NIH NATIONAL CANCER INSTITUTE

SOP340507: Tumor Frozen Needle Biopsy Specimen Collection, Handling and Shipping for PADIS, Frederick National Laboratory for Cancer Research (FNLCR)

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

IQC Approval: Li Li Approval: LI LI -S (Affiliate) Digitally signed by LI LI -S (Affiliate) Date: 2025.03.06 10:54:10 -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: 2025.03.06 12:07:53 -05'00'

DCTD OD Approval: Toby Hecht Approval: Toby T. Hecht -S Digitally signed by Toby T. Hecht -S Date: 2025.03.06 20:22:27 -05'00'

2. Change History

Revision	Approval Date	Description	Originator	Approval
I	01/02/2025	Added ETCTN STS instructions, additional ordering information, edits to PD Specimen Submission Form and Batch Record, and updated formatting.	LL/RA/AP	KFG
H	10/12/2021	Minor updates to specify requirements for samples shipping to PADIS	LL/RA/AP	KFG
G	6/19/2019	Minor updates to collection and shipping procedures.	KFG	REP
F	2/11/2015	Updated contact shipping address and process for advance notification of shipments.	KFG	REP
E	7/3/2013	Updated tube-type to 1.5-mL conical bottom screw cap tubes to allow for broader use in DCTD assays and minimize the need to transfer biopsies during sample extraction steps. Decreased maximum time from biopsy collection to freezing to 2 minutes.	YAE	REP
D	1/8/2013	Update handling in surgical suite including details on halving of biopsy. Record total time elapsed from biopsy collection to freezing.	YAE, MM	JJ
C	12/29/2010	Update sample snap freeze to dry ice/ethanol bath or liquid nitrogen.	YAE	JJ
B	7/24/2009	Updated SOP format and prepared for publication to the DCTD Biomarkers Web site	YAE	JJ
A	10/13/2006	Revision with New Shipping Address	YZ	JJ
--	8/25/2006	New Document	YZ	JJ

1.0 PURPOSE

Standardize the method for collecting and handling frozen needle tumor biopsies to enable specimen use for measurement of pharmacodynamic (PD) markers following treatment with anticancer agents. This document also details the procedures for shipping biopsies to PADIS, FNLCR.

2.0 SCOPE

This procedure applies to all personnel involved in the collection and handling of frozen needle tumor biopsies for use in PD marker assays during clinical trials that will be shipped to PADIS, FNLCR. The goal of this SOP and associated training is to ensure consistency in tumor needle biopsy collection and handling between clinical sites.

3.0 ABBREVIATIONS

DCTD	=	Division of Cancer Treatment and Diagnosis
ETCTN	=	Experimental Therapeutics Clinical Trials Network
FNLCR	=	Frederick National Laboratory for Cancer Research
ID	=	Identification / Identifier
IQC	=	Internal Quality Control
LHTP	=	Laboratory of Human Toxicology and Pharmacology
PADIS	=	Pharmacodynamics Assay Development & Implementation Section
PD	=	Pharmacodynamic
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 ROLES AND 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. The Laboratory Director/Supervisor is responsible for ensuring the Certified Assay Operator following the SOP has sufficient experience to handle and ship clinical samples.

5.2 It is the responsibility of the Certified Assay Operator and/or PK/PD Support Lab personnel to confirm scheduled specimen 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 biopsy samples.

5.3 The Certified Assay Operator and/or PK/PD Support Lab personnel responsible for conducting the specimen collection and handling procedures are to follow this SOP and complete the required tasks and associated documentation. The Batch Record (Appendix 1) must be completed in ***real-time*** for each experimental run, with each page ***dated and initialed*****,** and maintained with the clinical sample information.

5.4 The responsible personnel are to check the DCTD Biomarkers Website (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 Stopwatch, total time in minutes and seconds required

6.2 1.5-mL Sarstedt O-ring screw cap, conical bottomed tubes (Sarstedt, Cat#: 72.703.416)

6.3 Disposable, fine-tipped tweezers (e.g., VWR, Cat#: 83009-010). Tweezer tips need to easily fit to the bottom of a 1.5-mL Sarstedt tube.

6.4 Thermal Transfer Printer (e.g., Zebra ZT411 or comparable printer)

6.5 Printable cryogenic microcentrifuge tube labels (e.g., Brady, FreezerBondz Cryogenic Matte Polyester Laboratory Labels for 3" Core Printers - 0.6" x 1.25", Cat#: THT-155-490-3)

6.6 Thermal Transfer Ribbon (e.g., Brady Labels, Thermal Ribbon 4300, Cat#: R4302)

6.7 81-place freezer boxes (e.g., Fisher Scientific, Cat#: 12-565-182)

6.8 Stainless steel or polystyrene ice bucket (e.g., Southern Labware, Cat#: SS111)

6.9 Floating foam rack (e.g., VWR, Cat#: 82017-634)

6.10 Liquid nitrogen or dry ice/ethanol bath

6.11 -80°C freezer (or colder)

6.12 Biohazard specimen bags

6.13 Insulating Styrofoam shipping container

6.14 Dry ice (at least 20 pounds per shipment)

7.0 OPERATING PROCEDURES

7.1 Record the name of the Certified Operator, the Clinical Site Name, the Clinical Protocol Number or CTEP Number, Patient ID, the Timepoint, Primary Diagnosis and the Collection Date in the Batch Record (Appendix 1).

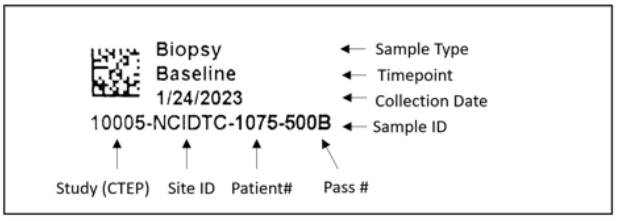
- The Batch Record for this SOP is sufficient for collection of a **single** set of biopsy samples collected from a single patient at a single timepoint. If collecting biopsy samples for more than one patient, prepare a separate Batch Record for each patient set.

7.2 Label Preparation

NOTE: For clinical protocols using ETCTN STS for sample tracking, follow ETCTN STS instructions to print labels (Appendix 3, Section 2). Usage of the ETCTN STS will be specified in the clinical trial protocol. For all other clinical protocols, follow the steps below to print labels.

7.2.1 Prepare enough pre-printed specimen labels for each whole or halved biopsy sample to be collected and frozen as defined in the clinical protocol; be sure to coordinate with the clinical center if they prepare the labels for sample collection. The pre-printed specimen labels should include the following information:

- Sample Type
- Specimen ID which includes:
  - Clinical Protocol/CTEP number
  - Site ID
  - Unique Patient ID
  - A sequential sample ID in series (NCI tumor biopsy samples for PD are numbered as part of a 500-series [see example label below]).
  - Pass information (i.e., A, B, C, D, E, etc.)
- Collection date
- Timepoint - which includes the treatment cycle, day, and hour (e.g., Cycle 2 Day 1 2hr)
- An example of a complete label for a frozen biopsy tube is shown below:



7.2.2 At least three labels will be needed for each frozen biopsy collected. Of the pre-printed labels prepared for each sample, one label will go on each 1.5-mL Sarstedt tube, one on the Batch Record (Appendix 1), and the last will be given to the research nurse to place onto the patient record sheet.

NOTE: Make sure that no patient identifiable information is included on the labels.

7.3 Tumor Needle Biopsy Collection and Handling

7.3.1 The research nurse is to notify the laboratory of scheduled PD sample collections, preferably giving at least 24 hr notice. Arrive at the biopsy collection site early enough to allow sufficient time to set up laboratory supplies, collect relevant clinical information, and ensure rapid flash freezing of specimens and transport from the procedure area to the laboratory where they will be placed into storage at -80ºC (or colder) after collection.

7.3.2 Bring all necessary lab supplies including disposable tweezers, one pre-chilled (on liquid nitrogen or dry ice/ethanol in an insulated bucket) labeled–1.5-mL Sarstedt tube per planned whole biopsy core according to the clinical protocol, and one pre-printed specimen label per biopsy to give to the research nurse for the patient record.

NOTE: Prepare and pre-chill additional 1.5-mL Sarstedt tubes for specimen collection in case the interventional radiologist collects additional passes or one of the tubes is compromised during the collection process.

7.3.3 The total time elapsed between biopsy collection and placement into the pre-chilled tube is of **key importance** to biomarker analysis; biopsies should be frozen within **2 minutes** of collection. The interventional radiologist will eject the biopsy onto a sterile slide (for optimal analyte recovery the slide should be pre-chilled). Start a stopwatch at this point and note the Specimen ID and the time in the first two lines of Appendix 1, Section 1 and immediately walk the slide to the sample preparation table.

NOTE: For clinical protocols using the ETCTN STS for specimen tracking, it is important to record the specimen collection time in the **Specimen Transmittal** form according to instructions in Appendix 3, Section 3.

7.3.4 In the Batch Record (Appendix 1, Section 1), indicate if a full or halved biopsy, as defined in the clinical protocol, is prepared.

7.3.4.1 For whole biopsies: Uncap an empty, pre-chilled 1.5-mL Sarstedt tube and using disposable tweezers, pick up the freshly collected needle biopsy with the tweezers at one end, and touch the opposite end of the biopsy to the inner surface of the prechilled 1.5-mL Sarstedt tube. This should attach the tissue to the tube, allowing it to be dropped into the tube while releasing the tissue from the tweezers without sticking. Note the time the biopsy was placed into the Sarstedt tube (Appendix 1, Section 1). Dispose of the tweezers in the appropriate biohazardous waste container. Re-cap the tube firmly.

7.3.4.2 For halved biopsies: Use 1-2 disposable tweezers and cut/shear the biopsy in half lengthwise while it is on the slide (do not pull or stretch the biopsy longitudinally). Use the tweezers to transfer the halved biopsies to sterile pre-chilled tubes as indicated above. Note the time the biopsy was placed into the Sarstedt tube (Appendix 1, Section 1). Dispose of the tweezers in the appropriate biohazardous waste container. Re-cap the tube firmly.

7.3.5 Immediately snap freeze the biopsy by placing the tube in liquid nitrogen or a dry ice/ethanol bath and note the time the biopsy was flash frozen in the tube (Appendix 1, Section 1). The use of a floating foam rack is recommended for this process to keep the tubes upright.

NOTE: DO NOT let the tubes tip over in the liquid nitrogen or dry ice/ethanol bath.

7.3.6 Calculate the total time elapsed from biopsy collection to biopsy freezing and record the total number of **minutes and seconds** elapsed in the Batch Record (Appendix 1, Section 1).

7.3.7 Note the specific anatomic location of each biopsy pass collected (*e.g.*, spleen, large left upper quadrant splenic mass) and a description of the appearance of the biopsy (*e.g.*, large whole core or small, fragmented core) in the Batch Record (Appendix 1, Section 1).

7.3.8 Record the needle type and size that was used in the Batch Record (Appendix 1, Section 1).

7.3.9 Return to the sample processing laboratory and transfer the frozen biopsy specimen(s) to -80°C (or colder) for storage until shipment to the PD processing laboratory. Record the date and time which specimens are stored (Appendix 1, Section 2).

7.3.10 Review and finalize the Batch Record and document **ANY** and **ALL** deviations from this SOP in the Batch Record (Appendix 1, Section 1).

7.3.11 The Laboratory Director/Supervisor should review the Batch Record and sign to affirm the data contained within are correct (Appendix 1, Section 4).

8.0 SHIP TO PADIS, FNLCR FOR ANALYSIS

NOTE:

- If shipping to PADIS, FNLCR, use the following steps. If shipping to EET Biobank, follow instructions in SOP340567. For shipping to all other locations, follow the instructions provided in the clinical protocol or the local site appendix.
- For clinical protocol using ETCTN STS for specimen tracking, follow Appendix 3, Section 4 instead of Sections 8.3-8.5.

8.1 Sites are required to create a FedEx shipping label to accommodate the variable dry ice weight of the shipment package. Use only FedEx Priority Overnight Shipping. FNLCR PD Support will provide a FedEx account number to cover the cost of the shipment via NCI_PD_Support@mail.nih.gov.

8.1.1 By linking the FNLCR FedEx account number provided to the biopsy shipment, FNLCR PD Support can closely monitor the shipment, cover all shipping costs, and provide notification to pertinent staff of expected sample shipment arrival.

8.1.2 Please send all shipments via FedEx Priority Overnight shipping to the FNLCR PD Support address listed below:

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

8.2 Once a tumor biopsy has been collected from a patient and placed at -80ºC (or colder), FNLCR PD Support should be notified that the specimens are ready for shipment. Preferably, if additional biopsies will be collected from the same patient (i.e., post-dose timepoint[s]), the biopsies are to be stored in a local freezer at -80ºC (or colder) and shipped together as a full biopsy set in one single shipment.

8.3 Send an e-mail to FNLCR PD Support (NCI_PD_Support@mail.nih.gov) to inform that biopsy samples are being prepared for shipment. State "*Protocol Name* PD Specimens Ready for Shipment" in the subject line. Request a confirmation email that personnel will be available on the expected delivery date and time. Personnel are generally available to receive frozen shipments Tuesday through Friday, excluding government holidays. ***If needed, FNLCR PD Support can be contacted directly at (240) 344-5697 (Rachel Andrews) or (301) 401-8070 (Amy Pantella).***

8.4 Use the PD Specimen Submission Form template in Appendix 2 to generate a shipping list containing pertinent sample information.

NOTE: If submitting more than 8 specimens, please generate an additional PD Specimen Submission Form.

8.5 Prepare a copy or scan of the specimen Batch Records (Appendix 1) and PD Specimen Submission Form (Appendix 2) so that one copy can be sent to FNLCR with the biopsy samples and one copy can be maintained at the collection site for internal records.

8.6 Finalizing the Shipment

IMPORTANT: Ensure that the samples remain fully frozen when preparing the shipment.

8.6.1 Just prior to shipment, place specimen tubes into a biohazard specimen bag then in an insulating Styrofoam shipping container, surrounding the specimens in dry ice. The insulated Styrofoam shipping containers are required to have outer dimensions of ***at least*** 14″×11″×9″ (length, width, height), with a ***minimum*** of 20 pounds of dry ice. Sufficient dry ice is imperative to keep the samples fully frozen for up to 96 hours. Expect 5–10 pounds of dry ice to sublimate per day during transit.

NOTE: When shipping specimens in a batch, each biohazard specimen bag should contain specimen tubes from one individual patient at one collection time point. Label the bag with the trial number, the patient ID, the collection time point, and the number of biopsy cores contained in the bag.

8.6.2 All specimens are recommended to ship out on Monday through Thursday via FedEx Priority Overnight (excluding Fridays and any day before a federal holiday).

8.6.3 Record the shipping date, time, tracking number, and shipping information in the Batch Record (Appendix 1, Section 3).

8.6.4 Place the documents prepared in Section 8.5 (clinical protocols NOT using ETCTN STS) or Appendix 3, Section 4 (clinical protocols using ETCTN STS) inside the shipping box for all specimens.

8.6.5 Seal the box, then print and attach the shipping address onto the outside of the shipping container; make sure the container is labeled as containing biohazardous specimens, with a UN3373 label.

8.7 Once specimens arrive at the receiving laboratory, they should be immediately placed at -80ºC (or colder) pending delivery to the processing laboratory.

APPENDIX 1: BATCH RECORD

A ***separate*** Batch Record should be completed for **each patient sample set**.

Place copies of PD specimen labels here (e.g., RAVE labels)

Certified Operator: _____ Site Name: _____

Protocol Number: _____ Patient ID: _____

Timepoint: _____ Collection Date: _____

Primary Diagnosis: _____

1. Biopsy Collection

	1st Pass	2nd Pass	3rd Pass	4th Pass	5th Pass
Specimen IDs:					
Collection time: (24-hr designation)	:	:	:	:	:
Time biopsy placed in tube:	:	:	:	:	:
Required: Time elapsed from collection to placement in tube.	**min** **sec**	**min** **sec**	**min** **sec**	**min** **sec**	**min** **sec**
Biopsy size prepared for PD or histological analysis	☐ Full ☐ Halved	☐ Full ☐ Halved	☐ Full ☐ Halved	☐ Full ☐ Halved	☐ Full ☐ Halved
Description of Biopsy: (i.e. large intact core, small and fragmented core, etc.)					
Site of Biopsy: (note for each pass or write "same" for replicate cores)					
Notes: List any collection notes or deviations from SOP.					
Needle Type: (e.g., Temno)					
Needle Diameter & Gauge:					

2. Biopsy Storage

Date/time biopsy specimen(s) placed at ≤ -80°C: _____ _____ : _____

3. Shipment to FNLCR: *Include a copy of the PD Specimen Submission Form and/or ETCTN STS Shipping List for each shipment.* **NOTE:** Use a minimum of 20lbs of dry ice! Shipping containers are required to have outer dimensions of at least 14″×11″×9″ (length, width, height).

Date/time samples shipped: _____ _____ : _____ FedEx Tracking Number: _____

4. Review of Batch Record by Laboratory Director/Supervisor

_____(PRINT) _____(SIGN) Date:_____/_____/_____

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APPENDIX 2: PD SPECIMEN SUBMISSION FORM

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

Sender: *Clinical Site Name & Address* **Total # Specimens: _____ Shipment Date: _____**	**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.	Primary Diagnosis	Site of Biopsy	Time Point Cycle/Day/Hour	Collection Date	Collection Time (24-hr designation)
Ex. 1	*12345-MD999-0010-500*	*12345*	*Melanoma*	*Right forearm*	*Pre-dose D1*	*06/12/2024*	*08:50*
Ex. 2	*12345-MD999-0004-501*	*12345*	*leiomyosarcoma*	*colon*	*Cycle 1, D8*	*06/20/2024*	*16:05*
1						/ /	
2						/ /	
3						/ /	
4						/ /	
5						/ /	
6						/ /	
7						/ /	
8						/ /	

Chain of Custody Signatures

Task	Responsible Party	Name & Signature	Date
Verify shipment conditions of PD biopsies (adequate dry ice, cooler size, etc.)	**Clinical Site**		/ /
Specimen Receipt: QC/verify sample(s) & confirm shipping conditions.	**FNLCR**		/ /

APPENDIX 3: TUMOR FROZEN NEEDLE BIOPSY SPECIMEN TRACKING IN ETCTN STS

For clinical protocols that require tumor frozen needle biopsy specimens to be tracked in the ETCTN Specimen Tracking System (STS), fill out all required information in ETCTN STS according to the instructions below. Usage of the ETCTN STS will be specified in the clinical trial protocol.

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. 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 enough pre-printed specimen labels in ETCTN STS and label tubes.

A. 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 the **All Specimens** folder.

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

a. Open the **Specimen Tracking Enrollmen**t form

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

#	Timepoint	Specimen category	Specimen Type	Collection Tube Type	Block Number	Type of tissue	Surgical Path ID	Number of labels	Report	Report	Report	
1	Baseline	Frozen Tissue	Snap Frozen Tissue	_	_	Metastatic	_	1	_	_	_	
2	Baseline	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
3	Course 2 Day 1	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
4	Course 3 Day 1 (Pre)	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
5	Course 3 Day 1 (Pre)	Frozen Tissue	Snap Frozen Tissue	_	_	Metastatic	_	1	_	_	_	
6	Course 4 Day 1	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
7	Progression	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
8	Course 2 Day 1	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
9	Course 2 Day 1	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
10	Course 3 Day 1 (Pre)	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
11	Course 3 Day 1 (Pre)	Frozen Tissue	Snap Frozen Tissue	_	_	Metastatic	_	1	_	_	_	
12	Course 4 Day 1	Blood	Blood	cfDNA Streck	_	_	_	1	_	_	_	
13	_	_	_	_	_	_	_	_	_	_	_	

Add a new Log line | Inactivate

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

d. **Assessment Timepoint**: 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 "Frozen Tissue" from the dropdown list.

f. **Specimen Type**: Choose "Snap Frozen Tissue" from the dropdown list.

g. **Type of Tissue**: Choose disease type from the dropdown list.

h. **Surgical path ID (SPID)**: Enter the ID created by your institutional pathology department.

i. **How many labels are needed**: Enter "1" for 5 labels to be created in Step D.

j. An example of completed snap frozen tissue entry is circled below.

	Timepoint	Specimen category	Specimen Type	Collection Tube Type	Block Number	Type of tissue	Surgical Path ID	Number of labels	Report	Report	Report
1	Pre-Treatment	Formalin Fixed Tissue	Formalin Fixed Core Biopsy	_	_	Metastatic	_	1	_	_	_
2	Pre-Treatment	Blood	Blood	cfDNA Streck	_	_	_	2	_	_	_
3	Pre-Treatment	Frozen Tissue	Snap Frozen Tissue	_	_	Metastatic	_	3	_	_	_

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 or by individual checkboxes.

d. Five labels will be created by default when you enter "**1**" in the "**How many labels are needed**" field in the **Specimen Tracking Enrollment** form. An example is shown below.

	Specimen Enrollment Logline Number	Universal Participant ID	Specimen ID	Protocol TimePoint	Protocol TimePoint Coded Value	Specimen Category	Specimen Type/Tube Type	Relevant Codes	Biopsy Pass designation	How many labels?	Print (multiple selections allowed)
1	1	CEC505K3	10556-CEC505K3-1	Baseline	BASELINE	Frozen Tissue	Snap Frozen Tissue	M///A	A	1	
2	1	CEC505K3	10556-CEC505K3-1	Baseline	BASELINE	Frozen Tissue	Snap Frozen Tissue	M///B	B	1	
3	1	CEC505K3	10556-CEC505K3-1	Baseline	BASELINE	Frozen Tissue	Snap Frozen Tissue	M///C	C	1	
4	1	CEC505K3	10556-CEC505K3-1	Baseline	BASELINE	Frozen Tissue	Snap Frozen Tissue	M///D	D	1	
5	1	CEC505K3	10556-CEC505K3-1	Baseline	BASELINE	Frozen Tissue	Snap Frozen Tissue	M//		1	

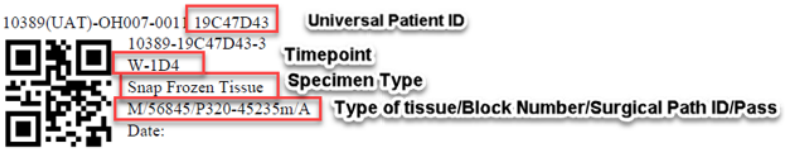
e. The first four will be designated with A, B, C and D to represent different passes of the biopsy procedure. Use the pass identifiers accurately to label the specimens: pass A should be for the first pass, B the second pass, etc. The fifth label will have no pass designation and can be used for any additional biopsy passes collected. Write the next letter "E or F" as pass ID on the label using a permanent marker.

f. Save the form.

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

E. Print three copies of each label received and hand-write the specimen collection dates on the labels. The three copies of each label will be used as decribed below in Step F.

An example label is shown below:



F. Verify all sample label information and affix one to each of the biopsy tubes, ensuring the correct biopsy pass designation is used. Place a duplicate label for each biopsy in the designated space on the Batch Record (Appendix 1) and transfer one to the research nurse to be maintained with the patient records.

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

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 automatically 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. **Site of Disease** will be automatically populated by the system.

e. **Primary Diagnosis Disease Group** will be automatically populated by the system.

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

g. **Date of Specimen Collection**: Enter date of the collection.

h. **Time of Specimen Collection**: Enter time of the specimen collection in 24 hr designation (e.g., 08:50)

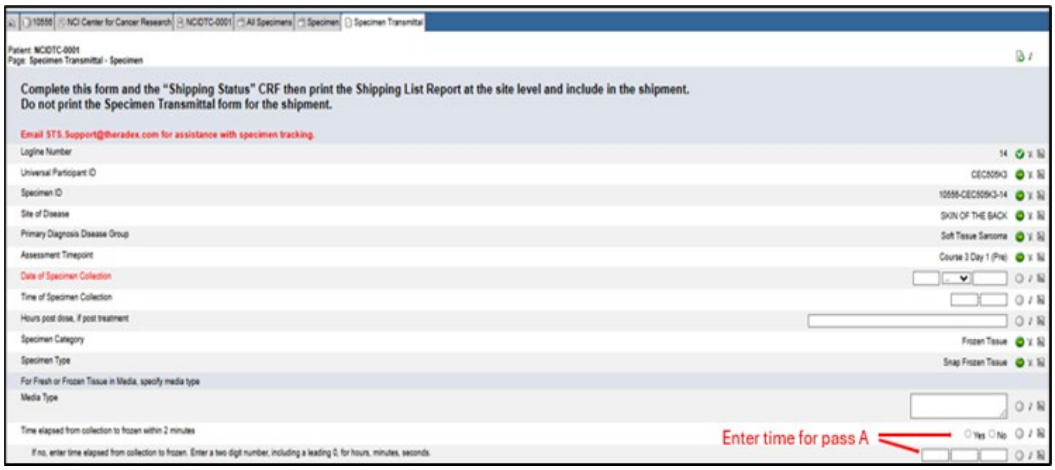
i. **Hours post dose, if post treatment**: Leave Blank. This will be automatically populated by the system after this form is completed.

j. **Specimen Category**: Select “Frozen Tissue” from the dropdown list.

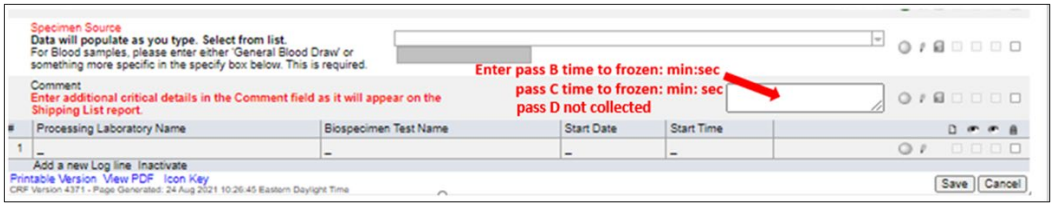
k. **Specimen Type**: Select “Snap Frozen Tissue” from the dropdown list.

l. Enter the **Elapsed time from collection to freezing** for each pass in the Specimen Transmittal form following the instructions below.

i) Record Pass A elapsed time in the appropriate fields as shown below.



ii) Record elapsed times for each additional biopsy pass in the **Comment** field near the bottom of the Specimen Transmittal form as shown below. Also indicate if biopsy passes were not collected in the **Comment** field as shown below.



m. **Number of containers used for collection (e.g., Total number of biopsies passes)**: Enter the number of biopsy passes.

n. **Number of sample containers or slides, after any processing at site, available for submission**: Enter the number of biopsy cores collected.

o. **Specimen Source**: Enter the biopsy site.

p. Save the form.

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

A. From the **Specimen Tranmittal** form of the specimen to be shipped, select the **Shipping Status** form. Click on the **Pencil** icon to fill out the fields listed 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**: Enter sender's name.

e. **Sender's Email Address**: Enter sender's email address.

f. **Number of Samples Sent**: Enter the number of frozen biopsy cores in the shipment.

g. **Shipping Conditions**: Select "Dry ice" from the dropdown list for tumor frozen needle biopsy.

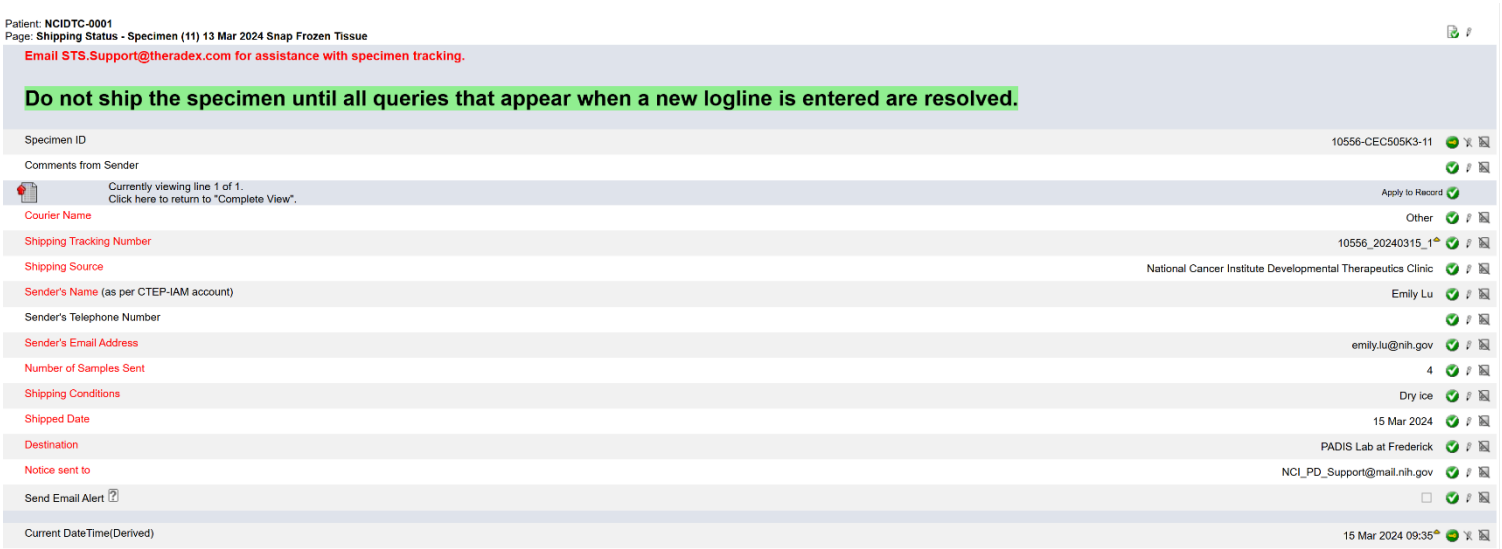
h. **Shipped Date**: Enter date of shipment.

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

j. **Notice sent to**: Select NCI_PD_Support@mail.nih.gov from the dropdown list

k. **Send Email Alert**: Click the **pencil icon** on the **Send Email Alert** line and check the box.

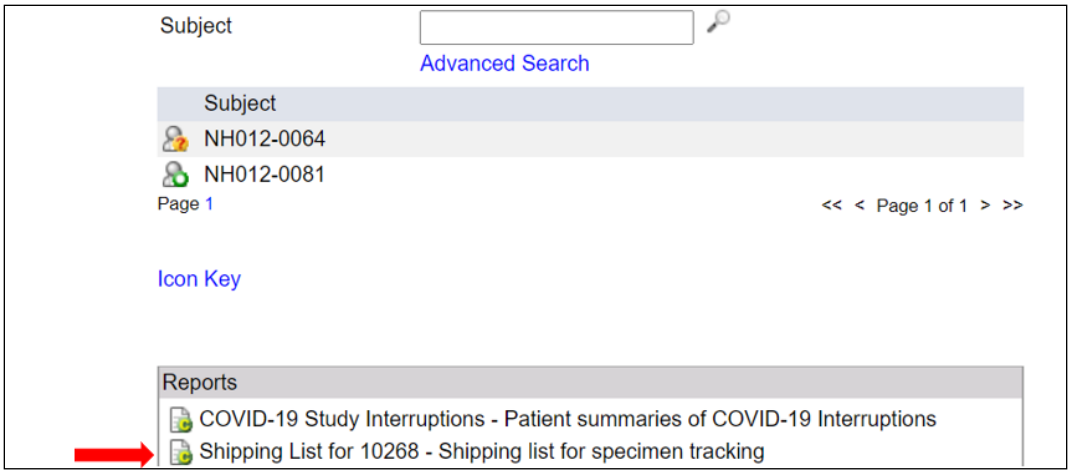
l. An example of completed **Shipping Status** form is shown below.



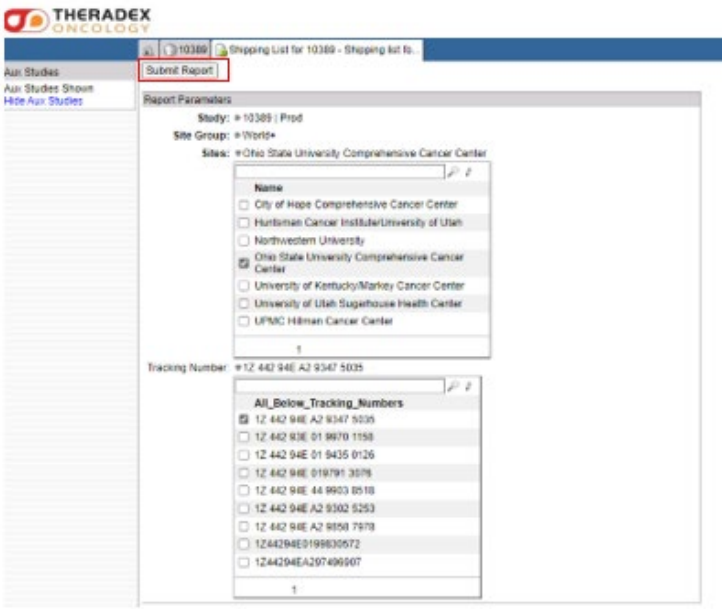
B. Select **Save**. After saving, verify that you see the log item populated on the **Shipping Status** page as shown below. A notification will be sent to mail to: NCI_PD_Support@mail.nih.gov. Only complete this step for one specimen in the shipment to avoid duplicate notifications.

C. Print the **Shipping List** report and place it in the box with the specimens (Section 8.6.4).

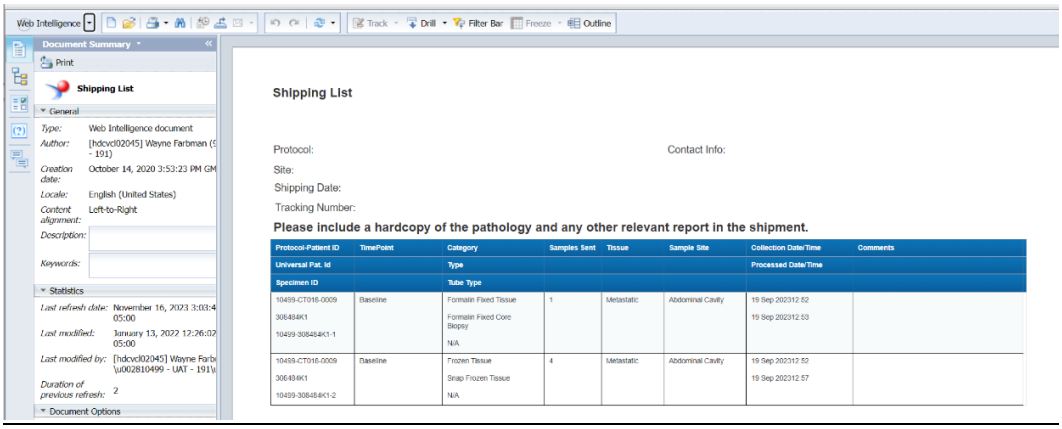
a. The **Shipping List** report is found in the report panel at the bottom of the window at the site level (an example is shown below); specimens from multiple patients can be included in a single shipment.



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 in the image below).



F. The shipment should include a hard copy of the **Shipping List** (Section 8.6.4) along with the Batch Record (Appendix 1). An example of a **Shipping List** is shown below:

Shipping List

Protocol: 10389 - UAT
Site: Ohio State University Comprehensive Cancer Center
Shipping Date: 10 Jul 2021
Tracking Number: 1ZF10W700199914880

Contact Info: Melissa Mineo
609-480-7366
mmineo@theradex.com

Please include a hardcopy of the pathology and any other relevant report in the shipment.

Protocol-Patient ID	TimePoint	Category	Samples Sent	Tissue	Sample Site	Collection Date/Time	Comments
Universal Pat. Id		Type				Processed Date/Time	
Specimen ID						Frozen in 2 min/Elapsed	
10389-OH007-0011 19C47D43 10389-19C47D43-1	Baseline	Blood Blood	1		General Blood Draw	21 Jun 202109:00 N/A	
10389-OH007-0011 19C47D43 10389-19C47D43-2	Archival	Formalin Fixed Paraffin Embedded Tissue FFPE Block	1	Metastatic	Esophagus	09 Jan 202115:00 N/A	
10389-OH007-0011 19C47D43 10389-19C47D43-3	Week -1 Day 4 (Expansion Cohort Only)	Frozen Tissue Snap Frozen Tissue	3	Metastatic	Esophagus	10 Jun 202111:10 N/A No/00:03:25	Pass B time to frozen: 02:20 ; Pass C time to frozen: 00:50