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LHTP003.08.19: Streck Tube: Human Blood Collection and Specimen Submission

Effective Date: 01/02/2025

Please check for revision status of the SOP at

http://dctd.cancer.gov/drug-discovery-development/assays/validated-biomarker-assays

and be sure to use the current version.

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Version History

1. Approvals

Technical Reviewer:	Brandon Miller	Approval: Brandon L. Miller -S (Affiliate) Digitally signed by Brandon L. Miller -S (Affiliate) Date: 2025.02.26 12:04:55 -05'00'
IQC Approval:	Li Li	Approval: LI LI -S (Affiliate) Digitally signed by LI LI -S (Affiliate) Date: 2025.02.26 12:18:50 -05'00'
LHTP Approval:	Katherine V. Ferry-Galow	Approval: Katherine V. Ferry-galow -S (Affiliate) Digitally signed by Katherine V. Ferry-galow -S (Affiliate) Date: 2025.02.27 20:47:07 -05'00'
DCTD OD Approval:	Toby Hecht	Approval: Toby T. Hecht -S Digitally signed by Toby T. Hecht -S Date: 2025.03.06 20:21:46 -05'00'

2. Change History

Revision	Approval Date	Description	Originator	Approval
A	01/02/2025	Addition of ETCTN Specimen Tracking System (STS) instructions; Change of document format.	LL/RA/AP	KFG
--	6/5/2019	New Document	AP/RA	RJK

1.0 PURPOSE

The purpose of this SOP is to describe the procedures for collection, handling, and shipment of human blood specimens in Streck blood collection tubes from clinical centers. The Streck blood tube collections will be used for enrichment and analysis of circulating tumor cells (CTCs).

2.0 SCOPE

This SOP applies to all clinical center personnel responsible for the collection, handling, and shipment of blood specimens from patients participating in clinical trials to Pharmacodynamic Assay Development and Implementation Section (PADIS), Laboratory of Human Toxicology and Pharmacology (LHTP), at Frederick National Laboratory for Cancer Research (FNLCR) for CTC analyses.

3.0 ABBREVIATIONS

CRT	=	Controlled Room Temperature
CTC	=	Circulating Tumor Cell
CTEP	=	Cancer Therapy Evaluation Program
DCTD	=	Division of Cancer Treatment and Diagnosis
ETCTN	=	Experimental Therapeutics Clinical Trials Network
FNLCR	=	Frederick National Laboratory for Cancer Research
LHTP	=	Laboratory of Human Toxicology and Pharmacology
OD	=	Office of the Director
OSHA	=	Occupational Safety and Health Organization
PADIS	=	Pharmacodynamic Assay Development and Implementation Section
PD	=	Pharmacodynamic(s)
PK	=	Pharmacokinetic(s)
RT	=	Room Temperature, 18-25°C
SOP	=	Standard Operating Procedure
STS	=	Specimen Tracking System

4.0 INTRODUCTION

Specimen handling, shipping, and storage procedures (pre-analytical variables) can have a significant impact on the reliability of biomarker measurements in the laboratory. Following detailed steps for sample collection and handling procedures and recording any deviations from this procedure allows retrospective identification of artifactual changes in biomarker readout and increases the reliability of the data and validity of the analytical results.

5.0 RESPONSIBILITIES

Laboratory Director/Supervisor	The Laboratory Director/Supervisor directs laboratory operations, supervises technical personnel and reporting of findings, and is responsible for the proper performance of all laboratory procedures. The Director/Supervisor oversees the personnel who follow the SOPs in the laboratory and is responsible for ensuring the personnel are certified and have sufficient experience to handle clinical samples.
Certified Assay Operator and/or PK/PD Support Lab Personnel	A Certified Assay Operator and/or PK/PD Support Lab personnel may be a Laboratory Technician/Technologist, Research Associate, or Laboratory Scientist who has been certified through DCTD training on this SOP and works under the guidance of the Laboratory Director/Supervisor. This person performs laboratory procedures and examinations in accordance with the current SOP(s), as well as any other procedures conducted by a laboratory, including maintaining equipment and records and performing quality assurance activities related to performance.

5.1 It is the responsibility of the Laboratory Director/Supervisor to ensure that all personnel have documented training and qualification on this SOP prior to the actual handling and processing of samples from clinical trial patients.

5.2 It is the responsibility of the Certified Assay Operator and/or PK/PD Support Lab Personnel to confirm scheduled sample collection time points, pre-print all labels and data collection sheets in advance, check documentation for accuracy, and verify that the required collection tubes, supplies, and equipment are available for successful collection and handling of blood samples.

5.3 It is the responsibility of the Certified Assay Operator and/or PK/PD Support Lab Personnel to ensure timely transport of the samples, enter and review all the required collection data, and archive all data sheets in the appropriate location.

5.4 Certified Assay Operators and/or PK/PD Support Lab Personnel following this SOP are required to be certified to work safely with bloodborne pathogens in research laboratories in accordance with current OSHA Bloodborne Pathogen Standards (29 CFR 1910.1030).

5.5 A Specimen Submission Form (Appendix 1) should be prepared for each batch of patient samples prior to shipment to the processing laboratory for analysis. All samples must be shipped via FedEx Priority Overnight on the same day as collection. This form must be completed for each sample shipment.

NOTE: If a sample is collected after the FedEx pickup for that day, it should go out on the first available pick up the next day (via FedEx Priority Overnight).

5.6 The responsible personnel are to check the DCTD Biomarkers site (http://dctd.cancer.gov/drug-discovery-development/assays/validated-biomarker-assays) to verify that the latest SOP version is being followed.

6.0 MATERIALS AND EQUIPMENT REQUIRED

6.1 **All blood shipment containers and specimen collection kits will be provided by FNLCR PD Support.** See Section 7.2 for ordering instructions.

6.2 Required blood collection and shipping supplies:

6.2.1 Blood Shipment Containers

- Cardboard shipping box
- Two controlled room temperature (CRT) gel packs
- Insulating Styrofoam container

6.2.2 Specimen Collection Kits

- Streck Cell-Free DNA BCT® blood collection tubes, 10.0 mL draw capacity (Streck, Cat#: 218962)
- 50.0 mL Falcon tube containing absorbent paper (secondary holding tube)
- 6″ × 9″ biohazard specimen bag
- Zip-lock bag—to protect Specimen Submission Form (Appendix 1) upon shipment

6.2.3 FedEx Priority Overnight return label(s) pre-addressed with NCI account and address information (Section 8.4.1.1)

NOTE: AccuCyte® Cell-Free DNA blood collection tubes, 9 mL draw capacity (RareCyte, Cat#: 20-1069-004), can be used in place of Streck blood collection tubes.

NOTE: Do not use blood collection tubes after the expiration date which is printed on each individual tube. Tubes must be used as specified by the manufacturer.

7.0 OPERATING PROCEDURES

7.1 Sample Collection, Handling and Shipping Requirements

7.1.1 **Processing limitation**: A *minimum* volume of 8.0 mL of blood in the 10.0 mL Streck blood collection tube is required for processing.

7.1.2 Blood samples **MUST** be stored, transported, and processed at RT (18–25°C).

7.1.3 Store CRT gel packs between 18°C and 25°C (RT). **Do not refrigerate or freeze** CRT gel packs.

7.1.4 All samples **MUST be shipped within 24 hours of collection** to ensure processing of blood samples within the 48-hour post collection time requirement.

7.1.5 Blood collections and sample shipments on Fridays, and/or any business day prior to a federal holiday are **not permissible**, due to the **48-hour processing restriction**.

7.1.6 FNLCR PD Support must be notified as soon as possible of all SOP deviations or issues, prior to shipment of sample(s); in addition, the deviations or issues must be noted on the Specimen Submission Form (Appendix 1)

7.2 Ordering Blood Shipment Containers and Specimen Collection Kits

Blood shipment containers and specimen collection kits can be requested by e-mail to FNLCR PD Support (**NCI_PD_Support@mail.nih.gov**).

7.2.1 Specify in the request the *number* of shipment containers needed.

7.2.2 Allow at least **six business days** for receipt of the blood shipment containers and supplies.

7.2.3 A confirmation e-mail with the expected shipping date will be sent from FNLCR PD Support (**NCI_PD_Support@mail.nih.gov**).

7.2.4 If needed, FNLCR PD Support can be contacted directly at (240) 344-5697 (Rachel Andrews) or (301) 401-8070 (Amy Pantella).

7.3 Preparation for Sample Collection

7.3.1 For blood sample collection for clinical studies using ETCTN STS for specimen tracking, follow ETCTN STS instructions (Appendix 2) to prepare and print labels.

7.3.2 For all other clinical protocols, create specimen labels for each Streck blood collection tube, including the following information detailed below.

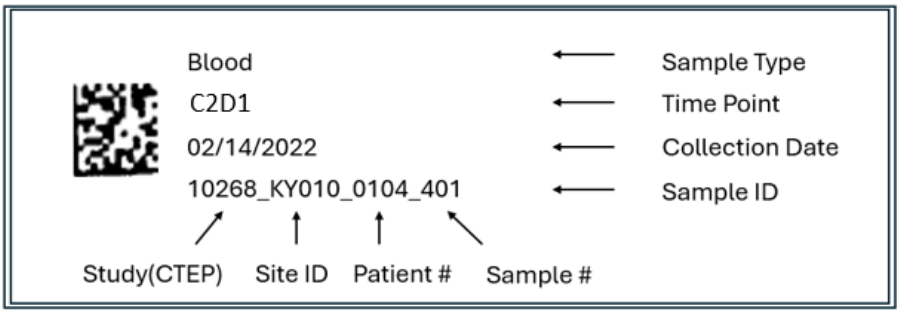
- Sample Type
- Specimen ID which includes:
  - Clinical Protocol/CTEP number
  - Site ID
  - Unique Patient ID

- A sequential sample ID in series (NCI samples for PD CTC blood samples are numbered as part of a 400-series [see example label below]).

- Collection date
- Timepoint - which includes the treatment cycle, day, and hour (*i.e.,* Cycle 1 Day 2hr)

NOTE: All required information must be *clearly* labeled and *legible*.

7.3.3 An example compliant specimen label is shown below:



IMPORTANT: If blood samples are initially collected by a second party (nursing staff, phlebotomist, etc.), ensure any clinical or personal identifiers are removed from the blood tube when received prior to placement of the appropriate pre-printed specimen label (as detailed above). Do not place the specimen label on top of a clinical label.

7.4 Collection and Storage of Blood Samples

7.4.1 Place a pre-printed specimen label, containing all the required information indicated in Section 7.3.2, on the Streck blood collection tube.

7.4.2 Collect whole blood aseptically into a Streck blood collection tube by venipuncture or from a venous port.

7.4.2.1 Fill the Streck blood collection tube with a *minimum* volume of **8.0 mL** for a **10.0 mL capacity tube**, to ensure the correct ratio of sample to anticoagulant and preservative.

7.4.2.2 In the event that < 8.0 mL blood volume is collected, make a note of this protocol deviation in the Specimen Submission Form (Appendix 1).

7.4.3 Immediately mix the specimen tube by *gently inverting* the tube 8–10 times. Tube inversion prevents clotting. **Do not** shake the tube, as vigorous mixing can cause hemolysis. Inadequate or delayed mixing may also result in inaccurate test results.

7.4.4 Blood samples must stay consistently between 18°C and 25°C (RT).

7.4.4.1 **Do not** freeze or place blood sample(s) on ice. If clinical staff accidentally place the Streck blood collection tube(s) on ice or refrigerate, make a notation on the Specimen Submission Form (Appendix 1) and bring the tube to RT before proceeding with sample processing or shipping.

7.4.5 Recheck the accuracy and completeness of all the information on the specimen label prior to shipment.

7.4.6 Blood specimens should be shipped ***within* 24 hours of collection to ensure processing within the 48-hour requirement**. Packaging and shipping instructions are in Section 8.0.

8.0 SHIPMENT OF SAMPLES

8.1 Ensure that the sample shipment is compliant with all requirements specified in Section 7.1.

8.2 Specimen Submission Form Instructions

8.2.1 Complete a Specimen Submission Form (Appendix 1) for all samples included in the shipment.

8.2.2 For each sample collected, *clearly* record the following information on the Specimen Submission Form:

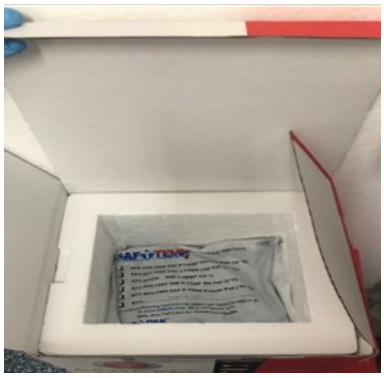
- Specimen ID
- Clinical Protocol/CTEP number
- Collection Date
- Collection Time
- Time Point (Cycle/Day/Hour)
- Clinical Diagnosis
- Comments: Any protocol issues and deviations must be noted in the comments field (e.g., < 8.0 mL blood collected, sample not shipped with proper ambient gel packs, etc.).

8.3 Packaging Instructions

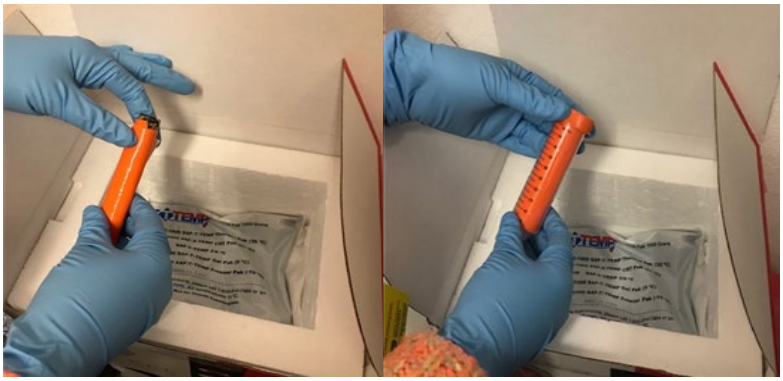
8.3.1 All blood shipping containers and specimen collection kits should be stored and utilized at RT.

8.3.2 The insulating Styrofoam container should be placed inside the cardboard shipping box.

8.3.3 Place one of two CRT gel packs at the bottom of a Styrofoam shipping container, as shown below.



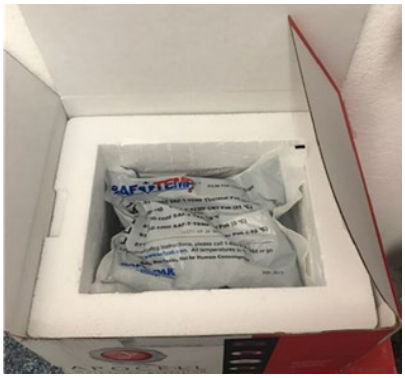
8.3.4 Wrap absorbent paper around the specimen-filled Streck blood collection tube, as shown below (left), and place in a 50.0 mL Falcon centrifuge tube, as shown below (right).



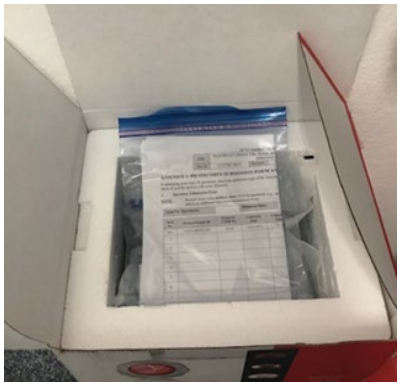
8.3.5 Place the Falcon tube containing the Streck blood collection tube in the biohazard specimen bag and seal securely.

8.3.6 Place the biohazard bag with the collection tube in the Styrofoam box, directly on top of the CRT gel pack, as shown below.

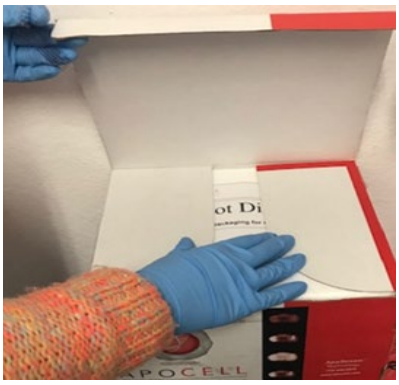
8.3.7 Put a second CRT gel pack on top of the sample, as shown below.



8.3.8 Insert the completed shipping form (Appendix 1) into the zip-lock bag on top of the second CRT gel pack, as shown below.



8.3.9 Close the insulating Styrofoam container with the accompanying lid and close the cardboard shipping box, as shown below.



8.4 Shipping Instructions

8.4.1 Seal the cardboard shipping box securely with adhesive shipping tape and attach the return shipping label to the outside of the box. **Do not** cover the **UN3373 (Biological substance, Category B)** sticker with the provided FedEx Priority Overnight shipping label (see Section 6.2).

8.4.1.1 Specimens should be shipped to the following address:

Attention: Leroy Smith
NCI-F/FNLCR
Natural Products and Tumor Repositories | Charles River
1073 Beasley Street, Building 1073
Fort Detrick
Frederick, MD 21701
Phone: 301 846-5748

8.4.2 For blood sample collection for clinical studies **NOT** using ETCTN STS for specimen tracking, before making the shipment, send a shipment notification by e-mail to FNLCR PD Support (NCI_PD_Support@mail.nih.gov) to ensure timely receipt and processing of the samples.

8.4.2.1 The subject line of the e-mail notification should state: "PD Clinical Shipment Notification".

8.4.2.2 For each sample being shipped, include the following information in the body of the e-mail message:

- Clinical Protocol/CTEP number
- Specimen ID(s)
- FedEx Tracking Number(s)
- Clinical Site Name

8.4.3 When collecting blood samples for clinical studies using ETCTN STS for specimen tracking, send shipment notification to FNLCR PD Support (NCI_PD_Support@mail.nih.gov)following ETCTN STS instructions (Appendix 2, Section 4) to ensure timely receipt and processing of the samples. Make sure all required specimen tracking information have been filled out in ETCTN STS according to instructions (Appendix 2).

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APPENDIX 1: PD SPECIMEN SUBMISSION FORM

If shipping more than 4 specimens, attach an additional copy of the Specimen Submission Form. Complete this Form for every sample shipment.

1. Specimen Submission Form

NOTE: *Ensure to send an email notification to FNLCR PD Support staff prior to sample shipment, at FNLCR PD Support(*NCI_PD_Support@nih.gov)

Sender: *Clinical Site Name & Address* **Total # Specimens:_____ Shipment Date: _____** **FedEx Tracking Number: _____**	**PD Specimen Submission Form**	**Recipient:** Leroy Smith NCI-F/FNLCR Natural Products and Tumor Repositories | Charles River 1073 Beasley Street, Building 1073 Fort Detrick Frederick, MD 21701 Phone: 301 846-5748

Item #	Specimen ID	Protocol / CTEP No.	Collection Date	Collection Time (24-hr designation)	Timepoint Cycle/Day/Hour	Clinical Diagnosis	Comments *(Note all protocol deviations for each sample here.)*
Ex.	*12345-MD004-0001-402*	*12345*	*10/24/2024*	*16:15*	*C1D1-2hr*	*sarcoma*	*Only collected 7ml of blood due to difficult draw.*
1							
2							
3							
4							

2. Chain of Custody Signatures

Task	Responsible Party	Name & Signature	Date
Verify shipment conditions of blood collection tubes (packaged with controlled temperature gel packs).	**Clinical Site**		/ /
Specimen Receipt: QC/verify sample(s) and confirm shipping conditions.	**FNLCR**		/ /

APPENDIX 2: BLOOD SAMPLE TRACKING IN ETCTN STS

For clinical trials that require blood samples to be tracked in the ETCTN Specimen Tracking System (STS), fill out all required information in ETCTN STS according to the instructions below.

NOTE: Be sure to include a copy of the STS shipping list with every shipment.

1. Prepare to use the ETCTN STS as follows:

   A. Contact CTSUContact@Westat.com for initial access to ETCTN STS.

   B. Contact sts.support@theradex.com for ETCTN STS technical assistance.

   C. Please review the following training videos for ETCTN STS before you start using the system:

      a. General ETCTN STS training: https://theradex.com/STS_training_18Feb2022/

      b. ETCTN STS Label Printing training: https://www.youtube.com/watch?app=desktop&v=9_Q6_k-KHHs

2. Prepare specimen labels in ETCTN STS and label tubes. Log into **ETCTN STS,** go to the **Enrollment** folder and confirm the **Histology and Disease** form and **Specimen Consent** form are complete.

   B. Go to **All Specimens** folder.

   C. Complete the **Specimen Tracking Enrollment** form for each specimen.

      a. Open the **Specimen Tracking Enrollment** form.

      b. Click **Add a new Log line** below the table to create each additional sample.

      c. The **Primary Diagnosis Disease Group** and **SnoMed Disease Term/Code** will be automatically populated from the **Histology and Disease** form.

      d. **Assessment time point**: Choose the time point from a dropdown list; the ETCTN STS will be populated with the relevant timepoints for each clinical trial.

      e. **Specimen Category**: Choose “Blood” from the dropdown list.

      f. **Specimen Type**: Choose “Blood” from the dropdown list.

      g. **Collection Tube Type**: Choose “cfDNA Streck”

      h. **Block Number**: Leave blank.

      i. **Type of tissue**: Leave blank.

      j. **Surgical path ID (SPID)**: Leave blank.

      k. **How many labels are needed**: Enter the number of labels needed.

      l. Click the “**Save**” button at the bottom of the form.

      m. An example of a blood specimen is shown below (red rectangle).

#	Timepoint	Specimen category	Specimen Type	Collection Tube Type	Block Number	Type of tissue	Surgical Path ID	Number of labels	Report	Report	Report
1	Baseline	Buccal Cell Sample	Buccal Swabs	_	_	_	_	1	_	_	_
2	Baseline	Blood	Blood	cfDNA Streck	_	_	_	2	_	_	_

D. Request labels using the **Print Labels** form located in the **All Specimens** folder following the steps below. Labels will be sent to the user's email address.

a. Open the **Print Labels** form and then click on the **Pencil** icon at the top of the page.

b. Select your Label Layout (one label per page or multiple labels per page).

c. Select the labels to be printed either by timepoint by selecting from the dropdown options next to "Available Protocol Timepoints" or by individual checkboxes on each specimen logline (the checkbox is in the "Print" column.

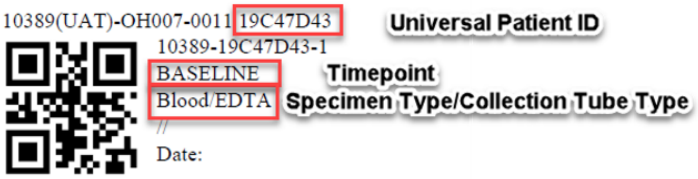
d. Save the form.

e. You will receive two emails: 1) containing a PDF attachment with the labels and 2) containing the URL link to the labels.

f. Print two labels for each blood sample, one for the blood tube and one to affix to the shipping list.

NOTE: RAVE recommends the use of the following adhesive cyrovial labels for laser printers: LabTag, Cat#: CL-23T1, 1.28″ x 0.5"

g. An example label is shown below:



E. Verify all sample label information, hand-print the date on each label, then affix one label to the blood tube and one to the shipping list for easy reference by the receiving laboratory.

3. Complete the **Specimen Transmittal** form by selecting the specimen from the list in the **All Specimens** folder following the instructions below.

A. Populate the relevant fields as detailed below. Fields that are not relevant for this specimen type can be left blank.

a. **Logline Number** will be populated by the system.

b. **Universal Participant ID** will be automatically populated by the system.

c. **Specimen ID** will be automatically populated by the system.

d. **Assessment Timepoint** will be automatically populated by the system.

NOTE: A comment should be recorded in the **Comment** field of the **Specimen Transmittal** form if the actual collection timepoint deviates from the protocol timepoint (e.g., collected on C1D2 instead of C1D1), see item j below.

e. **Date of Specimen Collection**: Enter the date of specimen collection.

f. **Time of Specimen Collection**: Enter the time of specimen collection.

g. **Number of containers used for collection**: Record the number of tubes collected.

h. **Number of sample containers or slides, after any processing at site, available for submission**: Enter the number of tubes that will be shipped.

i. **Specimen Source**: Choose "Blood" from the dropdown list in the first box and enter "General Blood Draw" in the second box (if required).

j. **Comment**: Record the patient diagnosis as well as any issues or deviations with the sample collection, storage, etc.

NOTE: The information in the **Comment** field will be captured on the Shipping List form.

B. Select "**Save**". After saving, the Collection Date and Specimen Type will be added to the Specimen folder name.

C. An example of completed Specimen Transmittal form for a blood sample collected in cfDNA Streck tubes is shown below.

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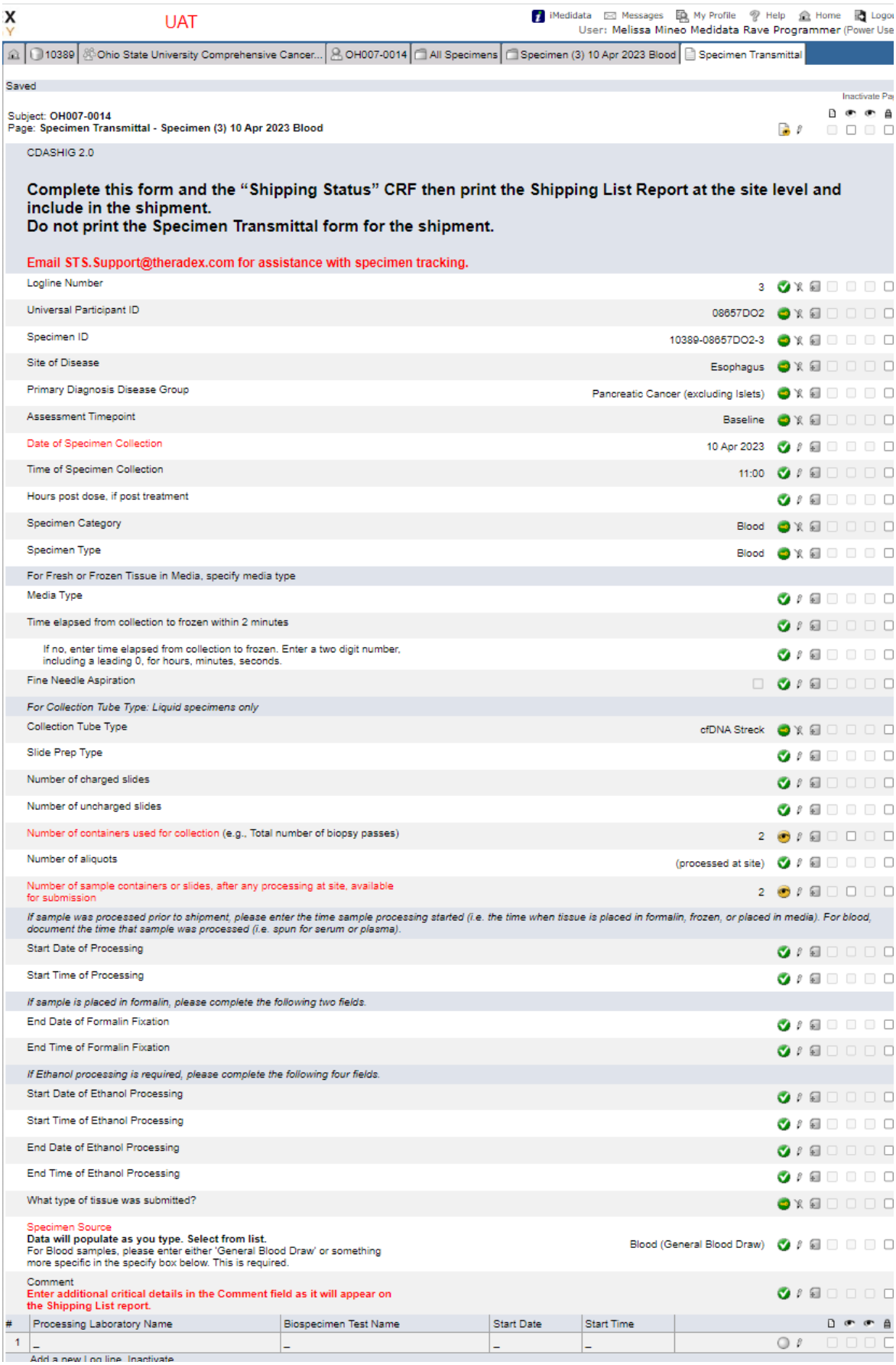


4. Complete the **Shipping Status** form and print the Shipping List when specimens are ready to be shipped.

A. From the **Specimen Transmittal** form of the specimen to be shipped, select the **Shipping Status** form. Click on the **Pencil** icon at the far right of the first log line to fill out the fields detailed below:

a. **Courier Name**: Enter "FedEx" as the courier.

b. **Shipping Tracking Number**: Enter the specific FedEx tracking number for the shipment.

c. **Shipping Source**: Select collection institution from the dropdown list.

d. **Sender's Name** will be automatically populated by the system.

e. **Sender's Email Address** will be automatically populated by the system.

f. **Number of Samples Sent**: Enter the number of tubes of blood that will be shipped for this specimen (typically, "1").

g. **Shipping Conditions**: Select "Ambient Pack" from the dropdown list for Blood.

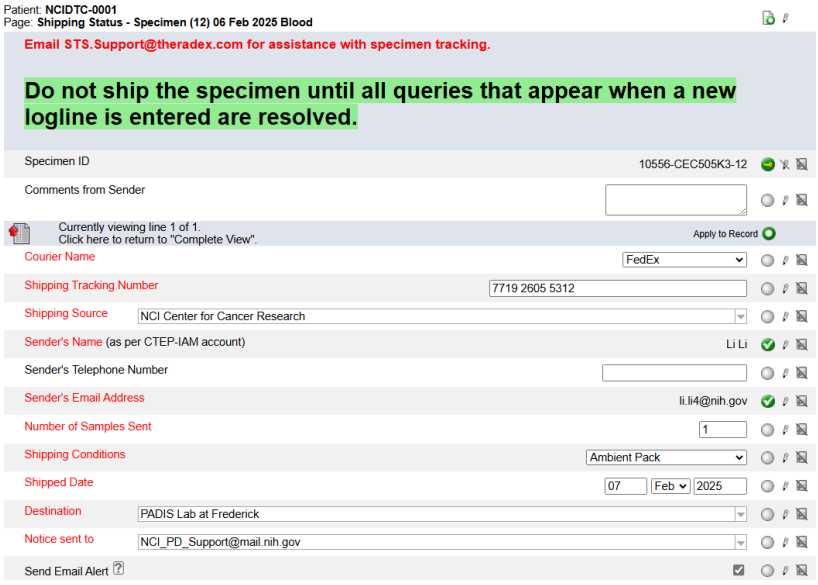
h. **Shipped Date**: Enter date of shipment.

i. **Destination**: Select "PADIS Lab at Frederick" from the dropdown list for FNLCR PD Support.

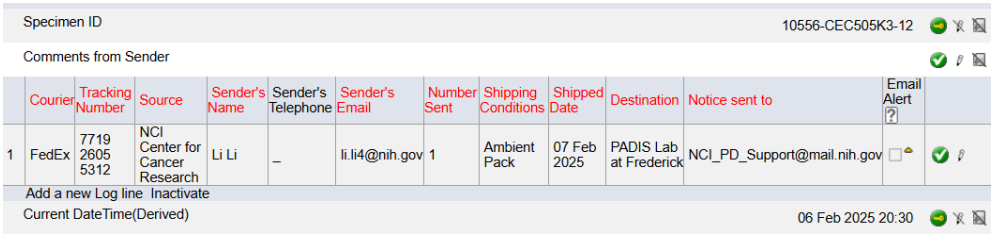
j. **Notice sent to**: NCI_PD_Support@mail.nih.gov

k. **Send Email Alert**: Click the pencil on the **Send Email Alert** line and check the box as shown below.

l. An example of a completed **Shipping Status** form is shown below.



B. Select **Save.** After saving, verify that you see the log item populated on the Shipping Status page as shown below.



Specimen ID 10556-CEC505K3-12

Comments from Sender

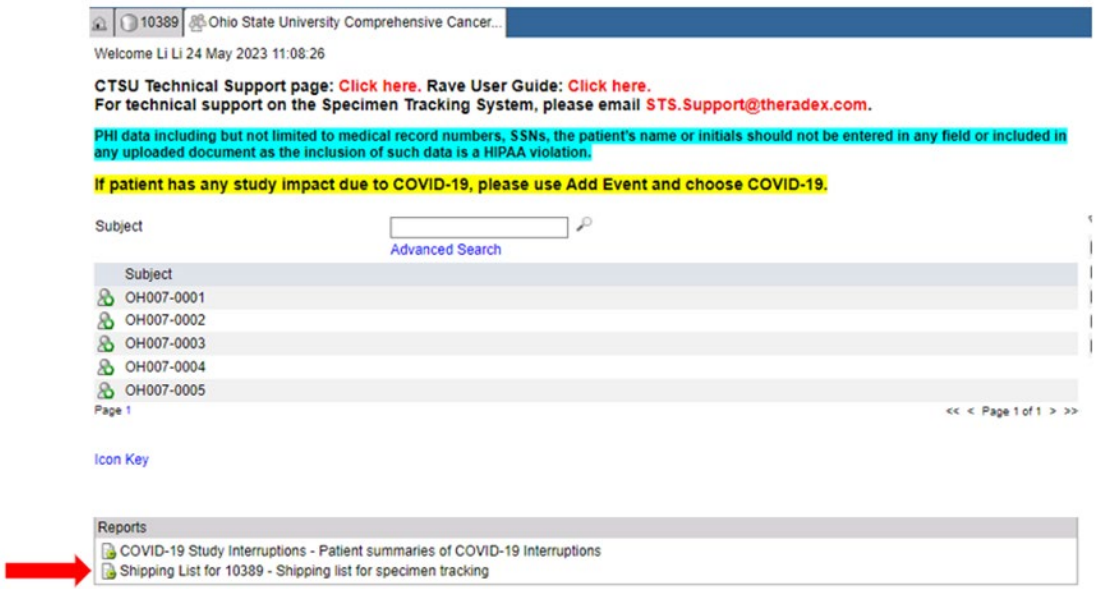
	Courier	Tracking Number	Source	Sender's Name	Sender's Telephone	Sender's Email	Number Sent	Shipping Conditions	Shipped Date	Destination	Notice sent to	Email Alert
1	FedEx	7719 2605 5312	NCI Center for Cancer Research	Li Li	–	li.li4@nih.gov	1	Ambient Pack	07 Feb 2025	PADIS Lab at Frederick	NCI_PD_Support@mail.nih.gov	

Add a new Log line Inactivate

Current DateTime(Derived) 06 Feb 2025 20:30

C. Print the **Shipping List** report and place it in the box with the specimens (Section 8.3.8).

a. The **Shipping List** report is found in the reports panel at the bottom of the window at the site level (an example is shown below); specimens from multiple patients can be included in a single shipment.



10389 Ohio State University Comprehensive Cancer...

Welcome Li Li 24 May 2023 11:08:26

CTSU Technical Support page: Click here. Rave User Guide: Click here.
For technical support on the Specimen Tracking System, please email STS.Support@theradex.com.

PHI data including but not limited to medical record numbers, SSNs, the patient's name or initials should not be entered in any field or included in any uploaded document as the inclusion of such data is a HIPAA violation.

If patient has any study impact due to COVID-19, please use Add Event and choose COVID-19.

Subject

Advanced Search

Subject
OH007-0001
OH007-0002
OH007-0003
OH007-0004
OH007-0005

Page 1 << < Page 1 of 1 > >>

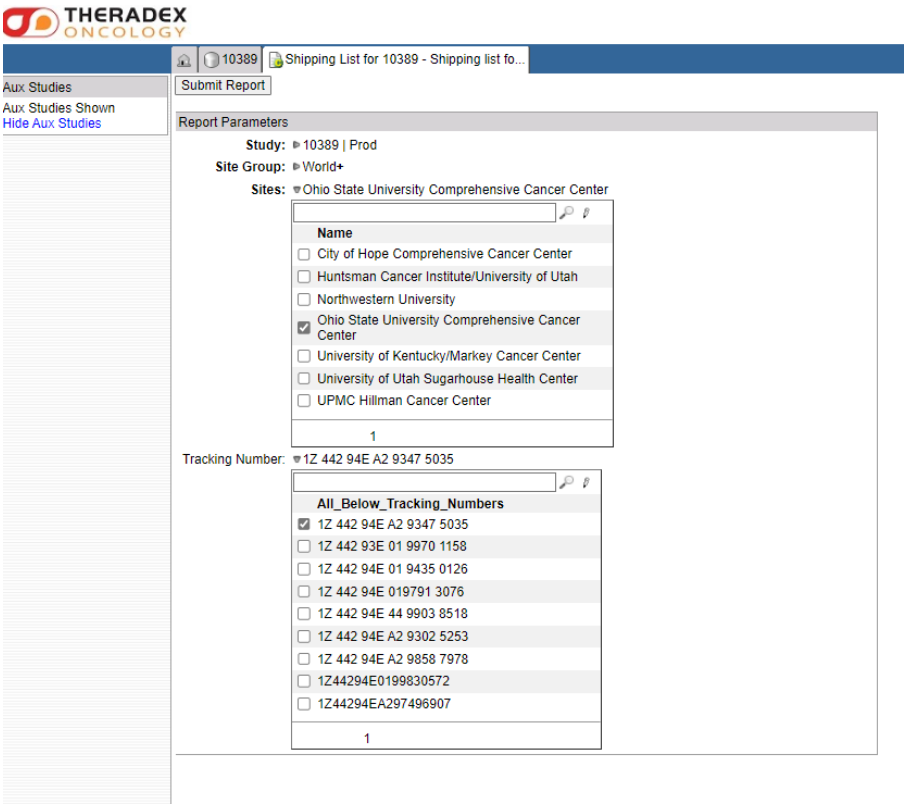
Icon Key

Reports

COVID-19 Study Interruptions - Patient summaries of COVID-19 Interruptions

Shipping List for 10389 - Shipping list for specimen tracking

D. Click the gray arrow in the Tracking Number field to see the full list of tracking numbers. Check the box next to the appropriate tracking number, as shown in the image below. Then click **Submit Report** and **OK.**



E. Click the **Print** icon to export a PDF of the Shipping List (as shown below). Include a printed copy of the **Shipping List** in the shipment box. An example shipping list is shown below.