



## **Clinical Research Consortium for SCA (CRC-SCA)**

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BIOSPECIMEN COLLECTION & PROCESSING

# Specimen Uniformity and Quality

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GENERAL REMINDERS



# Specimen Uniformity and Quality

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

- Standardization of processing across sites is key
- Reference the *BioSEND Specimen Collection, Processing, and Shipment Manual* as needed
- Do not replace or supplement any kit components without first receiving approval from BioSEND/NINDS

Questions? Email [biosend@iu.edu](mailto:biosend@iu.edu)

# Site Equipment

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Sites will need to supply the following items:

## Phlebotomy

- Gloves
- Alcohol wipes
- Butterfly needles
- Tourniquet
- Gauze pads
- Bandages
- Sharps bin and lid



# Site Equipment

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Sites will need to supply the following items:

## Processing

- Crushed ice
- Microcentrifuge tube rack
- Calibrated pipettes and pipette tips
- Centrifuge capable of maintaining 4°C
- -80°C Freezer
- Dry ice



# Collection Protocol

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Sample Type & Volume	All Visits
Plasma aliquots, 1ml	6
Serum aliquots, 1ml	6
Buffy Coat	2
Whole Blood, 3ml	2
CSF aliquots, 1ml	10

# Kit Ordering – Biosend.org

The screenshot shows the Biosend.org website navigation menu. At the top left is the **NINDS BioSEND** logo. To its right are five main menu categories: **Accessing Biospecimens**, **Banking Samples**, **Active Studies**, and **About BioSEND**. A white dropdown menu is open under **Accessing Biospecimens**, listing the following study resources: AJPD Study Resources, CHANGE-HD Study Resources, DLB Study Resources, DVRP Study Resources, EpiBioS4Rx Study Resources, LBD Study Resources, LETBI Study Resources, MBPS Study Resources, PBS Study Resources, PHD3 Study Resources, PSP Study Resources, SBPD Study Resources, **CRC-SCA Study Resources** (highlighted with a blue arrow), and READISCA Study Resources. Below the menu are three image-based navigation buttons: **About BioSEND** (with a photo of a building), **Banking Samples** (with a photo of a metal container), and **Biospecimens** (with a photo of a lab setting). A partial text box on the right side of the image reads "and other neuropsychiatr to researchers".

# Kit Ordering

Direct link to ordering system :

<http://kits.iu.edu/biosend/crc-sca/>

**BioSEND**    Accessing Biospecimens    Banking Samples    Active Studies    About BioSEND

## Clinical Research Consortium for SCA (CRC-SCA) Study Page

Welcome CRC-SCA Study staff, coordinators, and PIs. This section encompasses study specific tools and resources for your reference. If you have any questions, comments, or new ideas please contact biosend@iu.edu or by phone directly at (317)278-0594.

### Specimen Table

Cohort	Population	Plasma	Genomic DNA	Serum	CSF
MBPS	Participants with a diagnosis of SCA 1, 2, 3, 6, or 7	✓	✓	✓	✓

### Study Resources

#### Kit Request Module

Please follow the below link to access the CRC-SCA Kit Request Module. This link will direct you to a REDCap database where study coordinators and staff may request kits, individual supplies, and/or labels. Please allow a total of two weeks for kit requests to be compiled and delivered to your site.

[Kit Request System](#)

### Downloads

- Sample Shipment Form (pdf)
- Manual of Procedures
- New Coordinator Training Slides

### Additional Resources

- Online Sample Form
- Kit Request System

### Contact Us

biosend@iu.edu  
317-278-0594



# Confirm/Update Shipping Information

Select your Study Site from the drop down box to populate the most current information we have for your site. Please confirm or update your site's information as needed.

<b>Study Site</b> <small>* must provide value</small>	Indiana University
Indiana University School of Medicine Carolyn Dunifon Dept. of Medical & Molecular Genetics 351 West 10th Street, TK-318 Indianapolis, IN 46202-3002 (317) 274-5751 cdunifon@iu.edu	
<b>Is the contact name above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No <a href="#">reset</a>
<b>New Contact Name</b> <small>* must provide value</small>	Claire Wegel
<b>Is the shipping address above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <a href="#">reset</a>
<b>Is the e-mail address above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <a href="#">reset</a>
<b>Is the phone number above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <a href="#">reset</a>

*Note: The form includes blue arrows pointing to the 'Study Site' dropdown, the 'New Contact Name' input field, and the 'Is the contact name above correct?' radio buttons. A dashed box highlights the 'Study Site' dropdown with the text 'Select your site from the drop-down list'. Another dashed box highlights the 'Is the contact name above correct?' radio buttons with the text 'Verify contact information and update if needed'.*

# Kit Ordering – Kit Options

Selecting a kit option will populate contents for that kit

## Kit Type

**\*\*Please allow two weeks for shipment\*\***

\* must provide value

- Blood Collection Kit
- CSF Kit
- Supplemental Kit
- Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

## Blood Collection Kit Contents:

- 2 - EDTA (Lavender) tube, glass (10 ml)
- 2 - Serum (Red) tube, glass (10ml)
- 2 - EDTA (Purple) tube, plastic (3ml)
- 15- Siliconized cryovial (2ml)
- 2 - Disposable transfer pipette (3ml)
  
- 1 - 25-Slot Cryobox
- 1 - Warning label packet (incl. dry ice label)
- 1 - Airway bill envelope
- 1 - Shipping container for dry ice shipments
- 2 - Biohazard bag with absorbent sheet
- 6 - Individual bubble sleeves for tube
- 30 - Cryohold specimen/case labels

# Kit Ordering – Blood Kits

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<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <small>* must provide value</small>	<input checked="" type="checkbox"/> Blood Collection Kit <input type="checkbox"/> CSF Kit <input type="checkbox"/> Supplemental Kit <input type="checkbox"/> Extra Supplies
	<small>Please specify in comments if you need kits before the standard two week shipment time.</small>

Kits are not specific to a subject or time point. After collection, sites will indicate the subject and time point to which BioSEND should link the samples.

# CSF Kits

**Kit Type**  
**\*\*Please allow two weeks for shipment\*\***  
\* must provide value

Blood Collection Kit  
 CSF Kit  
 Supplemental Kit  
 Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

**CSF Sprotte® Needle Gauge**  
\* must provide value

22  
 24

reset

**CSF Kit Quantity**  
\* must provide value

**Comments**

Expand

**CSF Collection Kit Contents:**

*Note that labels for all sample types will be included with the Blood Collection Kits. Under Protocol Amendment 5.0, blood samples should be collected at all follow-up CSF collections.*

11 - Siliconized cryovials, sterile (2ml)  
2 - 15ml conical tube, individually wrapped  
2 - 50ml conical tube, individually wrapped  
1 - LP tray with 22 gauge Sprotte® needle  
1 - Medication Transfer Filter Straw

- CSF collection kits are ordered independently of blood kits
- CSF labels will be included with all blood kits, as blood should be collected any time CSF is collected

# Extra Supplies

This option allows you to order individual kit components. For ex, if you have a kit with blood tubes that have expired, you may order new collection tubes to replace them.

<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <small>* must provide value</small>	<input type="checkbox"/> V01 Visit Kit <input type="checkbox"/> Follow-Up Visit Kit (select Visit Type below) <input type="checkbox"/> CSF Kit <input type="checkbox"/> Supplemental Kit <input checked="" type="checkbox"/> Extra Supplies
<small>Please specify in comments if you need kits before the standard two week shipment time.</small>	
<b>Individual Tube Bubble Pouch</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
<b>25-Slot Cryobox</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
<b>Siliconized Cryovial (2 ml)</b>	<input type="radio"/> 10 <input type="radio"/> 20 <a href="#">reset</a>
<b>Air waybill envelope</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a> <small>Plastic envelope to affix air waybill to package</small>
<b>Lumbar Puncture Trays with Lidocaine, 24g</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
<b>Lumbar Puncture Trays with Lidocaine, 22g</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
<b>Medication Transfer Filter Straws (for LP)</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
<b>15ml conical tube, individually wrapped</b>	<input type="radio"/> 2 <input type="radio"/> 4

# Submit Request

- Click “Submit” to send order to BioSEND; staff will confirm receipt of your order
- Please allow two week turn-around time for kit shipments
- If urgent request needed, please note date needed by in comments and email BioSEND. We cannot guarantee urgent requests, but will do our best to accommodate.

**NINDS BioSEND** AAA

NINDS Biosend CRC-SCA Kit Request System

Study Site  \* must provide value

Columbia University

Contact Name  
Shipment Address  
Email  
Phone

Is the contact name above correct?  Yes  No \* must provide value [reset](#)

Is the shipping address above correct?  Yes  No \* must provide value [reset](#)

Is the e-mail address above correct?  Yes  No \* must provide value [reset](#)

Is the phone number above correct?  Yes  No \* must provide value [reset](#)

Kit Type \*\*Please allow two weeks for shipment\*\* \* must provide value

V01 Visit Kit  
 Follow-Up Visit Kit (select Visit Type below)  
 CSF Kit  
 Supplemental Kit  
 Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

Comments

[Expand](#)

**Submit**

# Sample Labelling

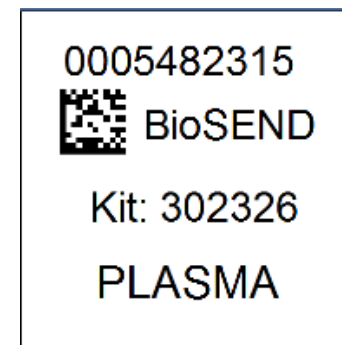
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**Labels are provided by Indiana University for BioSEND samples only**

- Please check that all samples are properly labelled with correct specimen type



Kit Labels



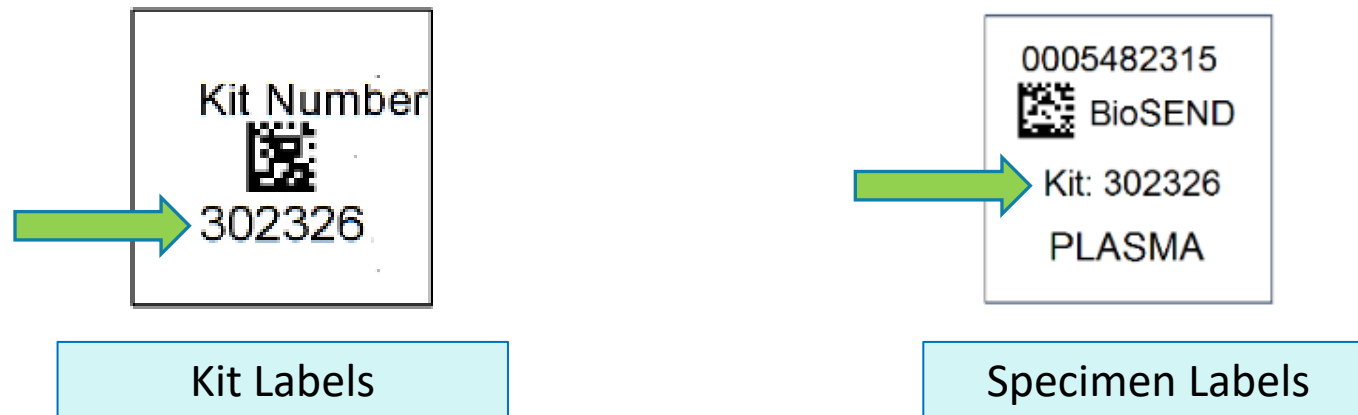
Specimen Labels

# Sample Labelling – Kit Number

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## Kit Number

- Each Blood Collection Kit will have a unique “Kit Number” used to track participant samples and provide quality assurance
- Any kit number can be used for any subject or visit—which is why it is very important to document which kit number was used for which subject and visit





# Sample Labelling – Kit Labels

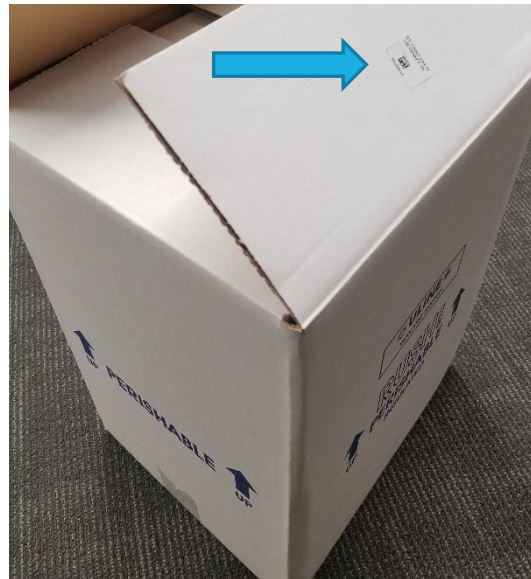
Kit Number



302326

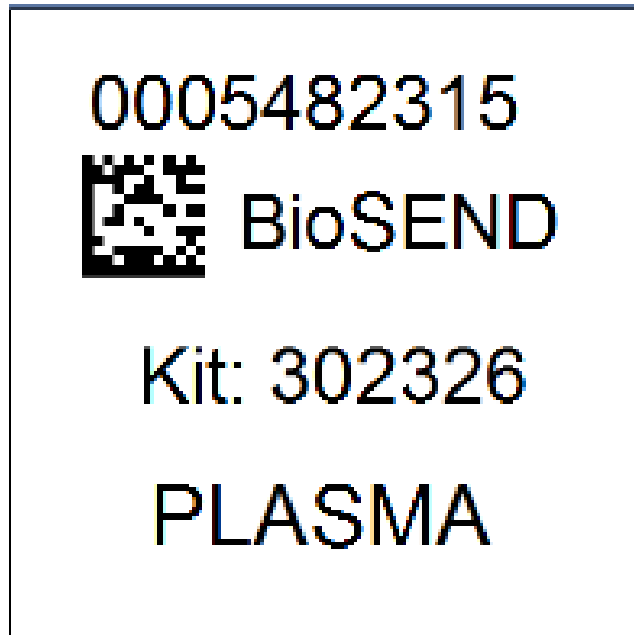
Kit labels are placed:

- On the biohazard bags
- On the lid of frozen shippers



# Sample Labelling – Specimen Labels

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**Unique Barcode**



**Biorepository Name**



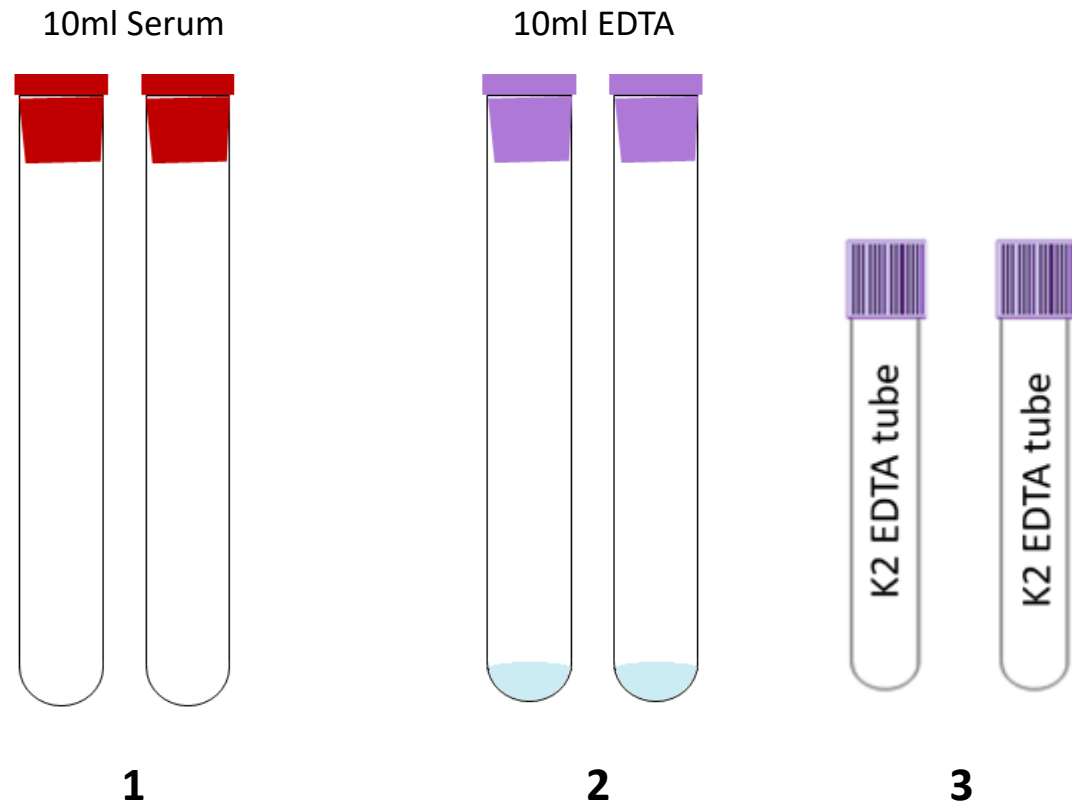
**Kit Number**



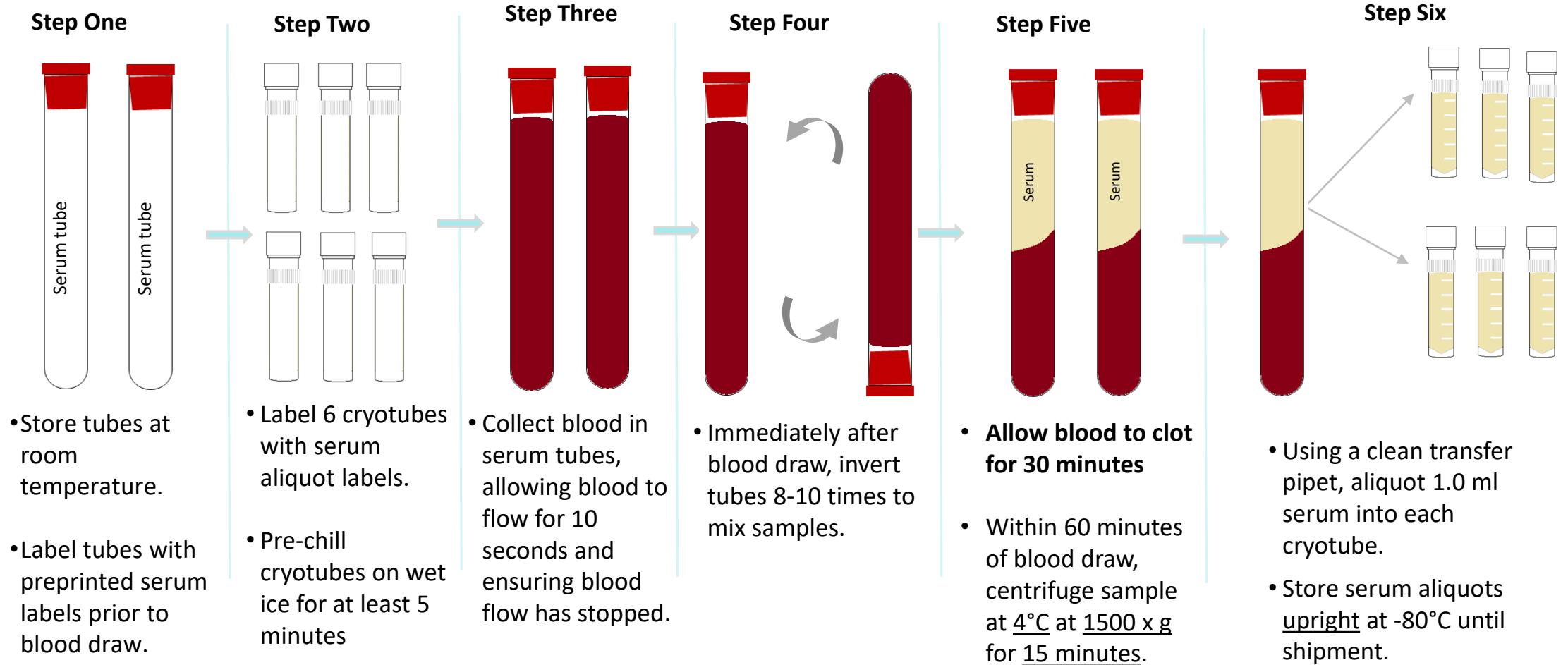
**Sample Type**

# Sample Collection and Processing

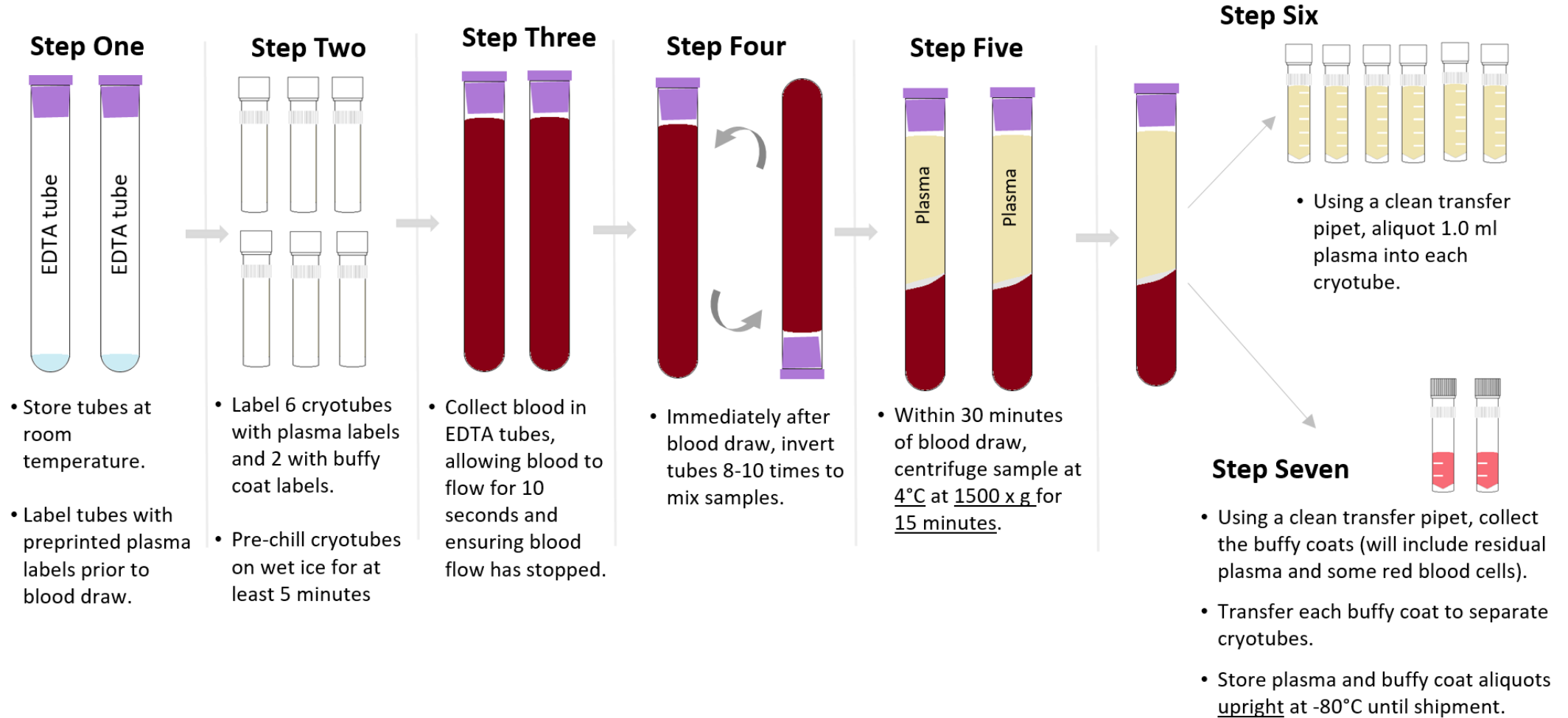
Blood Tube Draw Order



# Sample Collection and Processing: Serum



# Sample Collection and Processing: Plasma & Buffy Coat



# Sample Collection and Processing: Whole Blood

## Step One



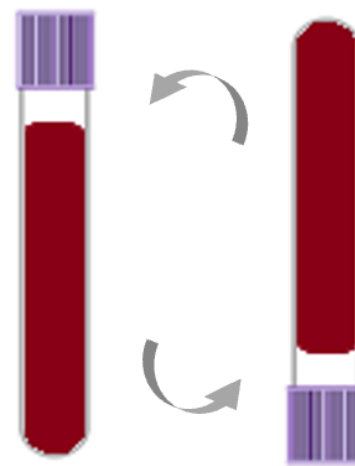
- Store tubes at room temperature.
- Label tubes with preprinted WBLD label prior to blood draw.

## Step Two



- Collect blood into both 3ml EDTA tubes, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

## Step Three



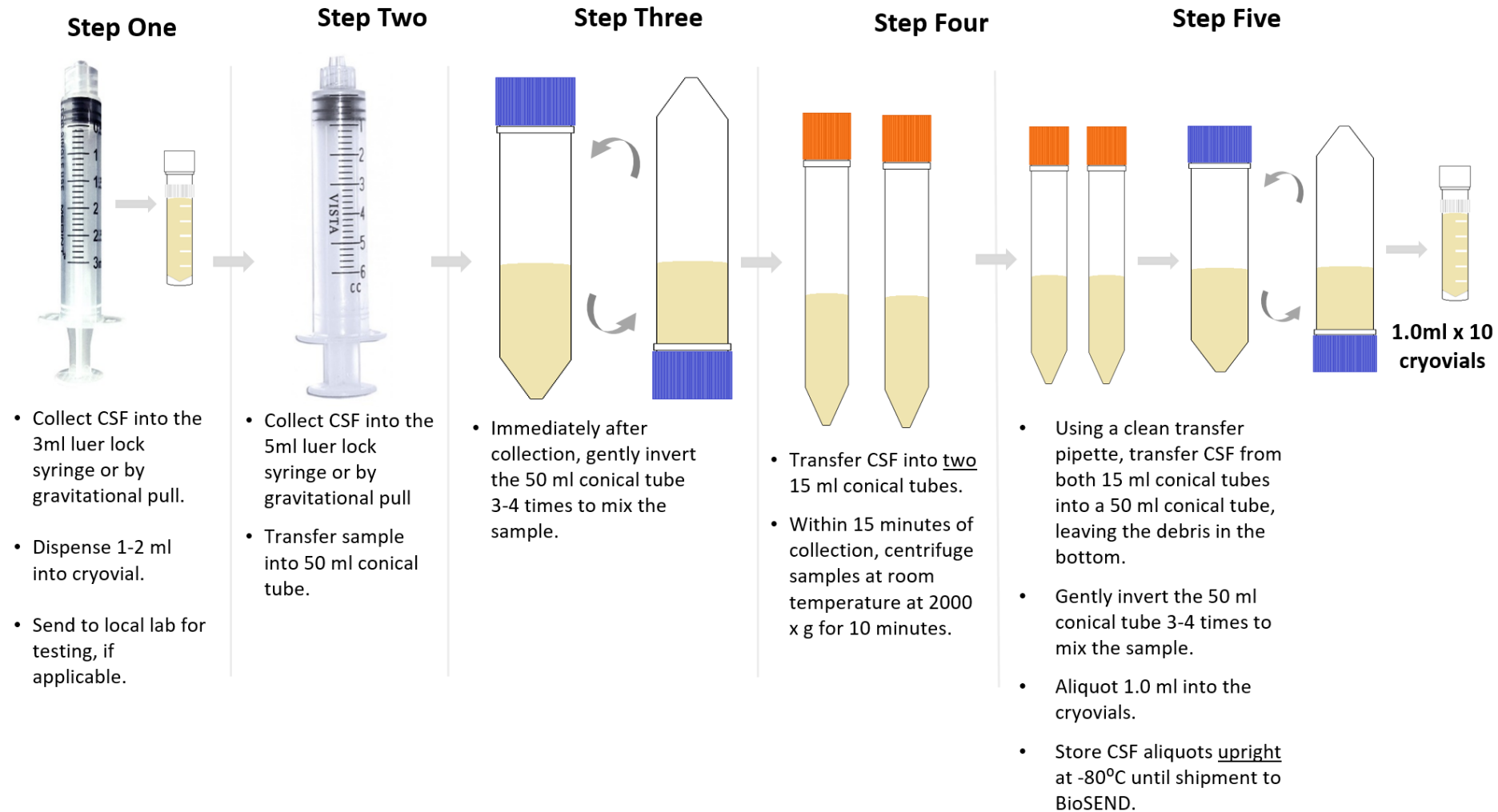
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

## Step Four



- Transfer to -80°C. Store upright and keep frozen until shipment to BioSEND.

# Sample Collection and Processing: CSF



# Shipping Samples: Frozen

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## Packing and Shipping Frozen Samples

- Please ship samples as they are collected (within two weeks of collection)
- All CRC-SCA samples ship frozen on dry ice
- Frozen samples should be shipped **Monday through Wednesday only**





# Shipping Samples: Frozen

## Packing and Shipping Frozen Samples

- Fill shippers with a minimum of 10lbs of dry ice
- Place cryobox and whole blood in separate biohazard bags
- Place layer of dry ice in between biohazard bags
- Do not pack shipment until the day of pickup



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

# Shipping Samples

Labeling frozen shippers

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.  $\frac{\quad}{\text{(Number pkgs)}} \times \frac{\quad}{\text{(wt)}} \text{ Kg}$

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

06426 1/01 FRD

# Shipping Samples

UPS resources available on BioSEND website on the “Shipping Information” page

The screenshot shows the BioSEND website navigation menu. The logo is 'NINDS BioSEND'. The main navigation items are 'Accessing Biospecimens', 'Banking Samples', 'Active Studies', and 'About BioSEND'. A blue arrow points from 'Banking Samples' to 'Active Studies'. Below 'Active Studies' is a dropdown menu with the following items: 'SPARX3 Study Resources', 'Udall Study Resources', 'Holiday Closures', 'Shipping Information' (highlighted with a blue arrow), 'Sample Shipment Form', and 'Withdrawn Subject Notification'. Below the menu are three small images: a building with green trees, a close-up of a metal container, and a dark interior space.

**NINDS BioSEND**

Accessing Biospecimens      Banking Samples → Active Studies      About BioSEND

- AJPD Study Resources
- CHANGE-HD Study Resources
- DLB Study Resources
- DVRP Study Resources
- EpiBioS4Rx Study Resources
- LBD Study Resources
- LETBI Study Resources
- MBPS Study Resources
- PBS Study Resources
- PHD3 Study Resources
- PSP Study Resources
- SBPD Study Resources
- CRC-SCA Study Resources
- READISCA Study Resources
- SPARX3 Study Resources
- Udall Study Resources
- Holiday Closures
- Shipping Information**
- Sample Shipment Form
- Withdrawn Subject Notification

# Shipping Information Page

Links on this page to:

1. Generate airwaybills & schedule pickups
2. View printed guide on how to use ShipExec™
3. Request user account and update site address in system
4. View video tutorial for using UPS ShipExec™

## UPS Shipping Resources

1 →

To generate air waybills and schedule UPS pickups for shipments to BioSEND, please visit the UPS ShipExec™ Thin Client [website](#).

2 →

For instructions on how to use the UPS ShipExec™ Thin Client website, please refer to the [BioSEND UPS ShipExec™ Thin Client Guide](#)

3 →

To request a new user account for UPS ShipExec™ Thin Client or to request an update to your site's address in the system, please [use this form](#) to submit your request.

## Navigating UPS ShipExec™

4 →

The screenshot shows the UPS ShipExec™ Thin Client Home Page. At the top, there is a navigation bar with the ShipExec logo and links for Home, Help, and User Profile. Below the navigation bar, the page title reads "Welcome to the ShipExec™ Thin Client Home Page". The main content area is divided into two columns: "System Notifications" and "Company Notifications". Under "System Notifications", there are two links: "ShipExec Documentation" and "Importing Your Personal Address Book". Under "Company Notifications", there is a message: "No Company notifications to display". A large video player overlay is centered on the page, showing a play button and a progress bar at the bottom indicating 0:58 / 9:18. The video player also includes volume, full screen, and other standard controls.

# Shipping Samples

UPS

- 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



# Shipping Samples: Frozen

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Please notify BioSEND ahead of shipment

- Please complete the Sample Record and Notification Form in REDCap ahead of shipment (can be completed day of shipment).
  - A completed copy of this form should be included in the sample shipper
- If you are having trouble unable to use REDCap, please complete Sample Form by hand and notify BioSEND directly of shipment at [biosend@iu.edu](mailto:biosend@iu.edu)

# Sample Collection and Processing Form

<http://kits.iu.edu/biosend/CRCSCASampleForm>

Form captures site contact info, basic subject and visit information, and sample manifest



Returning?

AAA



## CRC-SCA Sample Record and Shipment Notification Form

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the Sample Record and Shipment Notification Form will be emailed to you.

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

**Study Site:**

**Email address of staff member completing this form**

*Note: A copy of the completed sample form will be sent to this address.*

**Local ID:**

Formatted like IU-01-001

**IU Kit Number:**

6 digit number on BioSEND labels

**Sex (used for DNA quality control)**

**Visit:**

# Sample Collection and Processing Form

<http://kits.iu.edu/biosend/CRCSCASampleForm>

PDF form of responses will be emailed to you. **Print a copy and include with shipment.**

## CRC-SCA Sample Record and Shipment Notification Form Page 1

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the Sample Record and Shipment Notification Form will be emailed to you.

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

Study Site:

- Columbia University
- Emory University
- Houston Methodist Hospital
- Johns Hopkins University
- Massachusetts General Hospital (Harvard Medical School)
- Northwestern University
- University California-Los Angeles
- University California-San Francisco
- University of Chicago
- University of Florida
- University of Michigan
- University of Minnesota
- University of Montreal Hospital (CRCHUM)
- University of Pennsylvania
- University of South Florida
- University of Texas Southwestern
- University of Washington

Email address of staff member completing this form

\_\_\_\_\_

Note: A copy of the completed sample form will be sent to this address.

Local ID:

\_\_\_\_\_  
(Formatted like IU-01-001)

IU Kit Number:

\_\_\_\_\_  
(6 digit number on BioSEND labels)

Sex (used for DNA quality control)

- Female
- Male
- Other - provide details

Other - provide details

\_\_\_\_\_



# Shipping Samples: Closures

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

\*Please also consider weather when shipping. UPS will post service updates on their webpage. Please reach out to BioSEND if you are unsure if it is safe to ship.

# Non-Conformance

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Most common non-conformance issues:

- Samples shipped for weekend/holiday delivery
- Sample form incomplete/inaccurate
- Unlabeled or mislabeled tube(s)
- Sample hemolysis



# Non-Conformance

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- BioSEND will notify sites directly of any issues upon receipt
- Non-conformance is reported on a monthly basis to NINDS and NAF
- Continued non-conformance may result in required re-training and notification to site PI
- ***If you are experiencing issues, please reach out to us for help! It is much easier to prevent an issue before sample collection & shipment than trying to fix it after the fact***

# Contacts

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## Indiana University

General Questions/Shipment Notifications:

[biosend@iu.edu](mailto:biosend@iu.edu)