Contact Information

Questions?

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Training Overview:

- IU Path Lab information
- UNTHSC Information
- Collection Schedule
- Kit Request Module
- Specimen Labels
- Handling/Processing Study Specimens
- Incomplete or Difficult Blood Draws
- Packing and Shipping Samples
- Requisition Forms
- NCRAD Website
- Questions?
IU Path Lab Information

Address:
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350 W. 11th Street
Indianapolis, IN 46202
5th Floor, Rm 5013

Contact:
Karen Cleary - kcleary@iuhealth.org
Patti Jordan - pjordan@iuhealth.org

Volume questions and any questions related to testing:
David Bradley - dbradle3@iuhealth.org
Rustin Ball - rball3@IUHEALTH.ORG
Pamela Vollmer - pvollmer@iuhealth.org
UNTHSC Information

Address:
3420 Darcy Street
Fort Worth, TX 76107
Phone: 817-735-2638

Contact:
Tori Como, ITR Lab Manager, UNTHSC
- Tori.Como@unthsc.edu
# ABC-DS Blood Based Collection Schedule for 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>All visits</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SHIP TO:</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 for 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>Cycle 1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Cycle 2</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</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
Kit Request Module

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

• Kits and individual supplies are available to order:
  ◦ 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 Supplemental Supply Kit
  ◦ Lumbar Puncture Trays
  ◦ CSF Shipping Supply Kit
NCRAD Kit Request Module

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

- Indicate the quantity needed of each kit
- Once selected, kit components of the chosen kit will appear at the bottom of the screen (Pictured)
- Click “Submit” to turn in your request.
- The IU staff will notify you that your request has been received and address any issues.
- Use the comments section to indicate the quantity of extra supplies needed, if someone is covering while someone is away, kit modifications, etc.
- **Note: You can order more than one type of kit in a single kit request**

<table>
<thead>
<tr>
<th>Kit Description</th>
<th>Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC-DS DS Participant Blood Kit</td>
<td>1</td>
</tr>
<tr>
<td>ABC-DS Sibling Control Blood Kit</td>
<td></td>
</tr>
<tr>
<td>ABC-DS Blood Kit for Clinical Labs</td>
<td></td>
</tr>
<tr>
<td>ABC-DS Frozen Blood Shipping Kit</td>
<td></td>
</tr>
<tr>
<td>ABC-DS Ambient Blood Shipping Kit</td>
<td></td>
</tr>
<tr>
<td>Blood Supplemental Supply Kit</td>
<td></td>
</tr>
<tr>
<td>22G CSF Supplemental Supply Kit</td>
<td></td>
</tr>
<tr>
<td>24G CSF Supplemental Supply Kit</td>
<td></td>
</tr>
<tr>
<td>22G Lumbar Puncture Tray Kit</td>
<td></td>
</tr>
<tr>
<td>24G Lumbar Puncture Tray Kit</td>
<td></td>
</tr>
<tr>
<td>Frozen CSF Shipping Supply Kit</td>
<td></td>
</tr>
</tbody>
</table>

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

**Comments**

**Each ABC-DS DS Participant Blood Kit Contains:**
1. PAXgene™ Blood Collection Tube (2.5 ml)
2. EDTA (Lavender-Tip) Blood Collection Tube (10 ml)
3. Serum Separator (Gold-Tip) Blood Collection Tube (5 ml)
4. Serum (Red-Tip) Elutard Tube (3 ml)
5. 16 ml conical (individually wrapped)
6. 41. Siliconized cryovial tube (0.5 ml) with clear cap with lavender sticker
7. Siliconized cryovial tube (0.5 ml) with clear cap with red sticker
8. Cryovial tube (2.0) with blue cap
9. Disposable graduated transfer pipette (1 ml)
10. Pre-printed Kit Number Label
11. Pre-printed Collection and Allotment Tube Label
12. 1”x1” self-seal bubble bag
13. Renewable bag
14. Cryobox 81-cell
15. Microcentrifuge tube box (holds up to 25 microcylinders)
NCRAD Kit Request Module: When It Must be Used

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

• To order, sites will use the Indiana University online kit ordering module: [https://kits.iu.edu/ABC-DS](https://kits.iu.edu/ABC-DS)

• Allow a minimum of 2 weeks for your order to be processed and delivered.
Specimen Labels
Label Type Summary

1. Kit Number Labels
2. Site and BDS ID Labels
3. Collection and Aliquot Tube Labels
   ◦ Differ by specimen type
NCRAD and UNTHSC Specimen Labels

Provided by NCRAD
NCRAD and UNTHSC Specimen Labels: Kit Number Labels

- Used to track patient samples and provide quality assurance
- Will be placed on the following locations:
  1. Biological Sample and Shipment Notification Form
  2. Outside cryobox that houses aliquot tubes during storage and shipment
  3. Placed on NaHep tubes for karyotyping
     - Extra kit number label provided in DS
NCRAD and UNTHSC Specimen Labels: Site and BDS ID Label

1. Subjects will be identified by their site ID and BDS ID (PT ID)
   - Sites will be responsible for handwriting this onto the provided labels
   - Must use fine point permanent marker
   - Each site will receive 4 markers in initial kit supply

2. Will be placed on the following locations:
   - All Collection tubes (both blood and CSF)
NCRAD and UNTHSC Specimen Labels: Site and BDS ID Label (Cont.)

• Write information on label prior to adhering to tube

• Label will be placed on all collection tubes:
  ◦ Serum Separator (Gold-Top) Blood Collection Tube (5 ml) x 2
  ◦ NaHep (Green-Top) Blood Collection Tube (4 ml) x 1
  ◦ EDTA (Lavender-Top) Blood Collection Tube (10 mL) x 2
  ◦ PAXgene™ Blood Collection Tube (2.5 mL) for RNA x 1

*Each NaHep tube that is ordered will come with a Site and BDS ID Label
NCRAD and UNTHSC Specimen Labels:
Collection and Aliquot Tube Labels

Reminder: These labels are NOT included in Clinical Lab kits and NOT placed on NaHep tubes for karyotyping.
NCRAD and UNTHSC Specimen Labels: Collection and Aliquot Tube Labels

Labels to be placed on ALL collection and aliquot tubes

1. 5ml Serum Separator (Gold-Top) Blood Collection Tube (x2)
   ◦ Serum aliquots
2. 10ml EDTA (Lavender-Top) Blood Collection Tube (x2)
   ◦ Plasma aliquots
   ◦ Buffy coat aliquot
3. 2.5ml PAXgene™ Blood Collection Tube (x1)
NCRAD and UNTHSC Specimen Labels: Collection Tubes – Blood

- **NaHep Blood Collection Tube (4 ml)**
  - Kit Number Label
  - Site and BDS ID Label

- **Serum Separator (Gold-Top) Blood Collection Tube (5 ml)**
  - Collection and Cryovial Tube Label
  - Site and BDS ID Label

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

- **PAXgene™ Blood Collection Tube (2.5 ml)**
NCRAD and UNTHSC Specimen Labels: Aliquot Tube Labels – Serum, Plasma and Buffy Coat

- Collection and Aliquot tube label only
- Please place barcode near cap
Clinical Labs Kit
Labels
Provided by NCRAD
Clinical Labs Kit Labels:

Site and BDS ID Label

• Subjects will be identified by their site ID and BDS ID (PT ID)
  • Sites will be responsible for handwriting this onto the provided labels
    ◦ Must use fine point permanent marker
    ◦ Each site will receive 4 markers in initial kit supply

• Site and BDS ID labels are placed on all collection and aliquot tubes.
Clinical Labs Kit Labels:
Site and BDS ID Label (Cont.)

- Write information on label **prior** to adhering to tube

- Label will be placed on all collection and aliquot tubes:
  - Serum Separator (Gold-Top) Blood Collection Tube (5 mL) x1
    - Serum aliquots
  - Serum Separator (Orange-Top) Blood Collection Tube (5 mL) x1
    - Serum aliquots
  - EDTA (Lavender-Top) Blood Collection Tube (3 mL) x1
Clinical Labs Kit Labels: Collection Tubes – Blood

- Serum (Orange Top) Blood Collection Tube (5 ml)
- Serum (Gold Top) Blood Collection Tube (5 ml)
- EDTA (Lavender Top) Blood Collection Tube (3 ml)
Clinical Labs Kit Labels:
Aliquot Tubes – Serum

Side and BDS ID Label
Handling/Processing Study Specimens
# Site Required Equipment

<table>
<thead>
<tr>
<th>BLOOD COLLECTION/SAFETY EQUIPMENT</th>
<th>PROCESSING/STORAGE EQUIPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Personal Protective Equipment:</td>
<td>1. Centrifuge capable of ≥ 2000 x g with refrigeration to 4°C</td>
</tr>
<tr>
<td>1. lab coat, nitrile/latex gloves, safety glasses</td>
<td>2. Centrifuge capable of 1300 x g with refrigeration to 4°C</td>
</tr>
<tr>
<td>2. Tourniquet</td>
<td>3. -80°C Freezer</td>
</tr>
<tr>
<td>3. Alcohol Prep Pad</td>
<td>4. Wet Ice Bucket</td>
</tr>
<tr>
<td>4. Gauze Pad</td>
<td></td>
</tr>
<tr>
<td>5. Bandage</td>
<td></td>
</tr>
<tr>
<td>6. Butterfly needles (21 gauge) and hub</td>
<td></td>
</tr>
<tr>
<td>7. Microcentrifuge tube rack</td>
<td></td>
</tr>
<tr>
<td>8. Sharps bin and lid</td>
<td></td>
</tr>
</tbody>
</table>
***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 (3ml) for hematology
Draw Order – Option 2

Collection – Research and Clinical Labs on same day/visit

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

<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>x2</td>
<td><img src="image1.png" alt="Tube Image" /></td>
</tr>
<tr>
<td>2. Sodium Heparin (Green-Top) Tube (4 mL)</td>
<td>x1</td>
<td><img src="image2.png" alt="Tube Image" /></td>
</tr>
<tr>
<td>3. EDTA (Lavender-Top) Tube (10 mL)</td>
<td>x2</td>
<td><img src="image3.png" alt="Tube Image" /></td>
</tr>
<tr>
<td>4. Serum discard tube (3 mL) <strong>DO NOT send back to NCRAD</strong></td>
<td>x1</td>
<td><img src="image4.png" alt="Tube Image" /></td>
</tr>
<tr>
<td>5. PAXgene™ Tube (2.5 mL)</td>
<td>x1</td>
<td><img src="image5.png" 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 with Lavender Sticker</td>
<td>Plasma and Plasma Residual (&lt;0.25 mL) (Document Specimen Number and Volume of Residual Aliquot on Sample Form)</td>
</tr>
<tr>
<td>Clear Cap with Red Sticker</td>
<td>Serum and Serum Residual (&lt;0.25 ml)(Document Specimen Number and Volume of Residual Aliquot on Sample Form)</td>
</tr>
<tr>
<td>Blue</td>
<td>Buffy Coat</td>
</tr>
</tbody>
</table>

![Image of vials with different cap colors](image)
Serum Separator Tube (Serum Collection)

Create 16 to 21 aliquots of 0.25ml; if residual aliquot created, document specimen number and volume on sample form.
Serum Preparation (5 mL Gold-Top Tube)

- Store tubes at room temperature.
- Label tubes with preprinted labels prior to blood draw.
- Collect blood in (2) 5 mL Gold-Top tubes allowing blood to flow for 10 seconds and ensure blood flow has stopped.
- Immediately after blood draw, invert tube 8-10 times to mix samples.
- Allow blood to clot for 30 minutes.
- Within 2 hours of blood draw, centrifuge samples at 2000 x g at 4°C for 10 minutes.
- Using a clean transfer pipette, transfer Serum from both 5 mL Gold-Top tubes to the 15 mL conical tube. Mix the 15 mL conical tube gently by inverting 3-4 times.
- 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.
Sodium Heparin Tube (Karyotype)

• Drawn for DS Participants at Baseline ONLY AS NEEDED

• Used to obtain karyotype for full or partial trisomy 21.

• Once drawn, Sodium Heparin tubes MUST be shipped to NCRAD on the day of collection via overnight delivery. This is to ensure the specimen has the most viable cells available at extraction.
  • Fill out BDS ID and NaHep volume on Karyotyping form and send with sample. Form found in the MOP and NCRAD website.

• 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 already been done for the participant, please check “Yes” on the Biological Sample and Shipment Notification Form (Appendix B). Once drawn, Sodium Heparin tubes MUST be shipped to NCRAD on the day of collection via overnight delivery. This is to ensure the specimen has the most viable cells available at extraction.

These samples should only be collected Monday-Thursday. Please DO NOT collect these samples on Fridays.
Create up to 41 aliquots of 0.25ml; if residual aliquot created, document specimen number and volume on sample form.
EDTA Tube (Buffy Coat Collection)

Important Note:
• Buffy Coat aliquots will be distinguished from the plasma aliquots through a blue cap.
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 (10ml 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 5 times to mix samples.

**Step Four**
- Place thoroughly mixed tube on wet ice until centrifugation begins.
- Preferably within 30 minutes of blood draw, centrifuge samples at 2000 x g at 4°C for 10 minutes.
- Samples need to be spun, aliquoted, and in the freezer within 2 hours from the time of collection.

**Step Six**

**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.

Up to 24 sent to NCRAD
Up to 17 sent to UNTHSC

**Step Eight**
- Adhere preprinted labels to the blue cap cryovial.
- Using a clean pipette tip, collect the buffy 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 Preparation (2.5ml PAXgene™ Tube)

Step One
- Store tubes at room temperature.
- Label tubes with pre-printed labels prior to blood draw.
- Discard per your site’s regulations.

Step Two
- Draw Serum Discard tube prior to PAXgene™ Tube.

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.
- Discard per your site’s regulations.

Styrofoam racks
If field draw,

- Transfer tube **upright** in a **WIRE** rack at room temperature until storage in a -80°C freezer.
IMPORTANT NOTE:

UNTHSC samples take priority.

If equal to or less than 17 Plasma aliquots and equal to or less than 2 Serum aliquots are collected, place in 25-slot cryobox and ship to UNTHSC. Ship what is left to NCRAD.
IU Path Lab Sample Collection and Processing
# Clinical Labs Sample Collection - Blood

<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>x1</td>
<td>![Orange-Top Tube Image]</td>
</tr>
<tr>
<td>2. Serum Separator (Gold-Top) Blood Collection Tube (5 mL)</td>
<td>x1</td>
<td>![Gold-Top Tube Image]</td>
</tr>
<tr>
<td>3. EDTA (Lavender Top) Blood Collection Tube (3 mL)</td>
<td>x1</td>
<td>![Lavender Top 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>Red Cap</td>
<td>Serum (&lt;1 mL)</td>
</tr>
<tr>
<td>Clear Car</td>
<td>Serum (&lt;1 mL)</td>
</tr>
</tbody>
</table>

![Red Cap](image1.png) ![Clear Cap](image2.png)
Serum Separator (Orange-Top) Blood Collection Tube (5 mL)

Serum Separator Tube Immediately after Blood Draw

Serum Separator Tube after Centrifuge

Create 2 aliquots of 1 mL
Serum Separator (Orange-Top) Blood Collection Tube (5 mL)

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 1.0 ml of serum into each cryovial tube.
- Store serum aliquots in refrigerator until shipment.
For best results,

- For best results, serum samples should be spun within 1 hour from the time of collection.

**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 that it is a field-draw and the time it takes to process the samples.
Serum Separator (Gold-Top) Blood Collection Tube (5 mL)

Serum Separator Tube Immediately after Blood Draw

Serum Separator Tube after Centrifuge

Create 2 aliquots of 1 mL

SERUM

GEL MATRIX

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

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

**Step One**
- Store tubes at room temperature.
- Label tubes with preprinted 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.
For best results,

- 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.

**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 that it is a field-draw and the time it takes to process the samples.
EDTA (Lavender Top) Blood Collection Tube (3 mL)

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

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

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

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

Step Four
- Store whole blood tube in refrigerator until shipment.
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.
Incomplete or 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 slide 8 of the manual for re-draw instructions.
Situations may arise that prevent study coordinators from obtaining the total amount scheduled for biospecimens. In these situations, please follow the below steps:

**If the biospecimens at a scheduled visit are partially collected:**
1. Attempt to process and submit any samples that were able to be collected during the visit.
2. Document difficulties on the ‘Biological Sample and Shipment Notification Form’ prior to submission to UNTHSC and NCRAD.
   a. Indicate blood draw difficulties at the bottom of the ‘Biological Sample and Shipment Notification Form’ within the “Notes” section.
   b. Complete the ‘Biological Sample and Shipment Notification Form’ with tube volume approximations and number of aliquots created.
3. Contact a NCRAD coordinator and alert them of the challenging blood draw.
4. If samples are hemolyzed (see below), please do not send.

**If the biospecimens at a scheduled visit are not collected:**
1. 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.
2. Schedule participant for a longitudinal visit.
   a. 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 UNTHSC Sample Shipping
**Serum discard tube is not shipped to NCRAD. Please discard at site per site's requirements.**

<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></td>
<td></td>
<td></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>
Ambient Sample

• Sodium Heparin

• Only Monday-Thursday collection and same day shipping. Plan ahead to schedule FedEx or UPS pick-up.

• Samples must be received at IU one day after collection.

• Do NOT draw or ship ambient samples on Friday

• Include copy of Biological Sample and Shipment Notification Form

• Send Constitutional (Blood) Test Requisition Form ahead of shipment to NCRAD email: alzstudy@iu.edu

• **Please include shipping tracking number in email**

• DS Participants only, As Needed
Ambient Sample Shipping

- Place refrigerant pack in the freezer 24 hours prior to shipment.

- Place filled and labeled Sodium Heparin tube (kit number label and BDS ID label) within the slots in the absorbent pad and place in biohazard bag.

- Place the kit number label on biohazard bag.

- Place the refrigerant pack into the cooler on top of the filled biohazard bag. Place lid on cooler.

- Place the cooler in the small IATA Shipping Box.

- Place the Constitutional (Blood) Test Requisition Form (Appendix E) within the shipping box along with a list of contents form.

- Close shipping box and ensure labeled with UN3373 label.

- Place box within a provided shipping ClinPak, seal, and place shipping label on outside of package.
Frozen Sample Shipping

• **Ship Monday-Wednesday Only**
  - Serum, Plasma, Buffy Coat and RNA

• Hold packaged samples in a -80°C freezer until pickup.

• **Batch Samples together**
  - **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 8 participants accumulate, whichever is sooner. Up to 8 25-slot cryoboxes can fit in the shipper provided with dry ice included.
Frozen Shipping - Cryoboxes

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

TO NCRAD: 81-cell cryobox to contain Plasma, Serum and Buffy Coat aliquots

Place kit number label on top of cryobox

TO UNTHSC: 81-cell cryobox with RNA tube

TO NCRAD: 81-cell cryobox with RNA tube
Shipping Frozen Samples

Schedule FedEx or UPS (US and UK)


Send **Biological Sample and Shipment Notification Form** AND **UNTHSC Intake Form** ahead of shipment

- NCRAD email: alzstudy@iu.edu

  **AND**

- UNTHSC Lab Manager by email: Tori.Como@unthsc.edu

  **Please include shipping tracking number in email**
Please Note:

Please note that UNTHSC will not be receiving international shipments. International samples specified for UNTHSC will need to be shipped to NCRAD and will then be forwarded to UNTHSC.
Frozen Shipping – Dry Ice Requirements

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

• Each Styrofoam shipper must contain about 45 lbs. (20 kg) of dry ice.
Frozen Shipping – Dry Ice Requirements

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

Net weight of dry ice in kg

Your name & address

Repository name & address
International Shipping

1. All international shipments will utilize the same packing requirements as specified before in FrozenShipping Instructions.

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

3. NCRAD will provide an International FedEx return airbill to all International sites. However, these international sites are welcome to utilize the FedEx electronic system.

4. Detailed instructions on how to fill out each section of the FedEx return airbill are provided in the ABC-DS Manual of Procedures in section 8.3.
IU Path Lab Sample Shipping
# IU Path Lab Blood Sample Shipment Summary

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Tube Type</th>
<th>Number of Tubes Supplied in Kit</th>
<th>Processing/ Aliquoting</th>
<th>Ship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood for isolation of serum</td>
<td>Serum (Orange-Top) Blood Collection Tube (5 mL)</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>SERUM: 2.0 mL cryovials</td>
<td>2</td>
<td>1.0 mL serum aliquot per 2.0 mL cryovial (CLEAR CAP)</td>
<td>Refrigerated</td>
</tr>
<tr>
<td></td>
<td>Serum (Gold-Top) Blood Collection Tube (5 mL)</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>SERUM: 2.0 mL cryovials</td>
<td>2</td>
<td>1.0 mL serum aliquot per 2.0 mL cryovial (RED CAP)</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>Whole Blood for CBC Preparation</td>
<td>EDTA (Purple-Top) Blood Collection Tube (3 mL)</td>
<td>1</td>
<td>N/A</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>Whole Blood for A1C Preparation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. Label the 25-slot cryobox with the BDS ID Label.

2. Place all refrigerated, labeled aliquots of serum from the same subject in the cryobox.
   - Each 25-slot cryobox will hold approximately 4 serum samples.
   - Cryoboxes should contain all specimens from the same participant, per time point.
IU Path Lab
Refrigerated Sample Shipping (Cont.)

- Place 3ml EDTA tube in bubble wrap tube sleeve and place within the SAME biohazard bag as cryobox containing serum aliquots. These biohazard bags are large enough to contain one cryobox and the EDTA tube.
- Place the cryoboxes in the clear plastic biohazard bag (do NOT remove the absorbent material found in the bag) and seal according to the instructions on the bag.
- Ensure fluorescent round sticker is on biohazard bag.

Biohazard bag with 25-slot cryobox and 3ml EDTA tube inside.
3. Place biohazard bag within X-Small Insulated shipper with 2 cold packs.

4. Place X-Small Insulated shipper with fluorescent rectangular sticker within brown corrugated box and include air pouches.
5. Seal the outer cardboard shipping container with packing tape.

6. Apply all provided warning labels and the UPS return airbill on the outside of the package, taking are not to overlap labels.
   a. Ensure the large rectangular fluorescent sticker is on the outside of the brown corrugated box.

7. Include original copy of the IU Path Lab Req Form (Appendix D) inside the shipping box with the samples.

8. Specimens should be sent to the below address via **UPS Next Day Air**. Refrigerated shipments should be sent **Monday through Wednesday** to avoid shipping delays on Thursday or Friday.
   a. 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.

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**ABC-DS Study at IU Path Lab**

IU Health Pathology Laboratory

350 W. 11th Street
Indianapolis, IN 46202
5th Floor, Rm 5013
NCRAD and UNTHSC Requisitions and Biological Sample and Shipment Notification Forms
Biological Sample and Shipment Notification Form and UNTHSC Intake Form

• A copy of the Biological Sample and Shipment Notification Form AND UNTHSC Intake Form *must* be emailed or faxed to NCRAD and UNTHSC prior to the date of sample arrival.

• Please include sample forms in all shipments of frozen and ambient samples.

• Email: alzstudy@iu.edu and Tori.Como@unthsc.edu
Blood collected for:
- Serum
- NaHep (as needed)
- Plasma
- Buffy Coat
- RNA

Send by E-mail (alzstudy@iu.edu) prior to shipment, and include a copy in each shipment.
UNTHSC: Intake Form-Blood

Sample Intake Form

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 Laboratories to be prepared for the upcoming shipment of your samples, we ask that you answer a few questions regarding your samples so this will prevent any delay in obtaining your results.

**MINIMUM VOLUME REQUIREMENT**

Blood collected for:

- Serum
- Plasma

Send by E-mail ([Tori.Como@unthsc.edu](mailto:Tori.Como@unthsc.edu)) prior to shipment, and include a copy in each shipment.
Blood collected for:
• NaHep (as needed)

Send sample to:
ABC-DS at NCRAD
Indiana University School of Medicine
351 West 10th Street
TK-217
Indianapolis, IN 46202

Send by E-mail (alzstudy@iu.edu) prior to shipment, and include a copy in each shipment
IU Path Laboratory Requisitions and Biological Sample and Shipment Notification Forms
IU Path Lab: Requisition Form

This form must be completed by each site to gain access to the Portal to retrieve participant results. In October 2021, the Admin Core sent one for each site to the IU Health Path Lab, but if any information changes for any site, a new Research Request will need to be completed.

**Remember:** Include original copy of form inside the shipping container!
Additional Forms
1. 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.
Rate of Centrifuge Worksheet

Appendix A
Rate of Centrifuge Worksheet

Please complete and return this form by fax or email to the NCRAD Project Manager if you have any questions regarding sample processing. The correct RPM will be sent back to you.

Submitter Information
Name: [Blank]  
Submitter e-mail: [Blank]

Site: [Blank]

Centrifuge Information
Please answer the following questions about your centrifuge.

Centrifuge Type
Fixed Angle Rotor: ☐  
Swing Bucket Rotor: ☐

Radius of Rotation (mm): [Blank]

Determine the centrifuge’s radius of rotation (in mm) by measuring distance from the center of the centrifuge spindle to the bottom of the device when inserted into the rotor (if measuring a swing bucket rotor, measure to the middle of the bucket).

Calculating RPM from G-Force:

\[ RCF = \left( \frac{RPM}{1,000} \right)^2 \times r \times 1.118 \quad \Rightarrow \quad RPM = \sqrt{\frac{RCF}{r \times 1.118}} \times 1,000 \]

RCF = Relative Centrifugal Force (G-Force)
RPM = Rotational Speed [revolutions per minute]
r = Centrifugal radius in mm = distance from the center of the turning axis to the bottom of centrifuge

Comments: [Blank]

Please send this form to NCRAD Study Coordinator
317-321-2003 (Fax)  alzstudy@iu.edu
NCRAD Website
What to do for Friday Blood Draws

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

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

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

Holiday Closures

<table>
<thead>
<tr>
<th>Date</th>
<th>Holiday</th>
</tr>
</thead>
<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>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>
</tr>
</tbody>
</table>
ABC-DS Active Study Page

Welcome ABC-DS Study staff, coordinators and PIs. This section encompasses study specific tools and videos for your reference.

If you have any questions, comments, or new ideas, please contact NCRAD by email or phone 317-274-7546 or 800-526-2835.

Specimen Collection Overview

<table>
<thead>
<tr>
<th></th>
<th>RNA</th>
<th>Serum</th>
<th>Plasma</th>
<th>DNA</th>
<th>Karyotyping</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Visits</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Ship to:</td>
<td>NCRAD</td>
<td>NCRAD &amp; UNTHSC</td>
<td>NCRAD &amp; UNTHSC</td>
<td>NCRAD</td>
<td>NCRAD</td>
</tr>
</tbody>
</table>

Study Resources

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

Download Documents

- Downloadable Sample Form (pdf)
- Karyotyping Req Form Appendix E
- Manual of Procedures
- Lumbar Puncture Manual of Procedures
- Training Slides

Additional Resources

- Kit Request System
- Friday Blood Draws
- Shipping Address
- Holiday Closures

Questions/Comments

Email: olsstudy@iu.edu
Phone: 800-526-2839
Contact Information

Questions?

Please contact NCRAD Coordinators at:
Phone: (317) 278-9086 or 1-800-526-2839
◦ E-mail: zdpotter@iu.edu or alzstudy@iu.edu
◦ Website: www.ncrad.org

IU Path Lab Information
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