

mStudy LDMS Training Workbook

LDMS (Web)

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Specimen Management

Review LDMS User Manual section **Specimen Management-- Using the Specimen Management page**

Exercise 1: Track B Screening visit with Quick Add template

Review LDMS User Manual section **Specimen management -- Quick add**

Specimens were collected from a participant today at 07:25 for a 1/B Screening visit. In this example the template will be selected from a menu in Quick Add. The template is based on the mStudy Specimen Tracking sheet and will make entries for all expected specimens on a particular visit or event.

1. From the LDMS Menu Bar select Specimen Management then **Quick Add**.
2. Under Template Filters, select the following:

Project: mStudy

3. From the **Template** list, select **mStudy 1/B Screening**
4. Read the Note. This information is also present on the Specimen Tracking Sheet
5. In **Participant Information**, enter the following information.

PID: 123456

6. In **Visit Information**, enter the following information:

Clinic: Enter if not present

Collection Date: Current Date

7. When prompted to cascade the Collection Date to the Receive Date and Frozen Date, click **Yes**.
8. In Primary Information **Add**.

Collection Time: refer to mStudy Specimen Tracking sheet

Received Time: 08:30

Note: User must type the colon. Use Copy and Paste (Ctrl + C or V) to enter the time in the other primaries

9. In Aliquot Information, adjust:

Total Aliquots

For the hair aliquot adjust the TBD value for the site of hair collection

10. Click the **Add** button.

Exercise 2: Track A, 2 visit

Review LDMS User Manual section **Specimen management -- Quick add**

Specimens were collected from a participant today at 08:30 for a Track A, Visit 2 on mStudy. Use the template in Quick Add to accession the specimens

1. From the LDMS Menu Bar select Specimen Management then **Quick Add**.
2. Under Template Filters, select the following:
Project: mStudy
3. From the **Template** list, select **mStudy Track A**
4. Read the Note. These are also present on the Specimen Tracking Sheet
5. In **Participant Information**, enter the following information.
PID: 778899
6. In **Visit Information**, enter the following information:
Clinic: Enter if not present
Collection Date: Current Date
Visit Value: 2
7. When prompted to cascade the Collection Date to the Receive Date and Frozen Date, click **Yes**.
8. In Primary Information **Add**.
Collection Time: Refer to mStudy Specimen Tracking sheet
Received Time: 09:00
Notes: User must type the colon. Use Copy and Paste (Ctrl + C or V) to enter the time in the other primaries
9. In **Aliquot Information**, adjust:
Total Aliquots
For the hair aliquot adjust the TBD value for the site of hair collection
10. Click the **Add** button.

Exercise 3: Applying Filters

Filters are used to limit the information that is displayed in the working area on the page. For example, on the Specimen Management page, if a filter is applied with the value of mStudy to the Project field, only participants enrolled in the mStudy project will be displayed. The filters

that are available will vary, depending on the current page. To remove a filter after it has been applied, click on it or click Remove all filters.

Practice applying and removing filters to see how they limit the specimens displayed in the on the Specimen Management page.

Question 1: What is the broadest filter a user can apply? _____

Question 2: What is the most restrictive? _____

Before proceeding, set the filters to find the specimens entered in the exercises above.

Exercise 4: Adding post-processing information

Review LDMS User Manual section **Specimen Management—Primary Specimens--Modifying a primary specimen** and **Specimen Management—Aliquot Specimens--Modifying an aliquot specimen**

1. Stay on the specimen page
2. Click the **Edit** button next to the **Primary**. Enter the following:
 - Processing Date/Time
 - Change Tech initials if needed
3. Click the **Edit** button next to the **Aliquot**. Enter the following:
 - Frozen Date/Time (appropriate for each sample type)

Adjust the following, as needed:

- Condition Code
- Comments
- Aliquot volume

Multiple aliquots can be edited using the control key to highlight multiple samples.

4. Click **Save**

Exercise 5: Printing Labels

Review LDMS User Manual section **Labels--Printing labels anywhere**

1. Using the filters, locate a record entered during this training
2. In the Visit grid **Edit** button drop down arrow, click **Print Labels**. This option is available in each grid if specific labels are needed.

3. In the **Print Labels** menu, **Click Generate Labels**

A PDF file that contains the labels is generated and downloaded into the folder set by the internet browser. Instructions to set the default option in this menu are covered in the LDMS User Manual section **Labels-- Setting the default label format for a project**

Exercise 6: CSMC PBMC creation

The ambient whole blood specimens will be barcoded and will have an accompanying LDMS Shipping file. After the shipping file is processed, the specimen record is located. Aliquots are added to the primary. Processing and Freezing information is recorded along with the total count of cells harvested. The whole blood **aliquot** is updated to **QNS**. Finally labels are generated for the new aliquots.

Part 1: Import Shipping file

Refer to Shipping exercise 7 and import the LDMS shipping file. Note the batch number from the Shipment history page.

Part 2: Find Specimen record

1. In **Specimen Management**, expand the **Shipment Filters** category of the filter panel
2. Enter the **Shipment Number** for the batch that was received.

Batches are assigned a new number upon receipt, the number from the manifest will not work

Alternative method: Scan barcode on a whole blood tube

Part 3: Add aliquots

1. Refer to the **PBMC Tracking Sheet**.
2. To the right of the **Primary**. Click the **Edit** button and enter the **Specimen Processing Details** and **Total cell count**.
3. In the **Edit** drop down menu select **Add new aliquots**
4. Enter **Number of Aliquots** recorded on tracking sheet – This is the number of microtubes
5. **Derivative:** CEL
Sub Add/Der Type: DMS

6. **Volume:** *Cell count in each volume as 10^6 (5,100,000 = 5.1)*
Volume Units: CEL
7. Repeat for the pellets.
Derivative: PEL
Sub Add/Der Type: N/A

Part 4: Processing details

1. Click the **Primary Edit** button, in the menu enter:
 - Processing Date
 - Processing Time
 - Tech Initials
2. In the **Aliquot grid:** Enter the **Frozen Date** and **Frozen Time**. (This can also be changed in storage)

TIP: To edit multiple aliquots, use the control key to highlight and click one edit button

Part 5: Labels

1. In the **Aliquot grid**, click the **Edit** button for the 3 whole blood specimens that were consumed during processing. Update the **condition code** to **QNS**.
2. Move up one level to the **Primary** specimen. In the **Edit drop down** menu **select Print Aliquot Labels**.
3. The settings are preset to the defaults. **Click Generate Labels**. A PDF file will download.

Storage

The Storage page is used to create a virtual representation of the biorepository at your lab. This allows the Data Managers to ensure the specimen is being stored correctly while the specimen is in the lab's possession. The stored boxes are used as the basis for your shipments. Accurate storage creates accurate shipments.

Exercise 1: Adding a container to a level

Review LDMS User Manual section **Storage--Assigning storage locations--Adding a container to a level**

Levels and containers can be added to an existing storage unit if space permits, based on its configuration. If the rack is configured to hold 25 containers and there are currently 25 containers in the rack, you will not be able to add additional containers. Containers can be added to both racks and shelves.

1. Select **Stored Samples** from the **Storage** menu bar item
2. Click the **down arrow** next to the **Edit** button on the level that will hold the container, and then click **Add New Container**.
3. The Create container window will open.
4. Enter the number of new containers to add in the **Number to add** field.
5. Select the template created in the previous exercise in the **From template** field.
6. The information from the template will be populated into the remaining boxes.
7. Click the **Continue** button.
8. The Select position window will open.
9. Enter a descriptive name for the first container into the Name box. This is the label for the new container as it will appear in the storage tree.
10. Specify the position for the new container on its parent level by doing one of the following:
 - a. Select a position for the new container from the Position box.
 - b. Click on an available position in the Preview section.
11. Click the **Continue** button.
12. Repeat for remaining containers.

Exercise 2: Storing specimens

Review LDMS User Manual section **Storage--Assigning storage locations--Assigning a storage location to specimens**

Part 1: By barcode:

1. **Click** on the box name. The barcode image at the top of the screen will display a plus sign
2. **Scan** the barcode
3. **Choose** the position.
Note: Go to Administration – Lab Settings to activate auto-assign position to bypass this menu

Part 2: By selection

1. **Highlight** the desired box and click the **Edit** button **drop down arrow**.
2. Select **Store Specimens**
3. Select **Filters** to locate the new record. E.g., Project, Received Date
4. Specimens available to be stored will populate the **Available Specimens** grid.
5. Select the desired specimens by clicking the check box next to the grid.
Note: *As specimens are selected, the number of available spaces are calculated dynamically below the checklist. The Specimens will remain selected until they are either unchecked or the Clear Selected button is clicked. This allows the user to perform multiple filter searches.*
6. After the specimens are selected. Click **Continue**.
7. Select the box **position** for the indicated specimen or click to select Auto-fill all from selected position. Click **Continue**.
8. The samples will be stored in the designated positions within the box.
9. Click **Edit** for the box in which samples were just stored.
10. Click the **Report** dropdown arrow to generate the **Container Report** to assist in the physical storage of the specimens.

Exercise 3: Reports

Review LDMS User Manual section **Storage--Assigning storage locations--Generating a printable list of what is in storage and Container report**

1. In the storage tree, **locate the container** for which you need to generate a report.
2. To the right of the storage item, click **Edit**.
3. Click the **down arrow** next to the **Reports** button, and then click either **Storage Detail, Container, or Empty Storage Location**.
4. In the **File Type box**, select **PDF (*.pdf)** and then click **Generate Report**.
5. Repeat until you have successfully generated all three reports

The Storage Detail and Empty Storage Location reports are also available for the storage unit, level, and sub-level in the storage tree.

Exercise 4: Applying Filters in Storage

Practice applying and removing filters to see how they limit the specimens displayed in the on the Stored Specimens page.

Question 1: What do the filters in the Storage Filter category apply to? _____

Question 2: What do the other filters apply to? _____

Question 3: For all filters, what is the most restrictive filter? _____

Exercise 5: Adding Frozen Date and Time

1. Click the **Edit** button **drop down arrow** for a container
2. Select **Set Frozen Info**
3. **Highlight** one or multiple specimens
4. Enter a new **Frozen Date, Frozen Time, and Processing Tech Initials**
5. Click **Update Selected Specimens**
6. Click **Save**

Exercise 6: Edit button functions

Part 1: Specimen position

1. Click the **Edit** button to the right of a specimen.
2. In the Edit Stored Specimen window, **select a new position**.
3. Before saving the new position, click **Edit Specimen**, note the options available.
4. **Close** the **Edit Aliquot** window.
5. Click **Save** in the Edit Stored Specimen window.

Part 2: Edit Storage Container

1. Click the **Edit** button to the right of a container.
2. The user is able to **adjust** the following:
 - a. Name
 - b. Dimensions*
 - c. Labeling of Columns/Rows
 - d. Fill order
 - e. Excluded Positions*
 - f. Comment

* Limited if specimens are stored

Note: To change the position of a specimen, click in the position field or the edit button in the Stored Specimens grid. The Edit Stored Specimen window will pop-up (See Part 1).

The user can also consolidate a container by selecting the Consolidate Container button.

3. Click **Save**.

Part 3: Edit Level

1. Click the **Edit** button to the right of a rack or shelf.
2. The user is able to **adjust** the following:
 - a. Name
 - b. Dimensions*
 - c. Labeling of Columns/Rows
 - d. Fill order
 - e. Excluded Positions*
 - f. Comment

* Limited if positions are occupied

3. In the SubLevels grid:
 - a. Change position by clicking in the Position field
 - b. Click the Edit button to bring up the item's Edit menu
4. Click **Save**.

Exercise 7: Moving items in storage

Review LDMS User Manual section **Storage--Moving items in storage**

1. From the **Actions Box** select **Move Storage Item(s)**
2. **Select the items** to be moved using the checkboxes to the right. Specimens, containers, racks, or shelves can be moved.
3. Click next to **select the destination**. If specimens are selected, a container must be the destination. If containers are selected a rack or shelf must be the destination.
4. Proceed through the position selection menu. **Assign a location** to the specimen(s) in the container or containers on a rack or shelf.

Shipping

Use the Shipping module to batch specimens for shipping, prepare shipping files, view shipping history and print shipping related reports.

Exercise 1: Creating a new Batch

Review LDMS User Manual section **Shipping—New Shipments—Creating new shipments**

1. On the navigation menu, hover over **Shipping**, and then click **Pending Shipments**
2. Select **Create Shipment** in the **Actions** box. The **Pending Shipment Preview** window opens.
3. On the **General tab**, complete the **Shipment Date, Format, and Temperature** fields.
4. Click on the **Shipping Destination** tab.
 - a. For whole blood to CSMC set to 675
 - b. For biobanked specimens (Aldrovandi lab) set to 130
5. Click on the **Contact at Sending Lab** tab and complete the information: **Name, Phone Number, and E-mail**.
6. Enter any desired **Shipment comments** on the **Shipment Notes** tab.
7. Scroll to bottom of the screen, click **Save**.
8. Repeat these steps to create another batch to use in Exercises 2 and 3.

Exercise 2: Whole blood to CSMC

Review LDMS User Manual section **Shipping—New Shipments—Creating new shipments**

1. Click the **Edit/Ship** button of a batch created in the **Pending Shipments** page.
2. Click to open the **Shipment Contents** tab.
3. Click **Add New** above the **Shipping Containers** grid.
4. The **Create Shipping Container** menu opens.
5. Enter the **dimensions** of the shipping container (a bag is used as the example below):
Row: 3 (number of whole blood tubes)
Column: 1
Check Positions only
Fill order is Left to Right, Top to Bottom
6. Set the **Sort Order** to **Specimen ID**
7. Click the **Add Specimens** button above the Samples grid.
8. The **Select Specimens** window appears. **Scan the specimen barcode**

Alternatively, use the filters:

Visit Filters: Collection Date = Current Date

Specimen Filters: Derivative = BLD

9. The available specimens will be in the **Available Specimens** grid. **Select** the specimens to add to your batch by clicking the checkbox.
10. Click the **Continue** button
11. You will return to the **Create Shipping Container** menu. The selected specimens are displayed in the **Samples** grid.
12. Click the **Add** button
13. The container is listed in the **Pending Shipment Preview** menu. Scroll down and click **Save**.
14. Perform QA/QC – Exercise 4

Exercise 3: Stored specimens to biobanking

Review LDMS User Manual section **Shipping—New Shipments—Creating new shipments**

1. Click the **Edit/Ship button** of a batch created in the **Pending Shipments** page.
2. Click to open the **Shipment Contents** tab.
3. Click **Add New** above the **Storage Containers** grid. The available Storage Containers appear.
4. **Locate** the desired storage container and click the checkbox, and **Add Selected to Shipment** to add the container to the shipment. The selected storage container will display in the Pending Shipment Preview.

Note: If you assigned the Mark to Ship flag to a storage item, apply the filter to assist in selection.

5. Scroll down. Click **Save** to save the batch.
6. Perform QA/QC – Exercise 4

Exercise 4: Performing shipment QA/QC

Review LDMS User Manual section **Shipping— Shipment QA/QC—Performing QA/QC**

1. Click the **Edit/Ship button dropdown arrow** to select QAQC. The **QAQC Entry** window opens.
2. If empty, **enter initials** in the **Performed By** box.
3. Click on the **first position** in the 2D box image.
4. Scan the barcode of the specimen box that is displayed. If the specimen is in a cryovial box, ensure the location is correct.
If you cannot scan a barcode, carefully check the global specimen id and click the pass button.
5. If the batch has multiple containers, **choose the next container** in the drop down menu.
6. Click **Save**. Generate the QAQC report, if needed.

Exercise 5: Creating shipping files

Review LDMS User Manual section **Shipping—New Shipments— Sending a pending shipment**

1. Click the **Edit/Ship button** for the batch in the **Pending Shipments** list.
2. At the bottom of the Pending Shipment Preview page, scroll down, and click **Ship**, Click **OK**. The shipment message appears and the shipping file generates. Save the shipping file to the desired location.
3. This file must be sent to the Receiving lab.
4. The batch is automatically transferred to the **Shipment History** page.

Exercise 6: Shipment paperwork

Review LDMS User Manual section **Shipping—New Shipments— Generating a shipping manifest**

1. Select **Shipment History** in the **Shipping** menu listing.
2. Click the **View button dropdown arrow** and select **Generate Manifest**.
3. File type should be set to **.PDF**. Click **Generate Report**. Save the report to the desired location.
4. A printed copy of this report must be included in the shipment
5. **Repeat** steps 1-3 for the **Container** report
6. These files must be sent to the Receiving lab. see **Section 5 of EU5332 LPC**

Exercise 7: Importing whole blood specimens at CSMC

Review LDMS User Manual section **Shipping—Receiving shipments**

1. On the **Receive Shipments** page, click **Select File**
2. Browse to the shipping file and click **Open**
3. Click **Preview Shipment**
4. Select a **Ambient** in the **Confirm Temperature** list
5. Click **Receive Shipment**
6. Go to **Shipment History**. From the **Edit button drop down arrow** select **QA/QC**
7. Perform QA/QC on the new shipment. **See Exercise 4**
8. Note shipment number to facilitate searching in Specimen Management

Labels

Use the Print Labels page to re-print many labels across several specimens and participants. This is an alternative to printing labels from the Specimen Management page. Instructions to set the default label options are covered in the LDMS User Manual section **Labels-- Setting the default label format for a project**

Exercise 1: Bulk reprint of labels

Review LDMS User Manual section **Labels--Generating labels**

1. From the LDMS menu select **Labels**, and then click **Print Labels**
2. After setting the appropriate **filters**, specimens matching the criteria populate in the grid.
3. Set filters to show all specimens created during this training.
4. Use the check boxes to mark the specimens that need labels.
5. Click **Print Labels**.
6. In the **Print Labels** menu, select the **Format** (ACTG Spec) and **Size**, if not already highlighted.
7. Click **Generate Labels**.

Reports

Review LDMS User Manual section **Reports--Generating a report**

Exercise 1: Specimen processing report

Review LDMS User Manual section **Reports--Specimen reports**

Generate this report at the end of the day and check it against the tracking forms to insure the data was entered accurately and completely.

1. On the LDMS menu bar, hover over **Reports** and click **Standard Reports**.
2. Select **Specimen** in the Report Categories box.
3. Select **Specimen Processing Report** in the Report box.
4. In **Filter Criteria**:
 - a. **Field**: Project **Operator**: '=' **Value**=mStudy
 - b. **Field**: Received Date **Operator**: '=' **Value**=Current Date
5. Set **File Type** to PDF
6. Click **Generate Report**

Exercise 2: Specimens not in storage report

Review LDMS User Manual section **Reports--Storage reports**

1. On the LDMS menu bar, hover over **Reports** and click **Standard Reports**.
2. Select **Storage** in the Report Categories box.
3. Select **Specimens Not in Storage** in the Report box.
4. Set **File Type** to PDF
5. Click **Generate Report**

Exercise 3: LDMS codebooks

Review LDMS User Manual section **Reports--Miscellaneous reports**

1. On the LDMS menu bar, hover over **Reports** and click **Standard Reports**.
2. Select **Miscellaneous** in the Report Categories box.
3. Select **LDMS abbreviated codes report –or- LDMS primary, additive, derivative, sub additive/derivative codes Report** in the Report box.
4. Set **File Type** to PDF
5. Click **Generate Report**

Advanced Exercise 1: Custom Inventory Report

Review LDMS User Manual section **Reports--Custom Report Builder**

The custom report builder is used to export specimen data into a generic format to import into other programs such as Excel. The data fields listed under All Fields are available to include in the report under (Fields To Display) or to sort the data (Sort Fields By). The Name of the field will become the header in the export file.

To make the list of fields more manageable, limit the view by selecting/deselecting the category. Use the **Fields to Display** check boxes to include the data item in their respective columns. The order the fields are listed is the order they will appear in the report. **Select the following:**

Category	Information to Display
Specimen	PID Protocol Collection Date Collection Time Primary Additive Derivative
Storage	Stored (storage status) Storage Unit (Freezer) Level (ie. Shelf) Sub-level (ie. Rack) Container Position
Shipping	Original batch number Ship date Destination Lab ID

Note: In the field list, the primary participant identifier (PID, PTID, Subject ID) is ID1; the study identifier (protocol or study) is ID2; and the optional participant identifier is ID3

Optional: The content of the report can be limited by providing Selection Criteria. Highlight a field in the All Fields list, below in the Selection Criteria grid the data item autofills in the search box. Enter the search term either using by typing or using the drop-down menu.

After everything is selected, set the file type CSV, and click Generate Report.

LDMS Setup

Before using the LDMS, it must be configured. Each new install of LDMS has a blank Storage page. This allows each lab to customize the Storage Unit to match the layout and capacity of the freezers, refrigerators, or cabinets at their facility. This process only occurs in a new LDMS install or if a new Storage Unit has been purchased.

Exercise 1: Setting the default label format

Review LDMS User Manual section **Labels— Setting the default label format for a project**

1. On the navigation menu, hover over **Labels**, and then click **Default Label Setup**
2. Set the following:
 - a. **Project** mStudy
 - b. **Format** ACTG Specimen Barcdoe
 - c. **Label** *Choose Label size in use at your lab
3. Click **Add Default**
4. Click **Save**

Exercise 2: Adding a storage unit

Review LDMS User Manual section **Storage—Assigning storage locations—Adding a new storage unit**



In this example we are going to add a freezer with 4 shelves. The shelf is configured in a separate step.

1. Select **Stored Samples** from the Storage menu bar item.
2. Select **Add Storage Unit** from the **Actions** box.
3. **Define** the following:
 - a. Storage Unit Name: This is the name that will appear in the storage tree
 - b. Type: Freezer
 - c. Temperature: -80 C
 - d. Rows: 4 (equals number of shelves)
 - e. Columns: 1
4. Click **Save**.

Hint: When building a freezer the column equals one and the rows represent the number of shelves.

Exercise 3: Adding additional levels to a storage unit

Review LDMS User Manual section **Storage—Assigning storage locations—Adding a new level in a storage unit**

A shelf can be configured to hold racks or containers. When configuring for racks, the row is one and the columns represent the number of racks. For containers, the dimensions are increased to total the number of containers on the shelf. A 6x6 shelf can hold 36 containers.

Levels and containers can be added to an existing storage unit if space permits, based on its configuration. If the storage unit is configured to hold 4 shelves and there are currently 4 shelves in the unit, you will not be able to add additional shelves.

1. Click the **Edit button drop down arrow** to the right of the freezer created in the previous exercise
2. Select **Add new level**.
3. **Configure** the shelf to hold 25 containers:
 - a. Rows: 5 (how high can you stack the boxes)
 - b. Columns: 5 (how many boxes fit across the shelf)
 - c. Positions Only
 - d. Fill, Left to Right, Bottom to Top
4. Click **Continue**.
5. In the **position selection menu**, place the shelf in the first position of the new freezer.
6. Click **Save**.
7. *To add more shelves.* Click the **Edit button drop down arrow** to the right of the freezer and select **Add new level**. Repeat steps 1-6

NOTE: If the lab's freezer contains racks, create a shelf with 1 row and set the number of columns to the number of racks that can fit on the shelf. Create the rack level template in the exercise below and add to the shelf.

Exercise 4: Configuring a storage container template

Review LDMS User Manual section **Storage-- Storage templates--Creating storage item templates**

A template will save time when adding a new box to the storage module by automatically filling out the menu options

Name: mStudy 9x9 cryovial box

Dimensions: Rows: 9 Columns: 9

Check Positions Only

Fill Order: Left to Right, Top to Bottom

Excluded Position(s): None

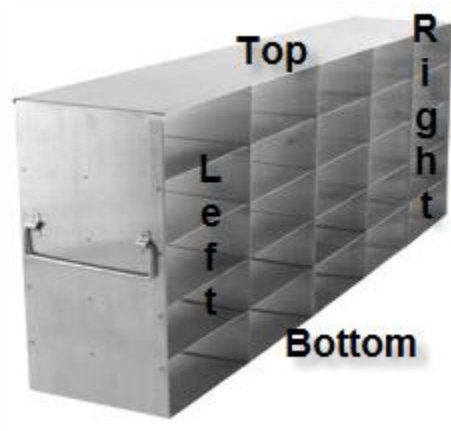
1. Select **Container Templates** from the **Storage** menu bar item.
2. Configure the desired box specifications, indicating the following:
 - a. **Name**
 - b. **Number of Rows, Number of Columns**
 - c. Select the **fill order** and **labeling** information (or positions only)
3. Click **Save Template**.

The newly-created container template will be available in the Saved Templates listing.

Note: *The ability to create a template is also available when adding a new container.*

Exercise 5: Configuring a level template [Rack]

Review LDMS User Manual section **Storage--Storage templates--Creating storage item templates**



In this example we are building a template for a 5x5 stainless steel rack.

Name: 5 x 5 stainless steel rack

Dimensions: Rows: 5 Columns: 5

Column Labels (Circle): Numeric Alphabetic
Left to Right Right to Left

Row Labels (Circle): Numeric, Alphabetic Left, Right
Top to Bottom Bottom to Top

Fill Order (Circle): Left to Right Right to Left
Top to Bottom Bottom to Top

Excluded Position(s): _____

1. Select **Level Templates** from the Storage menu bar item.
2. **Configure** the rack specifications, indicating the following:
 - a. Name
 - b. Number of Rows, Number of Columns
 - c. Select the fill order and labeling information (or positions only)
3. Click **Save Template**.

The newly-created rack template will be available in the Saved Templates listing.