



Theradex Specimen Tracking System (STS) User Guide Version 6 (November 2024)



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Access

Access to your study in Rave is overseen by CTSU and is granted based on the role assignment in the roster (and protocol DTL if applicable) for your site. You will need to contact your site's RSS or DTL administrator to request the addition of your name on the roster. Information on new Rave accounts is in the protocol (section 4 for protocols that use the newest CTEP template). Please contact the CTSU Help Desk for more assistance CTSUContact@Westat.com

The Theradex Specimen Tracking System is integrated within a study in Rave. Contact your RSS or DTL site administrator or CTSU to ensure you are on the site roster for your study with the role of **Rave Clinical Research Associate** (CRA) for each protocol you need to enter data. For protocols that require a DTL: A staff member who is on the roster as Rave CRA but not on the DTL will only receive an invitation of Read Only. Once they are on the DTL, CTSU will send the Rave CRA invitation.

CTEP-IAM and Rave Account Setup

All individuals are required to have an active CTEP-IAM account prior to being granted access to Rave. To create a CTEP-IAM account, proceed as follows:

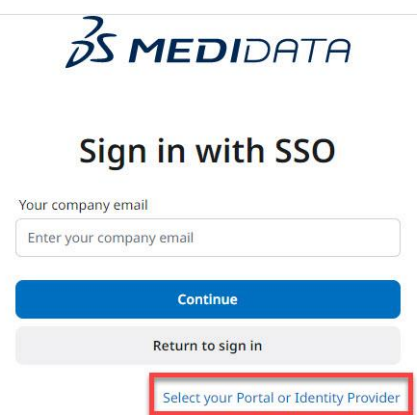
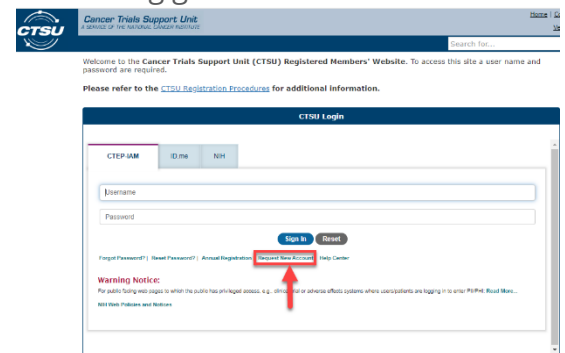
1. Go to the following URL:
https://www.ctsu.org/public/default_login.aspx
2. Under the buttons, click **Request New Account**. This will take you to the CTEP-IAM page.
3. Follow the prompts to enter the required identifying information for your account. Choose the Associate Plus application
4. You will receive an authorization email in **24-48 hours**.

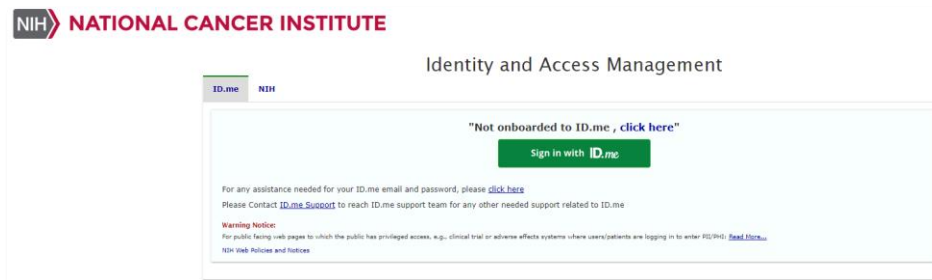
5. After receiving the CTEP-IAM authorization (which may take up to 48 hours), *documentation must be uploaded to the CTEP Registration and Credential Repository (RCR) to complete your registration.*

6. After these steps are completed, go to the following URL:
<https://login.imedidata.com/login>

7. Click on **Sign in with SSO**
8. Click on **Select your Portal or Identity Provider**

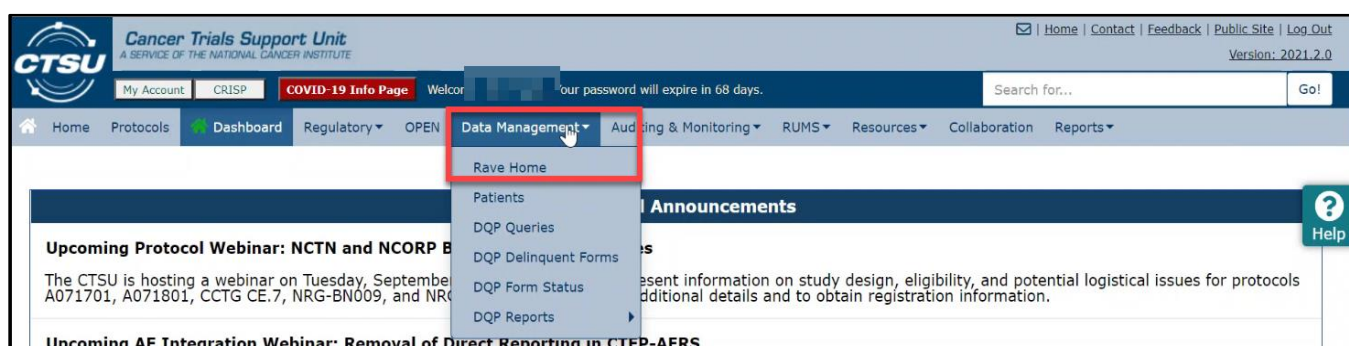
9. From the menu, choose **CTEP-IAM IdP**.
10. Click **Select**
11. At the NCI Identity and Access Management (IAM) screen, enter your **ID.me** credentials.





Logging in through CTSU

1. Go to the following URL: <https://www.ctsu.org/Public/Default.aspx>
2. Click **Log in**.
3. At the NCI Identity and Access Management (IAM) screen, enter your **ID.me** credentials.
4. Click **I agree and logon**.
5. Go to the **Data Management** menu.
6. Click **Rave Home**.

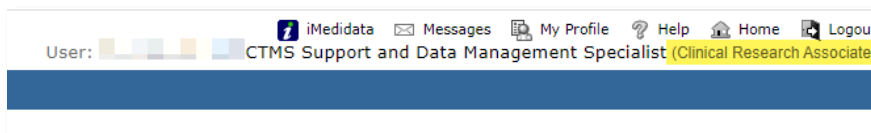


Current role in Rave

After logging in to Rave and select your study. If you only have the **Clinical Research Associate** role you will see it next to your name in the top right hand corner of the website after selecting the study.

If your role is Read Only, you will not be able to enter or edit data.

The CTSU Help Desk will be able to advise you further on why you do not have Clinical Research Associate access.



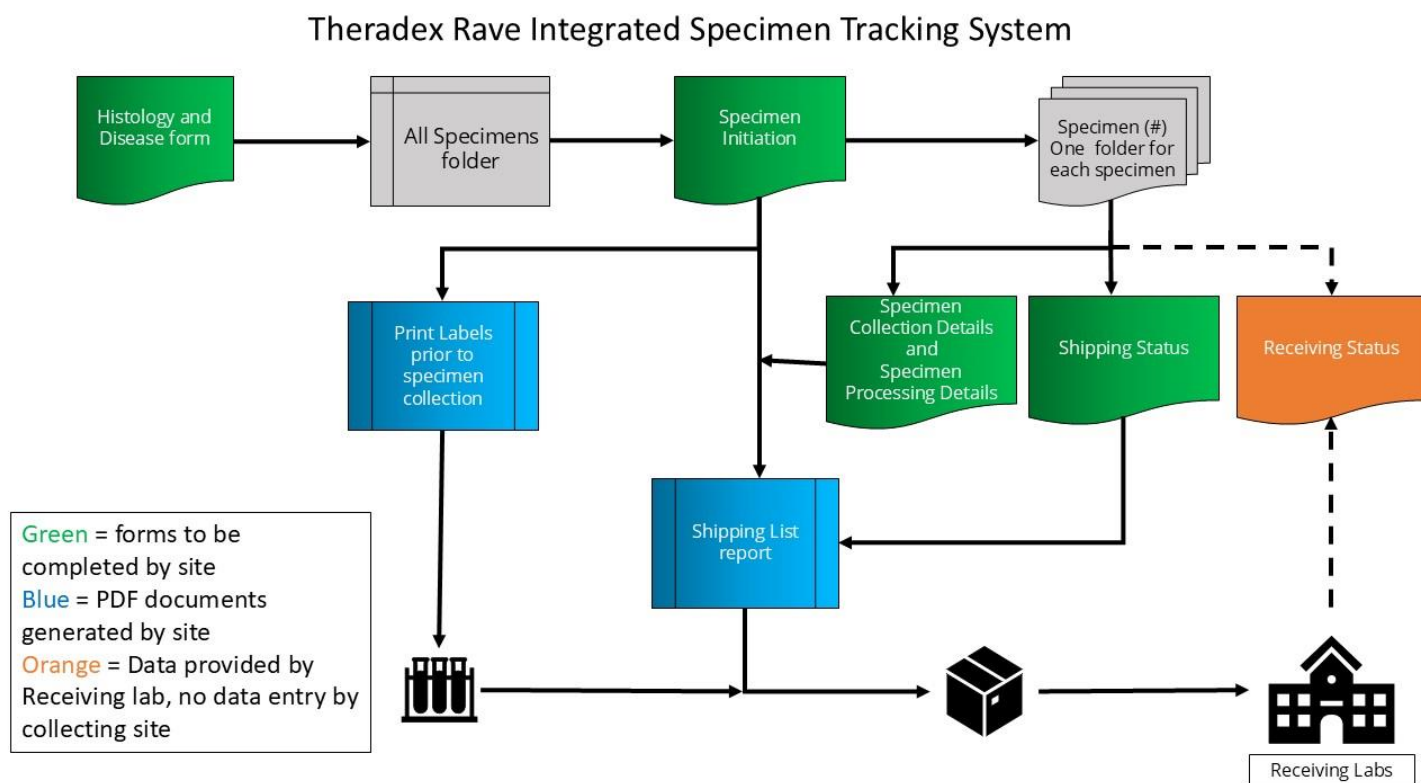
If your role is **Clinical Research Associate** and you are working on an older study (10300 and lower), contact STS support as we may need to add the **CRA Specimen Tracking** role to your account

Specimen Tracking System Overview

The specimen tracking system was initially designed in conjunction with the Biopathology Center at Nationwide Children's Hospital. In earlier protocols they were known as the ETCTN Biorepository. Currently they have an NCI contract as the EET Biobank (Early-Phase and Experimental Clinical Trials Biospecimen Bank).

The Specimen Tracking System is made up of several parts. It is important to complete all the specimen tracking forms for every specimen collected from a participant. The system's programming depends on completion of the **Histology & Disease** form found in the Enrollment folder. Be sure this form is completed before entering specimen data. The remaining forms are located in the **All Specimens** folder.

Important – If the **Histology & Disease** form is not completed, the other forms/steps of STS will not function properly



Summary of STS data entry

All steps must be completed prior to shipping the specimen. Hand delivery of specimens within the same institution is considered shipping and completion of all steps is required.

1. Go to **Enrollment** folder and complete the [Histology & Disease](#) form.
2. If patient has changed their consent for specimens to be collected and/or stored, update the [Consent](#) form.
3. Go to the [All Specimens](#) folder.
4. Complete the log line in the [Specimen Initiation](#) form for each specimen collected.
5. Complete the [Print Labels](#) form. Labels will be sent to the user's email address.
6. Open the **Specimen (#)** folder within the All Specimens folder. The number corresponds to the log line in the Specimen Initiation form. The date and specimen type are also present to help in selection.
7. On the **day of collection**, complete the [Specimen Collection Details](#) form.
8. If the specimen is processed, complete the [Specimen Processing Details](#) form.
9. When **ready to ship**, complete the [Shipping Status](#) form for each individual specimen.
10. Print the [Shipping List](#) report to send with the specimens (see page 19). Put the shipping list report and hard copies of relevant pathology reports in the box with the specimens.

Enrollment folder - Histology & Disease form

In the **Enrollment** folder, confirm the **Histology & Disease** form has been completed for the participant.

This is the first step in specimen tracking and **ALWAYS** needs to be completed before entering specimen data. Fields in red are required fields.

If all of the information is not known, at minimum, complete the SnoMed field (see information below). The remaining required fields, if blank, will trigger a query after saving but you can proceed to enter specimens and return to finish this form later.

The screenshot shows the 'Histology and Disease' form for patient AL09262024. The form includes fields for Disease Stage (Stage IA), Tumor Grade (Well Differentiated), SnoMed Disease Term/Code (Lung Carcinoma = 448993007), Histology/Cytopathology (Non small cell carcinoma), Initial Diagnosis Date (20 Sep 2024), and Date of Confirmation of Histology (22 Sep 2024). A yellow warning box states: 'On-study specimen specific reports should not be uploaded here. Upload on-study specimen reports on the Specimen Tracking Enrollment form. Any report must have PHI and PII redacted from the report and the filename. Keep the size of the uploaded file as small as possible to avoid adversely impacting Rave EDC performance.' Below this is a table for Report Type and Report Upload. The bottom of the form has a 'Save' button and a 'Cancel' button.

Enter the **Disease Stage** and **Tumor Grade**, if known and applicable. Not all diseases are staged or graded.

Enter the **SnoMed Disease Term/Code**. Start typing in the box and the options will narrow based on what you type.

The screenshot shows a dropdown menu with the text 'Kid' entered. The dropdown list shows three options: 'Kidney Oncocytoma = 254922006', 'Kidney Wilms Tumor = 25081006', and 'Kidney Wilms Tumor = 302849000'.

The SNOMED Disease Term/Code list is a combination of several sources. Some terms may be duplicated, select the first instance in the list.

In the **Histology/Cytopathology** field, briefly transcribe the findings in the pathology report which the patient’s diagnosis is taken.

Initial Diagnosis Date is the date of the procedure, pathology report or evaluation used to determine the diagnosis.

In the bottom of the form, the supporting documentation can be uploaded. Use the Edit pencil to open the first row. Select the Report Type. Use the file browser to select the PDF in the Report Upload field. Use Add a New Log line to add any additional documents.

Notes on report uploads:

- The EET Biobank requires a Pathology report for tissue specimens.
- The upload of pathology and other reports depends on the protocol, however if the only samples collected are blood samples, these reports are generally not needed.
- Pathology reports that correspond to samples entered in the Specimen Tracking Enrollment form (i.e., collected on study) are uploaded on that form.
- **Any report must have PHI and PPI redacted from within the report and removed from the filename. Patients' initials are considered PHI, please see list below for other relevant data points.**
- The participant ID and UPID displayed must be included in the report.
- An extra specimen label is an easy way to add IDs onto the report before scanning.

Examples of PHI/PPI

- Names and initials
- Geographic subdivisions smaller than a state (e.g., street address, city, county, etc.).
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URLs
- Biometric identifiers, including finger or voice prints
- Full face photographic images and any comparable images
- Internet Protocol address numbers
- Any other unique identifying number characteristic or code (e.g., DNA)

Consent form

The consent to collect, test, and store specimens is recorded in the combined Consent form in the Study & Specimen Consent folder. This form auto-populates with consent data that is entered in OPEN during registration. The auto populated data cannot be edited. Changes to consent are recorded in the log at the bottom of the form.

The questions which appear under **Consent for Optional Studies** are specific to each study and may differ from the screen shot below. The steps to complete the form, remain the same.

10629

Patient:

Page: Consent - Study & Specimen Consent

NOTE: Initial Consent reflects data entered in OPEN and are not modifiable. Any changes should be recorded on a new logline below Ongoing Consent.

I. Initial Consent

Informed Consent Version Date	01 Jun 2024			
Date (of initial consent)	01 Oct 2024			
Consent Type	Consent			
I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies indicated.				
	Yes			
Consent for Optional Studies				
I agree that my samples and related health information may be used for the laboratory studies described in the study consent.				
	Yes			
I agree that my samples and related health information may be kept in a biobank for use in future health research.				
	Yes			

II. Ongoing Consent

After enrollment, add a log line for any change to consent.
If the participant withdraws consent, select No for the consent withdrawn and provide a reason in the box.

#	Informed Consent Version Date	Date (of consent change)	Consent Type	Informed Consent	Sample and Health Information	Storage	
1	—	—	—	—	—	—	

Add a new Log line Inactivate

[Printable Version](#)
[View PDF](#)
[Icon Key](#)

CBF Version 3435 - Prod/Generated: 18 Oct 2024 13:22:48 Eastern Daylight Time
 Save
Cancel

Informed Consent Version Date: The date of the IC document presented to the participant and which the patient signed.

Date (of initial consent): Date the participant signed the IC document.

Consent Type:

I have read this consent form ... : Affirmative statement from IC document. Participant response captured in OPEN.

Samples for laboratory studies ... : Participant affirms to have specimens collected and analyzed as described in the IC document.

Samples for future research ... : Participant affirms to allow specimens to be stored and used in future research.

If the Patient changes their consent (including withdrawal from study) or if the patient is reconsented, use the **Edit** pencil (red arrow) to expand the log line to record this information.

For Study Reconsent, enter the version date of the IC document and the date of consent.

For Study Withdrawal, enter the date of consent change and select the Study Withdrawal radio button. To the right of the consent statement, select No and enter the participant's reason to withdrawal from the study. Be sure to respond to the remaining questions in the Consent for Optional Studies section.

For Optional Studies, enter the Date (of consent change), select the Optional Studies radio button, and complete the questions after Consent for Optional Studies. For No, please enter the participant's reason for withdrawal of consent for lab testing and/or storage.

Any further changes in consent can be documented by using **Add a new Log Line** at the bottom of the form. For any erroneous entries, use the **Inactivate** function.

All Specimens folder



Ensure the Histology and Disease form in the Enrollment folder is complete before proceeding with any data entry.

Return to the participant level by clicking the tab with the participant ID and open the **All Specimens** folder.

AL09262024

Enrollment

Study & Specimen Consent

Comment

Baseline

Tumor Serology

Lesion Evaluations

Logs: VS - Preg - CM - TR

Physical Exam

Pre-Biopsy Lesion Sc

All Specimens

PK/PD/PG

Lab: Hematology

Lab: Blood Chem - He

Lab: Blood Chem - Re

Lab: Chemistry - Pancreatic/Thyroid & Cardiac

Lab: Other Serum Chemistries

Lab: Red Cell Indices

Lab: Creatinine Clear

Lab: Urinalysis

Lab: Other Urinalysis

Lab: Literal

Lab: Unanticipated

Lab: Bone Marrow

Lab: Blood Gases

Visit

Task Summary: Patient

NonConformant Data

Open Queries

Answered Queries

Overdue Data

Add Event

...

Add

Icon Key

CRF Version 7425 - Page Generated: 27 Sep 2024 11:03:51 Eastern Daylight Time

10629

Theradex

AL09262024

Grid View

Click Here for Customer Support Information

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Specimen Initiation form



Ensure the Histology and Disease form in the Enrollment folder is complete before proceeding with any data entry.

The Specimen Initiation form contains a list of all expected specimens based on the Summary Table for Specimen Collection in the protocol. Each specimen is listed by **Timepoint** in ascending order and labeled as either **Mandatory** or **Optional**. If there are alternative specimens accepted by the study, these will be labeled as preferred or alternate based on their designation in the protocol. Collection details, shipping destinations, or other instructions are present in the **Notes** field for each specimen.

Patient: AL11152024
Page: Specimen Initiation - All Specimens

Protocol required specimens are listed below. If specimen is collected as required, record date of collection and information about the specimen. If specimen is not collected, check the checkbox and select a reason it was not collected.

***Note: Do not inactivate pre-populated log lines.**

#	Specimen Number	Notes	Timepoint	Collection Category	Submission Type	Collection Tube Type	Mandatory/Optional	Date of Specimen Collection	Block Number	Tissue Type	Surgical Path ID	Sample Not Collected	Reason	Specimen ID	
1	1		Archival	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block		Mandatory - Preferred					☐		(Derived)	
2	2	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Stained Slide		Mandatory - Alternate					☐		(Derived)	
3	3	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained uncharged slide		Mandatory - Alternate					☐		(Derived)	
4	4		Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained charged slide		Mandatory					☐		(Derived)	
5	5	Molecular Oncology Laboratory at JHU: 1 tube	Cycle 1 Day 1 Pre-dose	Blood	Plasma	ctDNA Streck	Mandatory					☐		(Derived)	

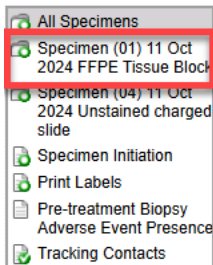
For Tissue specimens:

1. Click the **Edit** pencil to open the row for editing.
2. Enter the **Date of Specimen Collection**. This date is when the specimen collection occurred and must match the date on the specimen label.
3. Enter the **Block Number** from the corresponding pathology report. Alphanumeric entries are supported.
4. Select the **Tissue Type** from the drop-down menu.
5. Enter the **Surgical Path ID** from the corresponding pathology report, if available.
6. Click **Save**.

For non-Tissue specimens (i.e. blood, urine, CSF)

1. Click the **Edit** pencil to open the row for editing.
2. Enter the **Date of Specimen Collection**. This date is when the specimen collection occurred and must match the date on the specimen label.
3. Click **Save**. After saving, the **Specimen ID** will be displayed in the last column.

#	Specimen Number	Notes	Timepoint	Collection Category	Submission Type	Collection Tube Type	Mandatory/Optional	Date of Specimen Collection	Block Number	Tissue Type	Surgical Path ID	Sample Not Collected	Reason	Specimen ID
1	1		Archival	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block		Mandatory - Preferred	11 Oct 2024	1A	Primary	SP1993285	☐		10629-GL14P4-1 (Derived)
2	2	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Stained Slide		Mandatory - Alternate					☒	Not Required	(Derived)
3	3	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained uncharged slide		Mandatory - Alternate					☒	Not Required	(Derived)
4	4		Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained charged slide		Mandatory	11 Oct 2024	1A	Primary	SP1993285	☐		10629-GL14P4-4 (Derived)



After saving, the **Specimen ID** will be displayed in the last column of the form. A folder will appear in the folder panel on the left labeled with the Specimen number, collection date and specimen type. The [Specimen Collection Details](#), [Specimen Processing Details](#), and [Shipping Status](#) forms for the specimen are located in these folders. These forms need to be completed prior to shipment.

Samples Not Collected

Use this checkbox to mark any sample that was not collected, then select a Reason in the drop-down menu in the next column.

- For **Mandatory – Preferred** specimens, this will **automatically** check when the Alternate specimen is collected.
- For **Mandatory – Alternate** specimens, this will **automatically** check when the Preferred specimen is collected.

Reasons

Use this menu in conjunction with the Samples Not Collected Checkbox. Select the best fitting reason to explain why the sample was not obtained.

- For **Mandatory – Preferred** specimens, this will **automatically** be selected with 'Protocol Specified Alternate Submitted' when the Alternate specimen is collected.
- For **Mandatory – Alternate** specimens, this will **automatically** be selected with 'Not Required' when the Preferred specimen is collected.

Specimen collection issues

Protocol Specified Alternate Submitted

The protocol may list alternative specimen types that can be submitted if the required specimen is not available (pertains mostly to tissue specimens). The requested specimen is listed as Mandatory – Preferred and the alternative specimens are Mandatory – Alternate in the Specimen Initiation form.

Time Point	Specimen	Send Specimens To:
Archival		
	- Formalin-fixed paraffin-embedded (FFPE) tumor rich tissue block¹ (Mandatory) If a block is not available, then submit: 20 unstained charged slides (5 µm)	EET Biobank

For this example, when the collection date and tissue specific fields are entered for the slide specimens, the FFPE block is automatically updated. The Not Collected checkmark is active and Protocol Specified Alternate Submitted is chosen from the Reason menu.

#	Specimen Number	Notes	Timepoint	Collection Category	Submission Type	Collection Tube Type	Mandatory/Optional	Date of Specimen Collection	Block Number	Tissue Type	Surgical Path ID	Sample Not Collected	Reason	Specimen ID
1	1		Archival	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block		Mandatory - Preferred					☒	Protocol Specified Alternate Collected	(Derived)
2	2	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Stained Slide		Mandatory - Alternate	11 Oct 2024 ^a	1A ^a	Primary ^a	SP1993285 ^a	☐		10629-GL14P4-2 (Derived)
3	3	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained uncharged slide		Mandatory - Alternate	11 Oct 2024 ^a	1A ^a	Primary ^a	SP1993285 ^a	☐		10629-GL14P4-3 (Derived)
4	4		Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained charged slide		Mandatory	11 Oct 2024 ^a	1A ^a	Primary ^a	SP1993285 ^a	☐		10629-GL14P4-4 (Derived)

Not Collected: Specimen was not obtained.

Collection Delayed: Use as a temporary selection when the collection of this specimen is expected at a later time than others collected at the same time point. When the sample is eventually collected, this reason should be removed, and the Sample not Collected checkbox unchecked. If the collection timepoint has elapsed, this reason needs to be changed to Not Collected

Patient Refused: Patient refused this sample collection. If the patient has changed their consent for all future collections, document this in the medical record and on the Consent form.

Less than Complete Specimen Collection: The quantity of sample was not sufficient for processing and submission.

Local Testing: The specimen will be tested locally and not entered into the STS.

Treatment Delayed\held\withdrawn: The specimen is treatment related and not necessary as the patient's treatment has been delayed or withdrawn.

Not Required: This reason is automatically selected for any Mandatory – Alternate specimen when the preferred specimen is collected. Do not manually apply this to any Mandatory specimen without checking with the study team and data management first.

Patient enrolled in a different treatment Arm, Cohort or Subgroup: The patient's treatment has changed, and the specimen is no longer necessary.

Not Feasible: Specimen collection was attempted but was not able to be obtained or other external factors prevented specimen collection. Do not use this selection if a patient refuses to be drawn.

Incorrect Sample Collected – Destroyed: An error was made in specimen collection or processing (i.e., wrong tube type, tissue processed incorrectly, etc.) and the decision is made by the **PI in consultation with the Biobank** to destroy the sample or return it to the site.

Incorrect Sample Collected – Submitted: An error was made in specimen collection or processing, but the decision is made by the **PI in consultation with the Biobank** to keep the sample for analysis. The protocol defined sample is marked Not Collected, and this reason should be selected. Then a separate entry needs to be made in Specimen Initiation for unexpected sample.

In the example below, the protocol requires a blood collection in a cfDNA Streck tube to be processed for Plasma and then shipped to the repository. There was a mix up at the lab and whole blood was shipped. The study team has decided to keep the sample.

- 1. Go to the log line entry in **Specimen Initiation** for the that was incorrectly processed.
- 2. Click on the **Sample Not Collected** checkbox.
- 3. Select **Incorrect Sample Collected – Submitted** in the **Reason** dropdown.
- 4. Click **Save**.

44	44	1 tube sent to Molecular Oncology Laboratory at JHU and 1 tube sent to Rudin laboratory at MSKCCs	End of treatment Pre-dose	Blood	Plasma	cfDNA Streck	Mandatory	☐					☒	Incorrect Sample Collected – Submitted
----	----	---	---------------------------	-------	--------	--------------	-----------	--------------------------	--	--	--	--	-------------------------------------	--

Proceed to make an entry for the sample as it was collected/processed:

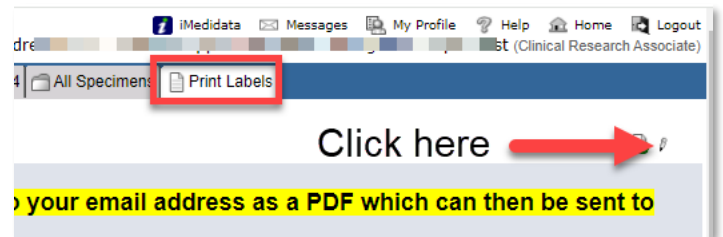
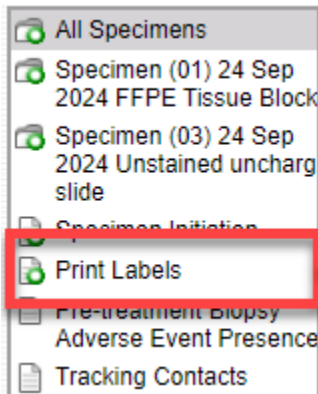
- 1. Go to the bottom of the **Specimen Initiation** form, click **Add a New Log line**.
- 2. Set the **Protocol Timepoint**, **Specimen Category**, and **Specimen Type** fields.

6		End of treatment Pre-dose	Blood	Blood	cfDNA Streck
---	--	---------------------------	-------	-------	--------------

- 3. Proceed to enter the **Collection Date** and the tissue sample fields if applicable.
- 4. Click **Save**.
- 5. After saving a Specimen (#) folder will populate with the remaining forms and the specimen will be available in Print Labels.

Print Labels

In the **All Specimens** folder, click on **Print Labels** to open the form.



1. At the top right of the form, click on the pencil to edit.
2. The quantity of labels defaults to 1, if more than 1 is needed edit the number in the **How many labels?** field.
3. Click **Save**. After updating, wait a few minutes for Rave to register the update.

10629 Theradex AL09262024 All Specimens Print Labels

Patient: AL09262024
Page: Print Labels - All Specimens

Labels will be delivered to your email address as a PDF which can then be sent to your printer. For a standard printer, use this product. These labels are 0.5 inches high and 1.28" wide.

Label Layout is a mandatory field – after the first use, click the edit pencil to the right. If no value is selected it is defaulted to "Multiple labels per page".

Label Layout New Information

If you have previously used this form, click the edit pencil to the right to specify a timeout.

Available Protocol Timepoints New Information

- If the number of labels you need are listed below already, click the checkbox next to any row (multiple rows are allowed) or choose a protocol timeout from above, then save the form.
- If you need a different number of labels, update the below values, and save the form without clicking any checkboxes. Wait a few minutes for Rave to make clinical view updates, then either select the protocol timeout above or click any of the checkboxes below, then save the form.
- Carefully match the Pass letter (A, B, C, D) which is at the end of a list of codes just above the Date to the specimen collected during that pass. Every Biopsy collected specimen will have 4 pass specific labels. You need only print the relevant ones.

#	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	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/A	A	New Information 3	New Information ☐	☒
2	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/B	B	New Information 2	New Information ☐	☒
3	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/C	C	New Information 1	New Information ☐	☒
4	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/D	D	New Information 1	New Information ☐	☒
5	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324		New Information 1	New Information ☐	☒

10629 Theradex AL09262024 All Specimens Print Labels

Labels will be delivered to your email address as a PDF which can then be sent to your printer. For a standard printer, use this product. These labels are 0.5 inches high and 1.28" wide.

Label Layout is a mandatory field – after the first use, click the edit pencil to the right. If no value is selected it is defaulted to "Multiple labels per page".

Label Layout Multiple labels per page

If you have previously used this form, click the edit pencil to the right to specify a timepoint.

Available Protocol Timepoints

- If the number of labels you need are listed below already, click the checkbox next to any row (multiple rows are allowed) or choose a protocol timepoint from above, then save the form.
- If you need a different number of labels, update the below values, and save the form without clicking any checkboxes. Wait a few minutes for Rave to make clinical view updates, then either select the protocol timepoint above or click any of the checkboxes below, then save the form.
- Carefully match the Pass letter (A, B, C, D) which is at the end of a list of codes just above the Date to the specimen collected during that pass. Every Biopsy collected specimen will have 4 pass specific labels. You need only print the relevant ones.

#	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	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/A	A	New Information 1	☐	☒
2	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/B	B	New Information 1	☐	☒
3	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/C	C	New Information 1	☐	☒

For **tissue** specimens, five separate labels will automatically be created in the form. These will be labeled for four separate biopsy passes A, B, C, D and one unlabeled. If the sample has less than four passes, the extra labels can either be discarded or use the Print checkbox (see below) to only print the passes needed.

There are two ways to print labels – **CHOOSE ONE METHOD ONLY.**

- Printing labels by manual selection – the user can select individual Specimen IDs by clicking the checkbox under the column Print.
- OR--
- Printing labels by Available Protocol Timepoints.

Printing labels by manual selection

10629 Theradex AL09262024 All Specimens Print Labels

Patient: AL09262024
Page: Print Labels - All Specimens

Labels will be delivered to your email address as a PDF which can then be sent to your printer. For a standard printer, use [this product](#). These labels are 0.5 inches high and 1.28" wide.

Label Layout is a mandatory field – after the first use, click the edit pencil to the right. If no value is selected it is defaulted to "Multiple labels per page".

Label Layout Multiple labels per page

If you have previously used this form, click the edit pencil to the right to specify a timepoint.

Available Protocol Timepoints

- If the number of labels you need are listed below already, click the checkbox next to any row (multiple rows are allowed) or choose a protocol timepoint from above, then save the form.
- If you need a different number of labels, update the below values, and save the form without clicking any checkboxes. Wait a few minutes for Rave to make clinical view updates, then either select the protocol timepoint above or click any of the checkboxes below, then save the form.
- Carefully match the Pass letter (A, B, C, D) which is at the end of a list of codes just above the Date to the specimen collected during that pass. Every Biopsy collected specimen will have 4 pass specific labels. You need only print the relevant ones.

#	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	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/A	A	New Information 3	☒
2	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/B	B	New Information 2	☒
3	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/C	C	New Information 1	☐
4	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/D	D	New Information 1	☐
5	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324		New Information 1	☒

- Select the **Label Layout**:
 - Multiple labels per page** (default) — for standard laser printers
 - One label per page** — for special purpose thermal label printers
- Skip over** Available Protocol Timepoints
- Click the **Print** checkbox for each specimen needed (multiple selections allowed).
- Click **Save** button.

*If both protocol timepoint and the print check box are used, no email will be issued. Only **one type** should be chosen.*

Printing labels by Available Protocol Timepoints

Patient: AL09262024
Page: Print Labels - All Specimens

Labels will be delivered to your email address as a PDF which can then be sent to your printer. For a standard printer, use this product. These labels are 0.5 inches high and 1.28" wide.

Label Layout is a mandatory field – after the first use, click the edit pencil to the right. If no value is selected it is defaulted to "Multiple labels per page".

Label Layout  Multiple labels per page

If you have previously used this form, click the edit pencil to the right to specify a timepoint.

Available Protocol Timepoints  Archival

- If the number of labels you need are listed below already, click the checkbox next to any row (multiple rows are allowed) or choose a protocol timepoint from above, then save the form.
- If you need a different number of labels, update the below values, and save the form without clicking any checkboxes. Wait a few minutes for Rave to make clinical view updates, then either select the protocol timepoint above or click any of the checkboxes below, then save the form.
- Carefully match the Pass letter (A, B, C, D) which is at the end of a list of codes just above the Date to the specimen collected during that pass. Every Biopsy collected specimen will have 4 pass specific labels. You need only print the relevant ones.

#	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	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/A	A	New Information ▼ 3	☐	
2	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/B	B	New Information ▼ 2	☐	
3	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/C	C	New Information ▼ 1	☐	
4	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324/D	D	New Information ▼ 1	☐	
5	1	4248G2K1	10629-4248G2K1-1	Archival	ARCHIVAL	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block	P/2A/SP199324		New Information ▼ 1	☐	

- Select the **Label Layout**:
 - Multiple labels per page** (default) — for standard laser printers
 - One label per page** — for special purpose thermal label printers
- Select one of the **Available Protocol Timepoints** from the dropdown.
- Skip over** the Print checkbox.
- Click the **Save** button.

*If both protocol timepoint and the print check box are used, no email will be issued. Only **one type** should be chosen.*

Label emails

After saving the Print Labels form, the system will generate the same two emails shown above for manual selection, however these will include the timepoints that match the user selected values.

Once the user saves the form, two emails will be sent. One email will be sent with the QR Coded labels as a pdf attachment. Open in Acrobat Adobe reader and follow the printing instructions.

Specimen Labels for patient AL09262024 in protocol 10629

L

IWRS Administrator <local.administrator.iwrs@therade

To

☺

↩ Reply

↩ Reply All

➡ Forward

📧

⋮

Fri 10/4/2024 10:39 AM

📎

10629(UAT)_AL09262024_20241004_103919.pdf

22 KB

PDF with QR code labels

Medidata Rave Specimen Tracking System

Dear Rave STS user,

Attached is a PDF of your specimen labels with the parameters as you have set them – one label per page or multiple labels in columns. Please print this on your chosen device and apply the labels to the specimen containers.

There is space on the label to handwrite the date and optionally the time.

10629(UAT)-AL09262024 4248G2K1

10629-4248G2K1-1

ARCHIVAL

FFPE Tissue Block

P/2A/SP199324/A

Date:

10629(UAT)-AL09262024 4248G2K1

10629-4248G2K1-1

ARCHIVAL

FFPE Tissue Block

P/2A/SP199324/B

Date:

10629(UAT)-AL09262024 4248G2K1

10629-4248G2K1-1

ARCHIVAL

FFPE Tissue Block

P/2A/SP199324

Date:

A second email will be sent to the user with an active link to download the QR code pdf. Users can copy / paste the link into a browser or click on the active link and pdf will be downloaded in the download folder.

Specimen Labels for patient AL09262024 in protocol 10629

N

noreply@mdsol.com

To

☺

↩ Reply

↩ Reply All

➡ Forward

📧

⋮

Fri 10/4/2024 10:39 AM

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe. Please click on the "Phish Alert" button on the top right of the Outlook dashboard to report any suspicious emails.

Dear Rave STS user,

Please click this link [https://spectrack.theradex.com/GeneratePDF.aspx?StudyID=10629\(UAT\)&PatientID=AL09262024&LogLineIds=1|2|5&paperConfig=2&emailAddress=alohrum@theradex.com](https://spectrack.theradex.com/GeneratePDF.aspx?StudyID=10629(UAT)&PatientID=AL09262024&LogLineIds=1|2|5&paperConfig=2&emailAddress=alohrum@theradex.com) to download the PDF of your specimen labels with the parameters as you have set them – one label per page or multiple labels in columns. Check your Downloads folder, then please print this on your chosen device and apply the labels to the specimen containers. There is space on the label to hand write the date and optionally the time.

Apply labels to the specimen(s), and hand write the collection date and time on the label.

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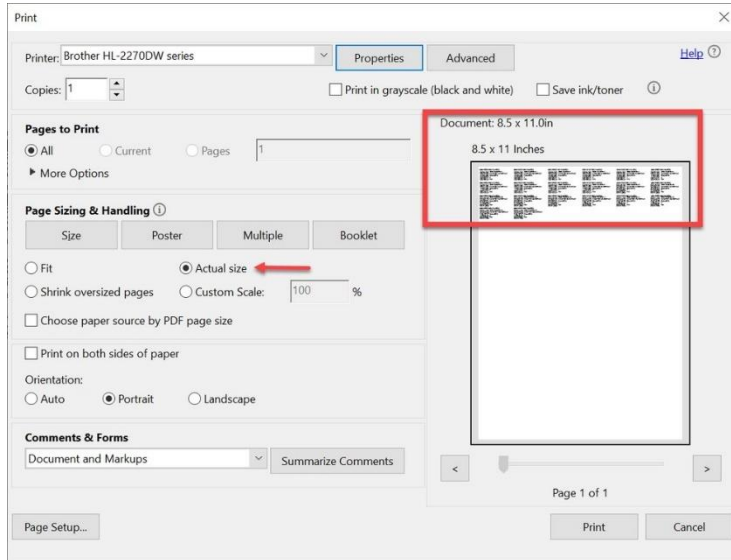
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Printing in Adobe

The PDF document needs to be printed through Adobe Acrobat reader (free version) and not the embedded PDF viewer in Chrome or Edge.

Multiple Labels per page:

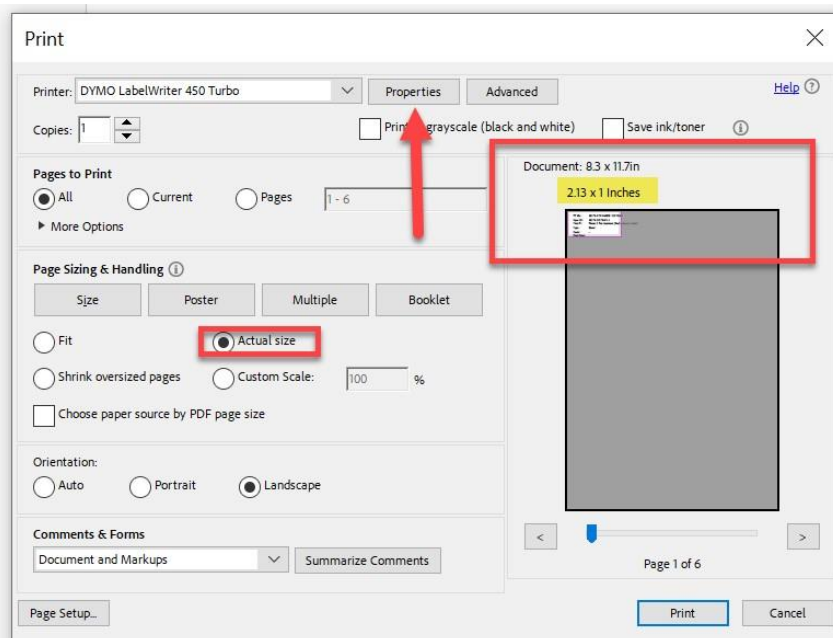


In the Print menu:

Under **Page Size and Handling**, select **Actual Size**.

In the preview, the document is 8.5 x 11, there are grey lines on the outside of the document, these are the programmed margins to match the LabTag supported laser printer labels.

One per page:



In the Print menu:

Under **Page Size and Handling**, select **Actual Size**.

Under **Properties**, the **Paper Size** needs to match the label size loaded into the printer.

In the **Document** preview, the white printing area should overlay the label that is in the top right hand corner of the document. You can confirm that the correct label size is selected (highlighted in image). You may need to set the **Portrait/Landscape** orientation, again refer to the preview.

Once you have tested and found the correct settings. Be sure to change the page size in the Windows Printer settings for the label printer so you will not have to do this each time they print through adobe. The Actual Size and Orientation should remain selected in Adobe but may change if toggling between printers.

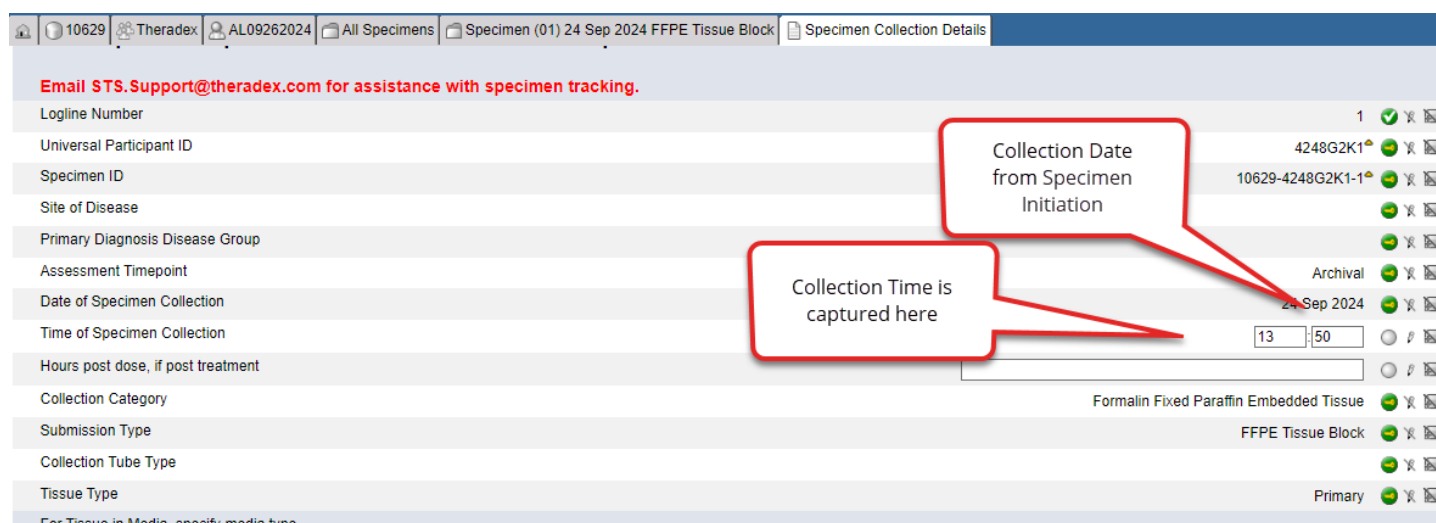
Specimen Collection Details



This form should be completed the same day as specimen collection even if the specimen is to be shipped at a later date.

After completing a logline in the **Specimen Initiation** form, a folder will have populated, **Specimen (#)** for each specimen line. **Specimen Collection Details** is the first form in the Specimen (#) folder. Required fields are in red font. Not all fields are relevant for all specimens.

At top of the form, several fields have a key icon . These fields are display only as the data is taken from other forms or not applicable to the Specimen Type. If changes are needed to the **Collection Date** or **Tissue Type**; the changes need to be made on the corresponding **Specimen Initiation** log line. Refer to the **Logline Number** in the first field of the form.



Email STS.Support@theradex.com for assistance with specimen tracking.

Logline Number 1

Universal Participant ID 4248G2K1

Specimen ID 10629-4248G2K1-1

Site of Disease

Primary Diagnosis Disease Group

Assessment Timepoint

Date of Specimen Collection 24 Sep 2024

Time of Specimen Collection 13:50

Hours post dose, if post treatment

Collection Category Formalin Fixed Paraffin Embedded Tissue

Submission Type FFPE Tissue Block

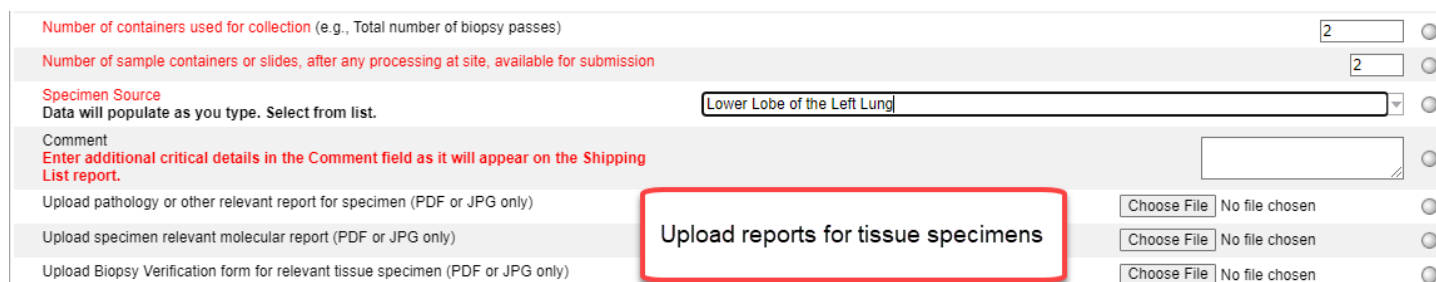
Collection Tube Type

Tissue Type Primary

For Tissue in Media: specify media type

Number of containers used... : Enter the number of tubes for blood or other liquid samples. For tissue in formalin, each cassette counts as 1 container. Do not submit free-floating tissue as it can be damaged during shipping.

Number of sample containers ... submission: Enter the number of samples that are available after any processing that will be submitted to the repository or testing lab.



Number of containers used for collection (e.g., Total number of biopsy passes) 2

Number of sample containers or slides, after any processing at site, available for submission 2

Specimen Source Lower Lobe of the Left Lung

Comment

Enter additional critical details in the Comment field as it will appear on the Shipping List report.

Upload pathology or other relevant report for specimen (PDF or JPG only) Choose File No file chosen

Upload specimen relevant molecular report (PDF or JPG only) Choose File No file chosen

Upload Biopsy Verification form for relevant tissue specimen (PDF or JPG only) Choose File No file chosen

Example 1: 2 tubes of blood are collected and there is no processing. Number of containers used is 2, number to submit is 2.

Example 2: 2 tubes of blood are collected then processed for plasma; 4 aliquots are made. Number of containers used is 2, number to submit is 4.

Example 3: 1 FFPE block is collected and processed into 20 unstained uncharged slides. Number of containers used is 1, number to submit is 20.

Specimen Source: If the specimen is blood, select **Blood** from drop down. For tissue specimens, specify the anatomical site.

Report Upload: The remaining three fields are for the upload of related reports for tissue specimens. Please upload the pathology, molecular or Biopsy Verification form using the appropriate field. Click **Choose File** and the Windows file explorer box will open for you to select the **De-identified** report (including removal of **PII/PHI** from filename).

After all necessary fields are entered, click **Save**.

Specimen Processing Details

This form records the processing start and end time associated with the specimen. This information is not applicable to all specimen types.

Specimen (01) 24 Sep 2024 FFPE Tissue Block

Specimen Collection Details

Specimen Processing Details

Shipping Status

Receiving Status

Interventional Radiology Biopsy Report

Pre-Analytic Results

Solid Tissue Pathology Verification and Assessment

CRF History

AL09262024 - Specimen Processing Details

AL09262024 - Specimen Collection Details

AL09262024 - Specimen Initiation

AL09262024 - Specimen

10629 Theradex AL09262024 All Specimens Specimen (01) 24 Sep 2024 FFPE Tissue Block Specimen Processing Details

Patient: AL09262024

Page: Specimen Processing Details - Specimen (01) 24 Sep 2024 FFPE Tissue Block

If sample was processed prior to shipment, please enter the time sample processing started (i.e. the time when tissue is placed in formalin, frozen, or placed in media). For blood, document the time that sample was processed (i.e. spun for serum or plasma).

Specimen ID

10629-4248G2K1-1

Start Date of Processing

24 Sep 2024

Start Time of Processing

14:30

If sample is placed in formalin, please complete the following two fields.

End Date of Formalin Fixation

End Time of Formalin Fixation

If Ethanol processing is required, please complete the following four fields.

Start Date of Ethanol Processing

Start Time of Ethanol Processing

End Date of Ethanol Processing

End Time of Ethanol Processing

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 7425 - Page Generated: 18 Oct 2024 14:26:39 Eastern Daylight Time

Save

Cancel

For processing blood specimens, the date and time recorded should be the start of centrifugation. If the blood specimen is not centrifuged, the date and time the cap is removed should be recorded.

For formalin fixed tissues, enter the start date and time of formalin fixation. The end date and time are recorded in the next two fields. If the tissue is to be further processed in Ethanol, use the next four lines to record the start and end date/time.

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Shipping

Shipping Status form

Complete the **Shipping Status** form for **each specimen** when it is ready to ship. The data on this form should only pertain to the specimen recorded on the Specimen Transmittal form. Each **Shipping Status** log line corresponds to a line item on the **Shipping List** report.

The Specimen Tracking System will now create a unique **Shipment ID** to organize and batch the specimens into a shipment. The Tracking Number provided by the shipper is still recorded but can be entered at a later time and is no longer required to create an outgoing shipment.

Creating a new Shipment

10629 Theradex AL09262024 All Specimens Specimen (01) 24 Sep 2024 FFPE Tissue Block Shipping Status

Patient: AL09262024
Page: Shipping Status - Specimen (01) 24 Sep 2024 FFPE Tissue Block

Email STS.Support@theradex.com for assistance with specimen tracking.

Specimen ID 10629-4248G2K1-1

Comments from Sender

#	Choose from list to add this specimen to existing shipment or choose New:	Shipment ID (Derived)	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														

Add a new Log line Inactivate
Current DateTime(Derived)

Printable Version View PDF Icon Key

CRF Version 7425 - Page Generated: 09 Oct 2024 10:20:33 Eastern Daylight Time

Save Cancel

1. In the **All Specimens** folder click on the **Specimen (#)** folder for the first specimen.
2. Click on the **Shipping Status** form in the folder panel.
3. Click the **Edit** pencil on empty logline.

10629 Theradex AL09262024 All Specimens Specimen (01) 24 Sep 2024 FFPE Tissue Block Shipping Status

Patient: AL09262024
Page: Shipping Status - Specimen (01) 24 Sep 2024 FFPE Tissue Block

Email STS.Support@theradex.com for assistance with specimen tracking.

Specimen ID 10629-4248G2K1-1

Comments from Sender

Currently viewing line 1 of 1.
Click here to return to "Complete View".

Choose from list to add this specimen to existing shipment or choose New: New (Complete and save this form once, then edit the log line to fill in the details)

Number of Samples Sent 2

Current DateTime(Derived)

Printable Version View PDF Icon Key

CRF Version 7425 - Page Generated: 09 Oct 2024 10:35:05 Eastern Daylight Time

Save Cancel

4. To start a new shipment, select **New** in the Choose from list ... menu. This entry will always be at the bottom of the list.
5. Enter the quantity in the **Number of Samples Sent** field. This number should match the quantity in the Specimen Collection Details form if everything is being sent.
6. Click **Save**.

10629 Theradex AL09262024 All Specimens Specimen (01) 24 Sep 2024 FFPE Tissue Block Shipping Status

Patient: AL09262024
Page: Shipping Status - Specimen (01) 24 Sep 2024 FFPE Tissue Block

Email STS.Support@theradex.com for assistance with specimen tracking.

Specimen ID 10629-4248G2K1-1

Comments from Sender

#	Choose from list to add this specimen to existing shipment or choose New:	Shipment ID (Derived)	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	New (Complete and save this form once, then edit the log line to fill in the details)	-	-	-	-	Andrew Lohrum	-	alohrum@theradex.com	2	-	-	-	-	-

Add a new Log line Inactivate

Current DateTime(Derived) 09 Oct 2024 10:40

Printable Version View PDF Icon Key
CRF Version 7426 - Data Generated: 09 Oct 2024 10:41:57 Eastern Daylight Time

Save Cancel

Specimen ID 10629-4248G2K1-1

Comments from Sender

Currently viewing line 1 of 1.
Click here to return to "Complete View".

Choose from list to add this specimen to existing shipment or choose New: New (Complete and save this form once, then edit the log line to fill in the details)

Shipment ID (Derived)

Courier Name FedEx

Shipping Tracking Number (enter if available)

Shipping Source Theradex

Sender's Name (as per CTEP-IAM account) Andrew Lohrum

Sender's Telephone Number

Sender's Email Address alohrum@theradex.com

Number of Samples Sent 2

Shipping Conditions Cold Pack

Shipped Date 30 Sep 2024

Destination EET Biobank

Notice sent to BPCBank@nationwidechildrens.org

Send Email Alert ☒

Current DateTime(Derived) 09 Oct 2024 10:40

Printable Version View PDF Icon Key
CRF Version 7426 - Data Generated: 09 Oct 2024 10:40:42 Eastern Daylight Time

Save Cancel

- After saving, click the **Edit** pencil again.
- Complete the fields in red:

Courier: Select the courier used by your institution. The tracking number is not required at this time but should be entered for completeness of data and to allow tracking of the specimen on the courier website.

Shipping Source: Your site. This field will have your site at the top.

Shipping Conditions: Select the temperature of the shipping container.

Destination: Choose the destination from the drop down menu. **If the drop down does not populate, go back to the Histology & Disease form and be sure it is complete. Do not manually enter data into this field. The destination must be selected from the drop down menu.**

Notice sent to: This field changes based on the entry made in the *Destination* field above it.

Email Alert: Click the checkbox to send a shipment announcement to the destination. **This field only needs to be used once per shipment.**
- Click **Save**. After saving, Rave will create a **Shipment ID**.

Specimen ID 10629-4248G2K1-1

Comments from Sender

#	Choose from list to add this specimen to existing shipment or choose New:	Shipment ID (Derived)	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	New (Complete and save this form once, then edit the log line to fill in the details)	S007-0001-10629	FedEx	-	Theradex	Andrew Lohrum	-	alohrum@theradex.com	2	Cold Pack	30 Sep 2024	EET Biobank	BPCBank@nationwidechildrens.org	☒

Add a new Log line Inactivate

Current DateTime(Derived) 09 Oct 2024 12:57

Printable Version View PDF Icon Key
CRF Version 7426 - Data Generated: 09 Oct 2024 12:57:50 Eastern Daylight Time

Save Cancel

Additional Specimens

The Shipping ID was created by following the steps above. Now it will be available to select for any additional specimens added to the shipment.

Specimen ID: 10629-4248G2K1-3

Comments from Sender

#	Choose from list to add this specimen to existing shipment or choose New:	Shipment ID (Derived)	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														

Printable Version View PDF Icon Key

CRF Version 7425 - Page Generated: 09 Oct 2024 13:18:02 Eastern Daylight Time

Save Cancel

1. In the **All Specimens** folder click on the **Specimen (#)** folder for the first specimen.
2. Click on the **Shipping Status** form in the folder panel.
3. Click the **Edit** pencil on empty logline.
4. Select the **Shipment ID** from the drop-down menu. The menu entry will also include the shipment date and destination to help in selection.

Specimen ID: 10629-4248G2K1-3

Comments from Sender

Currently viewing line 1 of 1.
Click here to return to "Complete View".

Choose from list to add this specimen to existing shipment or choose New:

Number of Samples Sent

Current DateTime(Derived)

Printable Version View PDF Icon Key

CRF Version 7425 - Page Generated: 09 Oct 2024 13:18:24 Eastern Daylight Time

Apply to Record

12-Jan-2024, Analytical Phar, S005-0001-10629, Ambient Pack
11-Jan-2024, Charles Rudin L, S004-0001-10629, Cold Pack
02-Jan-2024, NCLN Genomics L, S002-0001-10629, Dry ice
01-Jan-2024, EET Biobank, S001-0001-10629, Ambient Pack
01-Jan-2024, EET Biobank, S006-0001-10629, Ambient Pack
30-Sep-2024, EET Biobank, S007-0001-10629, Cold Pack
New (Complete and save this form once, then edit the log line to fill in the details)

5. Enter the quantity in the **Number of Samples Sent** field. This number should match the quantity in the Specimen Collection Details form if everything is being sent.
6. Click **Save**.

Specimen ID: 10629-4248G2K1-3

Comments from Sender

#	Choose from list to add this specimen to existing shipment or choose New:	Shipment ID for DSL(Derived)	Shipment ID (Derived)	Courier	Tracking Number	Source	Sender's Name	Sender's Telephone	Sender's Email	Number Sent	Sub Specimen ID	Shipping Conditions	Shipped Date	Destination	Notice sent to	Receiver Name	Email Alert
1	30-Sep-2024, EET Biobank, S007-0001-10629, Cold Pack	30-Sep-2024, EET Biobank, S007-0001-10629, Cold Pack	S007-0001-10629	FedEx		Theradex	Andrew Lohrum		alohrum@theradex.com	20		Cold Pack	30 Sep 2024	EET Biobank	BPCBank@nationwidechildrens.org	Biobank Staff	1

Add a new Log line Inactivate

Current DateTime(Derived)

09 Oct 2024 13:23

The information for the shipment will automatically populate. This specimen is complete, proceed to add any further specimens to the shipment using the same steps above.

Receiving Status form

This form is used by the recipient lab only. **The sending lab should not enter or modify any data in this form.**

The number of samples listed in Shipping Status will correspond to the number of loglines in Receiving Status.

If queries are noticed on the Receiving Status form, check the **Shipping Status** form for errors (such as quantity sent) and address them on the **Shipping Status** form.

Tracking Contacts form

This form is machine controlled. **Rave Users should not enter or modify any data in this form.**

If no Destinations are present in the Shipping Status form and the Tracking Contacts form is blank. Go to the **Enrollment** folder and complete the **Histology and Disease** form.

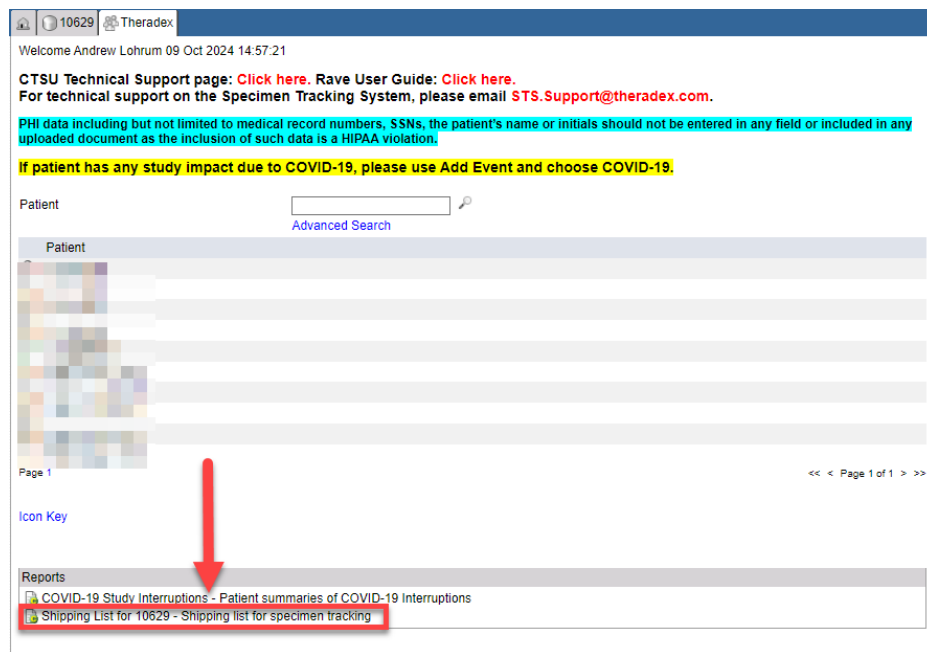
If you believe changes are needed in this form, please contact sts.support@theradex.com.

Shipping List

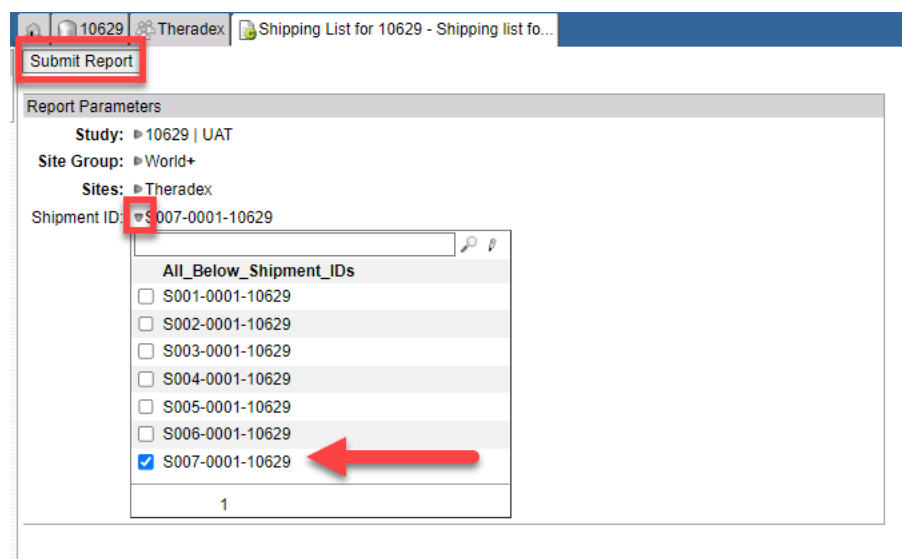
The Shipping List is indexed on the tracking number. Rave will pull entries from the Shipping Status forms with the same tracking number form and create a line in the Shipping List.

Check contents of the shipping container against the Shipping List prior to shipping.

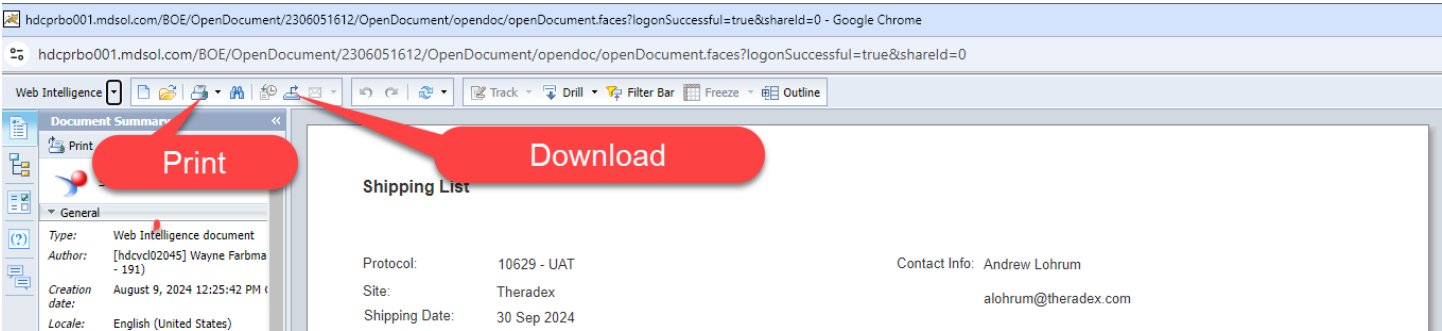
1. Click on the tab with your site name. Below the list of participants, in the **Report** box, click **Shipping List**.



2. Click on the **Shipment ID** arrow.
3. Select the Shipment ID from the list. As each ID is created, the serial number increases so the most recent shipment will be the highest number.
4. Click **Submit Report**.



5. Use the print icon or the download icon in the pop-up window.
6. Put shipping list report and hardcopies of relevant pathology reports in the box with the specimens.



NOTES:

- If the shipment includes specimens from multiple participants, the Shipping List will have a separate page for each participant.
- The number sent on the shipping list must correspond to the number of that specific sample that are packed in the box. This value is recorded on the Shipping Status form.

Shipping List

Protocol:

10629 - UAT

Site:

Theradex

Shipping Date:

30 Sep 2024

Shipment ID:

S007-0001-10629

Tracking Number:

Contact Info: Andrew Lohrum

alohrum@theradex.com

Specimen Initiation

Specimen Collection Details

Shipping Status

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		Tube Type					
10629-AL09262024	Archival	Formalin Fixed Paraffin Embedded Tissue	2	Primary	Lower Lobe of the Left Lung	24 Sep 2024 13:50	
4248G2K1		FFPE Tissue Block				N/A	
10629-4248G2K1		N/A					
10629-AL09262024	Archival	Formalin Fixed Paraffin Embedded Tissue	20	Primary	Left Lung, Inferior Lobe, Anterior Basal Segment	24 Sep 2024 13:50	
4248G2K1		Unstained uncharged slide				N/A	
10629-4248G2K1		N/A					

Line # in Specimen Initiation

Adverse Events in Specimen Collection

Adverse events that occur as a result of specimen collection **prior to treatment** are recorded on forms within the STS. These forms may not be present for your study.

If the event occurs during treatment, record the adverse event form in the current Course folder. See the Rave User Guide for more information.

Pre-treatment Biopsy Adverse Event Presence

Subject: [REDACTED]
Page: Pre-treatment Biopsy Adverse Event Presence - All Specimens

This form and the associated Adverse Events form should ONLY be used for AEs that occur as a result of tissue biopsy specimens collected prior to the initiation of treatment.

Are there any pre-treatment adverse events related to protocol-mandated biopsy collection? ☒ Yes ☐ No

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Save **Cancel**

If an adverse event occurs during the collection of a tissue specimen prior to treatment, click the **Yes** radio button and then click **Save**.

Subject: [REDACTED]
Page: Pre-treatment Biopsy Adverse Event Presence - All Specimens

This form and the associated Adverse Events form should ONLY be used for AEs that occur as a result of tissue biopsy specimens collected prior to the initiation of treatment.

Are there any pre-treatment adverse events related to protocol-mandated biopsy collection? Yes ☒ No ☐

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Save **Cancel**

After saving the form, the **Adverse Events** and **Expedited Reporting Evaluation** form will be available to collect more information.

Adverse Events (All Specimens)

The specimen associated with the adverse event must be entered into **Specimen Tracking Enrollment** and **Specimen Transmittal** before completing this form.

10403 Dana-Farber/Harvard Cancer Center All Specimens Adverse Events

Subject: [redacted]
Page: Adverse Events - All Specimens

This form should only contain Adverse Events that occur as a result of tissue biopsy collection procedures carried out prior to study treatment.

Form Instructions ?

* Red asterisk before a field denotes that it is required by the system for rules evaluation.

* Course/Cycle # 0 ✓ ✕

* Start date of this course/cycle 25 Mar 2020 ✓ ✕

* Start date of first course/cycle 25 Mar 2020 ✓ ✕

* Treatment assignment code Zone 1 DL1: Gemcitabine 175mg/m2 (Day 1 and 8) BAY 1895344 20mg twice daily (Days 2-3 and 9-10) ✓ ✕

REMINDER: Depending on your settings in Rave, this table may be paginated. If the options are available, click on **Paginate** and select **Show All Lines** or click on the numeric page numbers at the bottom right corner of the table. If these options are not available, you are already viewing the entire table.

Please confirm AEs reported as ongoing in the previous cycle are still ongoing ?

Adverse Event # (Verbatim term)	Adverse event term (CTCAE v5.0)	MedDRA adverse event code (CTCAE v5.0)	Related to Specimen Correlation	Hospitalization (initial or prolonged)	Life Threatening	Death	Disability or Permanent Damage	Congenital Anomaly or Birth Defect	Required Intervention	Other Serious Important Medical Events	Was the event considered a dose limiting toxicity?	What action was taken with study treatment?	Therapy	*AE Number	SAE report recommended	Date/Time of Collection	Time zone	Submitted by
1																		

Add a new Log line Inactivate

INSTRUCTIONS: When entering new or modifying existing data in this form remember to resubmit the changes to CTEP-AERS for rules evaluation by completing and saving the **Expedited Reporting Evaluation** CRF in Rave.

AE Comment

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Save Cancel

The standard fields at the top of the form are auto-populated with values from the Enrollment folder. To enter the first observed adverse event, click on the dash (-) in any empty field or use the Edit pencil to expand the log line.

The auto-populated fields in the form are not open to editing. The fields are either derived from previously entered data or will auto-populate with data based on your entries after saving the form. These fields will have a crossed out Edit pencil as they cannot be edited. See red boxes below.

10403 Dana-Farber/Harvard Cancer Center All Specimens Adverse Events

* Course/Cycle # 0 ✓ ✕

* Start date of this course/cycle 25 Mar 2020 ✓ ✕

* Start date of first course/cycle 25 Mar 2020 ✓ ✕

* Treatment assignment code Zone 1 DL1: Gemcitabine 175mg/m2 (Day 1 and 8) BAY 1895344 20mg twice daily (Days 2-3 and 9-10) ✓ ✕

REMINDER: Depending on your settings in Rave, this table may be paginated. If the options are available, click on **Paginate** and select **Show All Lines** or click on the numeric page numbers at the bottom right corner of the table. If these options are not available, you are already viewing the entire table.

Please confirm AEs reported as ongoing in the previous cycle are still ongoing ?

Currently viewing line 1 of 1.
Click here to return to "Complete View".

Adverse Event (Verbatim term) Sub dermal pooling of blood at biopsy site

* Adverse event term (CTCAE v5.0) Hematoma

* MedDRA adverse event code (CTCAE v5.0)

* Adverse event evaluated this cycle?

CTCAE Grade 2

Adverse event grade description

Start Date 25 Mar 2020

End Date

Ongoing

Relationship to Study Treatment Unrelated

Related to

Specimen Correlation (if any) (10403-EAD5JV02-2) Formalin Fixed Core Biopsy (1 Apr 2020)

10403 Dana-Farber/Harvard Cancer Center All Specimens Adverse Events

Subject: [Redacted]
Page: Adverse Events - All Specimens

This form should only contain Adverse Events that occur as a result of tissue biopsy collection procedures carried out prior to study treatment.

Form Instructions ?

- * Red asterisk before a field denotes that it is required by the system for rules evaluation.
- * Course/Cycle # 0
- * Start date of this course/cycle 25 Mar 2020
- * Start date of first course/cycle 25 Mar 2020
- * Treatment assignment code Zone 1 DL1: Gemcitabine 175mg/m2 (Day 1 and 8) BAY 1895344 20mg twice daily (Days 2-3 and 9-10)

REMINDER: Depending on your settings in Rave, this table may be paginated. If the options are available, click on Paginate and select Show All Lines or click on the numeric page numbers at the bottom right corner of the table. If these options are not available, you are already viewing the entire table.

Adverse Event #	Adverse Event (Verbatim term)	*Adverse event term (CTCAE v5.0)	*MedDRA adverse event code (CTCAE v5.0)	Adverse event evaluated this cycle?	CTCAE Grade	Adverse event grade description	Start Date	End Date	Ongoing	Relationship to Study Treatment	Related to ?	Specimen Correlation	Hospitalization (initial or prolonged)	Life Threatening	Death	Disability or Permanent Damage	Congenital Anomaly or Birth Defect	Required Intervention	Other Serious (Important Medical Events)	Was the event considered a dose limiting toxicity?	What action was taken with study treatment?
1	Subdermal pooling of blood at biopsy site	Hematoma	10019428 Vascular disorders	Yes	2	(2) Minimally invasive evacuation or aspiration indicated	25 Mar 2020	-	Yes	Unrelated	-	(10403-EAD5JVO2-2) Formalin Fixed Core Biopsy (1 Apr 2020)	No	No	No	No	No	No	No	No	Not Applicable

Add a new Log line Inactivate

Expedited Reporting Evaluation (All Specimens)



Whenever the AE form is updated, the adverse events must be evaluated to determine if expedited reporting is recommended each time. Use the Send all AE's checkbox and save the form to determine if expedited reporting is recommended

10403 Dana-Farber/Harvard Cancer Center All Specimens Expedited Reporting Evaluation

Subject: [Redacted]
Page: Expedited Reporting Evaluation - All Specimens

Form Instructions ?

A delay is expected when the safety system is called for AE evaluation.

Note: Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious adverse event occurs this course/cycle, amend the report so both events are entered on the same ticket.

Send all AEs for evaluation

Whenever the AE form is updated, the adverse events have to be evaluated to determine if expedited reporting is recommended. Please check this check box and save the form to determine if expedited reporting is recommended. [QC017]
Opened To Site from System (06 Sep 2022)

Report ID

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CRF Version 5683 - Page Generated: 06 Sep 2022 16:12:55 Eastern Daylight Time

Save Cancel

After completing the adverse events form, a query is opened on the Expedited Reporting Evaluation form. **Click** the checkbox and then click the **Save** button. The query will automatically resolve when the box is checked and the form is saved.

If the CTEP-AERS determines that a report is needed (i.e. CREATE or EDIT) it will advise on the report type and due date. Click on the link to complete the safety report (see red box in next image).

The screenshot shows a web browser window with the title 'Expedited Reporting Evaluation'. The page has a header 'Form Instructions' with a help icon. Below the header, a bold instruction states: 'A delay is expected when the safety system is called for AE evaluation.' A note follows: 'Note: Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious adverse event occurs this course/cycle, amend report so both events are entered on the same ticket.' Below the note is a button 'Send all AEs for evaluation' with a plus icon, a green checkmark, and a document icon. The main section is titled 'Recommended action for report' and contains a red-bordered box with the text 'Click this link to complete the safety report'. To the right of this box is a red arrow pointing to a 'CREATE' button, which also has a green checkmark and a document icon. Below this is a table with four rows: 'Report ID', 'Recommended report type', 'Report due by', and 'Form Date'. The 'Recommended report type' row has a red arrow pointing to the text 'CTEP 24 Hour SAE Notification', which has a green checkmark and a document icon. The 'Report due by' row has a red arrow pointing to the date 'Wednesday, January 5, 2022', which has a green checkmark and a document icon. The 'Form Date' row shows the date and time '04 Jan 2022 13:48:04' with a green checkmark and a document icon.

Form Instructions ?

A delay is expected when the safety system is called for AE evaluation.

Note: Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious adverse event occurs this course/cycle, amend report so both events are entered on the same ticket.

Send all AEs for evaluation

Recommended action for report

Click this link to complete the safety report

Report ID

Recommended report type

Report due by

Form Date

CREATE

CTEP 24 Hour SAE Notification

Wednesday, January 5, 2022

04 Jan 2022 13:48:04

Please see the Adverse Events form, under the Course section, in the Rave User Guide for more information.