



**STRATEGY FOR IMPROVING STROKE TREATMENT
RESPONSE (SISTER) TRIAL**

Laboratory Manual

Protocol Number: TS23/DS9231-U202

National Clinical Trial (NCT) Identified Number: NCT05948566

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Summary of Changes from Previous Version:

Affected Section(s)	Summary of Revisions Made	Rationale
4.1	Inclusion of Coagulation Panel to baseline and post study drug administration tables	Clarification
4.3	*Note added to contact RCL if access to -80°C freezer is not possible.	Clarification

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1 List of Abbreviations and Definitions

α 2AP / a2AP	Alpha 2-antiplasmin
ADA	Anti-drug antibodies
BMP	Basic metabolic panel (glucose, calcium, sodium, potassium, carbon dioxide, chloride, and BUN creatinine)
BUN	Blood urea nitrogen
CBC	Complete blood count
CLIA	Clinical Laboratory Improvement Amendments
CMP	Complete metabolic panel
CPS	Clinical Performance Sites
EDTA	Ethylenediaminetetraacetic Acid
ELISA	Enzyme-Linked Immuno-Sorbent Assay
eMR	Electronic Medical Record
MMP-9	Matrix metalloproteinase-9
mRNA	Messenger Ribonucleic Acid
NT-proBNP	N-terminal pro-brain natriuretic peptide
PK	Pharmacokinetic
RCF	Relative Centrifugal Force (g force)
RCL	Reed Central Laboratory
SOP	Standard Operating Procedure
TS	Translational Sciences, Inc.
UN1845	Dry Ice Label
WebDCU™	Web based Clinical Trial Management System (CTMS) containing a web-based study drug shipping and management component, which allows for study central laboratory sample(s) management at the CPS.

2 Laboratory Contacts

Translational Sciences, Inc. (TS) will be the central lab providing frozen storage, inventory, and sample analysis for the SISTER trial.

Name:	Phone:	Email:
Inna Gladysheva, PhD	706-589-9100	igladysheva@translationalsciences.com
Joseph S.Y. Jeong, PhD	919-282-7718	sunyongj@translationalsciences.com
Ryan Sullivan, DVM, RLATG	352-213-1045	rsullivan@translationalsciences.com

WebDCU™ system will be utilized for all supply orders, tracking of site stored samples, and shipping matrices.

Access: [WebDCU™ \(musc.edu\)](http://WebDCU™(musc.edu))

Name:	Phone:	Email:
Katie Stever, MPH	843-876-1114	steverca@musc.edu
Aaron Perlmutter, MPH, MSW	843-792-2784	perlmutt@musc.edu
Riley Luckmann		luckmann@musc.edu

SISTER Trial Project Managers.

Name:	Phone:	Email:
Pam Plummer, MSN, RN, CCRC	513-885-2437	plummepa@ucmail.uc.edu

Dry Ice Sources:

Dry Ice Directory – <http://www.dryicedirectory.com>

Penguin Dry Ice – <http://penguindryice.com/>

Central Labs:

UACOMP Reed Laboratory
475 N. 5th Street
Biomedical Sciences Partnership Building, 8th Floor
Phoenix, AZ 85004
USA

KCAS Bioanalytical Services
12400 Shawnee Mission Parkway
Shawnee, KS 66216
USA

3 Introduction

This manual provides details and instructions regarding the laboratory procedures, timing, and sample processing necessary to complete the schedule of events as outlined in the SISTER trial protocol (TS23-A-U202). Focus has been given to the receipt of supplies, data acquisition, sample inventory, proper storage, and shipping or transfer of all study materials related to the central lab.

All activities related to local or central labs will be processed as outlined within this document in accordance with StrokeNet, Sponsor, institutional/local and Federal policies for safe, effective, ethical, and reproducible production and management of samples throughout the trial.

The main study considerations for central lab include:

- Plasma samples for Translational Science (TS) and KCAS Bioanalytical.

3.1 Study Overview

SISTER is a Phase IIa, Bayesian, adaptive, randomized dose-finding trial of TS23 (monoclonal antibody inactivating alpha-2-antiplasmin, a2AP) in patients with acute ischemic stroke. The study will randomize to 4 doses of TS23 (3, 5, 7, 10 mg/kg) and placebo. The trial will randomize and treat 300 subjects. The first 50 subjects will be randomized in a dose escalation burn-in period, allocating 10 subjects to each group starting with the lowest dose. Response Adaptive Randomization updates will occur every 50 subjects, thereafter, (favoring doses with maximum utility). For each block of 50 subjects, 13 are allocated to saline control. The trial may stop early for safety.

Up to 50 sites are planned for the trial. We hypothesize that TS23 will be safe and potentially more efficacious than placebo for the enrolled group of patients.

4 Central Laboratory

Translational Sciences, Inc. has a central laboratory located on the Phoenix Biomedical Campus in Phoenix, Arizona – REED CENTRAL LABORATORY (RCL). All designated RCL frozen plasma samples will be collected from the individual Clinical Performance Sites (CPSs) and shipped or transferred to the RCL for further processing according to a site-specific frequency schedule (batch shipping, ~6 months).

4.1 Laboratory Tests for SISTER Trial

All labs must be drawn from a venipuncture.

All local tests should be collected, processed, and result per institutional practice and SOPs.

- All CPS laboratory department CLIA certification and standard lab results document will be uploaded into the site regulatory place holders in WebDCU™.

All designated RCL plasma samples should be collected and stored per the corresponding sections within this manual.

Common vacutainer tubes used for sample collections:

Red top tube, serum separator = Serum (CMP, BMP, Lipids, Pregnancy test)

Purple/Lavender top tube, EDTA = Whole blood (CBC)

Light blue top tube, Sodium Citrate = Plasma (Clotting panel, Fibrinogen, a2AP, MMP-9, PK, ADA)

Baseline – Pre-Randomization & Randomization to Study Drug Administration

Test	Volume per test (mL of whole blood)	Sample and Site	Number of Time-points per Subject	Total Volume per Subject (mL)
		Local Lab		
		Reed Central Lab		
Pregnancy Test	3	Serum or Urine	1	3
Hematology – CBC*	3	Whole Blood	1	3
Serum chemistry* ^{&}	7	Serum	1	7
Coagulation Panel*	3	Plasma	1	3
Fibrinogen [#]	3	Plasma	1	3
α ₂ AP activity [#]	3	Plasma (-80°C; send to RCL)	1	3
MMP-9 [#]	3	Plasma (-80°C; send to RCL)	1	3
PK samples [#]	3	Plasma (-80°C; send to RCL)	1	3
Anti-drug antibodies [#]	3	Plasma (-80°C; send to RCL)	1	3

*Baseline laboratory evaluations (first measurements upon presentation to study hospital): Glucose, creatinine, aPTT, PT with INR, CBC, platelet count.

[#]Baseline laboratory evaluations (prior to study drug administration): fibrinogen, a2AP activity, MMP-9 level and PK studies.

[&]First value collected during hospitalization: hemoglobin A1C, Lipid Panel containing total cholesterol, HDL, LDL, and triglyceride.

Color Key: orange = samples for local labs, blue = samples for central lab (RCL)

Post Study Drug Administration: Up to and including Day 90

Test	Volume per test (mL of whole blood)	Sample and Site	Number of Time-points per Subject	Total Volume per Subject (mL)
		Local Lab		
		Reed Central Lab		
Hematology - CBC	3	Whole blood	2 (30h, 90d)	6
Serum chemistry [§] BMP / CMP <i>*If collected as SOC</i>	7	Serum	2 (30h, 90d)	14
Coagulation Panel	3	Plasma	1 (30h)	3
Fibrinogen	3	Plasma	2 (3h, 30h)	6

α_2 AP activity	3	Plasma (-80°C; send to RCL)	2 (3h, 30h)	6
MMP-9	3	Plasma (-80°C; send to RCL)	2 (3h, 30h)	6
PK samples	3	Plasma (-80°C; send to RCL)	3 (3h, 30h, 90d)	9
Anti-drug antibodies	6	Plasma (-80°C; send to RCL)	1 (90d)	6

[§]Serum chemistry: 30 (\pm 4) hour visit – BMP; 90 (\pm 7) day visit – CMP, Lipid Panel containing total cholesterol, HDL, LDL, and triglyceride.

Color Key: orange = samples for local labs, blue = samples for central lab (RCL)

4.2 Specimen Collection Schedule:

The SISTER study has 4 different clinical time points for RCL collections, for 4 different tests:

Test	Sample Type	Whole Blood Volume by Time Point				Total:
		Baseline	3 \pm 1 h	30 \pm 4h	90 \pm 7d	
PK	plasma	3 mL	3 mL	3 mL	3 mL	12 mL
Anti-drug antibodies	plasma	3 mL			6 mL	9 mL
α_2 AP activity	plasma	3 mL	3 mL	3 mL		9 mL
MMP-9	plasma	3 mL	3 mL	3 mL		9 mL
	Total:	12 mL	9 mL	9 mL	9 mL	39 mL
# of 2.7 mL Sodium Citrate tubes:		4	3	3	3	13
~Plasma Volume (<50% Blood Volume):		5 mL	4 mL	4 mL	4 mL	17 mL
Estimated 0.5 mL plasma cryovial aliquots:		10	8	8	8	34

4.3 Site Requirements

Sites will provide the following materials to provide plasma samples to RCL:

- 1) Packing Tape
- 2) Sodium Citrate Tubes (light blue top)
 - Example: BD Vacutainer® Plus Venous Blood Collection Tube Sodium Citrate Additive 2.7 mL BD Hemogard™ Closure Plastic Tube, BD#363083
 - Each subject will need 13 tubes total for RCL samples:
 - Baseline: 4 tubes
 - 3h: 3 tubes
 - 30h: 3 tubes
 - 90d: 3 tubes

Please Note: The blood collection tubes have expiration dates printed on them. Please be sure to monitor these expiration dates and reorder tubes locally as necessary throughout the study period.

- 3) Dry Ice (>5kg) for shipping (see links on pg. 5 if not available locally)

***Note:** Supplies costs are covered in the lab sample payment.

Sites will provide the following equipment:

- 1) Centrifuge (with appropriate tube size) – room temperature or refrigeration at 4-8°C
- 2) Refrigerator 4°C – if needing to hold samples prior to spinning
- 3) Freezer -80°C for aliquot storage*
- 4) Indelible/permanent marker (black or blue ink)

***Note:** Contact RCL if access to -80°C freezer is not possible.

4.4 Central Lab Kits

The central laboratory will provide sample collection kits throughout the study period. There is only a single kit, which can be utilized across all four collection time points. Each site will receive an initial shipment of ten (10) laboratory kits and one (1) shipping kit for frozen specimens. See section 4.4.4 for reordering of additional supplies.

Please Note: Each laboratory kit contains ten (10) cryovials. Not all ten (10) cryovials will be used at each time point (see Section 4.2 table). The unused vials can be simply disposed of locally.

4.4.1 Laboratory Kit Contents:

- 1) Kit bag: 5x8 inch, barcode label
- 2) 2.0 mL graduated cryovials with external thread cap (Qty. 10)
 - a. Pre-labeled with Study, Kit ID #, and barcode
- 3) Sterile transfer pipette (disposable)

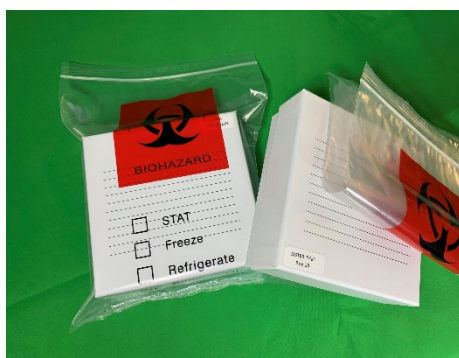
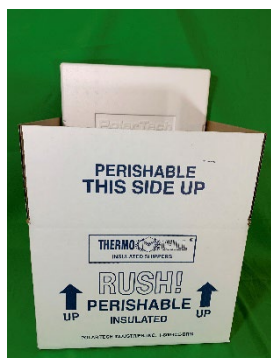


4.4.2 Lab Kit Inventory

- The study site is responsible for updating missing, shipped, and received kits through WebDCU™. Sites will be notified via email when the shipment is sent. Tracking information will be available in WebDCU™.
- Upon receipt, site study personnel will confirm receipt of lab kits in WebDCU™.
- As lab kits are used, the designated site study personnel will enter the lab kit ID in the appropriate biospecimen collection case report form (CRF) in WebDCU™.

4.4.3 Shipping Kit Contents:

- 1) Styrofoam shipper and exterior cardboard box (Qty. 1)
- 2) Shipping labels (Qty. 2 each: Dry Ice UN1845, Exempt Human Specimen)
- 3) Biohazard plastic bags (Qty. 2)
- 4) Storage cryoboxes (Qty. 2)
- 5) Pre-addressed shipping label



Shipping kits will be automatically shipped out to sites upon receiving samples at the RCL. An email notice will be forwarded to the sender for tracking details and date of expected arrival. Every attempt will be made to ensure arrival during business hours (M-F) and to avoid Federal Holidays.

4.4.4 Central Laboratory Supply and Resupply Order

Each site will receive initial supplies prior to site activation. As stated above, the initial supplies shipment will include 10 (ten) Laboratory Kits and one (1) Shipping Kit for frozen specimens. Each laboratory kit contains 10 (ten) cryovials and a sterile pipette.

WebDCU™ will automatically post laboratory kit requests. Resupply kits will be posted in WebDCU™ when the site inventory drops below 3 kits. The RCL cannot guarantee requests placed less than 6 working days before the expected delivery date. Please plan accordingly by allowing a minimum of 7 to 10 business days for receipt of additional supplies. An email notification will be sent to the site when the shipment is sent that includes tracking information.

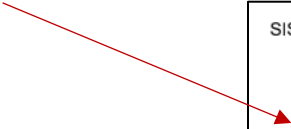
Shipping kits will be mailed directly by the RLC upon receipt of samples (expected batch shipping every ~6 months).


5 Blood Collection and Plasma Sample Processing

5.1 Steps for Plasma Sample Collection

- 1) Ensure all materials are present:
 - a. Central Lab - Plasma Collection Form (eCRF # from WebDCU)
 - b. Sodium citrate 2.7mL vacutainer (Qty. 3-4)
 - c. 2.0 mL cryovials (clear cap, Qty. 10) with vial labels (Lab kit)
 - d. Sterile transfer pipette (Lab kit)

- 2) Collect blood samples from the subject following local institutional policies and standard procedures. Each sodium citrate tube should be filled with 2.7 mL draw volume. Tubes should be >90% filled (9:1 ratio of blood to anticoagulant).
- 3) Immediately following collection, gently invert all tubes 8-10 times, end-over-end, to ensure blood and anti-coagulant are mixed thoroughly.
- 4) Centrifuge immediately after collection at 1500 to 2000 x g (RCF) for 15 minutes at room temperature or 4 °C to produce platelet poor plasma.
 - a. If needing to delay processing – filled sodium citrate tubes can be held at 4 °C for up to 4 hours prior to centrifugation.¹
- 5) Using a disposable pipette, transfer plasma (avoid buffy coat) into provided cryovials in 0.5 mL aliquots (please note if a partial vial, <0.5 mL is collected).
- 6) Return filled cryovials to the laboratory kit bag with label. Fill out label with missing details (Subject ID, Qty of vials, Time point – baseline, 3h, 30h, or 90d) using an indelible/permanent marker (blue or black ink).



SISTER Trial - TS23/DS9231-U202	
Lab Kit ID: 36211	
2mL cryovials x Qty 10; 1 pipette	
	
Subject ID : _ _ _	Qty: _ _
Time point : _____	

- 7) Freeze and store samples at -80°C until shipment to RCL in provided study cryobox.

5.2 Sample Identification Form Completion

Form **181 Biospecimen Collection and Processing** should be completed and printed from WebDCU™. A copy should be made and included with each shipment. Retain the original (source) at the site with the subject's research records or upload into eMR if paperless.

5.3 Plasma Sample Storage and Records

All aliquoted plasma samples should be stored at -80°C until shipping to RCL. Filled cryovials should be returned to the provided labeled Lab Kit Bag. Fill out the label blanks [Subject ID (3-digits), Qty of cryovials (2-digits), and timepoint (baseline, 3h, 30h, 90d)] with an indelible/permanent marker and place bag within the provided cryobox. Each cryobox can hold 4 bags worth of samples. *Tip - Fold bag in half and arrange vials in a single layer (see photos for example).



5.4 Specimen Shipping

Frozen specimens will be shipped in the provided shipper (Shipping Kit) using **FedEx Priority Overnight** courier service to **REED CENTRAL LAB** (RCL). Please email rsullivan@translationalsciences.com (Ryan Sullivan) to secure a printed shipping label.

For reference, the shipping address is:

UACOMP REED CENTRAL LABORATORY
475 North 5th Street
Biomedical Sciences Partnership Building, 8th Floor
Phoenix, AZ 85004
USA

All packaging and labeling provided is designed to:

- Maintain the viability of the specimens during shipping.
- Protect the specimens from damage during shipping.
- Ensure the proper routing and handling of packages when received at the RCL.
- Comply with International Association of Air Transportation (IATA) and US Department of Transportation (D.O.T.) regulations for shipping biospecimens on dry ice.
- All samples must be shipped in IATA compliant Specimen Transport Bags.

To prepare samples for shipping:

1. Verify that each specimen is labeled with the appropriate kit ID number. (Labels already applied to the cryovials.)
2. Print a copy of **F181 Biospecimen Collection and Processing** and include within the box (outside of Styrofoam).
3. Verify that the ID on the eCRF matches the labels on the cryovials.
4. Place each cryobox within a biohazard plastic bag. Remove as much trapped air as possible and seal the bag. Place within Styrofoam shipper.
5. Add >5 kg (maximum of 10kg) of Dry Ice to shipper and close Styrofoam lid. DO NOT SEAL with tape – The evaporating CO₂ gas needs to escape.
6. Tape the outside box closed – ensuring to leave some exposed seams for gas escape.
7. Remove the top copy of the FedEx Shipment Form and attach it to the top of the shipping box.
8. Fill out the provided Dry Ice label (UN1845) with necessary details and attach to the outside cardboard box along with an Exempt Human Specimen label.
9. Arrange for pickup per local site procedures or call FedEx at 1800-463-3339 to schedule directly for a pickup.
10. Once the shipping carrier is ready, follow instructions in 6.4 Specimen Shipping.

5.5 Shipping Schedule

Shipping should be scheduled such that arrivals do not occur on Fridays, Saturdays, Sundays or US Academic and Federal Holidays (listed below). When sending overnight, packages can be shipped Sunday – Wednesday to decrease issues with delays and ensure personnel are available to receive the temperature

sensitive package upon arrival at the RCL. Reminders of upcoming holidays and any lab closures will be shared via the news/update emails throughout the trial.

Holiday	2024	2025	2026	2027
New Year's Day	Mon, Jan 1, 2024	Wed, Jan 1, 2025	Thurs, Jan 1, 2026	Fri, Jan 1, 2027
Winter Closure			Fri, Jan 2, 2026	
Dr. Martin Luther King Jr. Day	Mon, Jan 15, 2024	Mon, Jan 20, 2025	Mon, Jan 19, 2026	Mon, Jan 18, 2027
Washington's Birthday	Mon, Feb 19, 2024	Mon, Feb 17, 2025	Mon, Feb 16, 2026	Mon, Feb 15, 2027
Memorial Day	Mon, May 27, 2024	Mon, May 26, 2025	Mon, May 25, 2026	Mon, May 31, 2027
Juneteenth	Wed, Jun 19, 2024	Thurs, Jun 19, 2025	Fri, Jun 19, 2026	Fri, Jun 18, 2027*
Independence Day	Thurs, July 4, 2024	Fri, July 4, 2025	Fri, July 3, 2026*	Mon, July 5, 2027*
Labor Day	Mon, Sept 2, 2024	Mon, Sept 1, 2025	Mon, Sept 7, 2026	Mon, Sept 6, 2027
Columbus Day	Mon, 14, 2024	Mon, Oct 13, 2025	Mon, Oct 12, 2026	Mon, Nov 11, 2027
Veterans Day	Mon, Nov 11, 2024	Tues, Nov 11, 2025	Wed, Nov 11, 2026	Thurs, Nov 11, 2027
Thanksgiving Day	Thurs, Nov 28, 2024	Thurs, Nov 27, 2025	Thurs, Nov 26, 2026	Thurs, Nov 25, 2027
Thanksgiving Closure	Fri, Nov 29, 2024	Fri, Nov 28, 2025	Fri, Nov 27, 2026	Fri, Nov 26, 2027
Christmas Eve	Tues, Dec 24, 2024	Wed, Dec 24, 2025	Thurs, Dec 24, 2026	Thurs, Dec 23, 2027*
Christmas Day	Wed, Dec 25, 2024	Thurs, Dec 25, 2025	Fri, Dec 25, 2026	Fri, Dec 24, 2027*
Winter Closure	Thurs, Dec 26 - Tues, Dec 31, 2024	Fri, Dec 26 - Wed, Dec 31, 2025	Mon, Dec 28 - Thurs, Dec 31, 2026	Mon, Dec 27 - Fri, Dec 31, 2027

* Indicates holidays that are observed on dates other than the actual day, due to the holiday falling on a weekend.

Sites with local requirements for shipping during hurricane season or other special circumstances related storage limitations should forward a copy of the corresponding policy to the RCL (rsullivan@translationalsciences.com) so that alternative shipping arrangements can be made as needed.

6 WebDCU™ Procedures

6.1 Access and Training for WebDCU™

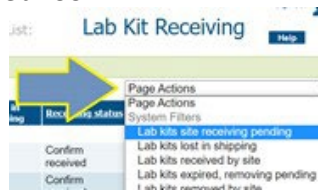
General access for WebDCU™ should be coordinated through the WebDCU™ team. The Primary Study Coordinator (PSC) can request access for those CPS team members who don't have access. They will need to be added to the Delegation of Authority log in WebDCU™ with the appropriate roles and responsibilities. WebDCU™ specific training is available through formal training events, self-study within the program (videos and tutorials), and upon request.

6.2 Lab Kit Receiving

1. Once you receive a lab kit at your site, log into WebDCU™, click on [Study Material Tracking] and then [Lab Kit Receiving].

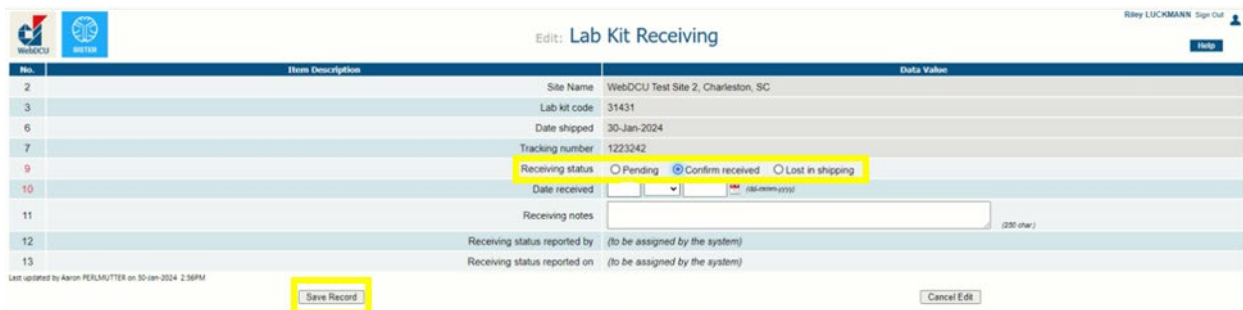
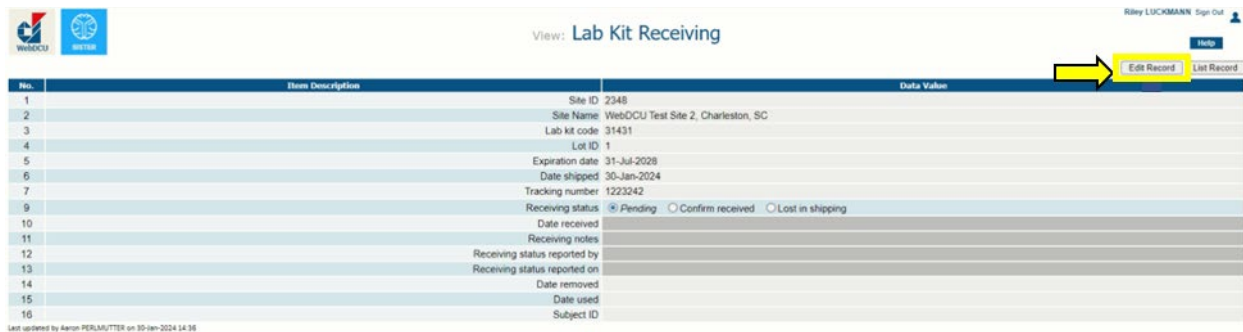


2. In the upper right-hand corner of the Lab Kit Receiving table, click on the 'Page Actions' drop-down menu to filter for 'Lab Kits site receiving pending'. This will show you all the lab kits that have been shipped to your site but not yet marked as received in WebDCU™.



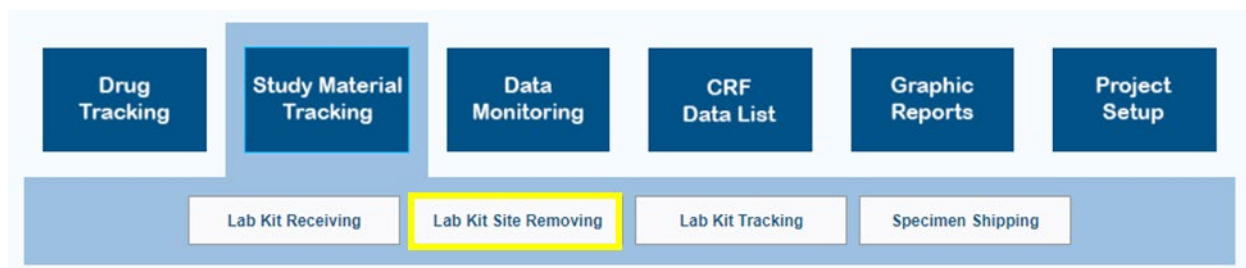
3. Find the lab kit code you received and click the blue hyperlink # next to that code.

4. When the record populates, click on 'Edit Record' and select the appropriate receiving status. Last, click on [Save Record].



6.3 Site Removing Lab Kit

1. This step should only be performed if an unused kit that has been sent to the site needs to be removed from the site's inventory (e.g., damaged, misplaced, etc.) To remove a lab kit at your site, log into WebDCU™, click on [Study Material Tracking] and then [Lab Kit Removing].



2. In the upper right-hand corner of the Lab Kit Removing table, click on the 'Page Actions' drop-down menu to filter for 'Lab Kits Expired, Removing Pending'. This will show you all the lab kits in inventory that have expired but have not yet been marked as removed in WebDCU™.
3. Find the lab kit code you want to remove and click the blue hyperlink # next to that code. Click and select confirm on this form to be edited. Enter the *Date Removed* and *Removing Type*; if *Other* is selected, provide additional information in *Other Reason for Removing*. Last, click on [Save Record].

No.	Item Description	Data Value
2	Site Name	WebDCU Test Site 2, Charleston, SC
3	Lab kit code	30931
5	Expiration date	31-Jul-2028
6	Date received	30-Jan-2024
Important instruction: Lab kits can be removed from site inventory due to any reason that makes the lab kit not available for subject use.		
7	Removing confirm	<input type="radio"/> No <input checked="" type="radio"/> Yes
9	Date removed	<input type="text" value=""/>
8	Removing type	<input type="radio"/> Expired <input type="radio"/> Damaged <input type="radio"/> Missing <input type="radio"/> Returned <input type="radio"/> Recall <input type="radio"/> Quarantined <input type="radio"/> Temperature excursion <input type="radio"/> Site closing <input type="radio"/> Other
10	Other reason for removing	<input type="text" value=""/>
11	Removing notes	<input type="text" value=""/>
12	Removing confirmed by	(to be assigned by the system)
13	Removing confirmed on	(to be assigned by the system)

6.4 Specimen Shipping

1. After **F181 Biospecimen Collection and Processing** in Subject CRF Binder in WebDCU™ has been completed, the collected specimen should be stored for shipment as outlined in this manual (shipping to be batched twice a year). To ship samples to the REED CENTRAL LAB, click on [Study Material Tracking] and then [Specimen Shipping].



- Find the lab kit code for the specimen you plan to send and click the blue hyperlink # next to the lab kit code.

#	Site ID	Site Name	Lab kit code	Lab kit expiration Date	Subject ID	Specimen collection date	Specimen shipping date	Specimen shipment tracking number	Specimen kit in shipping	Specimen central lab received on	Specimen in good condition
1	2347	WebDCU Test Site 1, Charleston, SC	30001	31-Jul-2028	102	25-Jan-2024					
2	2347	WebDCU Test Site 1, Charleston, SC	30126	31-Jul-2028	103	25-Jan-2024	25-Jan-2024			25-Jan-2024	Yes
3	2347	WebDCU Test Site 1, Charleston, SC	30247	31-Jul-2028	181	25-Jan-2024	25-Jan-2024			25-Jan-2024	Yes
4	2347	WebDCU Test Site 1, Charleston, SC	30252	31-Jul-2028	104	25-Jan-2024					
5	2347	WebDCU Test Site 1, Charleston, SC	30285	31-Jul-2028	188	30-Jan-2024					

- Click 'Edit Record' and select 'Yes' for *Specimen Shipping Confirm*. This will enable the remaining fields on this form to be edited. Enter the shipping date, FedEx tracking number, and any shipping notes (if needed). Last, click on [Save Record].

No.	Item Description	Data Value
2	Site Name	WebDCU Test Site 1, Charleston, SC
3	Lab kit code	30285
5	Subject ID	188
6	CRF ID	1834
7	Specimen collection date	30-Jan-2024
8	Specimen shipping confirm	<input type="radio"/> No <input checked="" type="radio"/> Yes
9	Specimen shipping date	30-Jan-2024
10	Specimen shipment tracking number	<input type="text" value=""/>
11	Specimen shipping notes	<input type="text" value=""/>
12	Specimen shipped by	(to be assigned by the system)
13	Specimen shipping dated on	(to be assigned by the system)

- To print the Lab Kit Packing Slip: From the [Specimen Shipping] list table, click on the green arrow icon link for the 'Specimen Packing Slip' column for the specimen lab kit(s) ID you plan to ship.
- Print the Lab Kit Packing Slip for each specimen lab kit(s) ID you plan to ship.

Note: The Lab Kit Packing Slip will not include a list of individual tubes.

- Check the accuracy of the package prior to shipping.
 - First, use the biospecimen collection eCRF to ensure that all samples collected for the specimens and Lab Kit ID are included in the package.
 - Then verify that the Lab Kit IDs listed on the packing slip match what is in the package.
- The study team member preparing the shipment should sign and date the packing slip. Please make sure to retain a copy of all forms packaged in the shipping kit in your regulatory binder.

6.5 Specimen Receiving

When the shipment is received or lost during shipment, the RCL representative will log into WebDCU™ to confirm receipt of each sample. Once receipt is entered into the program, the CPS will receive an automated email notification confirming shipment status. The automated email notifications do not need to be retained in the site's study record.

- Once confirmation of receipt of specimens has been entered into WebDCU™ by the central lab, an invoice will automatically be generated so that the CPS is paid for the specimens received. Please note, to receive this payment, all specimens required to be collected, per protocol, must be received.

6.6 Discrepancies of Items

If there are discrepancies found when receiving kits (either by the site or the RCL), or if the WebDCU™ system is inconsistent with any current site or Central Lab inventories, please utilize the contact list from Section 2 for the appropriate member.

7 References

1. Tuck MK, Chan DW, Chia D, Godwin AK, Grizzle WE, Krueger KE, Rom W, Sanda M, Sorbara L, Stass S, Wang W, Brenner DE. Standard operating procedures for serum and plasma collection: early detection research network consensus statement standard operating procedure integration working group. *J Proteome Res.* 2009 Jan;8(1):113-7. Doi: 10.1021/pr800545q. PMID: 19072545; PMCID: PMC2655764.

8 Attachments:

8.1 Plasma Collection Form

Step-by-Step Instructions:

1. Collect blood into a **2.7 mL Blue Top Sodium Citrate tube**.
2. Fill until blood flow stops.
- 3. The tube will not appear full.**
4. If the draw tube is less than 90% of the fill line, the sample should be recollected.
5. When using a winged blood collection set (butterfly needle with attached tubing) and the citrate tube is the first tube being drawn, first draw a discard tube using a non-additive tube.
6. The discard tube does not need to be filled completely.
7. Mix immediately by gently inverting the tube(s) at least 8 to 10 times.
8. Prior to centrifugation, gently rock the tube back and forth while examining the sample for visible clots.
9. If visible clot is seen, recollect the sample.

10. Promptly centrifuge at 1500 to 2000 x g for no less than 15 minutes until cells and plasma are separated. (Hold at 4°C if necessary to delay centrifugation up to 4 hours)
11. Use pipette to promptly transfer the plasma into the appropriately labeled **2.0 ml barcoded cryovial(s) with external thread cap**.
12. Do NOT touch or pipette the interface (hazy layer between the cells and plasma).
13. Freeze immediately and hold the collected samples at -80°C until shipment.
14. Shipments will be batched every ~6 months.

8.2 Dry Ice Label Instructions

How to fill out dry ice label (UN1845):

Note: It is required that CPS team members assigned to shipping specimens be trained in handling/shipping dry ice.

Shipper's Declaration not Required.
Part B is required.
Dry Ice amount must be in kilograms.
Note: 2 lbs. = 1 kg.

Airbills/Airbills must have the following:
1. "Dangerous Goods - Shipper's Declaration not required".
2. Dry Ice: 9; UN1845;
3. 1 x 6.0 kg
(Number of packages) (net)

DRY ICE
5.0 kg.

9

UN1845

Shipper's Name and Address
Site shipping
address

Consignee Name and Address
UACOMP REED LABORATORY
475 N 5th Street, BSPB 8th Floor
Phoenix, AZ 85004

- a. Enter number and weight of the entire box in kg (2 lb. = 1 kg)
- b. Enter the weight of the dry ice in kg
- c. Attach the Shipper's Name and Address Label
- d. Attach Consignee's/site address label (REED CENTRAL LAB shipping address)