

RAPA-501-ALS-EAP: INTERMEDIATE-SIZE EXPANDED ACCESS TRIAL OF AUTOLOGOUS HYBRID TREG/TH2 CELL THERAPY (RAPA-501) OF AMYOTROPHIC LATERAL SCLEROSIS

Update: Version 02

March 2025

| Section | Change |
|-----------------|--|
| Document Footer | Updated to "Version 02" |
| Section 3.1 | Removed contact information for Carolyn Dunifon, added information for Ashley Garwood |
| Section 3.4 | Updated link to BioSEND website |
| Section 6.1 | Updated specimen and kit label format |

National Institute of Neurological Disorders and Stroke Biorepository:

BioSpecimen Exchange for Neurological Disorders, BioSEND

Biospecimen Collection, Processing, and Shipment
Manual for Intermediate-Size Expanded Access Trial of
Autologous Hybrid TREG/Th2 Cell Therapy (RAPA-501)
of Amyotrophic Lateral Sclerosis

Version 02

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1.0 Purpose

The purpose of this manual is to provide collection site staff (PIs, study coordinators, and the sample collection and processing teams) at various study sites with instructions for collection and submission of biological samples. It includes instructions for biospecimen submission to the BioSpecimen Exchange for Neurological Disorders (BioSEND) located at Indiana University.

This manual includes instructions for the collection, processing, aliquoting and shipping of the following samples:

> Serum

These procedures are relevant to all study personnel responsible for processing blood specimens to be submitted to BioSEND.

2.0 Abbreviations

BioSend BioSpecimen Exchange for Neurological Disorders

DNA Deoxyribonucleic acid
EAP Expanded Access Program

IATA International Air Transport Association

RBC Red Blood Cells

RCF Relative Centrifugal Force RPM Revolutions Per Minute

3.0 BioSEND Information

3.1 BioSEND Contacts

Tatiana Foroud, PhD, Principal Investigator

Claire Wegel, Project Manager

Email: cwegel@iu.edu

Ashley Garwood, Research Coordinator

Email: hoviousa@iu.edu

General BioSEND Contact Information

Phone: 317-278-6158 Email: biosend@iu.edu Website: www.BioSEND.org

Sample Shipment Mailing Address

BioSEND
Indiana University School of Medicine 351
W. 10th Street. TK-217
Indianapolis, IN 46202-5188

3.2 Hours of Operation

Indiana University business hours are from 8 AM to 5 PM Eastern Time, Monday through Friday.

Frozen samples must be shipped Monday- Wednesday only.

For packaging and shipment details, please refer to Appendix C (Frozen Shipping Instructions) and Appendix D (UPS ShipExec[™] Thin Client Instructions).

Check the weather reports and the shipping courier website to make sure impending weather events (blizzards, hurricanes, etc.) will not impact the shipping or delivery of the samples. Couriers often report anticipated weather delays on their website.

3.3 Holiday Schedules

- ➤ Please note that courier services may observe a different set of holidays. Please be sure to verify shipping dates with your courier prior to any holiday.
- Weekend/holiday deliveries will not be accepted.

3.4 Holiday Observations

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

Please note that BioSEND has extended closures to inbound shipments around the Thanksgiving and Christmas holidays. In addition to sending advance notification of these closures to sites, dates will be posted on the BioSEND website. Frozen specimens collected during this period should be held at your site to ship after the first business day in January. If you are ever unsure whether or not it is safe to ship samples, please email biosend@iu.edu to confirm.

Please see https://biosend.org/holiday-closures for additional information.

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4.0 BioSEND Sample Requirements

Please make every effort to meet the approved biospecimen collection requirements. The expected sample volume collected and number of aliquots to be returned to BioSEND from each study visit are listed in sections 4.1-4.2. Because the fractionation of blood can vary, the number of serum aliquots created may deviate slightly from expected.

If a low volume draw (or any other deviations from standard processing) occurs at a particular visit, this should be recorded in the notes section of the **Sample Collection** and **Processing Form (see Appendix C).** This form is submitted with your sample shipment to BioSEND, and a copy of this form should be retained for your site records.

4.1 Collection Volumes

| Sample Type | Collection Tube(s) | Volume |
|-----------------------|--------------------|--------|
| Whole Blood for Serum | 1 x 10 ml Serum | 10 ml |
| | 10 ml | |

4.2 Protocol Schedule for Biospecimen Submission to BioSEND – RAPA-501-ALS-EAP

4.2.1 Number of Samples to be Submitted to BioSEND

| Sample Type | Screening/BL Day 0 | Apheresis | Cycle 1 Day 1 (D35) ± 14 | Cycle 2 Day 1 (D77) ± 14 | Cycle 3 Day 1 (D119) ± 14 | Cycle 4 Day 1 (D161) ± 14 | Follow-up Visit (D190) ± 14 |
|-----------------------|-----------------------|-----------|-----------------------------------|-----------------------------------|---------------------------|------------------------------------|--------------------------------------|
| Serum aliquots, 1.5ml | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

5.0 Specimen Collection Kits, Shipping Kits, and Supplies

BioSEND will provide labels and supplies only for those specimens that are to be shipped back to the BioSEND repository. Any tubes that will remain at the collection site or shipped to another laboratory should be labeled accordingly.

5.1 Kit Supply to Study Sites

Each individual site will be responsible for ordering collection kits from BioSEND. We advise sites to proactively confirm kits are on hand ahead of study visits.

The link to the kit request module is shown below:

o RAPA-501-ALS-EAP: https://redcap.link/rapakits

Please allow **TWO weeks** (10 business days) for kit orders to be processed and delivered.

5.2 Specimen Collection Kit General Contents

Collection kits contain the following (for each subject) as designated per your protocol and/or NINDS resource development agreement. Kits provide the necessary supplies to collect samples from a given subject. Do not replace or supplement any of the tubes or kit components provided with your own supplies unless you have received approval from the NINDS/BioSEND Study team to do so. *Please store all kits at room temperature until use.*

Each Blood Collection Kit contains the supplies to collect serum at one subjectvisit.

Shipping kits contain the supplies to ship up to 18 subject visits' worth of samples Once a cryobox has been filled with 18 subject visits, the box should be shipped to BioSEND. Please see **Appendix C – Frozen Shipping Instructions** for details.

| RAPA-501-ALS-EAP Blood Collection Kit | |
|---------------------------------------|----------|
| Component | Quantity |
| Cryogenic vials (2ml) with red caps | 3 |
| Serum (plastic) tube, 10ml | 1 |
| Disposable pipet, 3ml | 1 |
| Label set (kit & specimen labels) | 1 |

| RAPA-501-ALS-EAP ALS Shipping Kit | | | | |
|--|----------|--|--|--|
| Component | Quantity | | | |
| Cryobox, 81 cell | 1 | | | |
| Large Biohazard bag w/ absorbent sheet | 1 | | | |
| Fragile label | 1 | | | |
| UN3373 label | 1 | | | |
| Dry ice label | 1 | | | |
| Airway bill envelope | 1 | | | |
| Frozen shipper | 1 | | | |

5.3 Site Required Equipment

The following materials and equipment are necessary for the processing of specimens at the collection site and are to be **supplied by the local site**:

- > Personal Protective Equipment: lab coat, nitrile/latex gloves, safety glasses
- > Tourniquets
- Alcohol Prep Pads
- Gauze Pads
- Bandages
- > Butterfly needles and hubs
- > Microcentrifuge tube rack
- > Test tube rack
- > Sharps bin and lid
- Wet ice bucket
- Wet ice

In order to process samples consistently across all projects and ensure the highest quality samples possible, project sites must have access to the following equipment:

- > Centrifuge capable of ≥ 1500 rcf (1500 x g)
- > -80°C Freezer

In order to ship specimens, you must provide:

> Dry ice (minimum 10 pounds per shipment)

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6.0 Specimen Labels

Labels must be affixed on all collection and aliquot tubes to ensure unique specimen identity. BioSEND provides labels for all samples being collected and returned to BioSEND. The site is responsible for providing labels for biospecimens that will be retained at the site. If you have extra labels, please discard the unused labels.

6.1 Types of Labels

Each kit contains all labels required for the return of biospecimens to BioSEND.



The **Kit Labels** should be affixed on BioSEND forms and on specific packing materials. See Appendix C for further instructions.

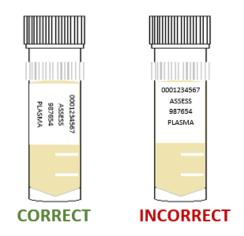


The **Specimen Labels** are placed on all sample collection and aliquot tubes. Each Specimen Label has a unique barcode that is tied to the Kit. See Appendix A for further instructions.

6.2 Affixing Labels

To ensure the label adheres properly and remains on the tube, <u>follow these</u> instructions:

- Place specimen labels on <u>ALL</u> collection tubes and cryovials <u>BEFORE</u> sample collection, sample processing, or freezing. This will help to ensure the label properly adheres to the tube before exposure to moisture or different temperatures.
- The blood collection tube labels contain a 2D barcode on the left hand side of the label. When turned horizontally, the barcode should be closer to the top (cap end) of the tube.
- Place label <u>horizontally</u> on the tube (wrapped around sideways if the tube is upright) and <u>just below the ridges</u> of the aliquot tubes (see attached labeling diagram).



• Take a moment to ensure the label is **completely affixed** to each tube. It may be helpful to roll the tube between your fingers after applying the label.

7.0 Specimen Collection and Processing Procedures

Consistency in sample collection and processing is essential for biomarker studies. All samples should be drawn in the same order and then processed in a uniform fashion. Please read the instructions before collecting any specimens. Have all your supplies and equipment out and prepared prior to drawing blood.

7.1 Order of Standard Blood Collection

| Draw Order | Collection Tube | Aliquot Volume | Number of Aliquots | Cryovial Cap Color | Collected at Visits |
|------------|------------------------------------|-------------------|-----------------------|-----------------------|--|
| 1 | 1 Serum (red-top) Tube, 10ml | 1.5ml | 3 | Red | Screen Apheresis Cycle 1 Day 1 Cycle 2 Day 1 Cycle 3 Day 1 Cycle 4 Day 1 Follow-up Day 190 |

7.2 Blood Collection Protocols

• Appendix A: Whole Blood Collection for Isolation of Serum

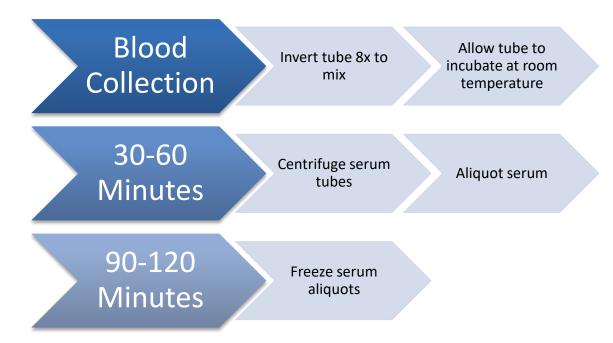
7.3 Filling Aliquot Tubes

In order to ensure that BioSEND receives a sufficient amount of sample for processing and storage, and to avoid cracking of the tubes prior to shipment, each aliquot tube should be filled to the specified volume (refer to detailed processing instructions for average yield per sample). Over-filled tubes may burst once placed in the freezer, resulting in a loss of that sample. Each kit includes the appropriate collection tubes to provide the specimen volume described in the Protocol Schedules for Biospecimen Submission (see Section 4). BioSEND provides only the supplies and labels for specimens intended for the BioSEND repository.

| Cap Color | Specimen Type | Aliquot Volume |
|-----------|---------------|----------------|
| Red | Serum | 1.5 ml |

Please fill as many aliquot tubes as possible to the standard volume, using any remaining sample to generate a single "residual" aliquot (i.e., less than standard volume).

7.4 Blood Processing Timeline



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8.0 Packaging and Shipping Instructions

ALL study personnel responsible for shipping should be certified in biospecimen shipping. If not available at your University, training and certification is available through the CITI training site (Course titled "Shipping and Transport of Regulated Biological Materials" at https://www.citiprogram.org/).

8.1 Sample Collection and Processing Form

The Specimen Collection and Processing Form should be completed for all samples submitted to BioSEND. The form can be completed and submitted via the REDCap link below:

https://redcap.link/RAPASampleForm

The second portion of this form is the Frozen Shipping Manifest, which should be completed at the time of shipping. A copy of the Frozen Shipping Manifest form should be physical included in the shipment to BioSEND. Please see Appendix B for details.

8.2 Shipping Instructions

All samples are shipped frozen on dry ice. Please reference Appendix K for frozen shipping instructions and Appendix D for generating air bills and scheduling pickups.

8.3 Shipping Address

All samples are shipped to the BioSEND laboratory:

BioSEND Indiana University School of Medicine 351 W. 10th Street. TK-217 Indianapolis, IN 46202-5188

9.0 Data Queries and Reconciliation

Appendix B must be completed the day that samples are collected to capture information related to sample collection and processing. This form includes information that will be used to reconcile sample collection and receipt, as well as information essential to future analyses.

BioSEND will contact the site as soon as possible when a discrepancy or issue is found with either the samples or paperwork.

Common non-conformance issues that will result in BioSEND staff contacting your site include:

- Missing samples (samples documented on the sample form that are not physically present in the shipment)
- Incorrect samples collected and shipped
- Damaged or incorrectly prepared samples
- Unlabeled or mislabeled samples
- Samples frozen and stored longer than three months at the site

10.0 Appendices

Appendix A: Whole Blood Collection for Isolation of Serum

Appendix B: Sample Collection and Processing Form

Appendix C: Frozen Shipping Instructions

Appendix D: UPS ShipExec™ Thin Client Instructions

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Appendix A - Whole Blood Collection for Isolation of Serum

One 10 ml red-top serum (plastic) tube and cryovials are provided by BioSEND for the collection and processing of serum.

- 1. Store kits and supplies at room temperature 64°F 77°F (18°C to 25°C) before use.
- 2. Place pre-printed "SERUM" specimen labels on the 10ml red-top serum tube and on 3 of the red-capped 2 ml cryovials prior to blood draw. 3 cryovials will be shipped to BioSEND.
- 3. Pre-chill labeled cryovials on wet ice for at least 5 minutes or longer.
- 4. Using a blood collection set and a holder, collect blood into the 10 ml red-top serum tube using your institution's recommended procedure for standard venipuncture technique.

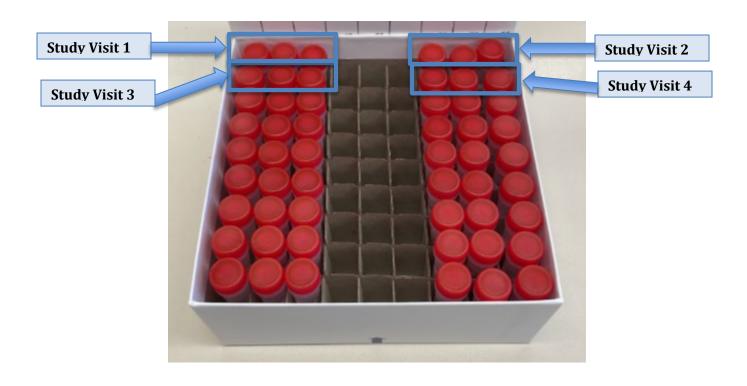
The following techniques should be used to prevent possible backflow:

- a. Place donor's arm in a downward position
- b. Hold tube in a vertical position, below the donor's arm during blood collection.
- c. Release tourniquet as soon as blood starts to flow into tube.
- d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.
- 5. Allow at least 10 seconds for a complete blood draw to take place. Ensure that the blood has stopped flowing into the tube before removing the tube from the holder. The tube with its vacuum is designed to draw 10 ml of blood into the tube.
- 6. Immediately after blood collection, gently invert/mix (180 degree turns) the serum determination tube 8-10 times. Do not shake the tubes!
- 7. Allow blood to clot at room temperature for at least 30 minutes.
- 8. Within 30 to 60 minutes from blood collection, centrifuge tube for 15 minutes at 1500 RCF (x g) at room temperature. It is critical that the tubes be centrifuged at the appropriate speed and temperature to ensure proper serum separation.

9. Remove the serum by tilting the tube and placing the pipette tip along the lower side of the tube wall. Use caution to pipet only the serum layer and not the red blood cell layer. Using a disposable tipped micropipette, transfer serum into the pre-labeled cryovials. Aliquot 1.5 ml per red-capped cryovial. Each red-top serum tube should yield approximately 4-5 ml of serum.

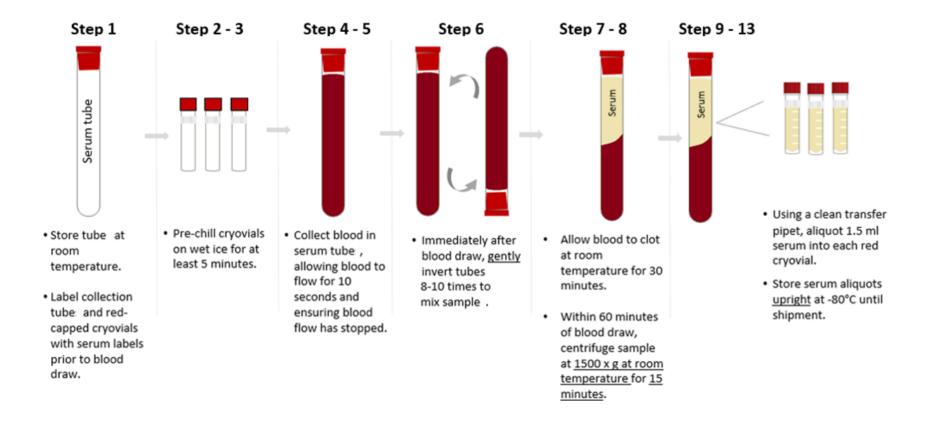
Note: If a low volume draw occurs, please generate as many 1.5ml aliquots as possible. Fewer standard size aliquots are preferred over 3 aliquots of non-standard size.

- RBC, WBC & Platelet Clot
- 10. After serum has been aliquoted into cryovials, **discard** the 10ml serum collection tube. Do not send the collection tube to BioSEND.
- 11. Place the labeled cryovials in the 81-slot cryobox according to the diagram below. Up to 18 study-visits may be included in a single 81-slot cryobox. Cryovials from a visit should be group together:



- 12. On the lid of the cryobox, place a kit label from the study visit that was just collected. As more visits are collected, take care to not cover the kit number of labels previously affixed to the lid.
- 13. Transfer cryobox to -80°C freezer as soon as possible and within two hours of collection. Store all samples at -80°C until shipped to BioSEND on dry ice.
- 14. Complete the sample form (Appendix B). Please note any issues that may have occurred during collection and processing.
- 15. Once a cryobox is filled completely (i.e., contains 18 visits), the cryobox should be shipped to BioSEND. Specimens should be shipped on at least a quarterly basis (i.e., every 3 months). If a cryobox is not filled completely at the end of the quarter, the partial cryobox should still be shipped to BioSEND. Please see **Appendix C** for details on shipping specimens to BioSEND.

Whole Blood Collection for Isolation of Serum



Appendix B –Sample Collection and Processing Form

A Sample Collection and Processing Form must be completed for each subject-visit submitted to BioSEND. This form includes a Frozen Shipping Manifest that should be completed in advance of shipping to BioSEND. A copy of this form should also be included in the shipper. A copy of the form will be emailed to you upon completion. The form can be completed via REDCap by following the bellow link:

 Link to Sample Collection and Processing Form: https://redcap.link/RAPASampleForm

Please note that there is a Save & Return option at the bottom of the survey. This may be used if, for example, you are ready to complete the Collection and Processing portion of the form, but not yet ready to complete the Frozen Shipping Manifest.

Clicking "Submit" at the end of the Frozen Shipping Manifest portion of the form will send an automatic notification to BioSEND of your shipment.

If unable to access REDCap during collection and processing, the below form may be printed and completed by hand during the visit. This form is provided to aid with processing data collection. Data should still be entered into the REDCap (https://redcap.link/RAPASampleForm) when site staff is able to do so.

| RAPA-501-ALS-EAP Subject ID: | | Visit: | Screening Apheresis Cycle 1 Day 1 | |
|----------------------------------|------------------|---|---|---|
| BioSEND Kit Number: | | | Cycle 2 Day 1 Cycle 3 Day 1 | |
| | | | Cycle 4 Day 1 Day 190 Follow-up | |
| Sex: M F | | | | |
| Blood Collection: | | | | |
| | | | | 7 |
| Date Drawn: | [DD/MMM/YYYY] | | Time of Draw: (24 HR) | 4 |
| Date Participant last ate: | [DD/MMM/YY\ | /Y] | Time subject last ate:AMPM | J |
| | | | | |
| Blood Processing: | | | | |
| 10ml Serum (Red-t | op) Tube | | Notes | |
| Total volume collected for serum | mL | | nl serum tube; 10ml expected | |
| | | | uld be set to incubate at room ure for 30-60 minutes. Centrifugation | |
| Time spin started: | ПАМ ПРМ | • | ccur within 60 minutes of collection | |
| Duration of centrifuge: | minutes | Tubes sho | ould be spun for 15 minutes | |
| 2 | | Tubes should be spun at room temperature. If spun | | |
| | | at another temperature, please specify in the | | |
| Temp of centrifuge: | Room Temperature | "Notes" section below. | | |
| Rate of centrifuge: | x g | Tubes should be spun at 1500 x g | | |
| | | | ml serum cryovials expected. If low volume urs, please generate as many 1.5ml | |
| # of serum aliquots created: | | aliquots as possible. Fewer standard size aliquots | | |
| (Red-capped cryovial) | | are preferred over 3 aliquots of non-standard size. | | |
| | | Cryovials should be frozen upright (in cryobox) | | |
| Time serum cryovials frozen: | | within 2 hours of collection. | | |
| Storage temperature: | °C | Cryovials should be stored at -80°C until shipment to BioSEND | | |
| | | | | |
| | | | | |
| | | | | |
| Notes | | | | |
| Notes: | | | | — |

Appendix C – Frozen Shipping Instructions

IMPORTANT!

Frozen samples must be shipped Monday – Wednesday only, using Next Day Air delivery

Please be aware of holidays and inclement weather and plan your shipments accordingly. Reach out to biosend@iu.edu if you have any questions

Specimens being shipped to BioSEND are Category B UN3373 specimens and as such must be triple packaged and compliant with IATA Packing Instructions. See the latest eEdition of the IATA regulations for complete documentation.

Triple packaging consists of a primary receptacle(s), a secondary packaging, and a rigid outer packaging. The primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging. Secondary packaging must be secured in outer packaging with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

IATA Packing and Labeling Guidelines

- The primary receptacle (cryovials or blood collection tubes) must be leak proof and must not contain more than 1 L total.
- The secondary packaging (plastic canister or biohazard bag) must be leak proof and if
 multiple blood tubes are placed in a single secondary packaging, they must be either
 individually wrapped or separated to prevent direct contact with adjacent blood tubes.
- Absorbent material must be placed between the primary receptacle (cryovials or blood collection tubes) and the secondary packaging. The absorbent material must be of sufficient quantity to absorb the entire contents of the specimens being shipped. Examples of absorbent material are paper towels, absorbent pads, cotton balls, or cellulose wadding.
- A shipping manifest listing the specimens being shipped must be included between the secondary and outer packaging.
- The outer shipping container must display the following labels:
 - ✓ Sender's name and address
 - ✓ Recipient's name and address
 - ✓ Responsible persons (shipper and recipient)
 - ✓ The words "Biological Substance, Category B"
 - ✓ UN3373
 - ✓ Class 9 label including UN 1845, and net weight of dry ice contained

BioSEND Packaging and Shipment Instructions – Frozen Shipments

- Serum aliquots will be stored in an 81-slot cryobox as they are collected. Once a cryobox is filled completely (i.e., contains 18 visits), the cryobox should be shipped to BioSEND. Specimens should be shipped on at least a quarterly basis (i.e., every 3 months). If a cryobox is not filled completely at the end of the quarter, the partial cryobox should still be shipped to BioSEND. Please see Appendix A for details on storing cryovials prior to shipment.
- 2. Generate airway bill and schedule courier pick-up, as needed.
 - For instructions on generating airway bills and scheduling using the UPS ShipExec™ Thin Client system, see Appendix D.
- 3. Record the tracking number onto the Frozen Shipping Manifest portion of the Sample Collection and Processing form (Appendix B) for all study visits in the shipment. By submitting the Frozen Shipping Manifest via REDCap, BioSEND will be alerted to your incoming shipment. It is essential that this step is completed so that BioSEND is aware of the shipment.
- 4. Print a copy of the Frozen Shipping Manifest form for each study visit in the shipment.
- 5. Place the cryobox in the clear plastic biohazard bag (do NOT remove the absorbent material found in the bag) and seal the biohazard bag according to the instructions on the bag.
- 6. Place approximately 2-3 inches of dry ice in the bottom of the Styrofoam shipping container.
- 7. Place the biohazard bag containing the cryobox into the provided Styrofoam shipping container on top of the dry ice. Please ensure that the cryobox is placed so that the cryovials are upright in the shipping container (as pictured below).



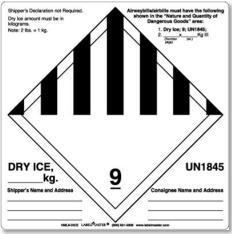




- 8. Fully cover the cryobox with approximately 2 inches of dry ice. Do not include more than one 81-slot cryobox in a shipper.
- 9. The inner Styrofoam shipping container must contain a minimum of 10 lbs (or 4.5 kg) of dry ice. The dry ice should entirely fill the inner box to ensure the frozen state of the specimens. This ensures that the specimens remain frozen in transit, as thawing may degrade certain proteins and small molecules.

- 10. Replace the lid on the Styrofoam container. Place the completed Frozen Shipping Manifests in the package on top of the Styrofoam lid for each study visit in the shipper, and close and seal the outer cardboard shipping carton with packing tape.
- 11. Print a copy of your UPS® airway bill generated through the UPS ShipExec™ Thin Client system (see Appendix D). Place airway bill into the provided airway bill envelope and affix envelope to the outside of the shipper.
- 12. 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 (this amount must match the amount recorded on the airway bill)
 - Consignee name and address:

BioSEND IU School of Medicine 351 W. 10th Street TK-217 Indianapolis, IN 46202



IMPORTANT!

Complete the required fields on your airway bill and Class 9 Dry Ice labels, or courier may reject or return your package.

- 13. Apply all provided warning labels (UN3373, Dry Ice Label and Fragile Label), taking care not to overlap labels with each other or with airway bill.
- 14. Hold packaged samples in -80°C freezer until time of courier pick-up/drop-off.
- 15. Specimens should be sent to the address below. Frozen shipments should be sent <u>Monday</u> through <u>Wednesday only</u> to avoid shipping delays on Thursday or Friday.

BioSEND IU School of Medicine 351 W. 10th Street, TK-217 Indianapolis, IN 46202

16. Use courier tracking system to ensure the delivery occurs as scheduled and is received by BioSEND.

In addition to tracking and reconciliation of samples, the condition and amount of samples received are tracked by BioSEND. Investigators and clinical coordinators for each project are responsible for ensuring that the requested amounts of each fluid are collected to the best of their ability and that samples are packaged with sufficient dry ice to avoid thawing in the shipment process.

Appendix D - UPS ShipExec™ Thin Client Instructions

- 1) Log in to the UPS ShipExec[™] Thin Client website: https://kits.iu.edu/UPS or https://kits.iu.edu/UPS or https://kits.iu.edu/UPS or https://kits.iu.edu/UPS or https://kits.iu.edu/UPS.
 - a. To request an account, complete the following survey: https://redcap.uits.iu.edu/surveys/?s=88TTWY3KAF
- 2) Find the "Shipping" dropdown menu in the top left corner of the screen and click on "Shipping and Rating".
- 3) Once the Indiana University page loads, look for the "Study Group" dropdown menu under "Shipment Information" on the right side of the screen. Choose your study from the dropdown menu.
- 4) After selecting your study, click on the magnifying glass icon on the left side of the screen under "Ship From".
- 5) An address book and filters will populate the screen. On the right side of the screen, a list of all the site addresses within the study you selected should populate.
 - a. Filter the list down more by looking to the left side of the screen and searching for their address by filling in the "Company", "Contact", or "Address 1" fields. Click on the Search button when ready.
 - b. Once you have found your site address, click on the "Select" button to the left of the address.
- 6) Make sure your address populated in the fields under "Ship From" on the main page.
 - a. If you accidentally selected the wrong address, click on the "Reset" button on the bottom right of the screen. After the page reloads and clears the information, select your study again from the "Study Group" menu and click on the magnifying glass icon again to search for your correct address.
 - b. To change the address for your site and study group, please complete the following survey: https://redcap.uits.iu.edu/surveys/?s=88TTWY3KAF
- 7) Enter the total weight of your package in the "Weight" field on the right side of screen under the name of your study.
 - a. Leave the "Dry Ice Weight" field empty or enter "0" if shipping an ambient sample.
- 8) Enter the weight of the dry ice for frozen shipments in the "Dry Ice Weight" field.
 - a. The "Dry Ice Weight" field can <u>never</u> be higher than the "Weight" field.
 - b. (Steps 9-10 can be skipped if you do not need to schedule a pickup)
- 9) After entering the weights, click on the blue "Pickup Request" button.
- 10) When the Create Pickup Request box pops up, enter information into all the fields provided.
 - a. Enter the "Earliest Time Ready" and "Latest Time Ready" in 24-hour format.
 - i. Scheulde pickup at a minimum 1 hour before the "Earliest Time Ready"
 - b. Choose a name and phone number that is the best contact if the UPS driver has question related to picking up your package
 - c. Entering the "Room Number" and "Floor" will help the UPS driver locate your package
 - i. The "Floor" field only allows numerical characters while the "Room Number" field is free text.
 - d. Click "Save" when done.
- 11) Once you are certain that all the correct information has been entered, click the "Ship" button in the bottom right corner of the screen.

- 12) If no red error messages pop up at the top of your screen after clicking on "Ship", then you should have 2 downloaded PDF files: Shipment Receipt & UPS Package Label
 - a. Shipment Receipt will list a "Pickup No." that references your specific package if there is ever an issue with UPS picking up your package
- 13) Print out the UPS airway bill to any printer at your location.
 - a. Fold the UPS airway bill and slide it inside the plastic UPS sleeve.
 - b. Peel the back off the plastic UPS sleeve and stick the sleeve to your package, making sure it is laying as flat as possible along the surface of the package.
- 14) Place your package in the spot designated in your pickup request, or wherever your daily UPS pickups occur.
- 15) If you need to reprint your airway bill or void your shipment, click on "History" at the top of the main screen.
 - a. If your shipment does not automatically pop up, enter the date of shipment and then click "Search".
 - b. To reprint your airway bill, click on the printer icon to the far left under "Action"
 - c. To void your shipment, click on the "X" icon to the far left under "Action"
 - i. If you created an airway bill that you no longer need, you must void the shipment to ensure your study will not be charged for the shipment.