

Unit Procedure

Data/Sample Management System

SOP No./WI No.: CTSI-CRC-PL-158

Department: Processing Laboratory

Version No.: 02

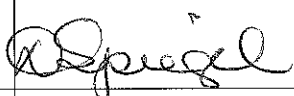
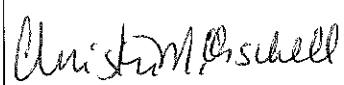
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Date	28 Dec 2016	28 Dec 2016	Dec 29, 2016



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1. OBJECTIVE

This Standard Operating Procedure (SOP) illustrates the procedure for recording sample information in the laboratory database, and conversely, for extracting information via data queries at the Indiana Clinical and Translational Sciences Institute (CTSI) Clinical and Translational Support Laboratory (CTSL).

2. SCOPE

This SOP describes the procedure for recording and tracking data of samples in the CTSL database and applies to all CTSL staff involved. It also describes the method for retrieving the information via data queries.

3. RESPONSIBILITIES

The CTSL personnel are responsible for compliance to this procedure when recording sample information into the database and performing data queries.

4. DEFINITIONS

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	PI: Principal Investigator
QC: Quality Control	SMF: Study Master File
SOP: Standard Operating Procedure	

5. ASSOCIATED DOCUMENTS

- 5.1. CTSI-CRC-QA-003 "Document Control and Management"
- 5.2. CTSI-CRC-CLN-030 "Handling of SOP Deviations"
- 5.3. CTSI-CRC-PL-151 "Management of Requests for Sample Processing Support"

6. PROCEDURE

- 6.1. Logging sample information into the Ca Tissue Database upon receiving new samples.
 - 6.1.1. Go to <https://biobank.compbio.iupui.edu/catissuecore/Login.do>
 - 6.1.1.1. Enter log-in email and password and click the "log-in" button.
 - 6.1.1.2. Register new Participant or Protocol IDs.
 - 6.1.2. Under the "Biospecimen Data Tab", select "Collection Protocol Based View". (Fig. 1)
 - 6.1.2.1. Under the "Biospecimen Data Tab", select "Collection Protocol Based View". (Fig. 1)

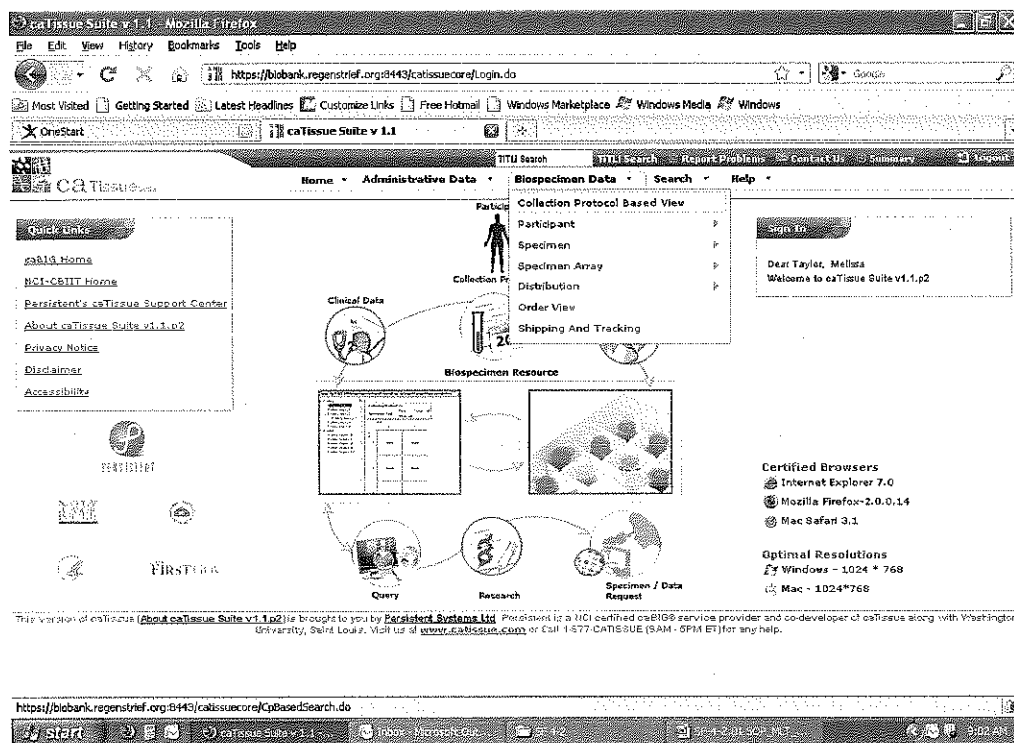
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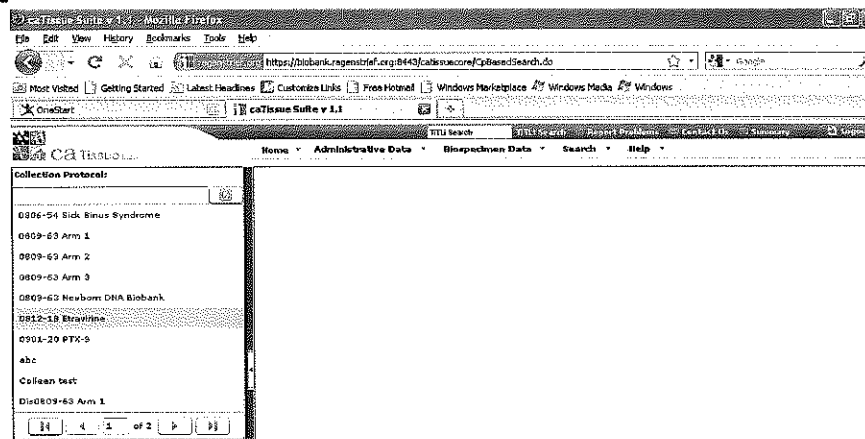
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FIG. 1



- 6.1.2.2. Select the applicable protocol of the sample(s) to be entered.
 - 6.1.2.2.1. Click on the arrow to the right of the blank box entitled "Collection Protocol".
 - 6.1.2.2.2. Select the desired study from the drop-down box. (Fig. 2)

FIG. 2



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- 6.1.2.3. Click on the “Register New” button located next to “Participant (Protocol ID).”
- 6.1.2.4. Type or scan in the Participant Protocol ID and the Registration Date.
- 6.1.2.5. Click on “Register Participant”. (Fig. 3)

FIG. 3

- 6.1.2.6. Select the desired collection point label, if applicable to that study, from the tree under “Specimen Details”.
- 6.1.2.6.1. The collection point labels display a black letter “A” to the left of them.
- 6.1.2.6.2. If there are no collection point labels listed, proceed to Section 6.1.2.10.
- 6.1.2.7. Edit the box entitled “Add Participant Registration”.
- 6.1.2.7.1. Type in the Registration Date and click “Submit”.
- 6.1.2.8. Click on the “View Participant” button. The letter A to the left of the collection point label that was just registered should turn from black to pink in color and a plus sign will appear. (Fig. 4)

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FIG. 4

caTissue Suite v 1.1 - Mozilla Firefox

https://biobank.regenstrief.org:8443/cattissuecore/CpBasedSearch.do

caTissue Suite v 1.1

Home Administrative Data Biospecimen Data Search Help

Section Protocols:

09-63 Newborn DNA Biobank

Participant (Protocol ID): Register New

0056

View Participant

Specimen-Details for N/A (0056)

- 0809-63 Arm 1:12-18-2009
- 0809-63 Arm 2:12-18-2009
- 0809-63 Arm 3:12-18-2009

Collection point labels

Edit Participant Registration

* Sub Collection Protocol 0809-63 Arm 1

Participant Name

Participant Protocol ID 0056

Study Calendar Event Point 0.0 Days

Offset 0

* Registration Date 12-18-2009 [MM-DD-YYYY]

* Activity Status Active

Submit Specimen Collection Group

- 6.1.2.9. Click on the plus sign and find the applicable event point.
- 6.1.2.10. Select the event point. A screen with a tab entitled “Edit Specimen Collection Group” should appear. (Fig 5) Event point labels have a black letter “g” listed to the left of them.

FIG. 5

caTissue Suite v 1.1 - Mozilla Firefox

https://biobank.regenstrief.org:8443/cattissuecore/CpBasedSearch.do

caTissue Suite v 1.1

Home Administrative Data Biospecimen Data Search Help

Collection Protocols:

0809-63 Newborn DNA Biobank

Participant (Protocol ID): Register New

N/A (0056)

View Participant

Specimen Details for N/A (0056)

- 0809-63 Arm 1:12-18-2009
- 0809-63 Arm 2:12-18-2009
- 0809-63 Arm 3:12-18-2009

Event point

Edit Specimen Collection Group

Collection Protocol 0809-63 Arm 1

Specimen Group Name 080963-0056

Study Calendar Event Point 0.0 Arm 1 Day 0 Days

Offset 0

Clinical Diagnosis Not Specified

Activity Status Active

Participant Name (Protocol ID) (0056)

Barcode 136143bn95hh4f

Collection Site

Surgical Pathology Number

Clinical Status Not Specified

Collection Status Not Collected

Comments

Events

Collected

Collector Taylor, Melissa

Date 12-18-2009

Time 11 Hr 39 Min

Procedure Use CP Defaults

Container Use CP Defaults

Received

Receiver Taylor, Melissa

Date 12-18-2009

Time 11 Hr 39 Min

Quality Use CP Defaults

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6.1.3. Create frozen events for samples to be frozen.

6.1.3.1. Expand the specimen tree by clicking on the plus signs located to the left of the collection, event, and/or parent specimen points until the desired sample is in view. (Fig. 6) Samples have a letter "S" located to the left of them.

6.1.3.2. Click on the sample to be frozen. The page defaults to the "Specimen Details" tab.

6.1.3.3. If all samples under a parent sample are to be frozen, a frozen event can be added to just the parent sample, and the event will be propagated down to all the daughter samples.

Note: frozen events for sample MUST be done before other data submission in order for the Frozen Event propagation feature to work.

6.1.3.4. Select the tab at the top of the screen entitled "Events".

6.1.3.5. Perform the following to add a frozen event to a sample that already has one listed under Event Parameter, where the user is unknown and there is a generic date and time (Fig. 6)

6.1.3.5.1. Double click on the work "Frozen".

6.1.3.5.2. Make the necessary changes to the user (i.e., the person doing the freezing), date and time the sample was frozen and the method of freezing.

6.1.3.5.3. Click the "Submit" button.

FIG. 6

The screenshot shows the 'caTissue Suite v 1.1' web application in a Mozilla Firefox browser. The 'Events' tab is selected for specimen 080963-0056-1.01. On the left, a 'Tree of samples' is visible with a circled area around the specimen ID. The main panel shows a table of existing events and a form to add a new 'Frozen Event'. The form fields are: User (Taylor, Melissa), Date (2-18-2009), Time (00:00), and Method (50 Freezer). A 'Submit' button is at the bottom.

Identifier	Event Parameter	User	Date / Time
080963-0056-1.01	Frozen	User Unknown	01-01-20090000

Existing events for the specimen with label '080963-0056-1.01'

Select Specimen Event To Add:

Event Details "Frozen Event"

User:

Date:

Time: Hr. Min.

Method:

Comments:

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- 6.1.3.6. Perform the following to add a frozen event to a sample that does not have existing frozen events as defined in Section 6.1.3.4.
 - 6.1.3.6.1. Click the drop-down box next to “Select Specimen Event” to add and select “frozen”.
 - 6.1.3.6.2. Make the necessary changes to the user (i.e., the person doing the freezing), date and time the sample was frozen and the method of freezing.
 - 6.1.3.6.3. Click the “Submit” button.
- 6.1.3.7. Note: Entering frozen events for samples MUST be done before other data submission in order for the Frozen Event propagation feature to work.
- 6.1.4. Edit Specimen Collection Group
 - 6.1.4.1. Click on the event point. Again, a screen with a tab entitled “Edit Specimen Collection Group” should appear.
 - 6.1.4.2. Fill out the relevant information. (Fig.7)
 - 6.1.4.2.1. Red asterisks denote required fields.
 - 6.1.4.2.2. Most fields are preset per study-specific protocol and do not require changing. Fields that often DO need attention are the “Collection Site”, “Collector”, “Receiver”, “Date” and the “Time” fields. The “Comments” field may be filled out if there is any pertinent information about the samples for this event point.
 - 6.1.4.2.3. For the purpose of the CTSI, the “Collection Site” field value is always “IU” unless otherwise noted.

FIG. 7

The screenshot displays the CTSI Data/Sample Management System interface. The main window is titled "Edit Specimen Collection Group" and contains several tabs: "Edit Specimen Collection Group", "View Surgical Pathology Report", "View Annotation", and "Consent". The "Edit Specimen Collection Group" tab is active, showing a form with the following fields and values:

- Collection Protocol:** 0809-63 Newborn DNA Biobank
- Participant (Protocol ID):** N/A (0056)
- Specimen Details for N/A (0056):**
 - 0809-63 Arm 1: 12-18-2009
 - 080963-0056-1.01
 - Whole Blood
 - Whole Blood
 - 080963-0056-1.01.DNA
 - 080963-0056-1.02
 - Whole Blood
 - Whole Blood
 - Whole Blood
 - 0809-63 Arm 2: 12-18-2009
 - 0809-63 Arm 3: 12-18-2009
- Study Calendar Event Point:** 0.0 Arm 1 - Day 0
- Offet:** 0
- Clinical Diagnosis:** Not Specified
- Activity Status:** Active
- Comments:** (Empty text box)
- Events:**
 - Collected:**
 - Collector:** Blankenbeger, Molly
 - Date:** 12-18-2009
 - Time:** 10 Hr. 20 Min.
 - Procedure:** Use CP Default
 - Container:** Use CP Default
 - Comments:** (Empty text box)
 - Received:**
 - Receiver:** Taylor, Melissa
 - Date:** 12-18-2009
 - Time:** 15 Hr. 32 Min.
 - Quality:** Use CP Default
 - Comments:** (Empty text box)
- Add Multiple Specimens:**
 - Number of Specimen(s):** 0
 - ☒ Specimen entry based on collection protocol
 - ☐ Print Labels
 - Buttons:** Submit, Add Specimen, Add Multiple Specimens, Delete

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- 6.1.4.3. Check the box at the bottom of the page that reads “Specimen entry” based on collection protocol and click the “Submit” button. (Fig. 7)
- 6.1.4.4. Click “OK if a Windows box appears that states “The collected and received events data that you have entered will be propagated to all specimens under this Specimen Collection Group and override any existing data. Do you want to continue?”
- 6.1.4.5. Once the updated Specimen Collection Group appears, select the first parent specimen under “Specimen Details by clicking the circle to the left of the label box. The derivative and aliquots for that parent should appear below it. (Fig. 8)
- 6.1.4.6. Enter the specimen data.
 - 6.1.4.6.1. Uncheck the box “Coll” next to any sample not collected.
 - 6.1.4.6.2. Make the changes to the “Label field” for a sample if needed.
 - 6.1.4.6.3. Enter assigned storage locations for each sample collected.
 - 6.1.4.6.4. Select “virtual” from the drop-down storage location box if a sample is not to be saved, stored, or if it is used for processing purposes.
 - 6.1.4.6.5. For other samples, select “manual” from the drop-down storage location box. Type in the storage location in the boxes to the right of the drop-down box.
 - 6.1.4.6.6. Verify storage location by following Section 6.3.
 - 6.1.4.6.7. Verify that all other data is correct on this page and make changes if necessary.

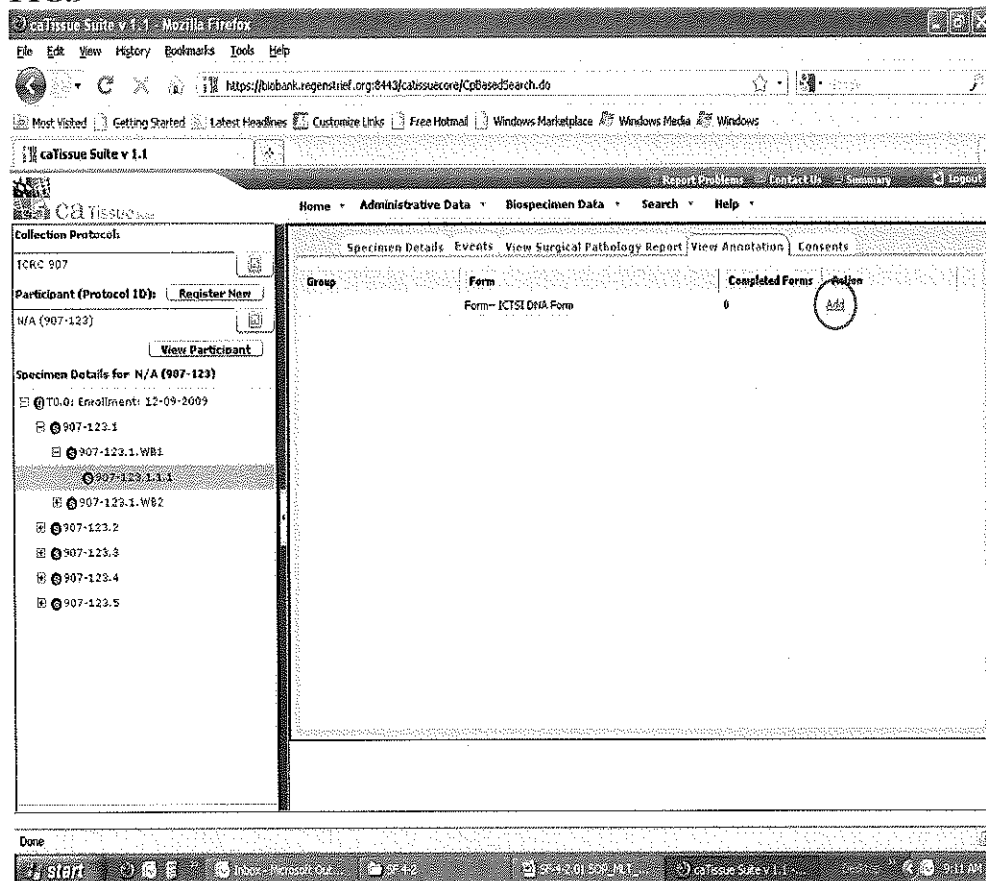
FIG. 8

The screenshot displays the 'CA Tissue Suite v1.1.1' application window. The main panel is titled 'Specimen Details' and shows a list of specimens. The first specimen, '080962-4', is selected, and its details are shown in the right-hand pane. This pane includes fields for 'Label', 'Barcode', 'Qty', 'Storage location', 'Tissue Side', and 'Tissue Site'. Below this, there is a section for 'Derivatives and aliquots for Parent Specimen 1', which lists derived specimens with their own labels, barcodes, quantities, and storage locations. The interface also includes a 'Collection Protocol' dropdown, a 'Participant (Protocol ID)' field, and a 'View Participant' button. At the bottom, there are 'Submit' and 'Add To My List' buttons. The status bar at the very bottom indicates 'Transferring data from biobank.regisntriel.org...'.

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- 6.1.4.7. Repeat the steps under Sections 6.1.4.5 and 6.1.4.6 for each additional parent specimen.
 - 6.1.4.7.1. Note: DO NOT click the “Submit” button until all modifications to all the parents’ derivatives/aliquots have been made!
 - 6.1.4.7.2. Click “Submit” only when all data entry and modifications are complete.
- 6.1.5. Add clinical annotation for DNA samples, if applicable.
 - 6.1.5.1. Expand the specimen tree by clicking on the plus signs located to the left of the collection, event and parent specimen points until the desired sample is in view.
 - 6.1.5.2. Click on the applicable sample.
 - 6.1.5.3. Select the “View Annotation” tab at the top of the page.
 - 6.1.5.4. Click on “Add” next to the form entitled “ICSTIDNA Form”. (Fig.9)

FIG.9



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- 6.1.5.5. Fill out the form (Fig. 10)
- 6.1.5.6. Click "Submit"
- 6.1.5.7. The form can be edited at any time by clicking on "edit" next to "ICTSIDNA Form".
 - 6.1.5.7.1. The form must be created first before the edit button will appear.

FIG.10

The screenshot shows the CaTissue Suite v 1.1 web application. The left sidebar has a 'Collection Protocols' section with a tree view showing protocols under 'ICRC 907' and 'N/A (907-123)'. The main panel is titled 'Specimen Details' and contains a form with the following fields:

- DNA Volume (uL): 300
- Concentration: 256.2
- Units: ng/uL
- Stage 1 Processing Begin: 12-10-2009 11:15
- Stage 1 Processing End: 12-10-2009 13:00
- Stage 2 Processing Begin: 12-11-2009 08:22
- Stage 2 Processing End: 12-11-2009 11:35
- Stage 3 Processing Begin: 12-15-2009 11:52
- Stage 3 Processing End: 12-15-2009 14:55
- Technician: 02- Melissa Taylor
- 260/280 Ratio (Normal Range 1.6-2.0): 1.95

At the bottom of the form are 'Submit' and 'Cancel' buttons.

6.2. Adding/modifying sample information to the CaTissue Database for samples that have existing protocol IDs.

- 6.2.1. Access the CaTissue Database per Section 6.1.1.
- 6.2.2. Under the "Biospecimen Data" tab, select "Collection Protocol Based View". (Fig.1).
- 6.2.3. Select the applicable protocol of the sample/s to view.
 - 6.2.3.1. Click on the arrow to the right of the blank box entitled "Collection Protocol".
 - 6.2.3.2. Select the desired study from the drop-down box. (Fig. 2)
- 6.2.4. Select the applicable Protocol ID of the sample/s to view.

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- 6.2.4.1. Click on the arrow to the right of the blank box entitled "Participant" (Protocol ID)
- 6.2.4.2. Select the desired ID from the drop-down box.
- 6.2.5. Perform the following to add to or modify sample information pertaining to a single sample.
 - 6.2.5.1. Expand the specimen tree by clicking on the plus signs located to the left of the collection, event, and parent specimen points until the desired sample is in view. (Fig. 11)
 - 6.2.5.2. Select the desired sample. The page defaults to the "Specimen Details" tab.
 - 6.2.5.3. Make any additions/ modifications needed under this tab.
 - 6.2.5.3.1. Add a storage location, if applicable, to the sample.
 - 6.2.5.3.2. Check the "Is Available" box and change the "Collection Status" to "Collected" in the drop-down box. (Fig.11)

FIG.11

The screenshot displays the CTSI Data/Sample Management System interface. The top navigation bar includes links for Home, Administrative Data, Biospecimen Data, Search, and Help. The main content area is divided into several sections:

- Collection Protocol:** Displays the protocol ID (0812-18 Ebravine) and a link to Register New.
- Participant (Protocol ID):** A dropdown menu showing N/A (409) with a View Participant link.
- Specimen Details for N/A (409):** A list of specimen points with expandable/collapsible icons. The selected sample is highlighted.
- Specimen Details:** A form with various input fields:
 - Parent Label: 0812-18/409/0/E-PLA1
 - Label: [Blank]
 - Class: Fluid
 - Tissue Site: Arm
 - Pathological Status: Not Specified
 - Initial Quantity: 1.0 ml
 - Lineage: [Blank]
 - Barcode: 136141bn958cutgh
 - Type: Plasma
 - Tissue Side: Not Applicable
 - Created On: [Blank]
 - Concentration: [Blank] µg/µl
 - Available Quantity: 0.0 ml
 - Activity Status: Active
 - Is Available?: [Checked]
 - Collection Status: Pending
 - Storage Position: Manual
 - Storage Location: CTSI_F1-1-2-7
 - Quantity per Aliquot: 1
 - Map: [Link]
- Comments:** A text area for adding comments.
- External Identifier(s):** A section for adding external identifiers.
- Biohazard(s):** A section for adding biohazard information.
- Create Child Specimen(s):** A section for creating child specimens with options for None, Aliquot, Derivative, and Create Aliquot/Derived Specimen as per CP.
- Count:** A field for entering the count.
- Quantity per Aliquot:** A field for entering the quantity per aliquot.
- Print Labels:** A checkbox for printing labels.
- Buttons:** Submit, More, and Add To My List.

- 6.2.5.3.3. Manually enter the assigned storage location of the sample.
- 6.2.5.3.4. Select "manual" from the drop-down storage location box.
- 6.2.5.3.5. Type in the storage location in the boxes located to the right of the drop-down box.

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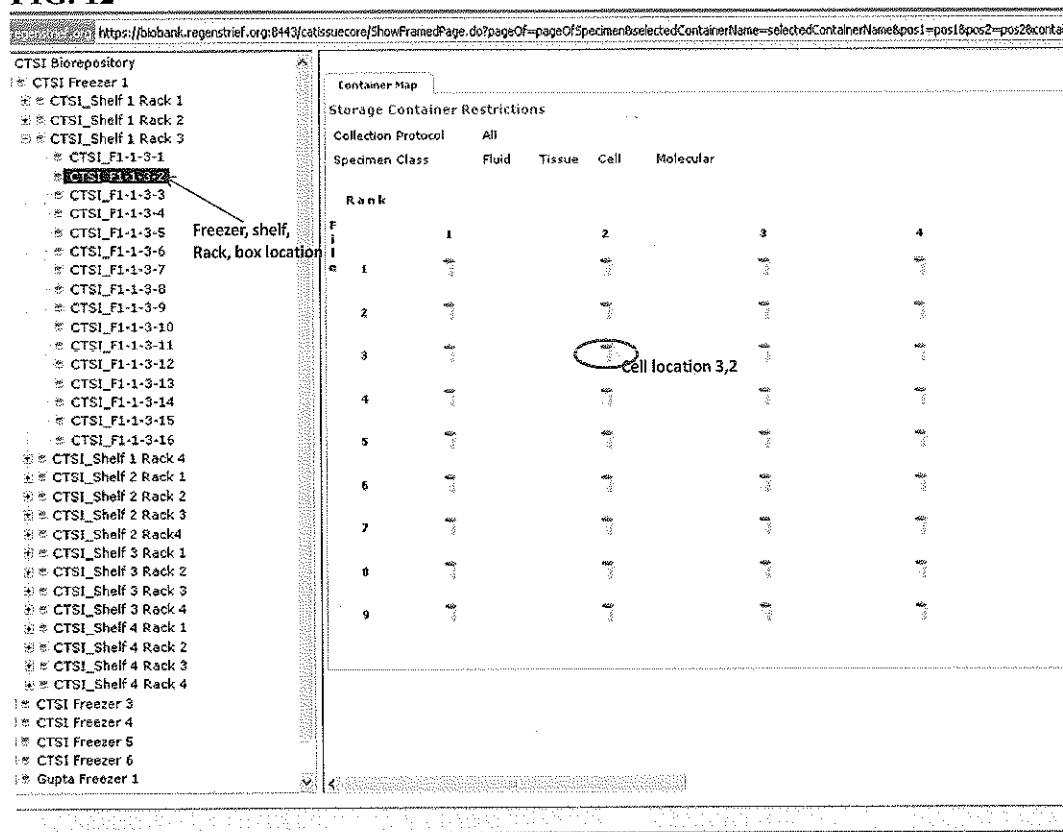
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- 6.2.5.3.6. Alternately, enter the storage location by “mapping the location”.
 - 6.2.5.3.6.1. Select “manual” from the drop-down storage location box.
 - 6.2.5.3.6.2. Click the “Map” button (Fig. 11)
 - 6.2.5.3.6.3. Choose the correct freezer, shelf, rack and box by expanding the location tree, clicking on the plus signs. (Fig. 12)
 - 6.2.5.3.6.4. Hover the mouse over the cell location of choice in the storage box and click on it.

FIG. 12

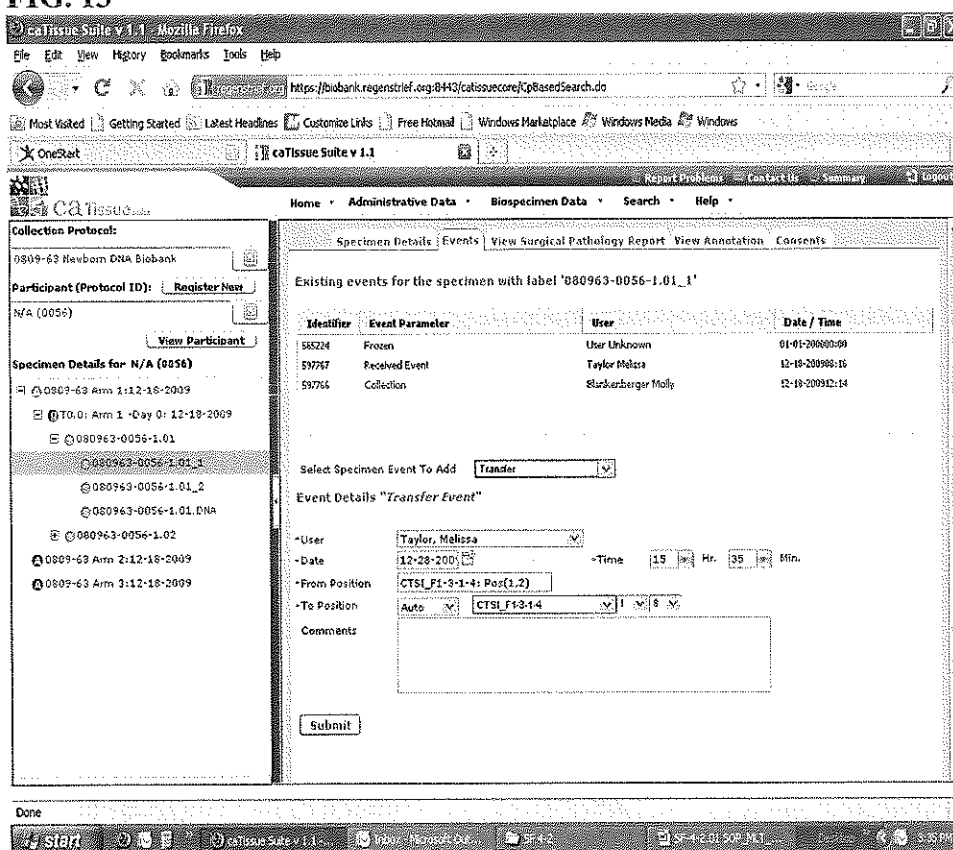


- 6.2.5.3.7. Click “Submit” at the bottom of the page.
- 6.2.5.4. Proceed with the following if modifications need to be made to a storage location of a sample.
 - 6.2.5.4.1. Click on the “Events” tab. (Fig. 13)
 - 6.2.5.4.2. Choose “Transfer” in the drop-down box Select “Specimen Event” to add.
 - 6.2.5.4.3. Select the applicable user, date, and time of the transfer.

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- 6.2.5.4.4. Select “manual” in the “To Position” field and type in the new location. The location can also be “mapped” as mentioned in Section 6.2.5.3.1.3.
- 6.2.5.4.5. Click “Submit”.
- 6.2.5.4.6. Verify storage location by following Section 6.3.
- 6.2.5.5. Add a frozen event to a sample, if applicable, by following Section 6.1.3.
- 6.2.5.6. Add clinical annotation to a DNA sample, if applicable, per Section 6.1.5.

FIG. 13



The screenshot shows the 'caTissue Suite v 1.1' web application in a Mozilla Firefox browser. The main content area displays the 'Transfer Event' form for specimen 080963-0056-1.01_1. The form includes a table of existing events, a dropdown to select the event to add (set to 'Transfer'), and fields for user, date, time, from position, and to position. The 'To Position' field is set to 'CTSI_F1-3-1-4'. A 'Submit' button is at the bottom.

Identifier	Event Parameter	User	Date / Time
585224	Frozen	User Unknown	01-01-200809:09
597767	Received Event	Taylor Melissa	12-18-200908:16
597766	Collection	Sturkenberger Molly	02-19-200912:14

Existing events for the specimen with label '080963-0056-1.01_1'

Select Specimen Event To Add: **Transfer**

Event Details "Transfer Event"

-User: **Taylor, Melissa**

-Date: **12-28-2009**

-Time: **15** Hr. **35** Min.

-From Position: **CTSI_F1-3-1-4: Pos(1,2)**

-To Position: **Auto** **CTSI_F1-3-1-4**

Comments:

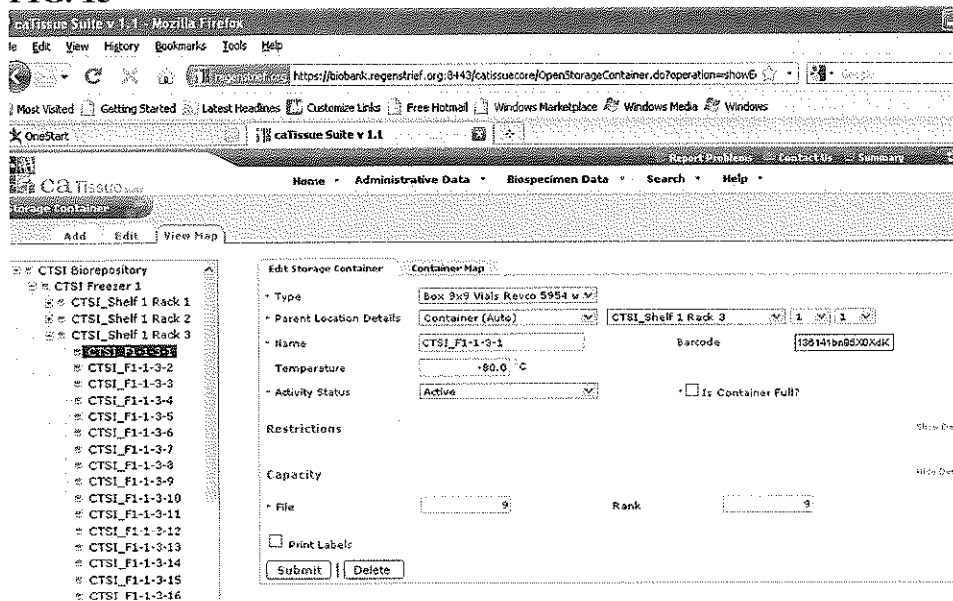
Submit

- 6.2.6. Refer to Section 6.1.4 for adding sample information to multiple samples at a time under a particular event point.
- 6.3. Verifying storage locations with the storage container map.
 - 6.3.1. Verifying storage locations with the storage container map.
 - 6.3.2. Under the “Administrative Data” tab, select “Storage Container”. (Fig. 14)
 - 6.3.3. Click on “View Map”.
 - 6.3.4. Choose the correct freezer, shelf, rack, and box by expanding the location tree, clicking on the plus sign.

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6.3.5. Click on the “Container” map tab once the page loads. Loading can take several seconds! (Fig. 15)

FIG. 15



6.3.6. Verify that samples are where they should be by viewing the container map. (Fig. 16)

6.3.6.1. A picture of a test tube denotes that a sample is present in that cell. An empty gray cylinder represents an empty cell.

6.3.6.2. Hover the mouse over an occupied cell to view the label of the sample in that cell.

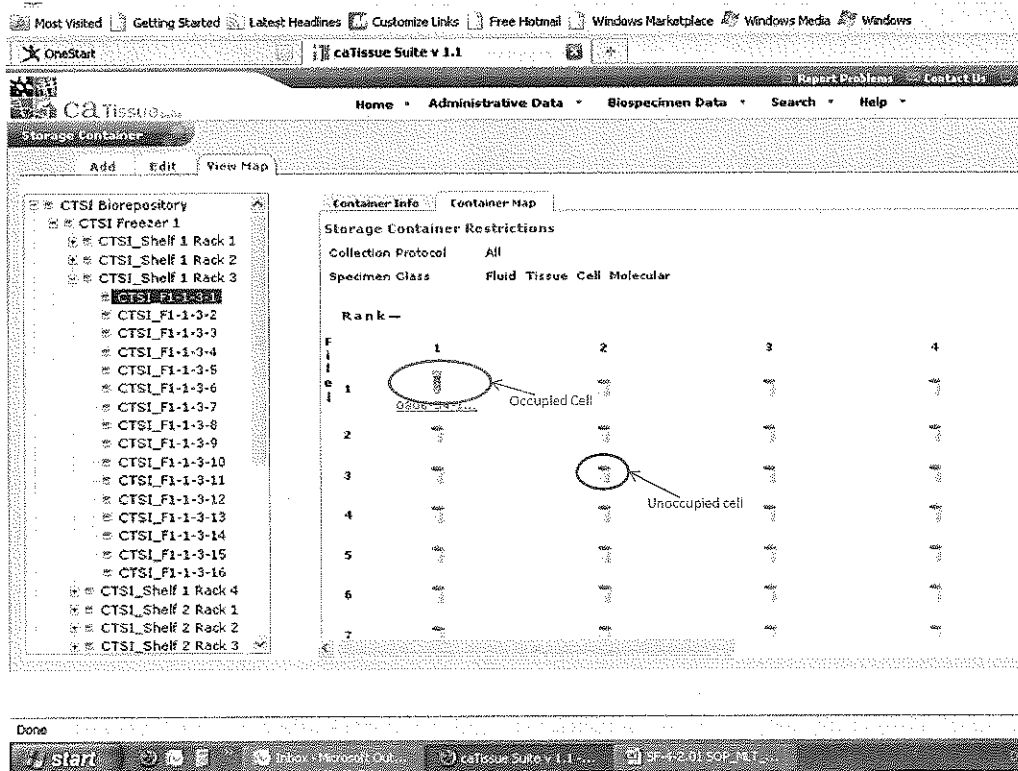
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FIG. 16

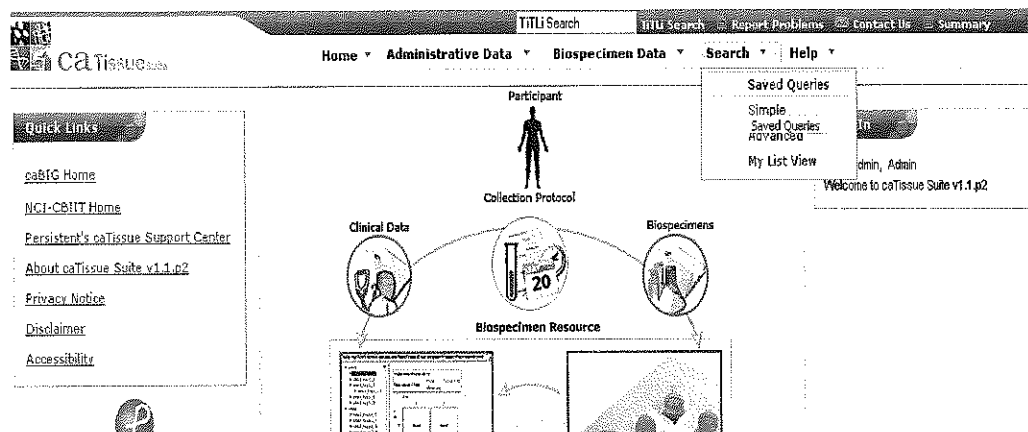


6.4. Locating samples in storage containers via the CTSI canned query.

6.4.1. Access the CaTissue Database per Section 6.1.1.

6.4.2. Click on the “Search” tab, and then on “Saved Queries”. (Fig. 17)

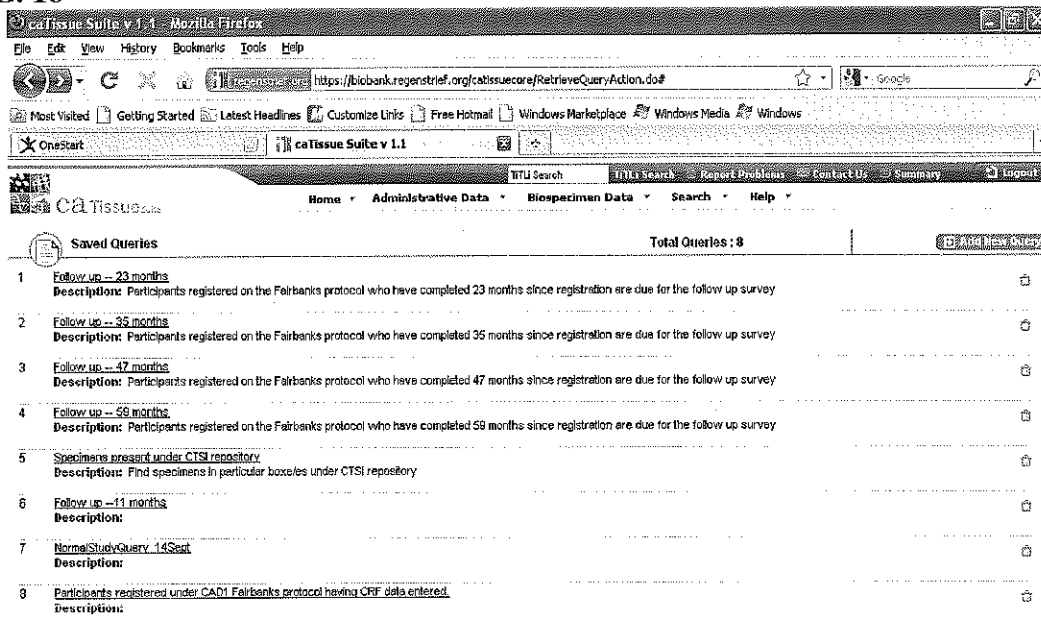
FIG. 17



6.4.3. Click on the canned query, “Specimens present under CTSI repository”. (Fig. 18)

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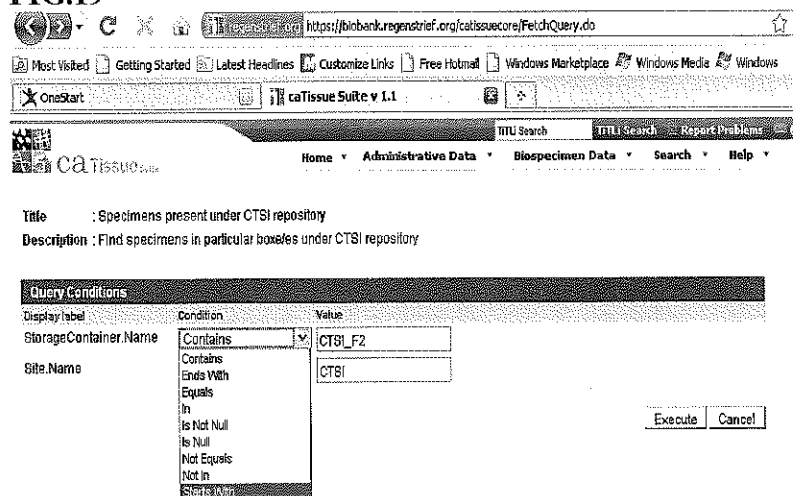
FIG. 18



6.4.4. Click on “Execute” without making changes to any fields to search within all CTSI storage containers.

6.4.4.1. Modifications can be made to the condition and value of the “Storage Container Name” if a more narrowed search is desired. For example, one could select the “Starts With condition and type” CTSI_F2 to search for all samples in all containers in CTSI Freezer 2 only. (Fig. 19)

FIG.19



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6.4.5. Change the columns in the search result, if desired.

6.4.5.1. Click on “Define View” on the search result page.

6.4.5.2. Select the attributes desired from the table on the left hand side by clicking on the check box corresponding to it and clicking on “Add to View”.
(Fig.20)

6.4.5.2.1. These attributes are added to the table on the right hand side.

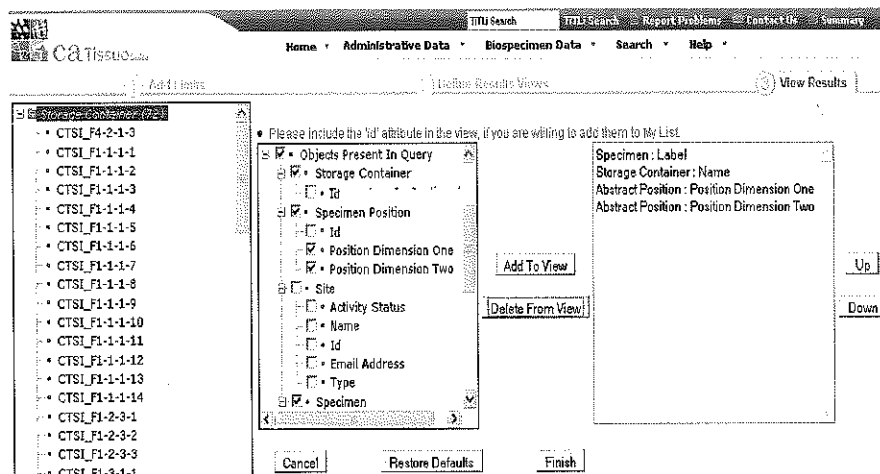
6.4.5.2.2. Include the specimen position and specimen label fields when doing a storage location search.

6.4.5.3. Select the attributes that are not desired from the table on the right and click “Delete From View”.

6.4.5.4. Arrange the order of the columns to be viewed by clicking on the “Up” and “Down” buttons.

6.4.5.5. Click “Finish”.

FIG. 20



6.4.6. Export the search results in to a .csv file for viewing and printing, if desired.

6.4.6.1. Click the check boxes next to samples to be exported. (Fig. 21)

6.4.6.2. Alternately, click “Check All” to select all results across all pages or click “Check All on This Page” to select the results displayed only on this page.

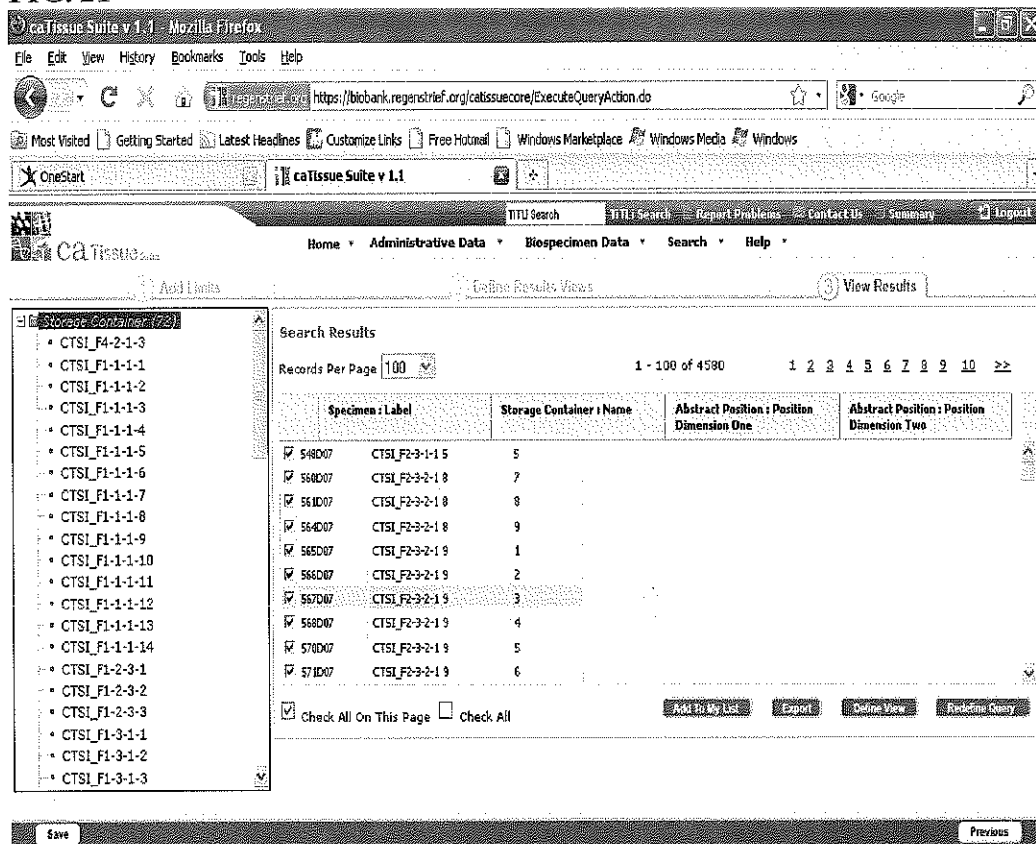
6.4.6.3. Click on “Export”.

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FIG. 21


6.4.6.4. Save the file.

6.4.6.5. Sort the data and print, if desired.

6.5. Sample Distribution Documentation

6.5.1. Records are maintained per CTSI-CRC-QA-003 "Document Control and Management".

6.5.2. All Deviations are managed per the CTSI-CRC-CLN-030 "Handling of SOP Deviations".

7. REFERENCES

None

8. APPENDICES

None



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9. AMENDMENT HISTORY

Date of Amendment:	16 Dec 2016
Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-025
Details of Amendment:	Updated the footer file location; Corrected SOP noted in 6.6.2;