DAIT-COVID-19-002

A PROSPECTIVE COHORT STUDY TO ASSESS LONGITUDINAL IMMUNE RESPONSES IN HOSPITALIZED PATIENTS WITH COVID-19

IMMUNOPHENOTYPING ASSESSMENT IN A COVID-19 COHORT (IMPACC)

LDMS User Guide

Sample Tracking and Labeling Guidelines

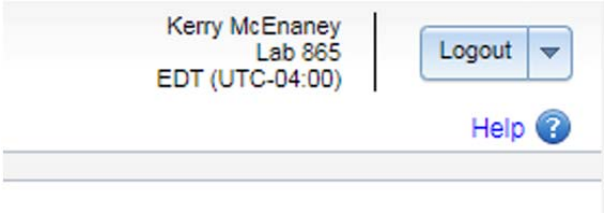
Contents

1. Accessing LDMS

1.1. LDMS is a web-based database that can be accessed from any internet-connected computer by connecting to: https://www.ldms.org/ and entering your unique username/password. Click on **LDMS LOGIN** in the top right corner.

1.2. To request a new user account, please contact Kerry McEnaney at Kerry.McEnaney@childrens.harvard.edu

1.3. The Lab# for the IMPACC study build is #865. If you have access to more than one lab in LDMS, please make sure you are signed into Lab 865 when processing IMPACC study samples. This is indicated in the top right corner under your name once you have logged in.



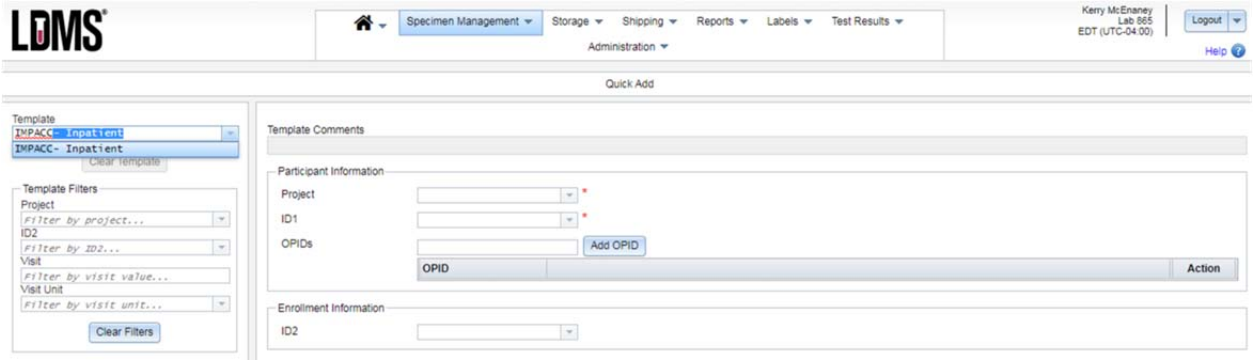
1.4. If you need to change labs, click the **Change** link next to the lab name in the upper-right corner, then select #865.

2. Adding samples to LDMS

2.1. Quick Add Templates

2.1.1. Data is entered into LDMS in a top-down fashion (i.e. Project->Patient->Primary Collection Tube-> Aliquot). It is highly recommended that Quick Add templates be used to enter visit data all at once. An **IMPACC-Inpatient** template has been set up for this project.

2.1.2. Under the **Specimen Management** menu, click on **Quick Add** which will bring up a blank Quick Add template. From the Templates dropdown menu on the left side, start typing and select **IMPACC-Inpatient** and then click **Confirm** to populate the Quick Add form with study specific primary collection tubes and aliquots.

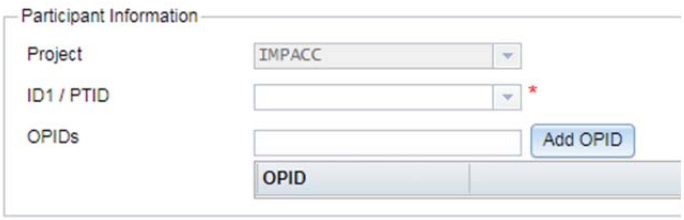


2.2. Modifying Template to Match Recorded Values

2.2.1. Primary collection tubes and aliquots will be pre-populated (including expected volumes and sample condition) on the IMPACC-Inpatient template. These values should be updated with sample specific volumes/conditions etc. as recorded on the SPF.

2.2.1.1. Enter new data, or confirm/update pre-populated data in the following template data fields. These data are all reported on the SPF.

2.2.1.1.1. Enter **ID1/PTID** in the "Participant Information" box.



2.2.1.1.2. Enter **ID2/Collection Kit ID** in the "Enrollment Information" box.

2.2.1.1.3. Update **ID3/Visit ID** in the "Visit Information" box. Please enter one of the following Visit IDs: Visit 1, Visit 2, Visit 3, Visit 4, Visit 5, Visit 6, 24 Hour Care Escalation, or 96 Hour Care Escalation.

2.2.1.1.4. **Clinic** should be left blank

2.2.1.1.5. Enter **Collection Date** in dd/mmm/yyyy format (or click on the dropdown arrow to bring up a calendar in order to select the date). Click **Confirm** to assign this collection date to all primary collection tubes.

2.2.1.1.6. Enter **Visit Value** by entering the Visit Number (or 24/96 if a Care Escalation visit).

2.2.1.1.7. Confirm **Visit Units** are set to "Vst" for a scheduled visit, or Update to "Uns" for an unscheduled visit (i.e. Care Escalation visit).

2.2.1.1.8. Update **Condition** based on the observed condition of the primary sample tube in the "Primary Information" box.

2.2.1.1.9. Enter **Collection Time** in 24hr format for each of the primary collection tubes in the "Primary Information" box.

2.2.1.1.10. Enter **Received Time** (time samples were received in lab) in 24hr format for each of the primary collection tubes in "Primary Information" box.

2.2.1.1.11. Confirm **Volume and Volume Units** (which are pre-populated) match what was actually observed/recorded on the SPF.

2.2.1.1.12. Enter **Additional Time** (processing time as calculated and reported on SPF) in minutes.

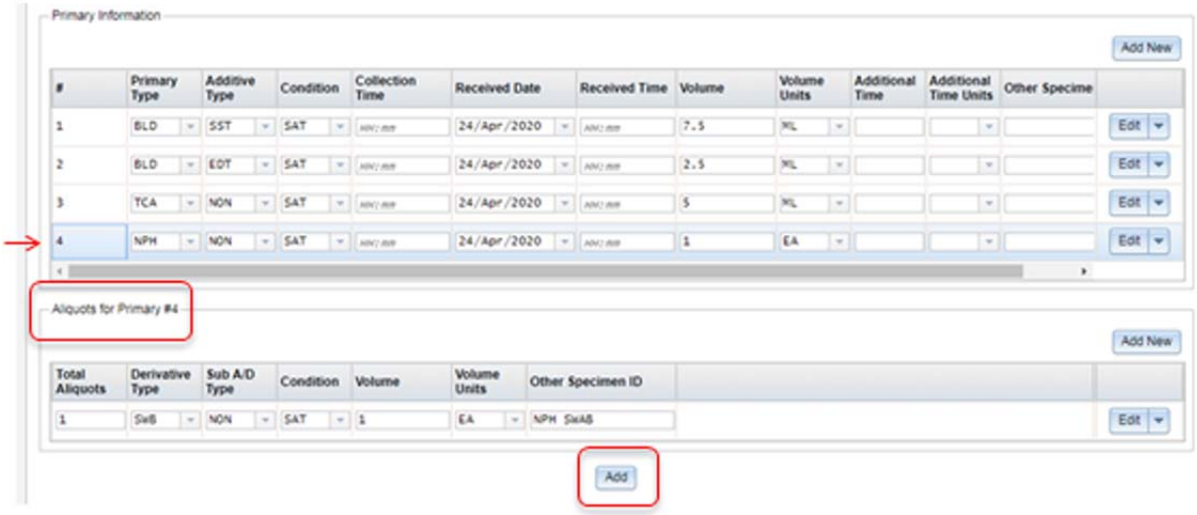
2.2.1.1.13. If any primary samples were <u>not collected</u> (e.g. Endotracheal Aspirate for non-intubated patients), **Delete** a primary collection tube by clicking on the dropdown arrow next to the "Edit" menu on the same line as the sample and select "Delete."

2.2.1.1.14. Click on each row in the "Primary Information" box to bring up the predefined aliquots in the "Aliquots for Primary X" box below.

2.2.1.1.15. Confirm aliquot **Condition** or update if anything other than "SAT" for satisfactory.

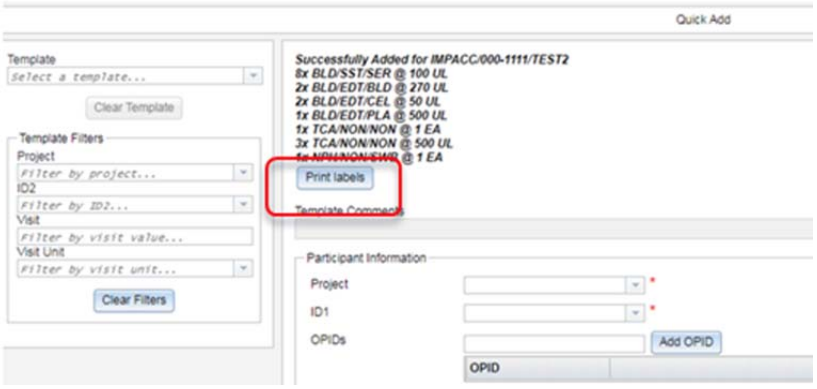
2.2.1.1.16. Confirm aliquot **Volume** or update if volume is different than pre-populated/protocol defined volume.

2.2.1.1.17. After all primary and aliquot samples have been updated, click **ADD** to add primary and aliquot information to LDMS.



3. Generating Labels at Time of Processing

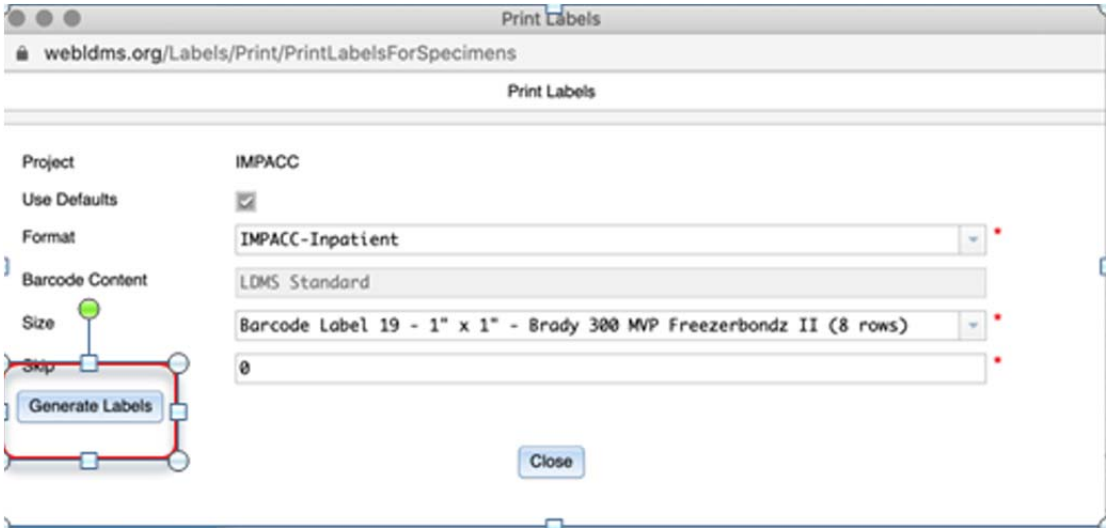
3.1. After adding samples from the **Quick Add** page, you will be brought to a confirmation page indicating successful upload of each of the aliquots entered on the previous page. Confirm the aliquots were added correctly. Then click **Print Labels** to access the Label Generation pop-up window.



3.2. From the **Print Labels** pop-up window, select "IMPACC-Inpatient" from the "Format" dropdown.

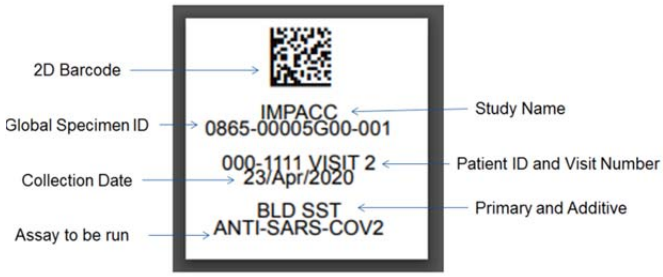
3.3. "Size" should be set to "Barcode Label 19 – 1" x 1" – Brady 300 MVP Freezerbondz II (8 rows).

3.4. Click **Generate Labels** on the left hand side to generate a PDF of the aliquot labels associated with this visit. The PDF can then be sent to your label printer for printing. Be sure to not click "Close" at the bottom of the Print Labels pop-up until you have generated the label PDF.



3.5. Label each aliquot tube with the appropriate sample label.

3.6. IMPACC Sample Label

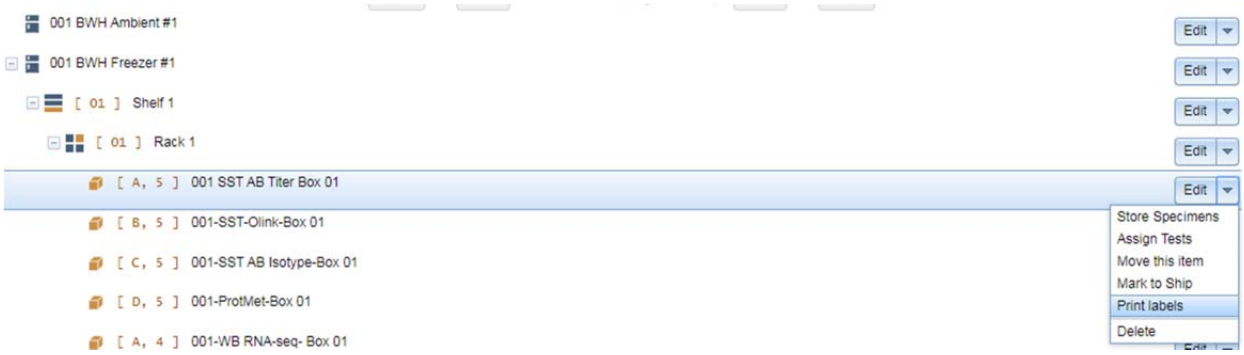


4. Reprinting Labels

4.1. Labels can be printed from multiple screens after samples have been added to LDMS.

4.2. From Storage:

4.2.1. Navigate to the box containing the sample you would like to reprint a label for. From the dropdown menu, select **Print Labels** to open up the **Print Labels** pop-up window. Select the samples you would like to reprint labels for, and follow label generation steps above.

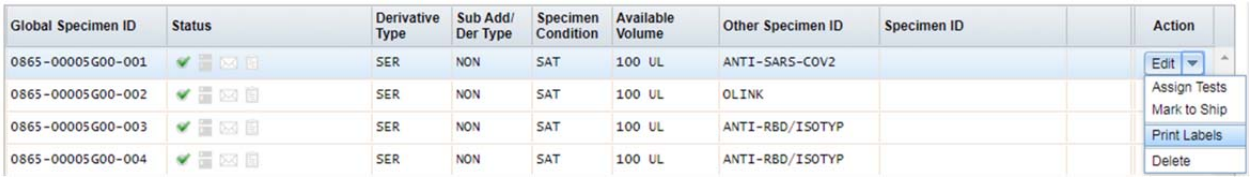


4.3. From Specimen Management:

4.3.1. Using the filters on the left hand side, filter to the Patient->Study Visit you would like to reprint labels for.

4.3.1.1. From here, you can either choose to print all aliquot labels from a given visit by selecting **Print Labels** from the dropdown menu associated with the Visit.

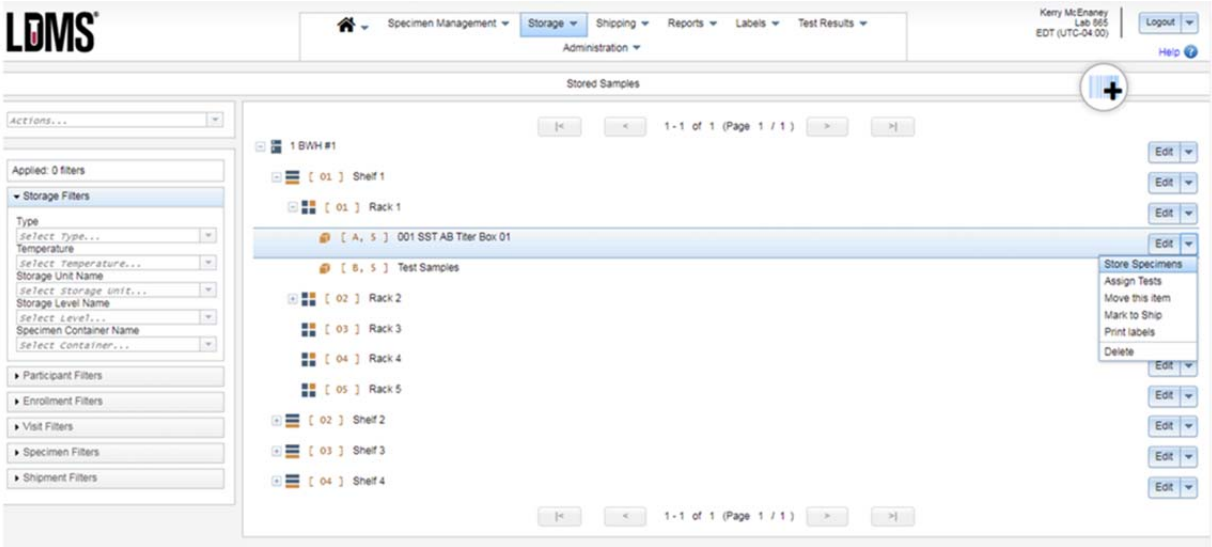
4.3.1.2. OR you can generate labels for individual aliquots as needed, by selecting the **Print Labels** from the dropdown menu associated with a given aliquot.



4.3.2. This will bring up the **Print Labels** pop-up window. Follow directions above to generate labels from here.

5. Storing Samples

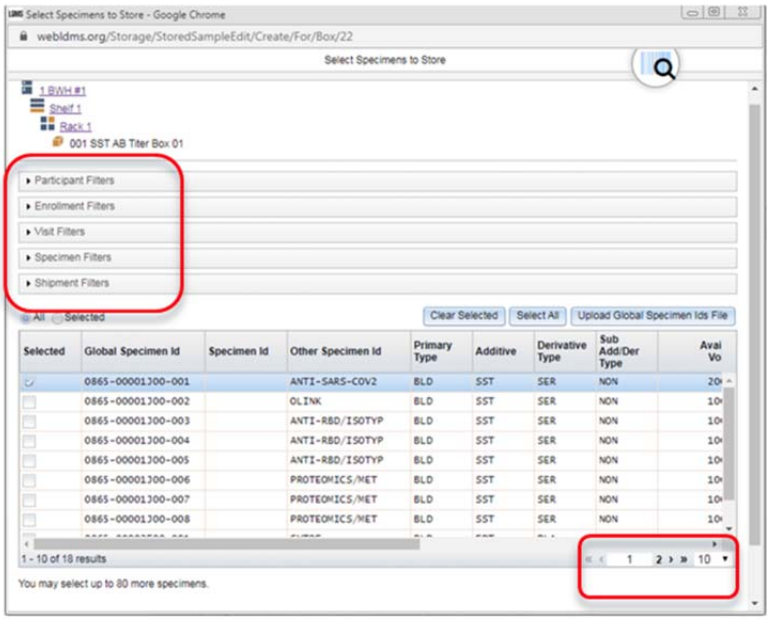
5.1. From the **Storage** menu, select **Stored Samples** to be brought to the storage tree. Navigate to the Shelf and Rack and storage Box in your Study Center's freezer where you would like to store the sample. From the dropdown menu on the same line as the box you would like to store the sample in, click **Store Specimens.**



5.2. The **Store Specimens** window will open. From here, you can choose to do one of the following:

5.2.1. Use filters to find specimens to limit the specimens displayed at the bottom of the page (If you can't find the specimen you are looking for, confirm your display is not limiting your results)

5.2.2. Scan a specimen barcode by clicking on the barcode icon at the top of the window.



5.2.3. If you do not see your sample, make sure that you are not limited by the display parameters. These can be adjusted in the bottom right corner of the **Store Specimens** box.

5.3. For each specimen to be stored, select the check box in the **Selected** column**.** You can also click **Select All** to store all currently displayed specimens.

5.3.1. If you change filters at this point, any specimens selected will remain selected.

5.4. At the bottom of the **Select Specimens** window, click **Continue** (this will store your samples in the desired location).

5.5. Boxes are configured to autofill Left to Right, Top to Bottom (e.g. A1, A2, A3…B1, B2, B3, etc). If you need to rearrange a sample location within a box, click **Edit** on the sample row edit menu and the **Edit Stored Specimen** box will open up. Click the appropriate cell in the box where you would like to store your sample and click **Save** to save the new sample location.

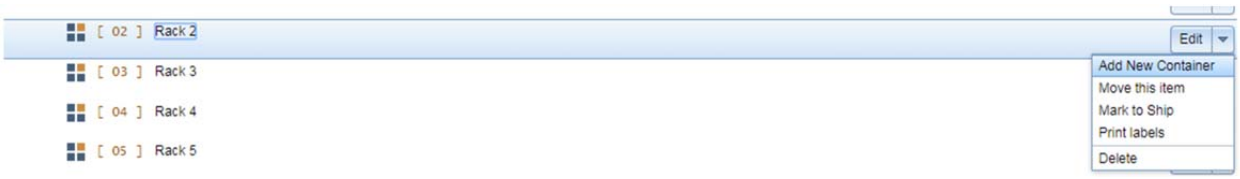
5.5.1. Purple = current specimen location

5.5.2. Grey = unavailable- contains another specimen

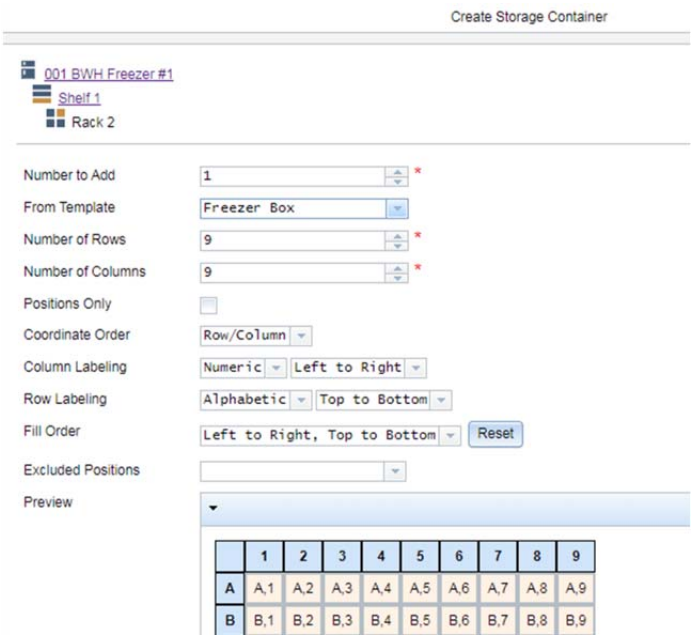
5.5.3. Light blue = selected NEW specimen location

6. Creating Containers (Boxes) Using Storage Template

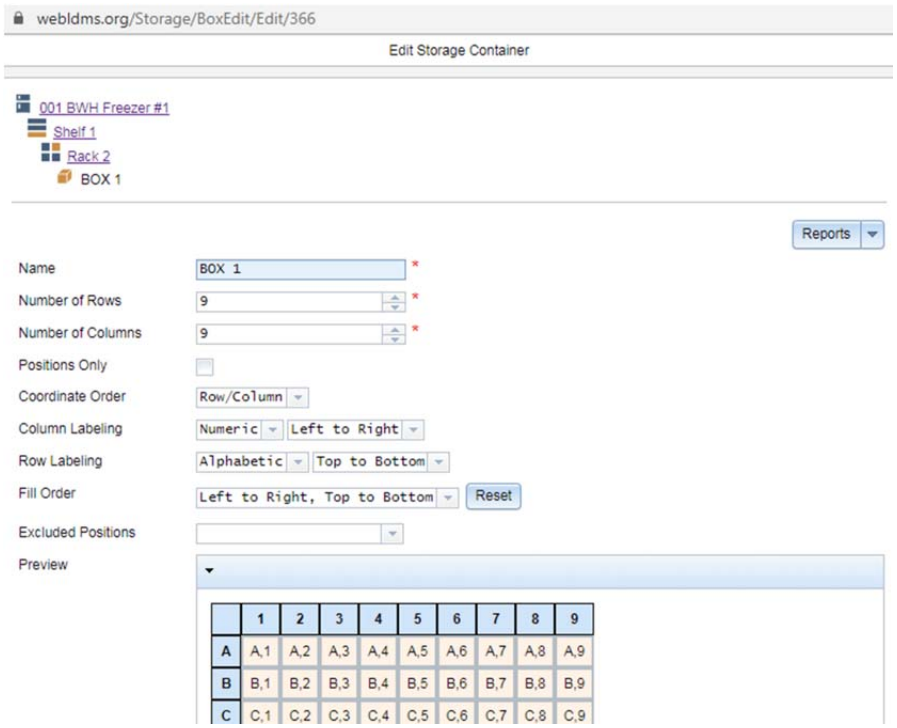
6.1. From the **Storage Tree,** navigate to the location in your freezer/ambient storage where you would like to add a new container. Click on **Add New Container** from the dropdown edit menu associated with that storage location. This will bring up the **Create Storage Container** pop up.



6.2. From the **Create Storage Container** pop-up, enter the number of boxes you would like to create in this location at this time. Select "Freezer Box" from the template dropdown to auto populate a 9x9 alphanumeric labeled box. Select **Continue** to create the box.



6.3. The box will now appear in your storage tree. To rename the box, click on EDIT (not the dropdown) to bring up the **Edit Storage Container** pop-up window. From here you can enter the new name of the box per naming structure outlined below. Click **Save** to save changes.



7. Box Labels

7.1. Two sets of labels for each box are provided by the CDCC as they cannot be generated in LDMS. Box labels should be affixed to the large face on the top of the box top, as well as to the

side wall of the box bottom (to ensure easy identification from a top or side view, as well as identify the contents of the box if the top and bottom of the box get separated).

7.2. Box names consist of Study Center # followed by the Primary sample collection tube identifier (e.g. SST, WB),the assay to be performed (e.g. AB Titer, Olink, AB Isotype, etc.) and finally the box number.

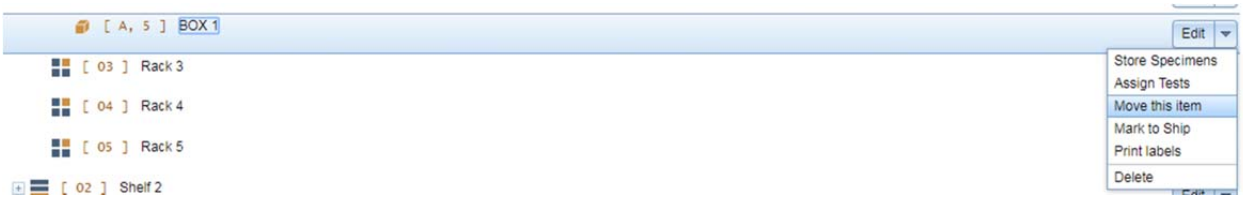
Box Name	Assay	Tube/Color Coder	Samples per visit
(Center #) SST AB Titer Box 01	Serum AB titer	Blue	1
(Center #) SST Olink Box 01	Serum Olink	Green	1
(Center #) SST AB Isotype Box 01	Serum AB Isotype	Purple	3
(Center #) SST ProtMet Box 01	Serum P/M	Brown	3
(Center #) WB RNA-seq Box 01	WB Bulk RNA-seq	Crystal Gen	2
(Center #) WB ProtMet Box 01	WB P/M	Yellow	1
(Center #) WB GWAS Box 01	WB GWAS	Pink	1*
(Center #) WB CyTOF Box 01	WB CyTOF	Gray	1
(Center #) Swab Box 01	SWAB	Zymo tube and swab	1
(Center #) TCA RNA-seq Box 01	TA Bulk RNA-seq	Zymo tube	2
(Center #) TCA CyTOF Box 01	TA CyTOF	Orange	1

*GWAS = 1 sample per patient, taken at an early timepoint (preferably Visit 1)

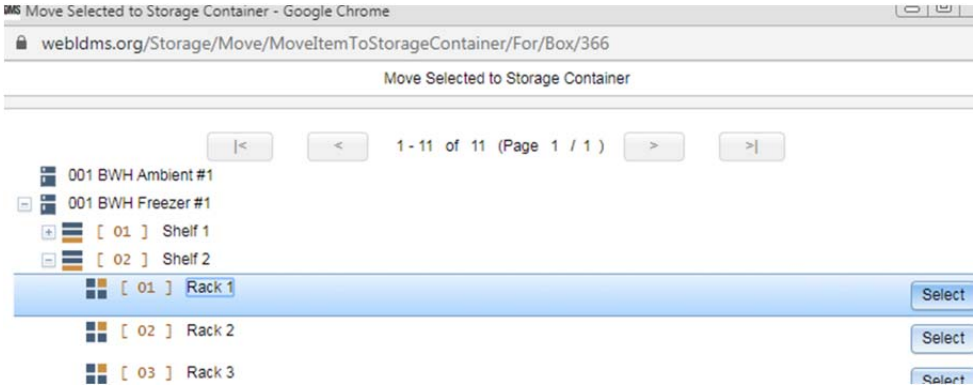
7.3. If you required additional box labels, please contact Kerry McEnaney (Kerry.McEnaney@childrens.harvard.edu) as soon as possible so that there will be enough time to ship these labels to your site.

8. Moving Boxes in Freezer or Ambient Storage

8.1. To move boxes from one location to another within the storage tree, select **Move This Item** from the edit drop down on the line associated with the box you would like to move. This will open the **Move Selected Storage Container** box.



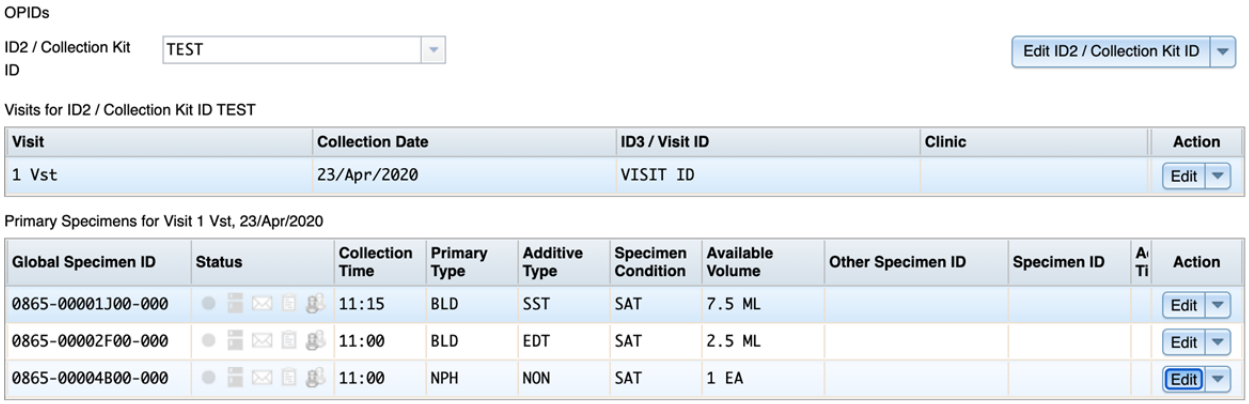
8.2. From the **Move Selected Storage Container** box, navigate to the new location you would like to move the box to. Navigate to the new storage container location from the storage tree, and click **Select** to move the box to this new location. Your box will move to the new location.



9. Adding Freeze Time for Samples Previously Stored at Ambient Temperature

9.1. From the Specimen Management menu, navigate to and select the sample you want to add the freezing time to. Double check the Visit ID and the Sample ID match your intended selection.

9.2. Click on the "Edit" menu on the same line as your selected sample.



9.3. This will open the "Edit Specimen" pop-up window. Confirm the Global Specimen ID in this pop-up window matches the Global Specimen ID on the sample label.

IMPACC 000-0000
TEST
1 Vst VISIT ID 23/Apr/2020
0865-00004B00-000
0865-00004B00-001

Global Specimen ID	0865-00004B00-001		
Specimen ID			
Other Specimen ID	NPH SWAB		
Enrollment	IMPACC/TEST *		
Derivative Type	SWB *		
Sub Add/Der Type	Sub Add/Der Type: NON *	Sub Add/Der Reagent:	
Is Available	☑		
Original Volume	Original Volume: 1.00 *	Original Volume Units: EA *	
Available Volume	Available Volume: 1.00 *	Available Volume Units: EA *	
Condition	Specimen Condition: SAT *	Secondary Condition:	
Specimen Processing Details	Processing Tech Initials: KM	Processing Date: 23/Apr/2020	Processing Time: HH:mm
Frozen	Frozen Date: 13/Jul/2020	Frozen Time: 10:00	

Barcode

IMPACC
0865-00004B00-001

000-0000 VISIT ID
23/Apr/2020

NPH NON
NPH SWAB

Global Specimen ID matching the barcode

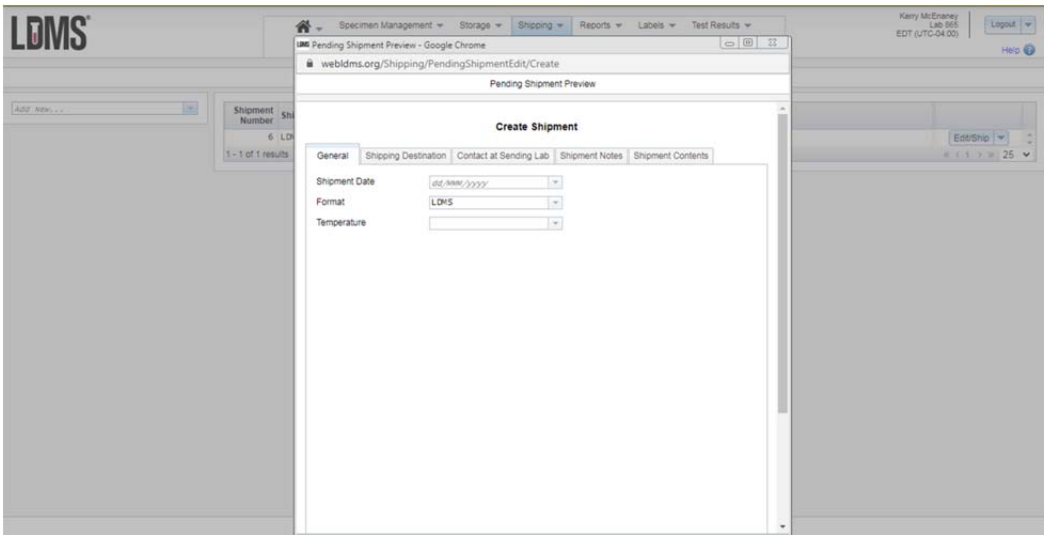
9.4. Update the Frozen Date and Frozen Time in this pop-up window with information recorded for specimen freeze time.

Frozen	Frozen Date: 13/Jul/2020	Frozen Time: 10:10
Additional Time	Additional Time:	Additional Time Units:
Total Cell Count	$\times 10^6$	
Tube Count		
Thaw Count	0 *	
Stored	No	
Shipped	No	
Imported	No	
Reason Specimen Not Collected		
Assigned Tests		
Comments	Frozen at a later date	

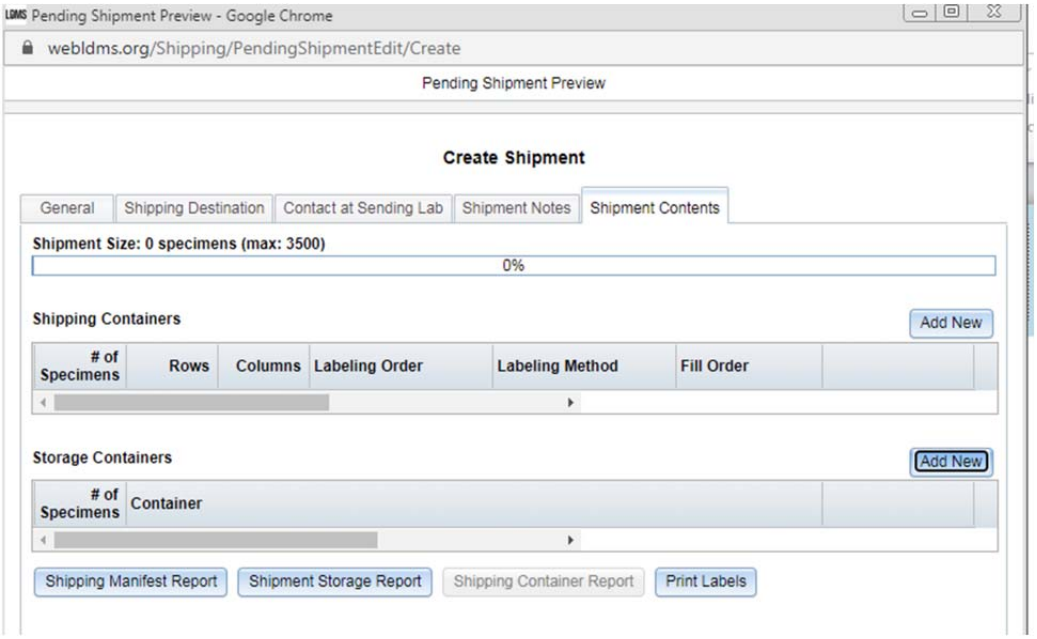
9.5. Update the Comment to indicate “Frozen at a later date”
9.6. Save

10. Creating a Shipment

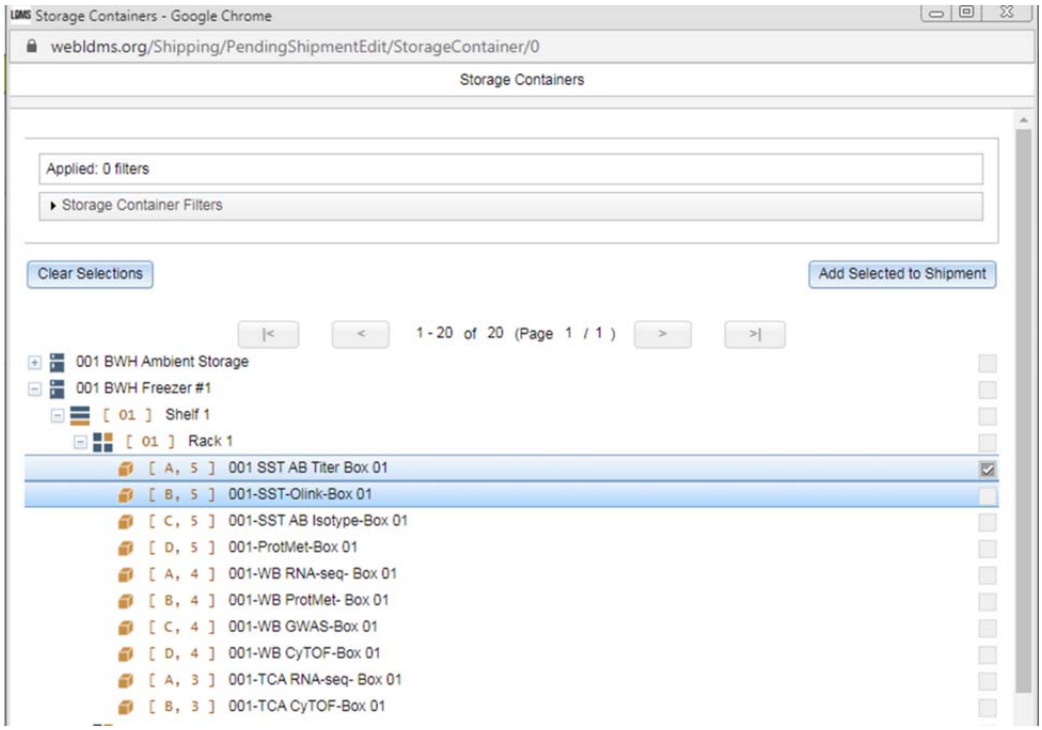
10.1. Select “Pending Shipments” from the Shipping Menu Dropdown.
10.2. From left-hand side, select “Create Shipment” from the Action Bar. This will open a new “Create Shipment” pop-up window.



10.3. Under the “General” tab:
    10.3.1. Enter the **Shipping Date** (or expected shipping date)
    10.3.2. Select **File Format** of .CSV
    10.3.3. Select **Temperature** of Dry Ice for all samples
10.4. Under the “Shipping Destination” tab:
    10.4.1. Select the desired core lab shipping contact information for the sample type you are shipping.
10.5. Under the “Contact at Sending Lab” tab:
    10.5.1. Enter your **Name**
    10.5.2. Enter your **Phone Number**
    10.5.3. Enter your **Email Address**
10.6. Under the “Shipment Notes” tab:
    10.6.1. Enter and **Comments** or **Disclaimers** related to this shipment (e.g. known missing samples, partially empty box, intentionally skipped cell in box, etc.)
10.7. Under the “Shipment Contents” tab:
    10.7.1. Select “Add New” Storage Container which will open the Storage Structure pop-up window. Navigate down through the storage units, shelves, and racks to the box(es) you would like to ship.



10.7.2. Select the check box next to the right of each box you would like to ship. Once all boxes are selected, click on "Add Selected to Shipment" and the selected boxes will now be listed in the Shipment Contents tab.

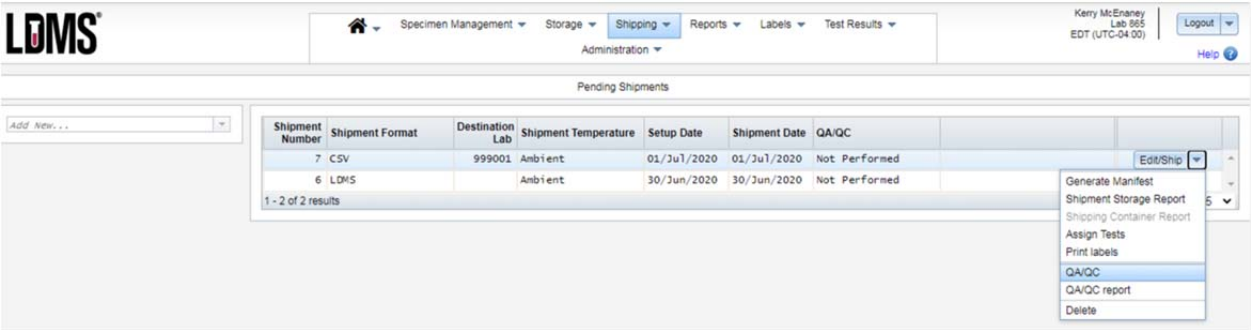


10.7.3. Save

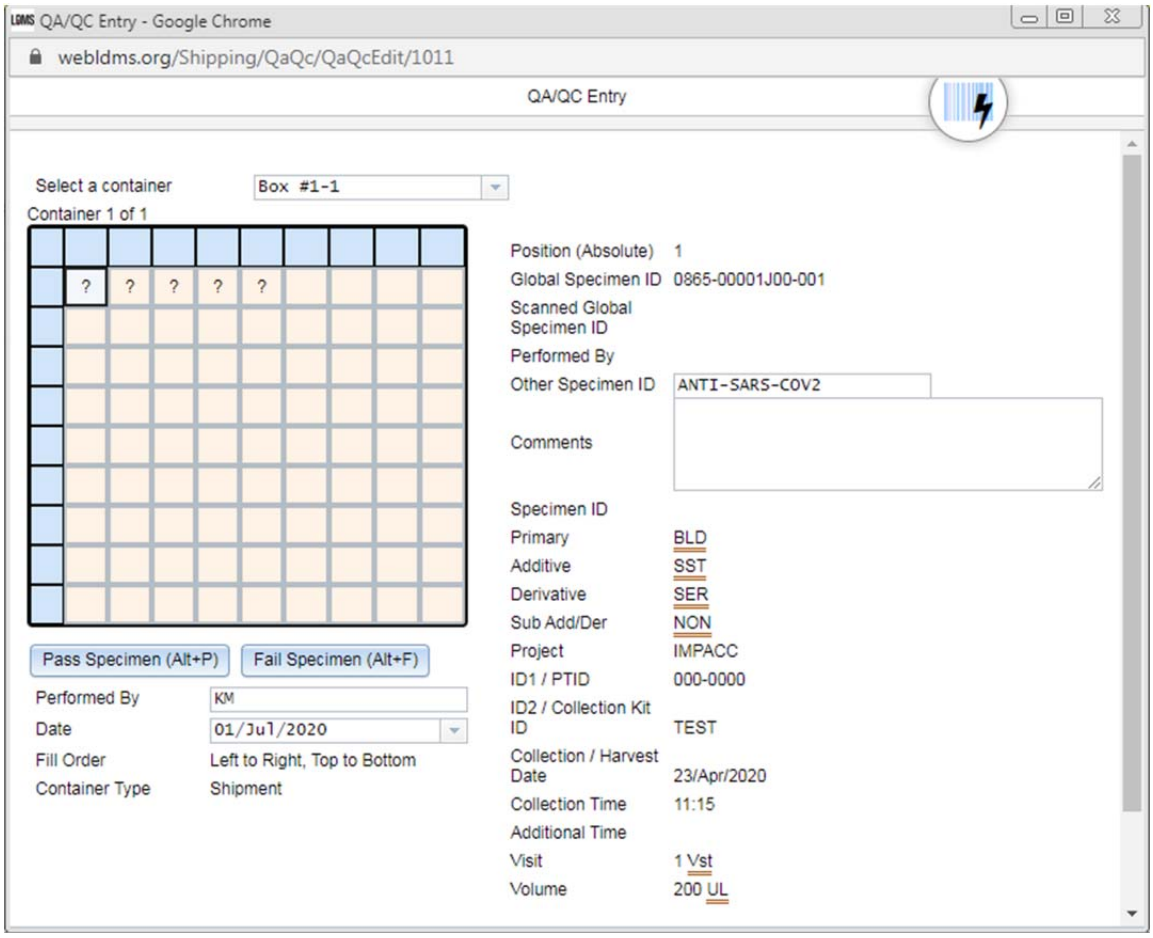
11. Shipping QA/QC process

11.1. The QA/QC process is designed to confirm the samples listed in LDMS are the samples that are being shipped. You will need a barcode scanner capable of scanning 2D barcodes for this process.

11.2. Select QA/QC from the down arrow menu next to the saved shipment in order to open the QA/QC pop-up window.



11.3. Select the container you are verifying against the shipment manifest from the "Select a Container" drop down.



11.4. Highlight the first position in the 2D box layout diagram.

11.5. Scan the barcode of the first sample stored in the position you just highlighted. The "?" will update to "OK" when a sample has been scanned. You may save and come back to the process if you need to.

11.6. Scan all samples in each box, and all boxes in each shipment.

11.7. Save.

12. Creating Shipping Files and Shipping Manifests

12.1. To create a Shipping File, select "Edit/Ship" next to the shipment you are ready to send to a Core Lab.

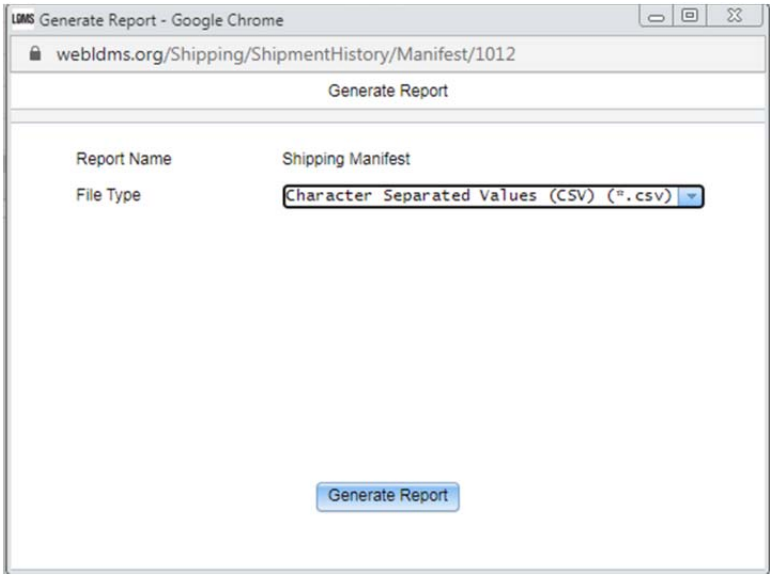
12.1.1. On the bottom of the pop-up window, select "Ship."

12.1.2. Save the Shipping File to a designated folder on your computer.

12.1.3. Close the pop-up window.

12.2. To create a Shipping Manifest, from the Shipping Menu, select "Shipment History"

12.2.1. Find your Shipment and select the down arrow next to the "View" button, then select "Generate Manifest."



12.2.2. Save file in .CSV format

12.2.3. Save manifest to a designated folder on your computer so that the file can be sent electronically to the Core Lab.