

BIOSPECIMEN COLLECTION & PROCESSING

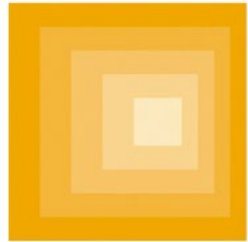
Overview

1. Specimen uniformity and quality
2. Site Equipment
3. Procedures
 - Kit Contents and Ordering
 - Sample Labelling
 - Sample Collection and Processing
 - Shipping Samples
 - Non-Conformance
4. Contact Information

Specimen Uniformity and Quality

I WILL REPEAT THESE WORDS A LOT. YOU MAY WANT TO START A TALLY.

Biorepositories at Indiana University



PARKINSON'S
PROGRESSION
MARKERS
INITIATIVE

Play a Part in Parkinson's Research



NCAA•DOD
Grand Alliance
CARE Consortium

NINDS
BIOSEND

Specimen Standardization and Quality

Most biomarkers are sensitive to *time* and *temperature*

- Standardization of processing across sites is key
- Specimens must be processed within 2 hours of collection
- Reference the *PBN Biomarker Specimen Collection, Processing, and Shipment Manual* as needed
- Do not replace or supplement any kit components without first receiving approval from Indiana

Questions? Email pbn@iu.edu

Site Equipment

Sites will need to supply the following items:

- Gloves
- Alcohol wipes
- Butterfly needles
- Tourniquet
- Gauze pads
- Bandages
- Microcentrifuge tube rack
- Sharps bin and lid
- Crushed ice
- Pipettes and pipette tips
- Centrifuge capable of maintaining 4°C
- -80°C Freezer
- Dry ice
- CryoStor® freezing media

Procedures

MAINTAINING SPECIMEN UNIFORMITY AND QUALITY

Subject ID: Assigning PBN Subject ID

- Each site will assign PBN Subject ID from list of unique, site-specific IDs provided by Broad Institute
- PBN Subject ID will be patient identifier throughout participation in study
- Batch of barcoded PBN Subject ID labels will be sent to each site with initial kit shipment
- Replacements and additional PBN Subject ID label sets can be requested from IUGB via the Kit Request Module <https://redcap.link/PBN-kits>
- Affix labels to:
 - Local site documents
 - Specimen kits
 - Biological specimens sent to local analysis labs
 - *Do NOT place on specimens sent to IUGB!*
- PBN Subject ID should also be entered into IUGB Sample Submission form when shipping to IUGB

Subject ID: Requesting the GUID

- Globally Unique Identifier (GUID) will be the “master” subject ID
- Random alpha-numeric string
- To request a GUID for a subject, you must set up an account with the NIMH Data Archive

<https://nda.nih.gov/s/guid/nda-guid.html>

In order to generate a GUID, the following PHI is required:

- Complete legal given (first) name of subject at birth
- If the subject has a middle name
- Complete legal family (last) name of subject at birth
- Day of birth
- Month of birth
- Year of birth
- Name of city/municipality in which subject was born
- Country of birth

Kit Contents and Ordering

- All sites will be sent a Supplemental Kit with their first kit shipment
 - Contains extra blood collection tubes, processing supplies, and LP needles
 - May be used to replace items in study visit kits
- Study Visit Kits should be ordered as soon as visits are planned
 - Contains collection, processing, and shipping supplies specific to each visit
 - Include barcoded labels
 - The supplies/labels in each study visit kit are intended for that visit only

Kit Contents and Ordering – REDCap Survey

<https://redcap.link/PBN-kits>

Order kits online through the Kit Request Module for:

- STANDARD Kits
- ALTERNATE Kits
- Subject Labels
- Extra Supplies

Please provide as much notice as possible when ordering kits and/or supplies.

The screenshot shows the 'PBN Kit Request System' form. At the top, the logo for 'Psychiatric Biomarkers NETWORK' is displayed. Below the logo, the text 'PBN Kit Request System' is centered. The form contains an email address field with 'reynoldh@iu.edu' entered. Below this is a 'Study Site' dropdown menu with a list of options: 'Icahn School of Medicine at Mount Sinai', 'Perelman School of Medicine at UPenn', 'Yale School of Medicine', and 'Northwell Health'. A 'Submit' button is located to the left of the dropdown menu. The form is set against a light green background.

Psychiatric
Biomarkers
NETWORK

PBN Kit Request System

Please provide your preferred email address to receive notifications about this request

reynoldh@iu.edu

Study Site

Submit

Icahn School of Medicine at Mount Sinai
Perelman School of Medicine at UPenn
Yale School of Medicine
Northwell Health

Kit Contents and Ordering: Confirm Site Info

PBN Kit Request Module

Study Site

Icahn School of Medicine at Mount Sinai ▾

Icahn School of Medicine at Mount Sinai

Site Contact: Byron Ramirez

Shipping Address:

Icahn School of Medicine at Mount Sinai
1470 Madison Ave, 8th Floor, Room 302
(101St Between Madison and 5th Ave)
New York, NY 10029

Phone: (347) 543-6065

Email: byron.ramirez@mssm.edu

Select your site from the drop-down list

Verify contact information and update if needed

Is the information listed for your site correct?

Yes

No

reset

Which information needs to be updated?

Contact name

Shipping address

Phone number

Email address

New contact name:

Kit Contents and Ordering: Kit Types

PBN Kit Request Module

What kit(s) and/or supplies do you need?

Please note, the STANDARD kit should be utilized for all visits unless the participant has not consented to collection of blood for PBMCs.

*

STANDARD (complete blood & CSF kit)

ALTERNATE (blood & CSF Kit without PBMC collection and shipping supplies)

Subject Labels

Extra Supplies

How many STANDARD Kits do you need?

Case (SCZ or BD)

Control

Control kits will not include supplies for anti-NMDA receptor sample collection or shipping.

Extra Shipping Supplies - Please indicate the quantity needed.

Your request will ship by **10-25-2024**. If you need kits or supplies sooner, please provide the date needed.

 M-D-Y

Although we will do our best to accommodate your request, please note that we cannot guarantee same-week receipt of kits or supplies.

Please provide any other information we should have about your request

Expand

Kit Contents and Ordering: Kit Breakdown

PBN Kit Request Module

Each STANDARD Collection Kit includes-

Blood Collection Contents:

- 1 - Gold-top SST tube (5 ml)
- 1 - Red-top glass serum tube (10 ml)
- 2 - Green-top sodium heparin tube (10 ml)
- 1 - Purple-top glass EDTA tube (10 ml)
- 2 - PAXgene™ tube (2.5 ml)
- 3 - Cryogenic vials (2 ml) with red caps
- 3 - Cryogenic vials (2 ml) with purple caps
- 1 - Cryogenic vial (2 ml) with clear cap
- 1 - Cryogenic vial (2 ml) with orange cap (Corning) included in CASE kits only*
- 3 - Cryogenic vials (2 ml) with blue caps
- 2 - Orange-cap screw-top centrifuge tubes (15 ml)
- 2 - Transfer pipette (3ml)


CSF Collection Contents:

- 2 - Blue-cap sterile screw-top centrifuge tubes (15 ml)
- 20 - Cryogenic vials (2 ml) with clear caps
- 2 - Cryogenic vials (2 ml) with orange caps (Corning)
- 1 - Cryogenic vial (4 ml) with orange cap included in CASE kits only*
- 1 - Lumbar puncture tray (22G)
- 1 - Medication transfer filter straw
- 1 - Transfer pipette (3ml)

Shipping Materials (for repository samples):

- 1 - Set of protective bubble pouches for tubes
- 1 - 81-slot Cryobox
- 1 - Shipping container for dry ice shipments (small)
- 1 - 95 kPa biohazard bag with absorbent sheet (large)
- 1 - Shipping label packet
- 2 - Clear UPS label sleeves
- 2 - Shipping instruction sheets (ambient & frozen)

Kit contents of selected kit will appear at the bottom of the page



Extra Supplies

Extra Blood Collection and Processing Supplies - Please indicate the quantity needed.

	2	5	10	20
EDTA tube, 10 mL (glass)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Serum tube, 10 mL (glass)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
PAXgene™ RNA tube, 2.5 mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
NaHep tube, 10 mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
SST tube, 5mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Purple-capped cryotube, 2 mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Red-capped cryotube, 2 mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Blue-capped cryotube, 2 mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Clear-capped cryotube, 2 mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Orange-capped cryotube, 2 mL (Corning)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Disposable pipettes, 3mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Orange-cap Conical tube, 15 mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Conical tube, 50 mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Orange-capped cryotube, 4mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra CSF Collection Supplies - Please indicate the quantity needed.

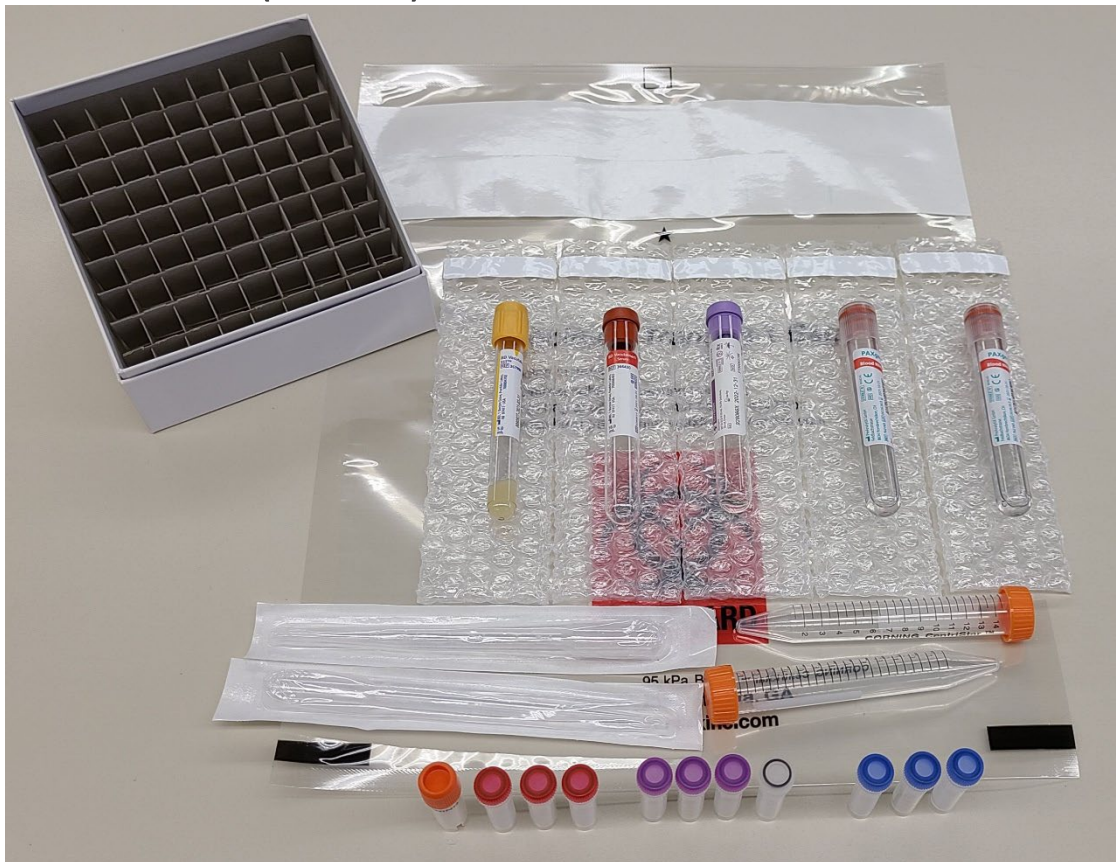
	1	2	3
22G LP Tray	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22G LP Needle w/ introducer, 3.5"	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22G LP Needle w/ introducer, 4.75"	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Medication transfer filter straw	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sterile Conical tube, 15mL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra Shipping Supplies - Please indicate the quantity needed.

	1	2	3
Ambient shipping kit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frozen shipping box (small)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
95kPa biohazard bag w/ absorbent sheet (large)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
UN3373 Category B labels	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
UN1875 Dry Ice label	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Clear UPS Label Sleeves	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frozen shipping box (XS) - for UPenn NMDA samples	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Kit Contents and Ordering: Blood Kits

Blood Kit (frozen):



PBMC supplies:



Kit Contents and Ordering: CSF Kits

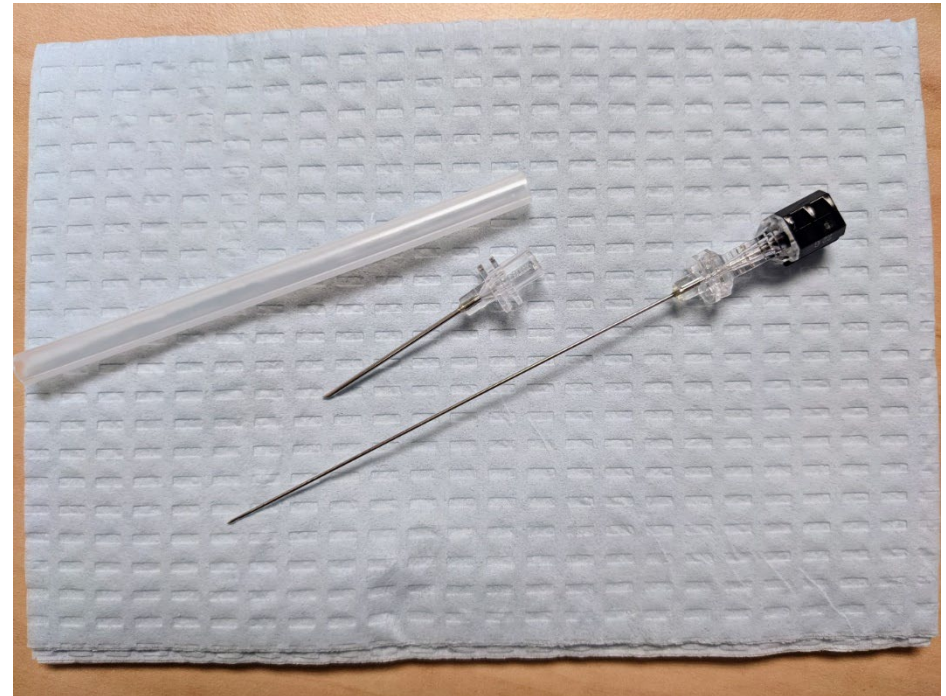
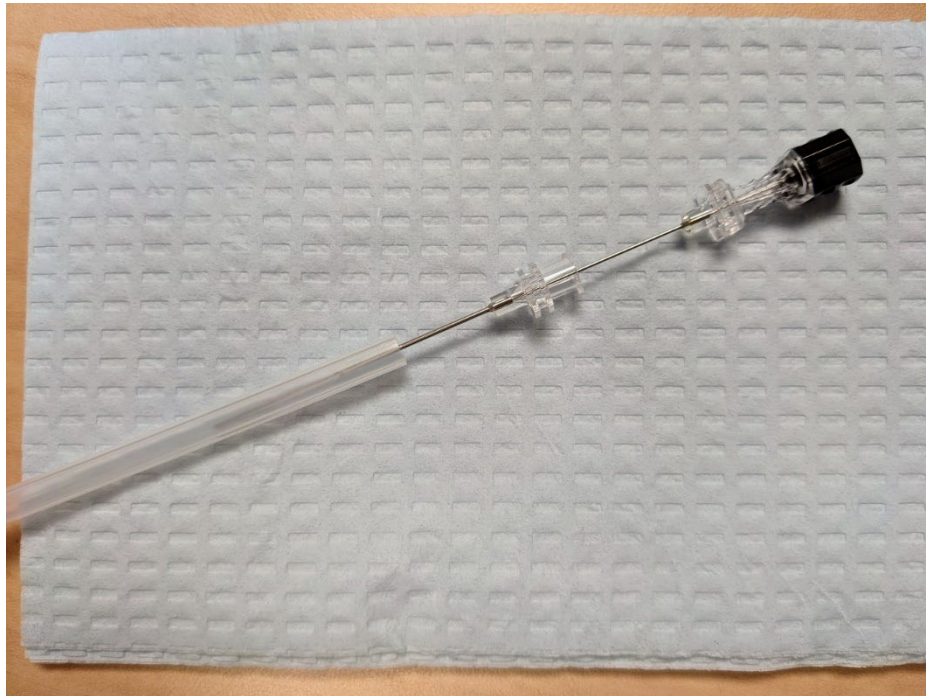
CSF:

LP Tray:



22G Needle with Introducer

These needles can be ordered from the Extra Supplies option of the SSBC Kit Request Survey



Kit Contents and Ordering: NMDA Kit

UPenn anti-NMDA Shipping Kit:



Collection Volumes

Total blood and CSF volumes

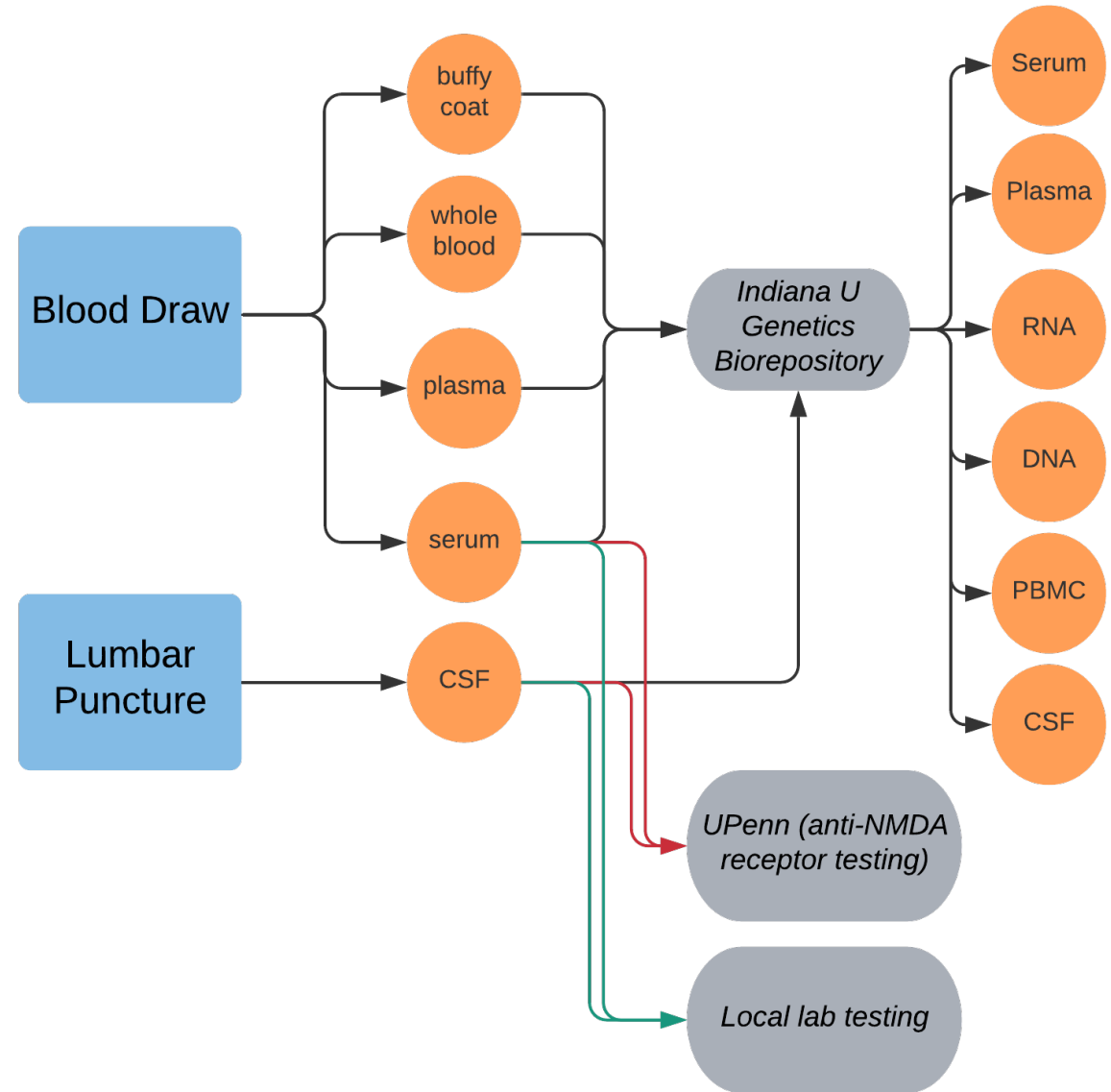
Sample Type	Amount
Whole Blood for Clinical Labs	5 ml
Whole Blood for RNA	5 ml
Whole Blood for Plasma and Buffy Coat	10 ml
Whole Blood for Serum	10 ml
Whole Blood for PBMCs (OPTIONAL)	20 ml
Cerebrospinal Fluid	13-15 ml

Maximum blood volume: 50 ml (approx. 8 teaspoons)

Maximum CSF volume: 15 ml (approx. 3 teaspoons)

Sample Flow

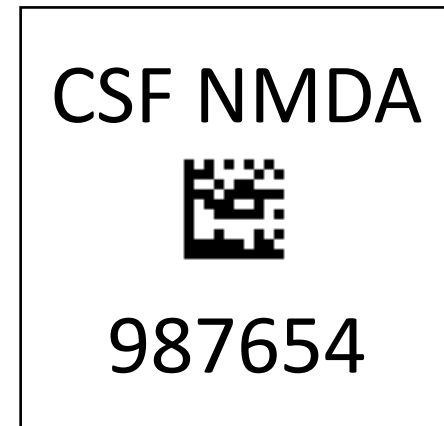
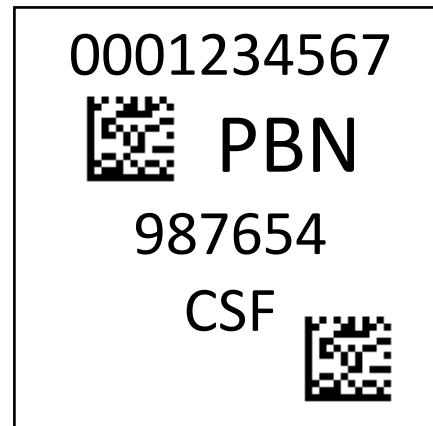
“Wait, *where* are these samples going?”



Sample Labelling: Example Labels

Labels are provided by Indiana University

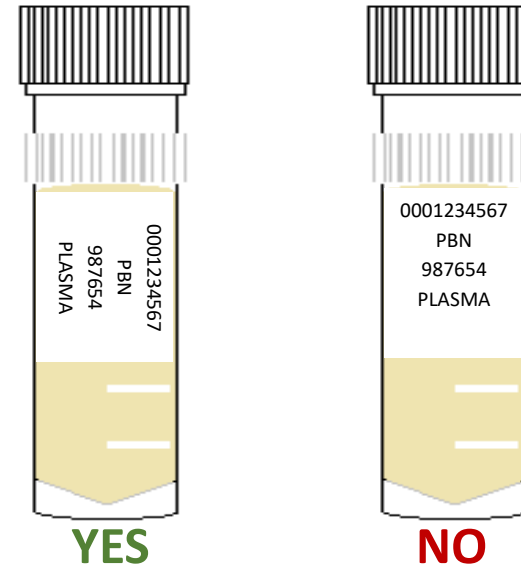
- Please check that all samples are properly labelled to ensure correct identification by IU
- If do not have enough labels to complete a visit, please contact IU *immediately*
- Labelling the tubes during processing prevents sample mix-ups



Sample Labelling: Label Placement

Please...

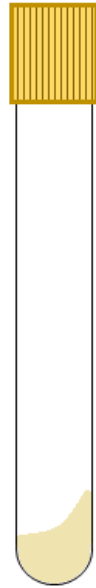
- Label all collection and aliquot tubes before cooling, collecting, processing, or freezing samples
- Label only 1 subject's tubes at a time to avoid mix-ups
- Wrap the label around the tube horizontally - label position is important for all tube types
- Make sure the label is completely adhered by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



Sample Collection and Processing

Blood Tube Draw Order

5mL SST for
Clinical Labs



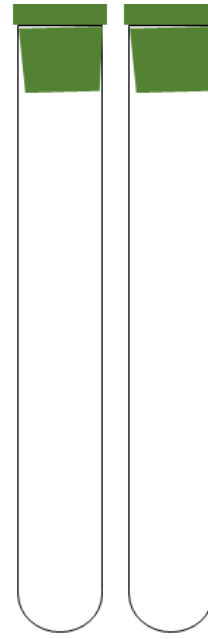
1

10mL
Serum



2

2 x 10mL NaHep
for PBMC



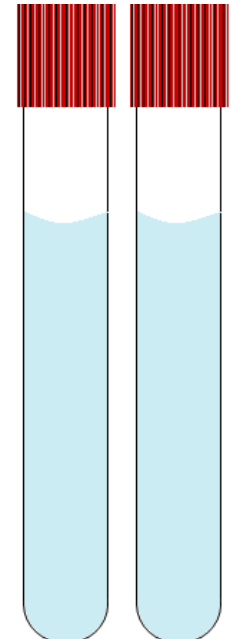
3

10mL EDTA
for Plasma



4

2 x 2.5mL
PAXgene™ for RNA



5

Sample Collection and Processing: Serum

Steps 1-2



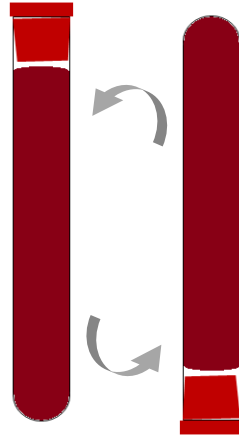
- Store tubes at room temperature.
- Label tubes with preprinted PBN serum label prior to blood draw.

Steps 3-4



- Collect blood in serum tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step 5



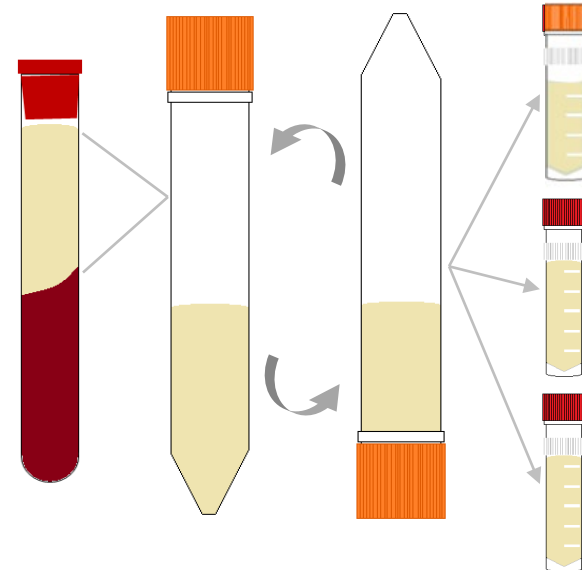
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

Step 6



- Allow blood to clot at room temp. for at least 15 minutes
- Within 60 minutes of blood draw, centrifuge sample at 4°C at 1500 x g for 15 minutes.

Steps 7-13



- Label red-capped cryotubes with SERUM labels and orange-capped cryotube with SERUM NMDA labels.
- Using a clean transfer pipet, transfer all serum into a 15 ml conical tube and mix gently by inverting 3-4 times.
- Aliquot 1 ml of serum into the orange-capped SERUM NMDA labelled tube. Aliquot 1.5 ml into each SERUM cryotube.
- If a residual aliquot (<1.5 ml) is created, place a blue cap on this aliquot.
- Store serum aliquots upright at -80°C until shipment.

Sample Collection and Processing: PBMCs

Steps 1-2



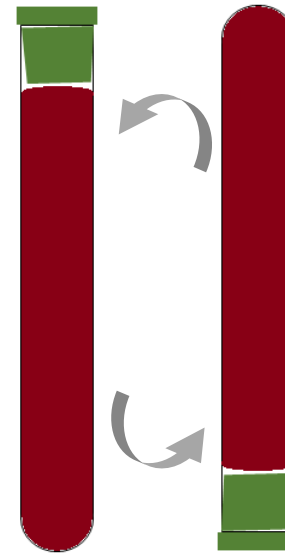
- Store tubes at room temperature.
- Label tubes with preprinted PBN PBMC label prior to blood draw.

Steps 3-4



- Collect blood in Sodium Heparin tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step 5



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

Step 7



- Store tubes at room temperature until shipment.
- ***Must be shipped ambient to IU on day of blood draw!***

Labeling Ambient NaHep

Position

Position the label so that one edge of the OnCore label starts at the back edge of the label with the PTID. Place label toward the bottom of the tube.

Attach

Attach the OnCore label to allow a viewing window down the length of the tube.

Avoid Stopper

If label must be placed near the top of the tube, do not allow label to come in contact with the stopper.



Correct label placement allows a clear view of the buffy coat.

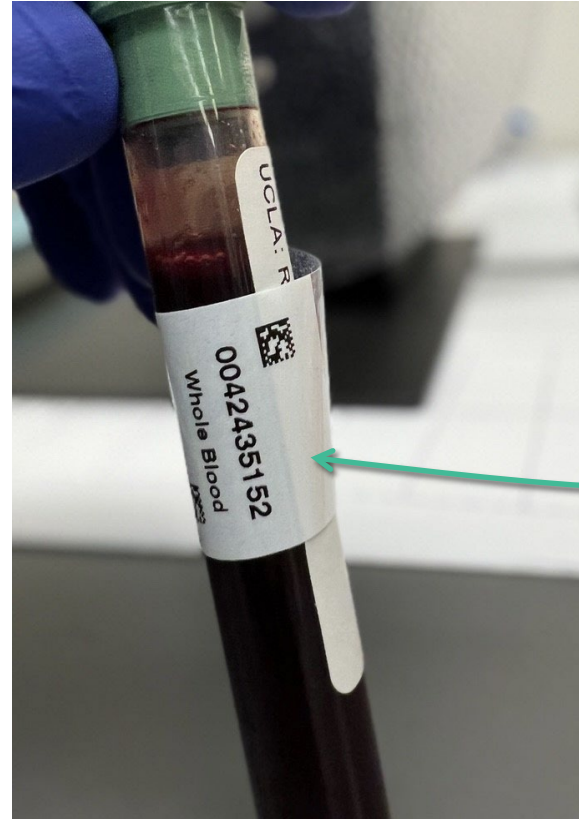
Labeling Ambient NaHep

Good label placement



This is an example of good label placement. The new label was started at the back edge of the existing label.

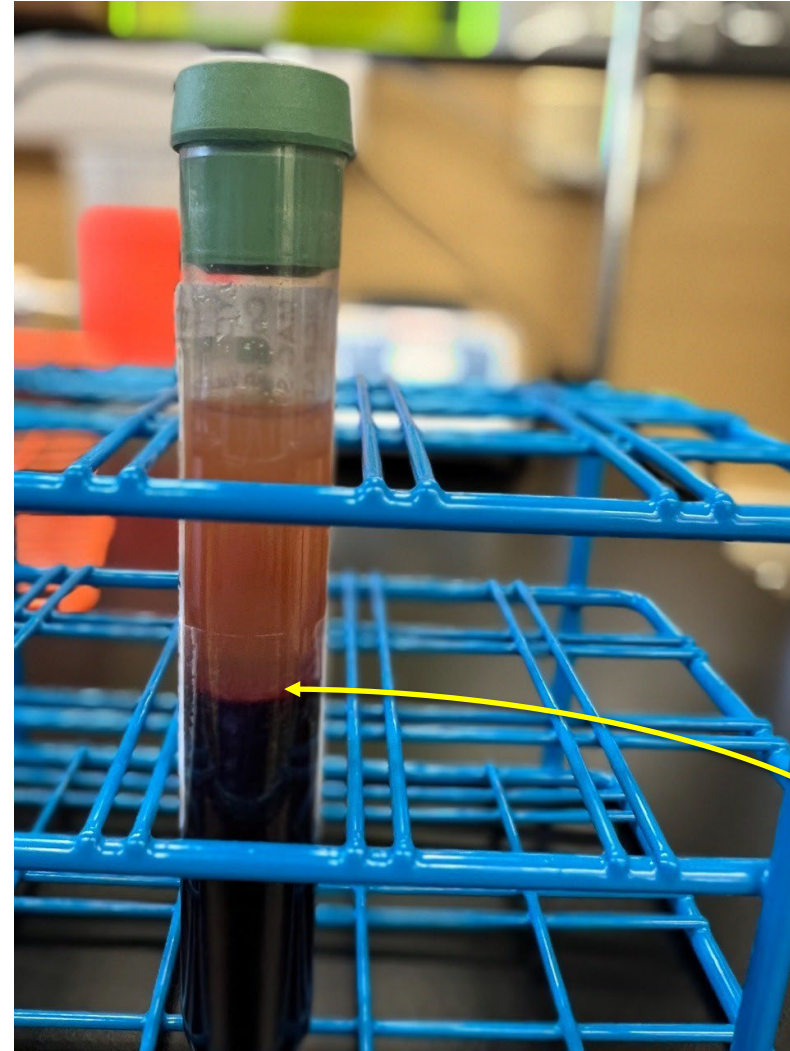
Poor label placement



This label was applied in a poor position. The window to view the buffy coat is not visible. The processing tech would need to remove the label to see and collect the buffy coat.

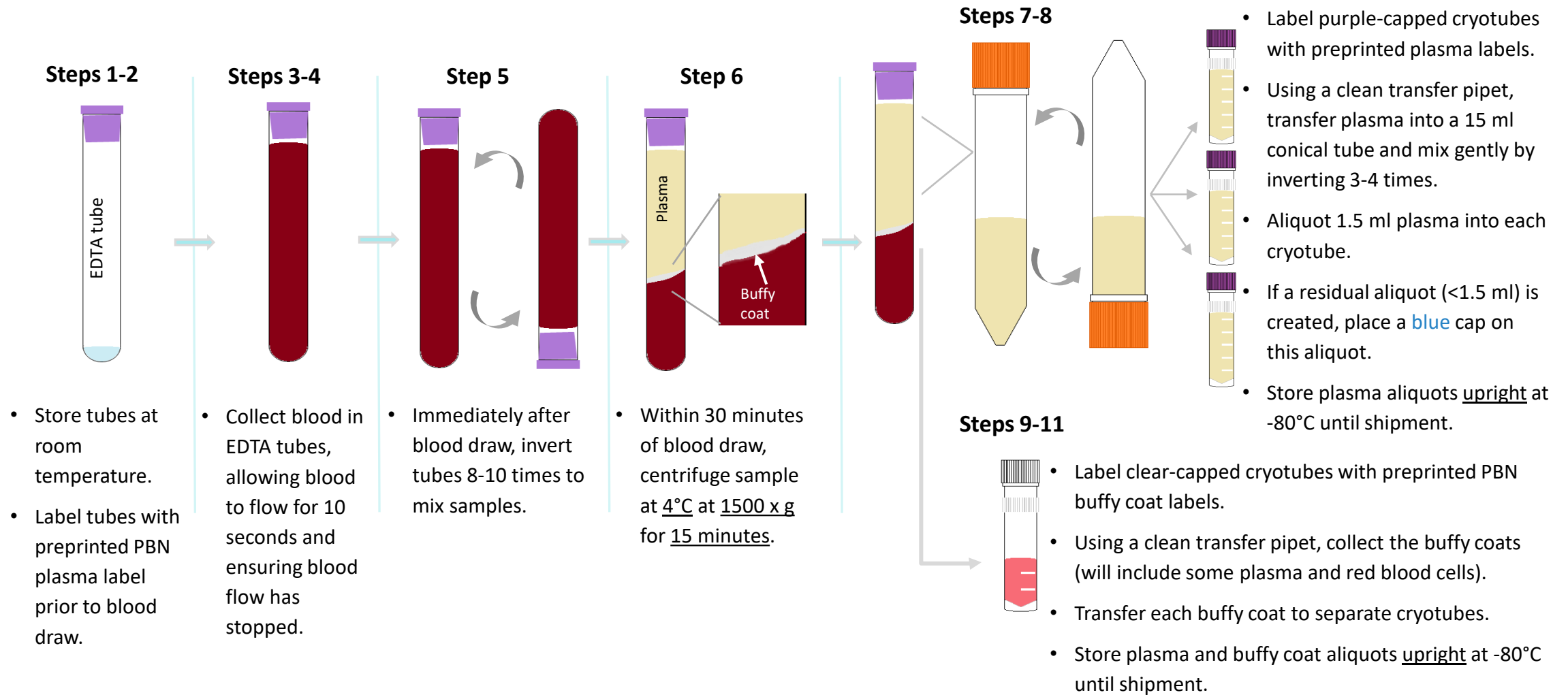
Labeling Ambient NaHep

Correct label placement will allow the processing lab to more easily see and collect the buffy coat layer after centrifugation.



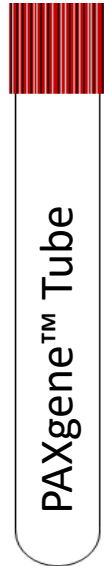
Correct label placement allows a clear view of the buffy coat.

Sample Collection and Processing: Plasma



Sample Collection and Processing: Whole blood RNA

Steps 1-2



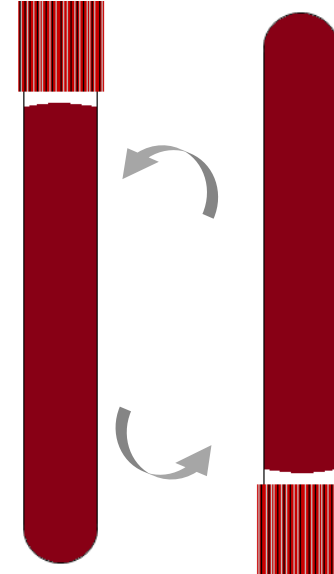
- Store tubes at room temperature.
- Label tubes with preprinted PBN RNA label prior to blood draw.

Steps 3-4



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

Steps 5



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

Steps 7-8



- Incubate the tubes at room temperature for 2 to 24 hours.
- Freeze tubes upright at -80°C until shipment. (DO NOT freeze in solid Styrofoam tube racks)

Sample Collection and Processing: CSF

Steps 1-3



- Prepare Mr. Frosty™



- Chill 15 ml conical tubes in their wrappings on wet ice.
- Label twenty *clear*-capped 2 ml cryotubes with preprinted PBN CSF labels.
- Label one *orange*-capped 2 ml cryotube with CSF PELLET label.
- Label one *orange*-capped 2 ml cryotube with CSF NMDA label.

Steps 4-5



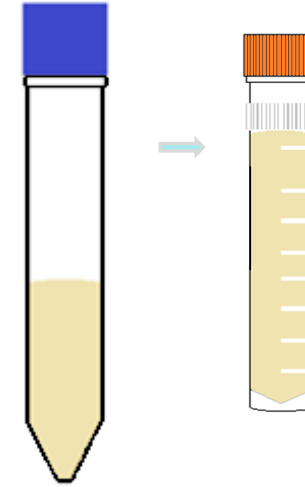
- Collect 15ml of CSF into 1 centrifuge tube.

Step 6 BASELINE ONLY



- **BASELINE VISIT ONLY:** Dispense 1ml into the CSF NMDA-labelled orange-capped cryovial

Step 7

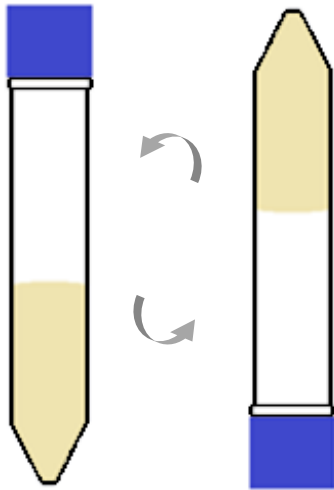


- Dispense 2-4ml CSF into the 4 ml orange-capped cryovial.
- Send to local pathology lab for testing. Label and handle sample per your local path lab's instructions.

Continued
on next slide

Sample Collection and Processing: CSF (cont'd)

Step 8



- Gently invert the remaining 10 ml of CSF in the centrifuge tube 3-4 times to mix the sample.

Step 9



- Within 30 minutes of collection, centrifuge samples at 300 x g for 10 minutes at 4° C.
- Aliquot 500 ul of supernatant directly into each of the prepared cryotubes, being careful not to disturb the pellet at the bottom of the conical tube.
- **Leave 500 ul of CSF in the conical tube.**

Steps 10-12



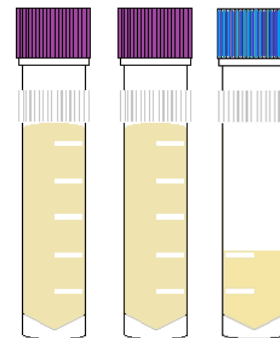
CSF PELLET aliquot

- Add 500 ul CryoStor® to 500 ul of CSF and cell pellet in the 15 ml conical tube.
- Resuspend pellet using pipetting technique.
- Transfer the resuspended CSF pellet to the pre-labeled orange cryotube.
- Within 60 minutes of CSF collection, freeze CSF aliquots **upright** in rack or cryobox at -80° C.
- Place pellet aliquot in the prepared Mr. Frosty™ and store at -80° C overnight.

Sample Collection and Processing: Aliquots

Filling biomarker serum, plasma, and CSF aliquots:

- Ensure that you are using the correct vials
 - Red cap = serum
 - Purple cap = plasma
 - Clear cap = CSF and buffy coat
 - Blue cap = residuals
 - Orange = CSF pellet, anti-NMDA samples
- Fill as many cryovials as possible to 1.5 ml (plasma & serum) or 0.5 ml (CSF)
- Over-filled vials may burst in freezer!
- Ship ALL material to IU, even if final vial is less than standard volume



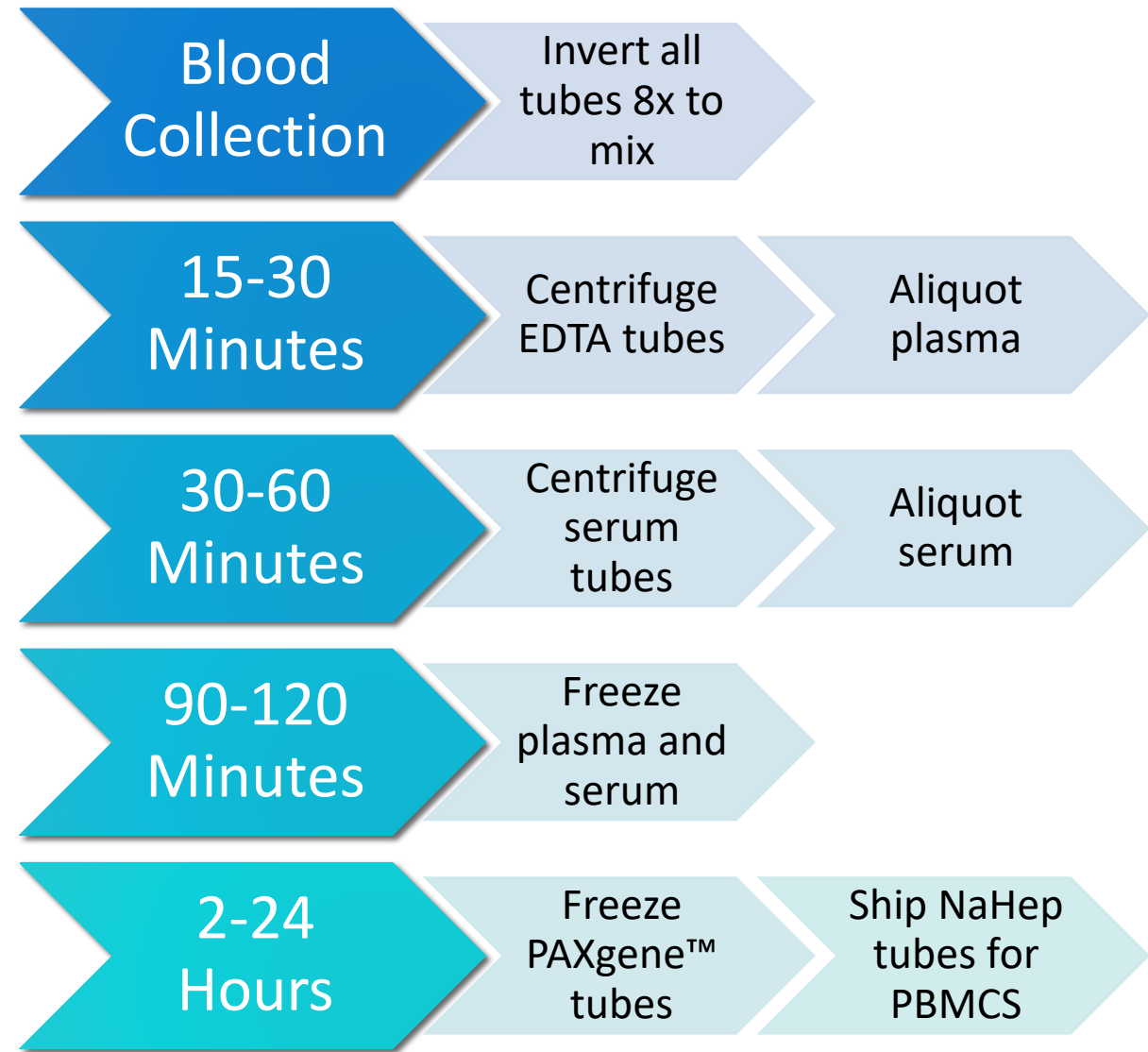
YES



NO

Sample Collection and Processing: Timeline

Timeline for blood processing



Sample Collection and Processing: Issue #1

Troubleshooting Blood Collection

Issue #1: Tube with little/no vacuum

- Always check expiration date on the tube before beginning blood draw and discard expired tubes
- Store tubes at “room temperature” – extreme temperature can affect vacuum
- Keep extra vacutainer tubes from supplemental kit nearby during blood draw to replace “bad” tubes
- If this is a frequent occurrence, report tube type and lot number to IU.

Sample Collection and Processing: Issue #2

Troubleshooting Blood Collection

Issue #2: Hemolyzed serum and/or plasma caused by incorrect collection

Cause: Blood Collection Methods	Corrective Action
Improper venipuncture site	Draw from median cubital, basilic, and cephalic veins from antecubital region of arm
Prolonged tourniquet use	Tourniquet should be released after no more than 1 min, excessive fist clenching should be avoided
Not allowing alcohol to dry on skin before venipuncture	Without touching, allow the venipuncture site to air dry
Use of too large/small bore needle resulting in excess force applied to blood	Avoid using too small/large needle. Needle size dependent on the subject's physical characteristics & amount of blood to be drawn. Most commonly used sizes are 19 – 23.
Pulling/pushing plunger too fast while drawing/transferring blood	Avoid drawing the syringe plunger too forcefully when collecting blood
Ensure all blood collection assemblies are fitted securely, to avoid frothing	

For more information, visit: http://www.bd.com/vacutainer/pdfs/techtalk/TechTalk_Jan2004_VS7167.pdf

Sample Collection and Processing: Issue #2 continued

Troubleshooting Blood Collection


Issue #2: Hemolyzed serum and/or plasma caused by incorrect processing

Cause: Sample Processing Methods	Corrective Actions
Vigorous mixing/shaking	Gently invert blood collection tube when mixing additive with specimen, follow guidelines in Biologics Manual regarding number of times to invert each type of tube
Not allowing serum to clot for recommended time	Serum tubes without clot activator should be allowed to clot for 60 min in a vertical position
Exposure to excessive heat or cold	Keep samples at ambient temperature until processing
Prolonged contact of serum/plasma with cells	Do not store uncentrifuged samples beyond recommended time

For more information, visit: http://www.bd.com/vacutainer/pdfs/techtalk/TechTalk_Jan2004_VS7167.pdf

Sample Collection and Processing: REDCap Survey

Specimen Collection and Processing Form

 **Psychiatric Biomarkers NETWORK**

[Returning?](#)

AAA
+ -

Please complete the Specimen Collection and Processing Form, below.

Page 1 of 3

Study Site	Icahn School of Medicine at Mount Sinai ▼
Email address of staff member completing this form	reynoldh@iu.edu
<i>Note: A copy of the completed sample form and the shipping manifests will be sent to this address.</i>	
PBN Subject ID:	MS123456 0 characters remaining
Is this participant a case or control?	SCZ ▼ CHR allowed for follow-up ONLY
Subject's biological sex (used for DNA quality control)	Female ▼
Visit	Baseline Visit ▼
Kit Number	9999996 0 characters remaining

[Next Page >>](#)

[Save & Return Later](#)

Blood Collection and Processing

Date of blood collection

11-01-2024  Today M-D-Y

Time of blood collection

09:57  Now H:M

Use 24 Hour clock.

Patient's fasting status at time of blood collection

Fasted 

1. SERUM (one red-top 10mL serum tube)

Was blood collected and processed for SERUM?

Yes

No

reset

Blood volume collected for SERUM

10

mL

Time of SERUM tube centrifugation

09:57  Now H:M

Use 24 Hour clock.

Rate of SERUM tube centrifugation

1500

x g

Duration of SERUM tube centrifugation

15

minutes

Temperature of SERUM tube centrifugation

4

degrees Celsius

Total volume of SERUM collected

4.5

mL

Sample Collection and Processing: Serum Data

Specimen Collection and Processing
Form

Sample Collection and Processing: Serum Data con't

Specimen Collection and Processing Form

Temperature of SERUM tube centrifugation

degrees Celsius

Total volume of SERUM collected

mL

Was a 1 mL aliquot of serum created for NMDA receptor testing?

If yes, set this aliquot aside to be shipped to UPENN.

[reset](#)

Required for all SCZ/BP/CHR visits.

Number of SERUM aliquots created to ship to the repository at IU

Aliquot to 1.5 mL, if possible.

Was a residual SERUM aliquot (less than 1.5 mL) created?

[reset](#)

If YES, please ensure the residual aliquot is capped with a blue top.

What is the approximate volume of the residual SERUM aliquot?

mL

Time SERUM was placed in freezer



H:M

Use 24 Hour clock.

SERUM storage temperature

degrees Celsius

SERUM notes

[Expand](#)

Sample Collection and Processing: PBMC Data

Specimen Collection and Processing Form

2. PBMCs (two green-top 10mL sodium heparin tubes)

Confirm participant consented to PBMC collection:

Yes

No

reset

Was blood collected for PBMCs?

Yes

No

reset

PBMCs should be collected at all visits.

Number of tubes collected for PBMCs

2

Total blood volume collected for PBMCs

16

mL

Reason volume was less than standard

Patient dehydrated



PBMC notes

Expand

Sample Collection and Processing: Plasma Data

Specimen Collection and Processing Form

3. PLASMA (one purple-top 10mL EDTA tube)

Was blood collected and processed for PLASMA?

Yes

Number of PLASMA aliquots created

3

Aliquot to 1.5 mL, if possible.

Was a residual PLASMA aliquot (less than 1.5 mL) created?

Yes

No

reset

If YES, please ensure the residual aliquot is capped with a blue top.

Was the BUFFY COAT collected?

Yes

No

reset

Time PLASMA and BUFFY COAT were placed in freezer

10:02



Now

H:M

Use 24 Hour clock.

PLASMA and BUFFY COAT storage temperature

-80

degrees Celsius

PLASMA notes

Sample Collection and Processing: RNA Data

Specimen Collection and Processing Form

4. RNA (two 2.5mL PAXGene™ tubes)

Was blood collected for RNA?

Yes

No

reset

Number of PAXGene™ tubes collected for RNA

2

Blood volume collected for RNA

5

mL

Note: Max collection volume per tube is 2.5 ml.

Date RNA were frozen

11-01-2024



Today

M-D-Y

Time RNA were placed in freezer

10:04



Now

H:M

Use 24 Hour clock.

RNA storage temperature

-80

degrees Celsius

RNA notes

Expand

CSF Collection and Processing

Was CSF collected?

 Yes No

reset

Date of CSF collection

11-01-2024



Today

M-D-Y

Time of CSF collection

10:05



Now

H:M

Use 24 Hour clock.

Approximate duration of CSF collection (in minutes)

5

minutes

Note: We are interested in the duration of the CSF collection, specifically the length of time the collection needle is in the subarachnoid space.

Patient's fasting status at time of CSF collection

Not fasted/no dietary limitation



Was CSF submitted for clinical labs?

 Yes No

reset

Was CSF collected using a syringe(s)?

 Yes No

reset

Total volume of CSF collected (incl. CSF submitted for clinical labs)

15

mL

Sample Collection and Processing: CSF Data

Specimen Collection and Processing Form

Sample Collection and Processing: CSF Data con't

Specimen Collection and Processing Form

BASELINE SCZ/BP/CHR ONLY: Was a 1 mL aliquot of CSF created for NMDA receptor testing?	<input checked="" type="radio"/> Yes <input type="radio"/> No
<i>If yes, set this aliquot aside to be shipped to UPENN.</i>	reset
Time of CSF tube centrifugation	10:07 <input type="button" value="🕒"/> <input type="button" value="Now"/> H:M Use 24 Hour clock.
Rate of CSF tube centrifugation	<input type="text" value="300"/> x g
Duration of CSF tube centrifugation	<input type="text" value="10"/> minutes
Temperature of CSF tube centrifugation	<input type="text" value="4"/> degrees Celsius
Number of CSF aliquots created to ship to repository at IU	<input type="text" value="20"/> Aliquot to 500uL, if possible.
Was the CSF PELLETT collected?	<input checked="" type="radio"/> Yes <input type="radio"/> No
	reset
Was the CSF PELLETT frozen in a prepared Mr. Frosty™?	<input checked="" type="radio"/> Yes <input type="radio"/> No
	reset
Time CSF, CSF NMDA (if collected), and CSF PELLETT were placed in freezer	10:07 <input type="button" value="🕒"/> <input type="button" value="Now"/> H:M Use 24 Hour clock.
CSF, CSF NMDA (if collected), and CSF PELLETT initial storage temperature	<input type="text" value="-80"/> degrees Celsius
Was the CSF PELLETT transferred to liquid nitrogen storage?	<input type="radio"/> Yes <input checked="" type="radio"/> No
	reset

Shipping Samples: Shipping Manifests

A copy of the Shipping Manifest should be included in every shipment to Indiana University

PBN Ambient Shipping Manifest

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the Ambient Shipping Manifest will be emailed to you for Subject MS123456. Please print a copy of that document and include it in the shipping container with Kit #9999996.

If you did NOT collect PBMCs, this form should be blank.



Shipping Information - Please complete.

Ambient shipments should be sent Monday-Thursday only. Please check for holiday closures prior to shipping. Contact us at pbn@iu.edu if you unsure whether or not it is safe to ship.

To generate an air waybill and schedule a UPS pickup, please go to the [IU Repository UPS Portal](#).

Date of shipment:

11-01-2024  Today M-D-Y

Did/will you use the IU UPS interface to generate the shipping label?

Yes

No

reset

Submit

Save & Return Later

PBN Ambient Shipping Manifest

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the Ambient Shipping Manifest will be emailed to you for Subject [subj_id]. Please print a copy of that document and include it in the shipping container with Kit #[kit_num]. If you did NOT collect PBMCs, this form should be blank.

Because blood for PBMCs was not collected from this subject, please skip this form.

Study Site:

PBN Subject ID:

Visit:

IU Kit Number:

Number of sodium heparin tubes collected for PBMC extraction:

Total volume of blood collected for PBMC extraction:

(mL)

Date of collection:

Time of collection:

(24-hour clock)

Shipping Information - Please complete.

Ambient shipments should be sent Monday-Thursday only. Please check for holiday closures prior to shipping. Contact us at pbn@iu.edu if you are unsure whether or not it is safe to ship. To generate an air waybill and schedule a UPS pickup, please go to the IU Repository UPS Portal.

Date of shipment:

Did/will you use the IU UPS interface to generate the shipping label?

Yes
 No

Which shipping service did you use?

UPS
 FedEx
 World Courier
 Other

What is the shipment tracking number?

Shipping Samples: Ambient Shipping Manifest

A copy of the Shipping Manifest should be included in every shipment to Indiana University

Shipping Samples: Frozen Shipping Manifest

A copy of the Shipping Manifest should be included in every shipment to Indiana University

PBN Frozen Shipping Manifest

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the Frozen Shipping Manifest will be emailed to you for Subject MS123456, Visit Baseline Visit.

Please print a copy of that document and include it in the Kit 9999996 shipping container.



Shipping Information - Please complete.

Frozen shipments may be sent Monday-Thursday, only (M-W preferred). Please check for holiday closures prior to shipping. Contact us at pbn@iu.edu if you unsure whether or not it is safe to ship.

To generate an air waybill and schedule a UPS pickup, please go to the [IU Repository UPS Portal](#).

Date of shipment:

11-01-2024



Today

M-D-Y

Did/will you use the IU UPS interface to generate the shipping label?

Yes

No

reset

PBN Frozen Shipping Manifest

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the Frozen Shipping Manifest will be emailed to you for Subject [subj_id], Visit [visit]. Please print a copy of that document and include it in the Kit [kit_num] shipping container.

Study Site:

PBN Subject ID:

Visit:

IU Kit Number:

Date of blood collection:

SERUM

Number of SERUM aliquots shipped:

Volume of residual SERUM aliquot:

(mL)

PLASMA

Number of PLASMA aliquots shipped:

Volume of residual PLASMA aliquot:

(mL)

Number of BUFFY COAT aliquots shipped:

RNA

Number of PAXGene™ tubes shipped

Shipping Samples: Ambient Shipping Manifests

A copy of the Shipping Manifest should be included in every shipment to Indiana University

Shipping Samples: NMDAR Shipping Manifest

A copy of the NMDAR Shipping Manifest should be included in every shipment to UPenn

PBN NMDAR Shipping Manifest

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the NMDAR Shipping Manifest will be emailed to you for Subject MS123456, Visit Baseline Visit.

Please print a copy of that document and include it in the Kit 9999996 shipping container for UPenn.

Shipping Information

Date of shipment:

11-01-2024



Today

M-D-Y

* must provide value

What is the tracking number on the preprinted UPS label provided with the NMDAR shipping kit?

1Z976R8W12345678

* must provide value

Samples shipping to:

Junxian Zhang
University of Pennsylvania
3610 Hamilton Walk
165 Johnson Pavilion/Neurology
Philadelphia, PA 19104

Phone: 215-898-0181

Email: junxian@penntmedicine.upenn.edu

Submit

Save & Return Later

PBN NMDAR Shipping Manifest

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the NMDAR Shipping Manifest will be emailed to you for Subject [subj_id], Visit [visit]. Please print a copy of that document and include it in the Kit [kit_num] shipping container for UPenn. If [subj_id] is a healthy control participant, disregard this manifest.

Study Site: _____

Email address of site contact: _____

PBN Subject ID: _____

Visit: _____

IU Kit Number: _____

SERUM

Number of 1 ml SERUM aliquots for anti-NMDAR testing: _____

Date of serum collection: _____

CSF

Number of 1 ml CSF aliquots for anti-NMDAR testing: _____

Date of CSF collection: _____

Shipping Information

Date of shipment: _____

Estimated date of arrival at Penn _____

What is the tracking number on the preprinted UPS label provided with the NMDAR shipping kit? _____

Estimated date and time of hand delivery (UPENN site only): _____

Please call the laboratory (215-898-0181) or text

Shipping Samples: NMDAR Shipping Manifests

A copy of the NMDAR Shipping Manifest should be included in every shipment to UPenn

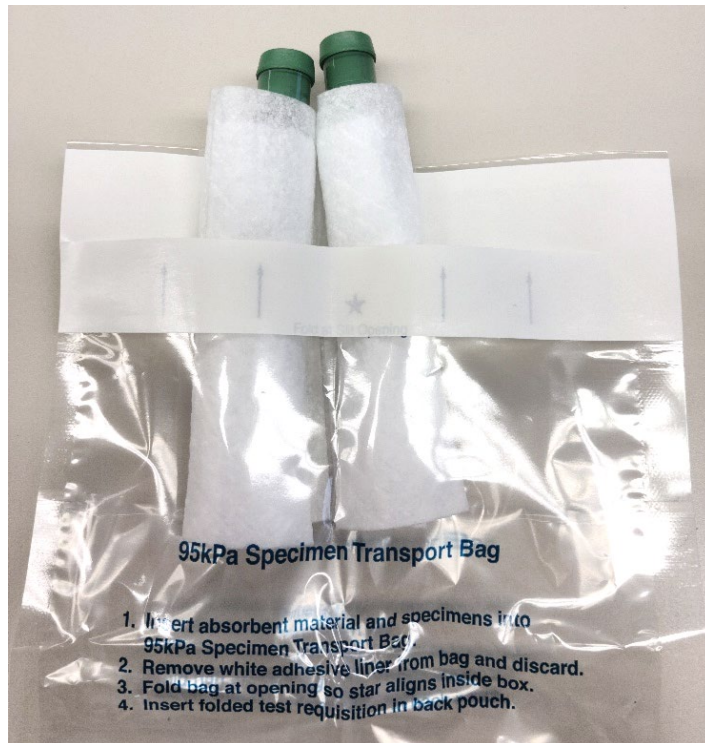
Shipping Samples: Ambient

Packing and Shipping Ambient Samples

- Whole blood for PBMCs ships at ambient temperature
- Ship ambient samples **only** Monday through Thursday
- Ship on **same day** of collection
- Only ship one subject's specimens in each shipping carton (unless otherwise instructed)

Shipping Ambient Samples

Packing and Shipping Ambient Samples



Shipping Frozen Samples: Tips

Packing and Shipping Frozen Samples

- Biomarker serum, plasma, buffy coats, CSF, and whole blood for RNA all ship frozen
- Ship frozen samples on dry ice
- Frozen samples should be shipped **only** Monday through Thursday
- Only ship one subject's specimens in each shipping carton
- Always fill carton to **top** with dry ice
- Do not pack shipment until the day of pickup



Shipping Frozen Samples

Special instructions for CSF cell pellet:

- Ship within ***two days*** of collection*
- CSF pellet must be frozen in Mr. Frosty™ / -80° C freezer overnight and shipped to IU the next day
- If frozen samples collected on Thursday, CSF pellet must be frozen in Mr. Frosty™ / -80° C freezer overnight and then placed in LN2 tank until shipment following Monday

**CSF pellet must be moved to LN2 if not shipped within 48 hours*



Class 9 Dry Ice Label should not be covered with other stickers and must be completed, or UPS will reject/return your package!

Shipping Samples

Packing and Shipping Frozen Samples

Shipper's Declaration not Required.

Dry Ice amount must be in kilograms.

Note: 2 lbs. = 1 kg.

Airwaybills / airbills must have the following:
1. Dry Ice; 9; UN 1845
2. $\frac{\text{Number}}{\text{(Number pkgs)}} \times \frac{\text{wt}}{\text{(wt)}} \text{ Kg}$

Net weight of dry ice in kg

Dry Ice kg.

Your name & address

Shipper's Name and Address

UN 1845

Consignee Name and Address

IU information and address

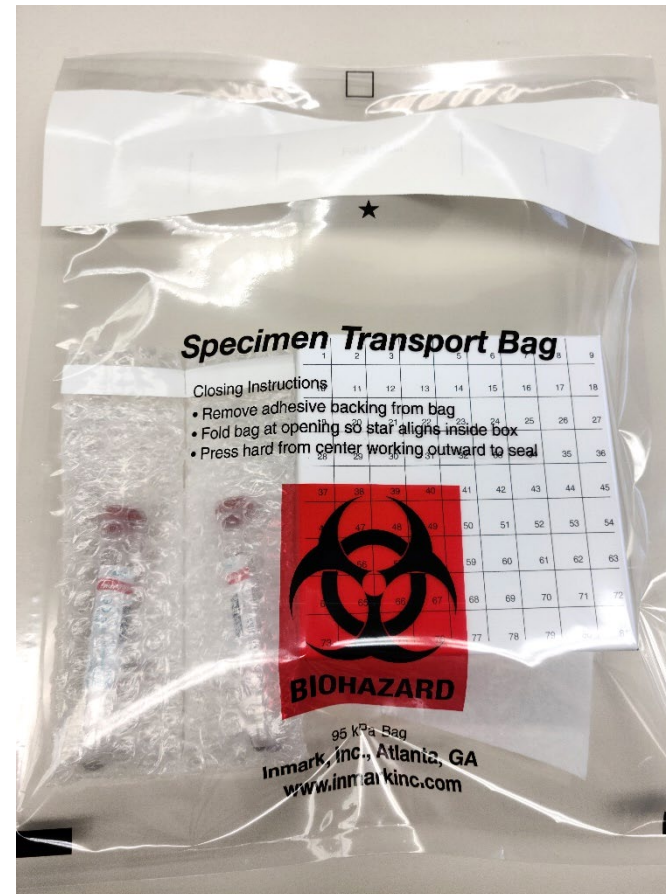
9

06426 1/01 RRD

The image shows a Class 9 Dry Ice Label template. It features a central diamond shape with a dashed border and a solid border. Inside the diamond, there are several vertical bars of varying heights. The label contains text for shipper's declaration, dry ice amount requirements, and airwaybill information. There are three main input areas: a box for the net weight of dry ice in kg, a box for the shipper's name and address, and a box for the consignee name and address. Red arrows point from external text labels to these input areas. The label also includes the hazard code 'UN 1845' and the hazard class '9'.

Shipping Samples: Frozen

Packing and Shipping Frozen Samples



Shipping Samples – UPS: <https://kits.iu.edu/UPS>

The screenshot shows the shipping interface for the Indiana University School of Medicine. The header includes the IU logo and the text "INDIANA UNIVERSITY SCHOOL OF MEDICINE and Affiliated Biorepositories". The interface is divided into two main sections: "Ship From" and "Shipment Information".

Ship From Section:

- Search for address: A search bar with a magnifying glass icon and a "Clear" button.
- Code: SSBC - MT. SINAI
- Company: Icahn School of Medicine - Mt. Sinai
- Contact: Byron Ramirez
- Address 1: 1470 Madison Ave
- Address 2: Pinto Lab, Floor 8, Room 302
- Address 3: (empty)
- City: New York
- State/Province: NY
- Postal Code: 10029
- Country / Territory: United States

Shipment Information Section:

- Study Group: SSBC/PBN
- Weight: 20 LB
- Dry Ice Weight: 10 LB
- Description of Return: Biological Specimens
- Pickup Request: A blue button.

Annotations:

- "Search for address": A dashed box with an arrow pointing to the search bar.
- "Choose Study": A dashed box with an arrow pointing to the Study Group dropdown.
- "Enter weight": A dashed box with an arrow pointing to the Dry Ice Weight input field.
- "Schedule Pickup": A dashed box with an arrow pointing to the Pickup Request button.
- "Click 'Ship'": A dashed box with an arrow pointing to the Ship button at the bottom right.

Buttons: "Reset" and "Ship" are located at the bottom right of the interface.

Shipping Samples via UPS

IU UPS ShipExec Shipping Portal

- Print out UPS air waybill
- Fold and insert UPS air waybill into clear plastic sleeve on package

JOHN SMITH
INDIANA UNIVERSITY
410 WEST 10TH STREET
INDIANAPOLIS IN 46202

2 LBS

1 OF 1

RS

SHIP TO:

SCHOOL OF MEDICINE
317-278-2694
INDIANA UNIVERSITY
TK 217
351 W 10TH ST
INDIANAPOLIS IN 46202



IN 461 9-01



UPS NEXT DAY AIR

1

TRACKING #: 1Z 976 R8W 84 3985 8595



BILLING: P/P
DESC: Biological Specimens
RETURN SERVICE

Reference No. 1: 4087277

XOL 20.03.09 NV45 83.0A 12/2019



Non-Conformance

Non-conformance to standard procedures may reduce the utility of the biospecimens:

- Not processing serum/plasma within 2 hours of collection allows for breakdown of certain proteins and small molecules
- Delayed shipping of PBMC samples leads to extraction failures
- Over/under centrifuging changes plasma, serum, CSF composition



Non-Conformance Reporting

IU will send non-conformance report for any specimen submission that does not meet requirements

- A copy of each report should be filed in the study binder
- Confirm procedures are being followed per the Biologics Manual
- Track issues over time to determine where changes may be needed

Shipping Issues Noted:

- Shipment notification not received, incomplete, or inaccurate
- Submission form not included in package, incomplete, or inaccurate
- Samples shipped for weekend or holiday delivery
- Samples improperly packaged
- Samples received damaged
- Frozen submission received thawed
- Other

Sample Collection Issues Noted:

- Submitted in non-standard tube(s)
- Unlabeled or mislabeled tube(s)
- Low volume received
- Sample discolored
- Other

Details/Comments:

Non-Conformance Reporting con't

Most common non-conformance issues:

- Shipment notification not sent
- Samples shipped for weekend/holiday delivery
- Sample form incomplete/inaccurate
- Low volume
- Unlabeled or mislabeled tube(s)
- Sample hemolysis



Contacts

Indiana University

General Questions:

pbn@iu.edu

Biorepository Project Manager:

Claire Wegel

Tel: 317.278.0594

Request kits:

<https://redcap.link/PBN-kits>

Biorepository Clinical Research Coordinator:

Holly Reynolds

Tel: 317.278.1217