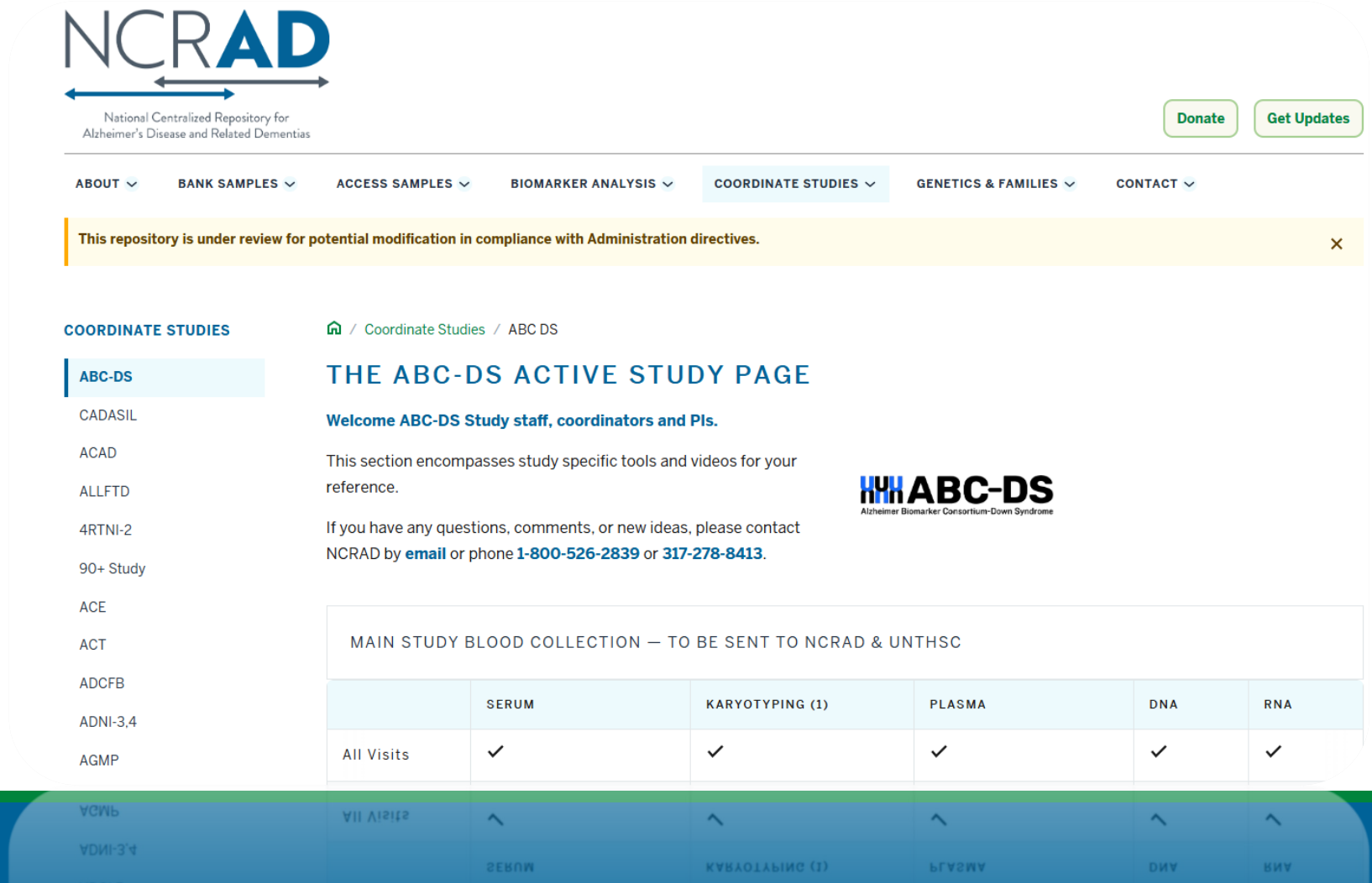
Note:
Please ensure forms are filled out in their entirety.
Complete during the participant study visit as samples are processed to guarantee accuracy.

NCRAD Website

National Centralized Repository for
Alzheimer's Disease and Related Dementias

NCRAD ABC-DS Study Page

[NCRAD - The ABC-DS Active Study Page]



NCRAD

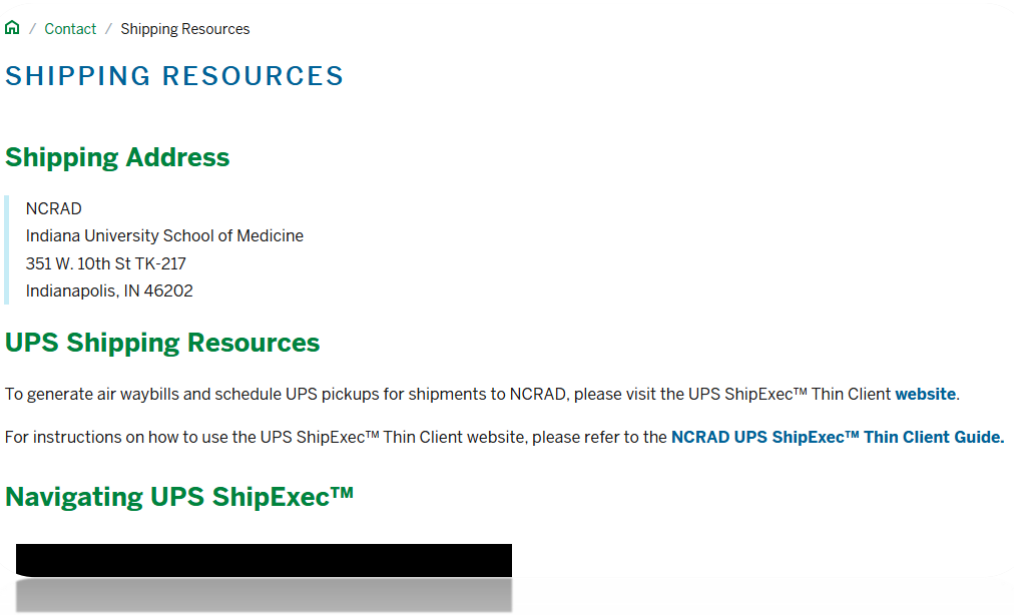
NCRAD Website: Helpful Pages

NCRAD - Holiday Closures

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

Please Note: *between December 24th and January 2nd, Indiana University will be open Monday through Friday for essential operations ONLY and will re-open for normal operations on January 2nd. If at all possible, biological specimens for submission to Indiana University should NOT be collected and shipped to Indiana University after the second week of December. Should it be necessary to ship blood samples for DNA extraction to Indiana University during this period, please contact the Indiana University staff before December 20th by e-mailing* ***alzstudy@iu.edu****, so that they can arrange to have staff available to process incoming samples.*

NCRAD - Shipping Address



Contact / Shipping Resources

SHIPPING RESOURCES

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™

[redacted]

Nonconformance Issues

National Centralized Repository for
Alzheimer's Disease and Related Dementias

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.

NCRAD

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