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 2.1

NCRAD
Contact Information

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Training Overview: ABC-DS

- IU Path Lab information
- UNTHSC Information
- Collection Schedule
- Re-draw Instructions and Timeframes
- Kit Request Module
- 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
- Questions?
IU Path Lab Information

• Shipping Address:
  IU Path Lab
  350 W. 11th Street
  Indianapolis, IN 46202
  5th Floor, Rm 5013

• Contact Information:
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• Shipping Address:
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• Contact:
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# NCRAD & UNTHSC Blood Based Collection Schedule:
## DS Participants and Sibling Controls

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

<table>
<thead>
<tr>
<th></th>
<th>Serum</th>
<th>Plasma</th>
<th>DNA</th>
<th>RNA</th>
<th>Karyotyping₁</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All visits</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>SHIP TO:</strong></td>
<td>NCRAD &amp; UNTHSC</td>
<td>NCRAD &amp; UNTHSC</td>
<td>NCRAD</td>
<td>NCRAD</td>
<td>NCRAD</td>
</tr>
</tbody>
</table>

₁DS Participants only (if needed)
## Clinical Labs Blood Collection Schedule:
**DS Participants ONLY**

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

<table>
<thead>
<tr>
<th></th>
<th>Serum – Free T4, Thyroid, Triiodothyronine, TSH, Vit B12, ATA Preparation</th>
<th>Vit D, BMP, Lytes, Lipid Preparation</th>
<th>CBC Preparation</th>
<th>A1C Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cycle 1</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Cycle 2</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>SHIP TO:</strong></td>
<td>IU Path Lab</td>
<td>IU Path Lab</td>
<td>IU Path Lab</td>
<td>IU Path Lab</td>
</tr>
</tbody>
</table>
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 Kit Request Module

https://kits.iu.edu/ABC-DS
ABC-DS Kit Request Module

- 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**

- 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.

- Please indicate the soonest date you will need the requested supplies
  - We typically return requests within 2-3 weeks from the order date.

- 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 Request Module Form

<table>
<thead>
<tr>
<th>Kit Type</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC-DS Participant Blood Kit Qty</td>
<td>1</td>
</tr>
<tr>
<td>ABC-DS Sibling Control Blood Kit Qty</td>
<td></td>
</tr>
<tr>
<td>ABC-DS Blood Kit for Clinical Labs Qty</td>
<td></td>
</tr>
<tr>
<td>ABC-DS Frozen Blood Shipping Kit Qty (High)</td>
<td></td>
</tr>
<tr>
<td>ABC-DS Ambient Blood Shipping Kit Qty</td>
<td></td>
</tr>
<tr>
<td>Blood Supplement Kit Qty</td>
<td></td>
</tr>
<tr>
<td>22G CSF Supplemental Kit Qty</td>
<td></td>
</tr>
<tr>
<td>24G CSF Supplemental Kit Qty</td>
<td></td>
</tr>
<tr>
<td>22G Lumber Puncture Tray Kit Qty</td>
<td></td>
</tr>
<tr>
<td>24G Lumber Puncture Tray Kit Qty</td>
<td></td>
</tr>
<tr>
<td>Frozen CSF Shipping Kit Qty</td>
<td></td>
</tr>
</tbody>
</table>

**Do you need Extra Supplies?**
- Yes
- No

Please indicate the soonest date you will need supplies from this request:

**Notes:**
- Indicate the soonest date you will need the requested supplies.
- We typically return requests within 2-3 weeks from the order date.
- 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
NCRAD and UNTHSC Specimen Labels

Provided by NCRAD
Three Label Types

Kit Number Labels

Collection and Aliquot Tube Labels

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
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
  - 10ml EDTA (Lavender-Top) Blood Collection Tube (x2)
    - Plasma aliquots
    - Buffy coat aliquot
  - 2.5ml PAXgene™ Blood Collection Tube (x1)
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:

Kit Number Label

Site and BDS ID Label

NaHep Blood Collection Tube (4 ml)
IU Pathology Laboratory
Specimen Labels

Provided by NCRAD
One Label Type

Site BDS ID and DOB Labels
Site BDS ID and DOB Labels

- 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

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.
SST and EDTA Collection Tube 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)
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°C
2) For IU Path Lab: Centrifuge capable of 1300 x g with refrigeration to 4°C
3) -80 °C Freezer
4) Wet Ice Bucket
***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. Serum discard tube (dispose at site)
- 5. 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 (3 ml) for hematology
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. Serum discard tube (dispose at site)
- 8. 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

<table>
<thead>
<tr>
<th>Tube Type</th>
<th>Number of Tubes Drawn</th>
<th>Tube Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Serum Separator (Gold-Top) Blood Collection Tube (5 mL)</td>
<td>X 2</td>
<td><img src="image1" alt="Image" /></td>
</tr>
<tr>
<td>2. Sodium Heparin (Green-Top) Blood Collection tube (4 mL) *</td>
<td>X 1</td>
<td><img src="image2" alt="Image" /></td>
</tr>
<tr>
<td>3. EDTA (Lavender-Top) Blood Collection Tube (10 mL)</td>
<td>X 2</td>
<td><img src="image3" alt="Image" /></td>
</tr>
<tr>
<td>4. Serum (Red-Top) Blood Collection Tube (3mL) **</td>
<td>X 1</td>
<td><img src="image4" alt="Image" /></td>
</tr>
<tr>
<td>5. PAXgene™ Blood Collection Tube (2.5 mL)</td>
<td>X 1</td>
<td><img src="image5" alt="Image" /></td>
</tr>
</tbody>
</table>

*DS participants only **Serum discard tube is not shipped to NCRAD. Please discard at site per site’s requirements.
# Aliquot Cap Colors

<table>
<thead>
<tr>
<th>Cap Color</th>
<th>Sample Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear cap with RED sticker</td>
<td>Serum and Serum Residual (&lt;0.25 mL)</td>
</tr>
<tr>
<td></td>
<td>(Document Specimen Number and Volume of Residual Aliquot on Sample Form)</td>
</tr>
<tr>
<td>Clear cap with LAVENDER sticker</td>
<td>Plasma and Plasma Residual (&lt;0.25 mL)</td>
</tr>
<tr>
<td></td>
<td>(Document Specimen Number and Volume of Residual Aliquot on Sample Form)</td>
</tr>
<tr>
<td>Blue Cap</td>
<td>Buffy Coat</td>
</tr>
</tbody>
</table>
Serum Collection

- 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

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 clear cap 0.5 mL Siliconized Cryovial with red sticker

Serum Separator Tube Immediately after Blood Draw

Serum Separator Tube after Centrifuge

NCRAD
Serum Preparation (5 mL Gold-Top Tube) x 2

Step One
- Store tubes at room temperature.
- Label tubes with preprinted labels prior to blood draw.

Step Two
- Collect blood in (2) 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 tube 8-10 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 20 minutes

Step Five
- 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.

Step Six
- Adhere preprinted labels to the clear cap cryovials with red stickers.
- Aliquot 0.25 ml into each cryovial tube.
- If a residual aliquot is created, document specimen number on Sample Notification Form.
- Store serum aliquots at -80°C until shipment.

Up to 19 sent to NCRAD
Up to 2 sent to UNTHSC
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 temperate 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).

NaHep Collection (for karyotyping)

Drawn for DS Participants at Baseline ONLY AS NEEDED

Used to obtain karyotype for full or partial trisomy 21.

• 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.
Plasma Collection

• 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

81 cell cryobox with 0.5 mL cryovials – sent to NCRAD

25 cell cryobox with 0.5 mL cryovials – sent to UNTHSC

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

- 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)

81 cell cryobox with 2.0 mL cryovials – sent to NCRAD

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**
- Store tubes at room temperature.
- Label tubes with preprinted labels prior to blood draw.

**Step Two**
- Collect blood in EDTA Tubes 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**
- Place thoroughly mixed tube on wet ice until centrifugation begins.

**Step Five**
- 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.

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

**Step Seven**
- Adhere preprinted labels to the clear cap cryovials with lavender stickers.
- Aliquot 0.25 ml into each cryovial tube.
- If a residual aliquot is created, document specimen number and volume on Sample Notification Form.
- Store plasma aliquots at -80°C until shipment.

**Step Eight**
- Adhere preprinted labels to the blue cap cryovial.
- Using a clean pipette tip, collect theuffy coat (may have residual plasma and some RBCs included).
- Transfer the Buffy coat into the cryovial tube.
- Store buffy coat aliquot at -80°C until shipment.
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.
RNA Preparation (2.5mL PAXgene™ Tube) x 1

Step One
- Draw Serum
- Discard tube prior to PAXgene™ Tube.
- Discard per your site’s regulations.

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

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

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

Step Five
- Store tubes at -80°C in a wire rack until shipment.

Styrofoam racks
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.
IU Path Lab (Clinical Labs)
Sample Collection and Processing
# IU Path Lab Research Blood Collection

**DS Participants ONLY**

<table>
<thead>
<tr>
<th>Tube Type</th>
<th>Number of Tubes Drawn</th>
<th>Tube Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Serum Separator (Orange-Top) Blood Collection Tube (5 mL)</td>
<td>X 1</td>
<td><img src="image1.jpg" alt="Tube Image" /></td>
</tr>
<tr>
<td>2. Serum Separator (Gold-Top) Blood Collection Tube (5 mL)</td>
<td>X 1</td>
<td><img src="image2.jpg" alt="Tube Image" /></td>
</tr>
<tr>
<td>3. EDTA (Lavender-Top) Blood Collection Tube (3 mL)</td>
<td>X 1</td>
<td><img src="image3.jpg" alt="Tube Image" /></td>
</tr>
</tbody>
</table>
# Aliquot Cap Colors

<table>
<thead>
<tr>
<th>Cap Color</th>
<th>Sample Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear Cap</td>
<td>Serum (&lt;1.0 mL)</td>
</tr>
<tr>
<td>Red Cap</td>
<td>Serum (&lt;1.0 mL)</td>
</tr>
</tbody>
</table>

![Clear Cap](image1) ![Red Cap](image2)
Serum Collection

• 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.
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

- 2 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

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

Serum Separator Tube Immediately after Blood Draw

Serum Separator Tube after Centrifuge

SERUM

GEL MATRIX

BLOOD CLOT
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.
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**
- EDTA tube

**Step Two**
- CBC A1C
  - Collect blood in EDTA Tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

**Step Three**
- CBC A1C
  - Immediately after blood draw, invert tubes 8-10 times to mix samples.

**Step Four**
- CBC A1C
  - Store whole blood tube in refrigerator until shipment.

- Store tubes at room temperature.
- Label tubes prior to blood draw.
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 Path Lab form (**Appendix D**) that it is a field-draw.
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

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- 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 redraw 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 below), 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).
Packing and Shipping Samples
NCRAD and UNT HSC Sample Shipping
# NCRAD and UNTHSC Blood Sample Shipment Summary

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Processing/ Aliquoting</th>
<th>Tubes to NCRAD</th>
<th>Tubes to UNTHSC</th>
<th>Ship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood for RNA extraction</td>
<td>N/A</td>
<td>1</td>
<td>0</td>
<td>Frozen</td>
</tr>
<tr>
<td>Whole blood for isolation of serum</td>
<td>0.25 mL serum aliquot per 0.5 mL siliconized cryovial (clear cap with RED sticker)</td>
<td>19</td>
<td>2</td>
<td>Frozen</td>
</tr>
<tr>
<td>Whole blood for isolation of plasma &amp; buffy coat (for DNA extraction)</td>
<td>0.25 mL plasma aliquot per 0.5 mL siliconized cryovial (clear cap with LAVENDER sticker)</td>
<td>24</td>
<td>17</td>
<td>Frozen</td>
</tr>
<tr>
<td></td>
<td>1 mL buffy coat aliquot per 2.0 mL cryovial (BLUE CAP)</td>
<td>2</td>
<td>0</td>
<td>Frozen</td>
</tr>
<tr>
<td>Whole blood for Karyotyping</td>
<td>N/A</td>
<td>1</td>
<td>0</td>
<td>Ambient</td>
</tr>
<tr>
<td>Serum Discard Tube</td>
<td>N/A **Discard at site</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
</tbody>
</table>
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
   - 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
   - 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.

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

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

Net weight of dry ice in kg

FedEx Dry Ice Sticker

UPS Dry Ice Sticker (UW-Madison Only)
Critical Frozen Shipping Instructions

1. Hold packaged samples in -80°C freezer until time of FedEx pick-up/drop-off.

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
   - 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).**
**Ambient Shipment Packaging:**

- 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.
Creating Airbills/Scheduling Pickups

1. Two components are necessary for international shipments:
   1. International FedEx return airbill
   2. International Commercial Invoice

2. NCRAD will provide an International FedEx return airbill to all International sites. However, these international sites are welcome to utilize the FedEx electronic system.
   1. Be sure to complete the FedEx return airbill with the following information:
      1. Section 1, From: Enter the date and your name, phone number, complete address, and FedEx account number.
      2. Section 2, To: This information will be preprinted with NCRAD’s return address and phone number.
      3. 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.
         1. Do not declare the value of the shipment to be over $2,500. This would require additional paperwork (a Shipper’s Export Declaration form).
      4. Section 4, Express Package Services: Please check FedEx Intl. Priority for both Frozen and Ambient Shipments. (Pictured)
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.
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 10th 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 10th 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).

<table>
<thead>
<tr>
<th>COUNTRY OF ORIGIN</th>
<th>DESCRIPTION OF GOODS</th>
<th>QUANTITY</th>
<th>UNIT PRICE</th>
<th>TOTAL PRICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada, Vancouver</td>
<td>Non-Infectious, non-contagious, human Plasma and Buffy Coat sample</td>
<td>1 Box (11 Aliquots)</td>
<td>100.00</td>
<td>100.00</td>
</tr>
</tbody>
</table>
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**

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

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, PJordan@IUHealth.org, rball3@IUHEALTH.ORG, AND 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).
Refrigerated Shipment Packaging:
Place all frozen 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.

Place Site BDS ID and DOB label(s) on cryoboxes
Refrigerated Shipment Packaging (cont.):

- Place biohazard bag within X-Small Insulated shipper with 2 cold brick packs and put lid on cooler.
- 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](https://www.ups.com). 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 NCRAD.
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

- **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.*
NCRAD Forms
Appendix B: Biological Sample and Shipment Notification Form

Sample Collection - Blood & Shipment Notification Form

Please fill out the form on or prior to the date of shipment.

Name: ____________________________  Date: ____________________________

Email: ____________________________  Phone: ____________________________

PT ID: ____________________________  Site ID: ____________________________

Cycle Visit (Circle One): 1 2 3 4

Sample Collection - Blood & Shipment Notification Form

1. Date drawn: ____________________________
2. Time of draw (24 hour clock): ____________________________
3. Last time subject ate (if applicable): ____________________________
4. Last time subject ate (24 hour clock): ____________________________

Blood Processing:

RNA Plus™ Tube

Narrow tube for harvesting (if not drawn, enter N/A by ml)

Original volume drawn (24 x 1 ml, RNA Plus™ tube): ____________________________ ml

Time spin started (24 hour clock): ____________________________

Time spin completed (24 hour clock): ____________________________

Temp of centrifuge: ____________________________ °C  Date of centrifuge: ____________________________

Duration of centrifuge: ____________________________

Narrow tube for harvesting (if not drawn, enter N/A by ml)

Original volume drawn (235 ml, Cellmax tube): ____________________________ ml

Time aliquoted: ____________________________

Temp of centrifuge: ____________________________ °C  Date of centrifuge: ____________________________

Duration of centrifuge: ____________________________

Number of 0.25 ml plasma aliquots created (on-site aliquoting): ____________________________

Number of 0.25 ml plasma aliquots used to serum: ____________________________

If applicable, volume of residual plasma aliquot (less than 0.25 ml [monitored]): ____________________________ ml

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

Time aliquots placed in freezer (24 hour clock): ____________________________

Storage temperature of freezer: ____________________________ °C

Notes: ____________________________
Appendix E: Constitutional (Blood) Test Requisition Form (link)
Appendix F: UNTHSC Intake Form

*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!
# Appendix G: UNTHSC Import Batch Form

## Import Batch Format:

- **Outside ID**: Participant/BDS ID
- **Outside Tube ID**: Barcode on Collection Tube and Aliquot Tube Labels provided by NCRAD
- **Outside Notes**: e.g., lipemic, hemolyzed, low volume, went through a freeze thaw cycle etc.
- **Outside Date**: Collection Date
- **Tissue Type**: Plasma or Serum
- **Visit Number**: 1, 2, 3, 4 (only numeric values)

### Important Notes:

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

### Table Format:

<table>
<thead>
<tr>
<th>OutsideId</th>
<th>OutsideTubeId</th>
<th>OutsideNotes</th>
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IU Path Lab Forms
### Appendix D: IU Path Lab Req Form

**Attention IUHPL: Add Cycle to Corner Comment**

<table>
<thead>
<tr>
<th>Test Code</th>
<th>Name (Abbrev)</th>
<th>Select Cycle</th>
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<tbody>
<tr>
<td>7599</td>
<td>1,25 Dihydroxyvitamin D</td>
<td>Cycle 1, Cycle 2</td>
</tr>
<tr>
<td>7462</td>
<td>Anti-Thyroglobulin Antibody QN</td>
<td>Cycle 1, Cycle 2</td>
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<td>6917</td>
<td>Basic Metabolic Panel</td>
<td>Cycle 1, Cycle 2</td>
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<td>127</td>
<td>CBC with Diff</td>
<td>Cycle 1, Cycle 2</td>
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<td>Hemoglobin A1C HPLC Bld QN</td>
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<td>6939</td>
<td>Lipid Panel SerPl QN</td>
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<td>6940</td>
<td>T4 Free Direct SerPl QN</td>
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<td>Thyroid Peroxidase Ab</td>
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<td>TSH 3rd Generation SerPl QN</td>
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<td>6691</td>
<td>Vitamin B12 SerPl QN</td>
<td>Cycle 1, Cycle 2</td>
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NCRAD Website: Helpful Pages

NCRAD - The ABC-DS Active Study Page

https://ncrad.org/holiday_closures.html

https://ncrad.org/shipping_address.html

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

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™