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\*\*Patient, as defined in this manual, is synonymous with subject/sample, as in the person or thing that is being discussed or described.

# CHAPTER 1: INTRODUCTION

Welcome to LIFECODES MATCH IT! Antibody Software. LIFECODES MATCH IT! Antibody Software is an accessory for the evaluation of test results from LIFECODES Antibody products.

The LIFECODES MATCH IT! Antibody Software is an aid to assist qualified laboratory personnel by suggesting the presence or absence of HLA antibodies. Due to the complex nature of HLA Testing, qualified laboratory personnel must review any result to assure correctness. The software is a laboratory aid and not meant to be the sole source of a definitive result.

## System Requirements

The following is required to successfully install and use LIFECODES MATCH IT! Antibody Software, v 1.3

### Computer Requirements

- Microsoft Windows 7 (32 or 64 bit version) or Windows 10 operating systems
- Pentium® 4 or Core 2 Duo
- 10 GB hard disk space
- 4 GB RAM
- 24-bit graphics adapter and display
- XGA display with 1024 x 768
- Mouse or other windows compatible pointing device

### Software Requirements

- Microsoft SQL Server 2012 Express (included with software and backwards compatible to 2008 Express)
- Microsoft .NET Framework Version 4.5.2 (included with software)
- (Optional) Microsoft SQL Server 2008 or 2012 for increased storage capacity

### Luminex Requirements

- The LIFECODES MATCH IT! Antibody Software is designed to import CSV files created by the xPONENT software versions.
- The data present in the CSV file must be generated using an unmodified Luminex template provided by LIFECODES.

# Networking Client Computers to a SQL Server

## For Standard or Enterprise Editions

- 1) From the **Start** Menu, Open the MATCH IT! database management utility drop-down. Choose the application and log-in required for this utility.
- 2) Click **Choose Server**.
- 3) Click **Available SQL Instances** drop-down to display known SQL instances.
- 4) Choose the SQL instance that contains the database.
- 5) Once the connection is established a list of available databases will be displayed. Choose the database and click **OK** to connect.
- 6) Open MATCH IT! Software.

## Troubleshooting

If the SQL instance does not appear in the dropdown then there are two options:

- 1) Type in the name of the SQL instance, if the instance is valid and Match IT! can connect to it then the databases it holds will be listed. Click **Connect** to establish the connection.
- 2) Click **Refresh Server List** to scan the network for Match IT! instances.

If the SQL instance appears but Match IT! can not connect to it:

- 1) Check to see if a port for the instance has been specified.

Ask the database administrator to check the port settings in SQL Server Configuration Manager.

- 2) If a port has been specified then add the port number to the SQL instance in the dropdown.

Example:

<Computer name>, <port number>

MatchITserver, 1500

# Networking Client Computers to a SQL Server Express

## For 2008 editions

- 1) From the **Start** Menu, Open the MATCH IT! database management utility drop-down. Choose the application and log-in required for this utility.
- 2) Click **Choose Server**.
- 3) Click **Available SQL Instances** dropdown to display known SQL instances.
- 4) Choose the SQL instance that contains the database. Click **Connect** to establish the connection.
- 5) Once the connection is established a list of available databases will be displayed. Choose the database and click OK to connect.

## Troubleshooting

On the computer that holds the database, verify the SQL Browser is off and TCP/IP is enabled.

Checking the SQL Browser state:

- 1) Open **SQL Server Configuration Manager**.
- 2) Click **SQL Server Services**.
- 3) Check that the SQL Server Browser is stopped. If it is not, right click the service and choose stop.

Checking TCP/IP state:

- 1) Open **SQL Server Configuration Manager**.
- 2) Click **SQL Server Network Configuration**.
- 3) Click the correct protocol. This will be the name of the instance that holds the database.
- 4) Verify the status of TCP/IP. It should be enabled. If it is not then, right click TCP/IP and choose Enable.

If the SQL instance does not appear in the dropdown then there are two options:

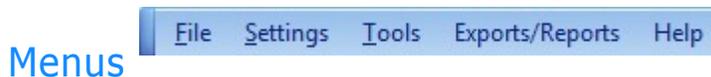
- 1) Type in the name of the SQL instance, if the instance is valid and MATCH IT! can connect to it then the databases it holds will be listed.
- 2) Click **Refresh Server List** to scan the network for Match IT! instances.

If the SQL instance appears but MATCH IT! can not connect to it:

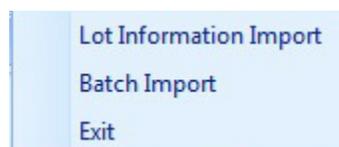
- 1) Check to see if a port for the instance has been specified.
- 2) Open **SQL Server Configuration Manager**.
- 3) Click **SQL Server Network Configuration**.
- 4) Click the correct protocol. This will be the name of the instance that holds the database
- 5) Double click **TCP/IP**.
- 6) Choose the IP Addresses tab.
- 7) Scroll to the bottom to find IPAll.
- 8) Check the TCP Port field. If a port has been specified then add the port number to the SQL instance in the dropdown.  
Example:  
<Computer name>, <port number>  
MatchITserver, 1500

# CHAPTER 2: MATCH IT! MENUS

This chapter provides descriptions of the home menu functions.



## File Menu



The **File** menu contains additional access to common functions found on the home screen. It allows the user to utilize keyboard shortcuts.

### Lot Information Import

Before importing ID data, the information necessary for analyzing the data generated by the Luminex instrument must be imported. The information is provided in lot-specific EDS files.



1) Click Lot Information Import. The dialog box will appear.

Note: The **Import EDS** button on the homepage will display the same window.

2) Navigate to the location, e.g., desktop, of the EDS file(s). Select all appropriate files that need to be imported. Use CTRL + left mouse button to select more than one EDS file at one time.

3) Click **Open**. A message will appear when all lots have been successfully imported.

### Batch Import



1) Click **Batch Import**. This will open the dialog box.

Note: The **Import CSV** button on the homepage will display the same window.

2) Navigate to the location of the CSV file(s). If importing from the computer connected to the Luminex, CSV files can be found in C:\Program-Data\Luminex\xPONENT\Output.

3) Select all CSV files to be imported. Use CTRL + left mouse button to select more than one CSV file at one time.

4) When the file is selected, the analysis is done automatically during the import process. Once the CSV file has been imported, it will appear on the Antibody Home tab under ID.

Note: A **CSV Import: Lot Import** may appear after selecting a CSV file. This can be due to:

- 1) The appropriate EDS file not being imported,
- 2) The EDS file not being available, or
- 3) The lot number not being indicated on the CSV file.

## Exit

Exit the software.

## Settings (Lab Settings) Menu



The **Settings** menu contains laboratory defined settings for the various assays.

## Preferences

This menu item contains several tabs for personal laboratory settings.

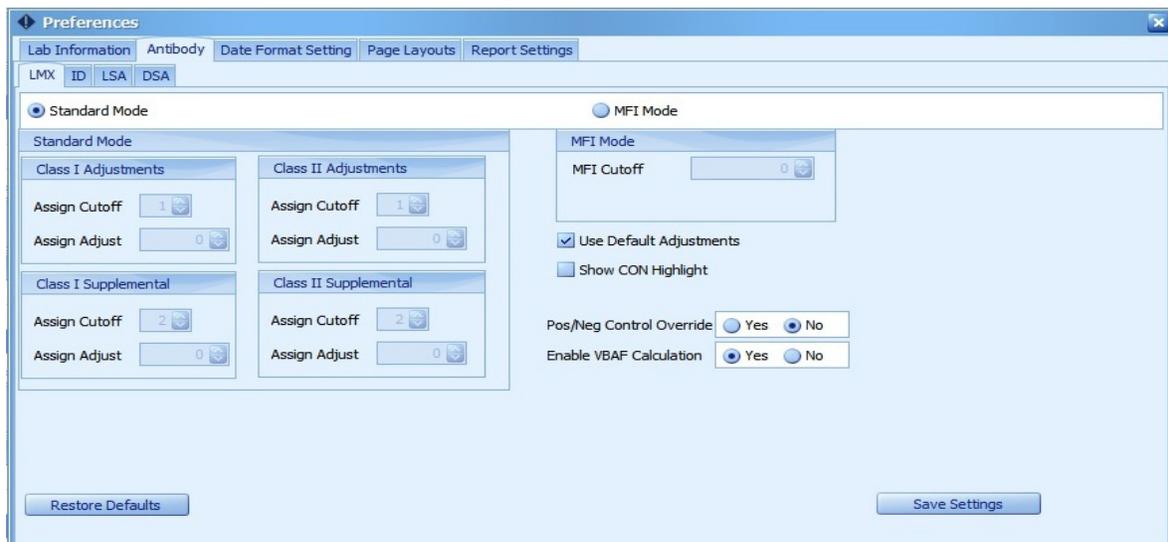
## Lab Information Tab

The screenshot shows a 'Preferences' window with a 'Lab Information' tab selected. The window contains two columns of input fields. The left column includes: Lab Name, Lab Address, Lab Address 2, Lab City, Lab State/Province, Lab Country, Lab Postal, Director, Supervisor, Email, Phone, and Fax. The right column includes: Lab Website, Lab Code, License(s) (with up/down arrows), and Lab Logo (with a 'No image data' button and a magnifying glass icon). At the bottom, there are 'Restore Defaults' and 'Save Settings' buttons.

The user can input personal laboratory information.

## Antibody Tab

This tab contains an individual tab for each antibody assay. Each assay specific tab includes analysis settings. The software is installed with default values for analysis. The default settings should only be altered by personnel knowledgeable in the field of HLA Antibody Analysis. Changing these values will result in altered specificity and sensitivity of the assay. The values may be changed using the up and down arrows next to the value, or by manually entering the value of choice. Once the values have been entered, they can be saved by clicking **Save Settings**. If at any time default settings need to be restored, click **Restore Defaults**.



## I) Class I and Class II Adjustments

**i) Assign Cutoff:** This value indicates the number of calculations, against different controls, that must be positive for the sample to be assigned as positive.

**ii) Assign Adjust:** This value is used by the software to determine if a bead value is positive. When a calculation is greater than or equal to the Assign Adjust, that value is considered positive. Therefore, by raising the Assign Adjust, the assay sensitivity decreases.

**II) Import Mode:** This allows the user to choose to apply either the Standard Assignment (**Standard Mode**) adjustments (Assign Cutoff and Assign Adjust) or to set cutoffs based on an MFI value (**MFI Mode**) upon import.

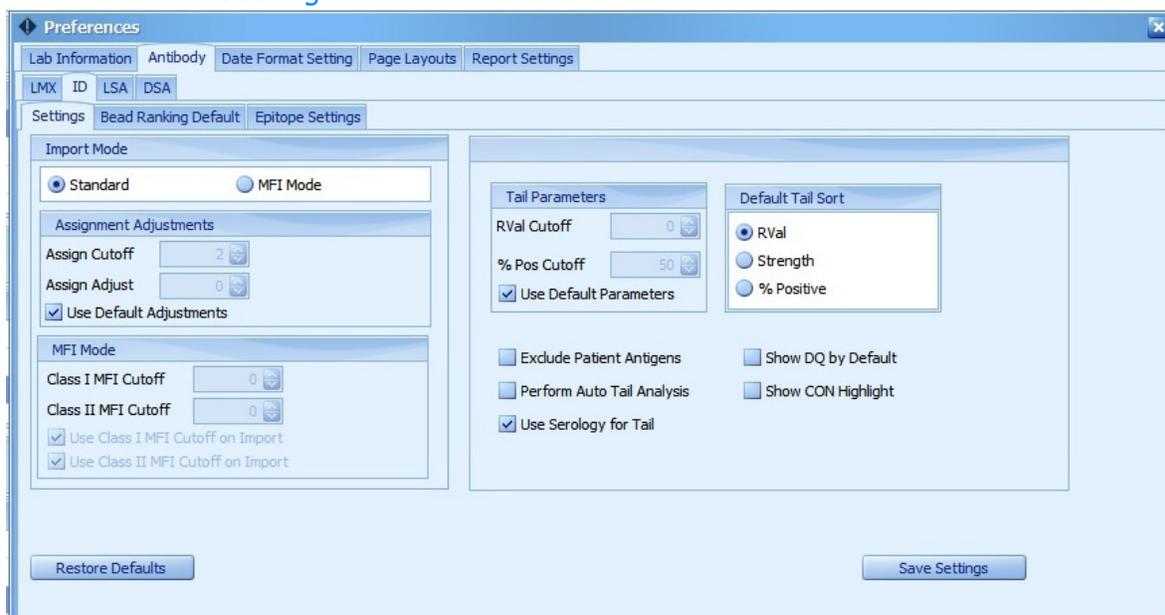
**III) Show CON Highlight:** Enabling this feature will have the software highlight all CON values outside of the observed QC range red.

**IV) Pos/Neg Control Override** (*only when submitting batches to Liquid Handler*): This allows the logged-in user to decide if this function should be enabled. When enabled, the entire batch is tied to the performance of the Positive and Negative control. All samples will be listed as failed if either the Positive or Negative Control samples fail.

- A Negative Control is considered as failed if any bead fails to meet the minimum bead count, or if the Negative Control has a positive assignment for Class I or Class II.
- A Positive Control is considered as failed if any bead fails to meet the minimum bead count, or if either of the Class I or Class II assignment is negative.

**V) Enable VBAF Calculation:** This allows the user to activate this feature. By default, this feature is inactivated.

## ID - Settings



**I) Import Mode:** This allows the user to choose to apply either the Standard Assignment (**Standard Mode**) adjustments (Assign Cutoff and Assign Adjust) or to set cutoffs based on an MFI value (**MFI Mode**) upon import.

### II) Assignment Adjustments

**i) Assign Cutoff:** This value indicates the number of calculations, against different controls, that must be positive for the sample to be assigned as positive.

**ii) Assign Adjust:** This value is used by the software to determine if a bead value is positive. When a calculation is greater than or equal to the Assign Adjust, that value is considered positive. Therefore, by raising the Assign Adjust, the assay sensitivity decreases.

### III) Tail Parameters

**i) RVal Cutoff:** In the tail analysis, the software will display all antigens with an R-value greater than or equal to the cutoff set. The range is 0 to 1 and the default setting is 0.

**ii) % Pos Cutoff:** In the tail analysis, the software will display all antigens with a % positive score greater than or equal to the cutoff set. The % positive score represents the percentage of beads containing a particular antigen that are positive. The range is 0 to 100% and the default setting is 50%.

**IV) Default Tail Sort:** This allows the user to define the parameter by which to rank the antigens. The default setting is RVal.

**V) Use Serology for Tail:** Use this feature if a 2-digit (serology) tail analysis is preferred as opposed to the 4-digit (allelic).

**VI) Show DQ by Default:** Use this feature to show all DQ antigens instead of just the ones on DQ enhanced beads.

**VII) Exclude Patient Antigens:** The user has the ability to **Exclude Antigens** on import if the following information is entered during Automated Batch Set-up (ID and LSA).

To exclude antigens for ID, the **Exclude Patient Antigen** box must be checked on the Settings tab in ID and the import **Exclude Antigen CSV file** (available from the Immucor website) must be imported into the LSA Preferences tab of the software.

Note: The sample's HLA type must be entered into the sample list or added to the **Sample Profile in Patient View** in order to display on the report. This feature is designed for batches submitted to Luminex through the MATCH IT! software. In order for antigens to be excluded they must match an antigen listed on the product worksheet and be separated by commas.

Example:

A2, A24, B56, B51

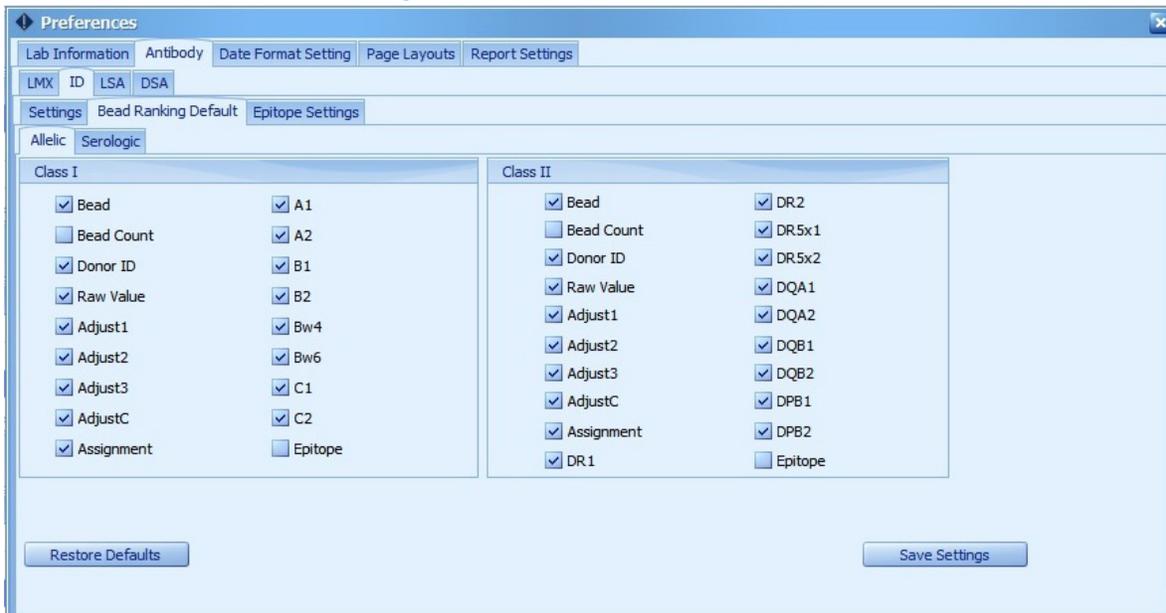
or

A\*02:01, A\*24:02, B\*56:01, B\*51:01

**VIII) Perform Auto Tail Analysis:** If this box is checked, the software to automatically perform a tail analysis when opening a batch for the first time.

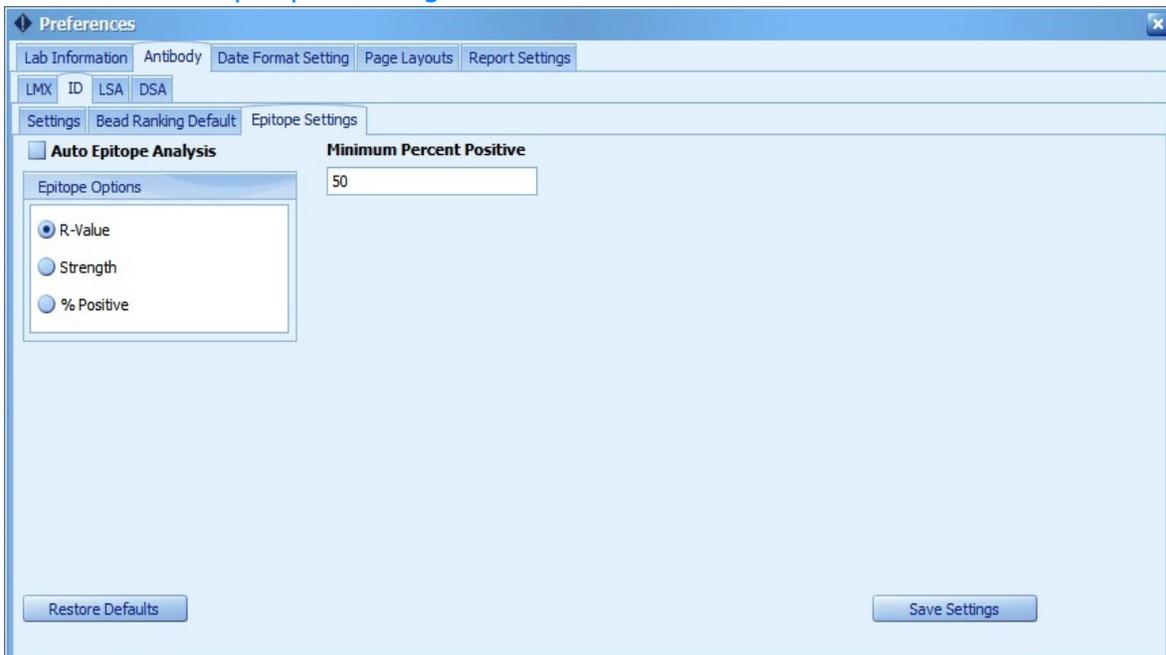
**IX) Show CON Highlight:** Checking this box will highlight all CON values outside of the expected QC range red.

## ID - Bead Ranking Default



Allows the user to define the columns that will be included on the **Bead Rank** report during export. The user can select individual columns by placing a check next to the item. Once all items have been selected, click **Save Settings**.

## ID - Epitope Settings



**Auto Epitope Analysis:** If this box is checked, the software will perform epitope analysis automatically when opening a batch for the first time or when saving a sample during analysis. This feature is found in the **Epitope Settings** tab.

Note: If **Use Serology for Tail** is turned on, the software will not calculate epitopes.

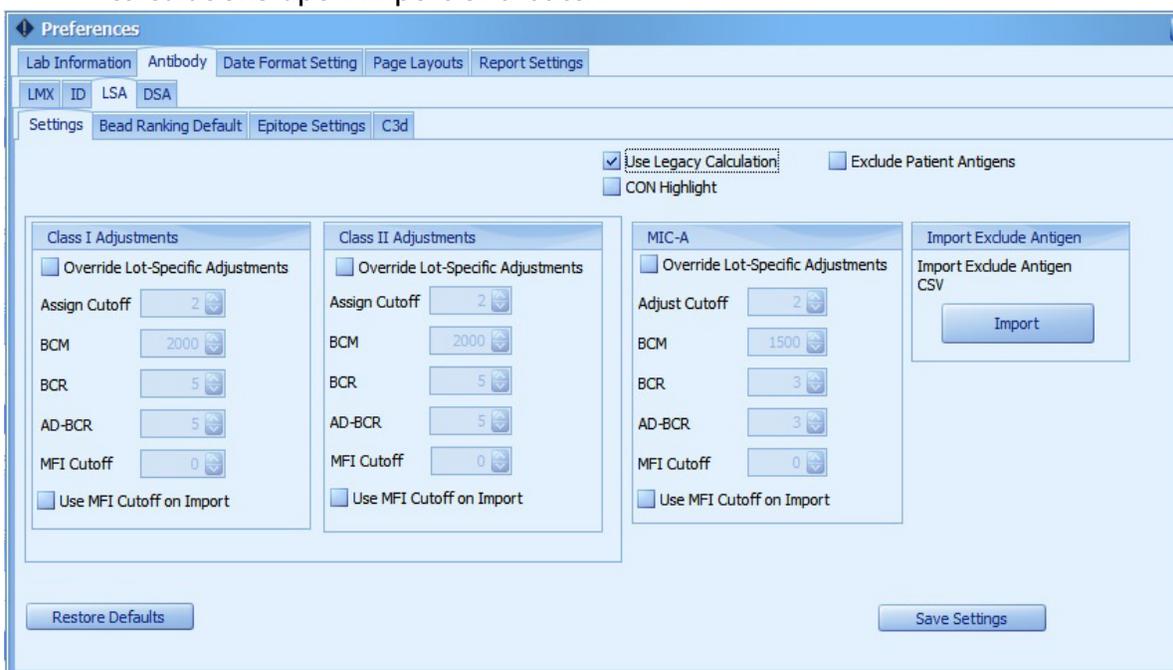
## LSA - Settings

The screenshot shows the 'Preferences' dialog box for LSA. The 'Settings' tab is active, showing options for 'Negative Control Sample Name' (set to 'Negative Control'), 'Use Legacy Calculation', 'Exclude Patient Antigens', and 'CON Highlight'. There are three main configuration panels: 'Class I', 'Class II', and 'MIC-A'. Each panel has an 'Override Lot-Specific Adjustments' checkbox and several numerical input fields for 'Antigen Adjustment', 'MFI Threshold', and 'MFI Cutoff'. Below these panels are two columns of color-coded checkboxes for MFI ranges: 0-499, 500-999, 1000-2999, 3000-4999, 5000-9999, and > 10000. At the bottom of the dialog are 'Restore Defaults' and 'Save Settings' buttons.

**I) Negative Control Sample Name:** The user must designate a Negative Control Sample Name that will be referenced for all LSA batches upon import.

If the **Negative Control Sample Name** in the batch does not match what is listed in **Preferences**, the user will be prompted to select a negative control upon import or proceed without one.

**II) Use Legacy Calculation:** The user can check this box to use LSA Legacy calculations upon import of a batch.



Note: If unchecked, all old LSA batches will use legacy calculations and all new batches will use new calculations.

**III) Class I and Class II Adjustments:** The user can override default adjustments with customized values to be used by the software during batch import.

**IV) Exclude Patient Antigens:** The user has the ability to **Exclude Antigens** on import if the following information is entered during Automated Batch Set-up.

To exclude antigens for LSA, the **Exclude Patient Antigens** box must be checked on the Settings tab in LSA and the import **Exclude Antigen CSV file** (available from the Immucor website) must be imported into the software.

Note: The sample's HLA type must be entered into the sample list or added to the **Sample Profile** in **Patient View** in order to display on the report. This feature is designed for batches submitted to Luminex through the MATCH IT! software. In order for antigens to be excluded they must match an antigen listed on the product worksheet and be separated by commas.

Example:

A2, A24, B56, B51

or

A\*02:01, A\*24:02, B\*56:01, B\*51:01

**V) CON Highlight:** Checking this box will highlight all CON values above 2500 MFI in red.

**VI) Import Exclude Antigen:** Use this to import the **Exclude Antigen CSV** file, found on the Immucor website.

**VII) Class I and Class II Adjustments:** The user can override default adjustments with customized values to be used by the software during batch import.

**VIII) MIC-A:** The user can override default adjustments with customized values to be used by the software during batch import.

**IX) Threshold Colors:** This allows the user to toggle color assignments on and off for specific Raw Value intervals (0-499, 500-999, 1000-2999, 3000-4999, 5000-9999, >10000).

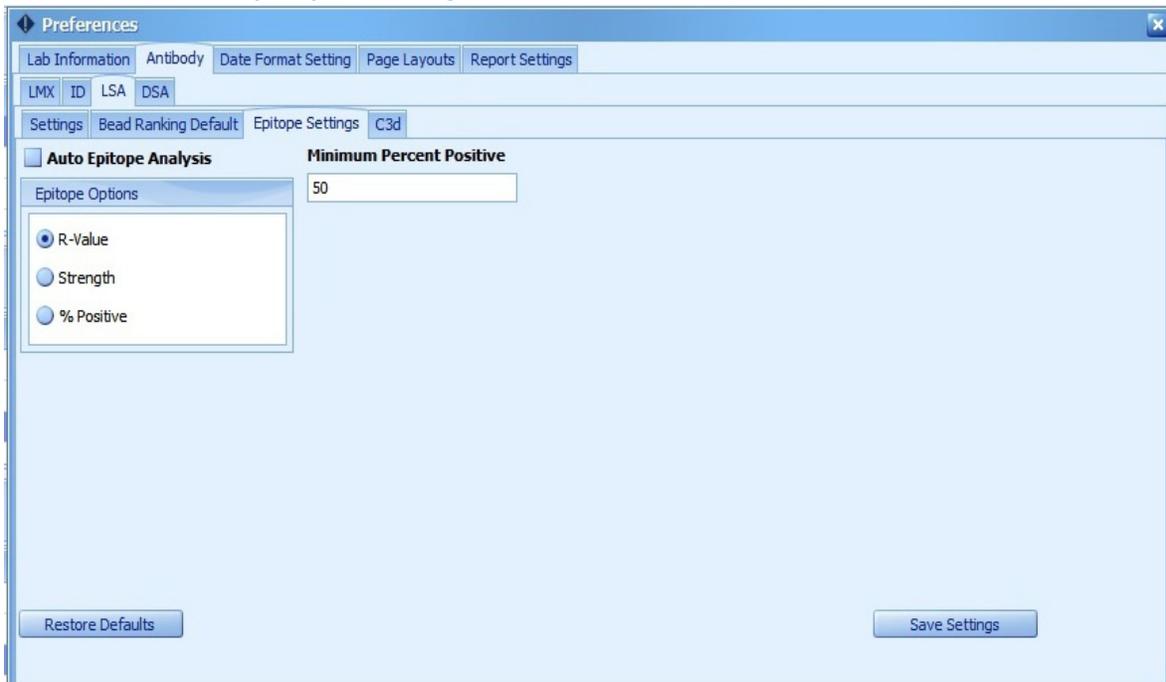
<input checked="" type="checkbox"/> 0-499	<input checked="" type="checkbox"/> 3000-4999	<input type="checkbox"/> 0-499	<input type="checkbox"/> 3000- 4999
<input checked="" type="checkbox"/> 500-999	<input checked="" type="checkbox"/> 5000-9999	<input type="checkbox"/> 500-999	<input type="checkbox"/> 5000-9999
<input checked="" type="checkbox"/> 1000-2999	<input checked="" type="checkbox"/> >10000	<input type="checkbox"/> 1000-2999	<input type="checkbox"/> > 10000

### LSA - Bead Ranking Default

The screenshot shows the 'LSA - Bead Ranking Default' settings window. It features a navigation bar with tabs for 'LMX', 'ID', 'LSA', and 'DSA'. Under the 'LSA' tab, there are sub-tabs for 'Settings', 'Bead Ranking Default', 'Epitope Settings', and 'C3d'. The 'Bead Ranking Default' sub-tab is active, showing three columns of settings: 'Class I', 'Class II', and 'MIC-A'. Each column contains a list of items with checkboxes. At the bottom, there are 'Restore Defaults' and 'Save Settings' buttons.

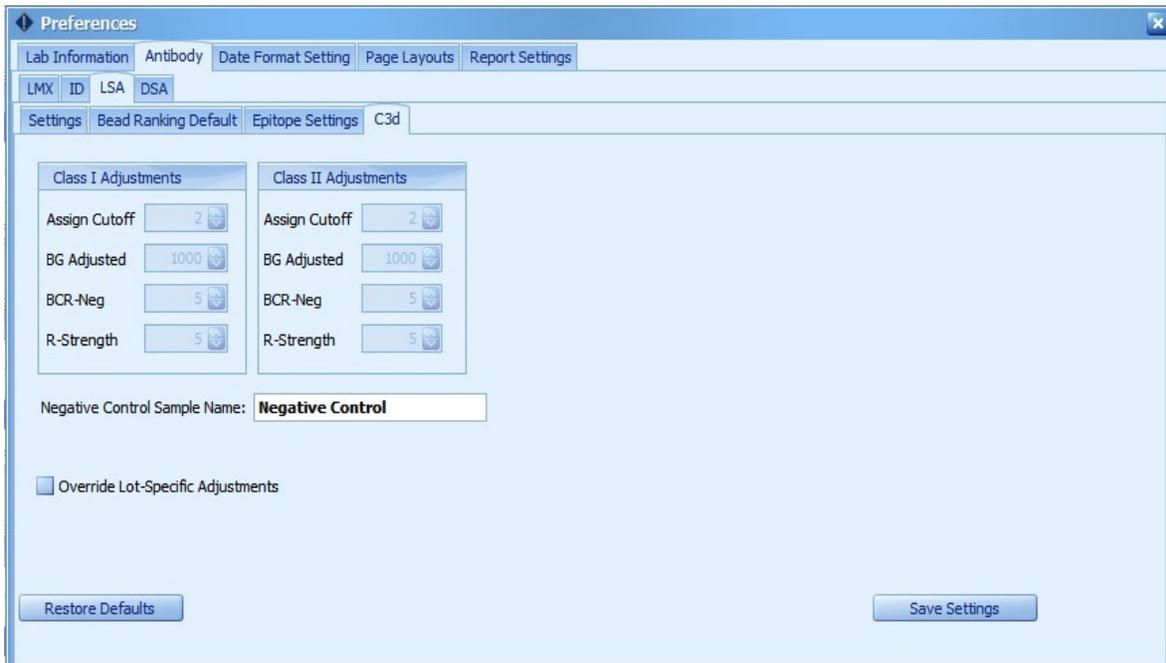
This tab allows the user to define the columns that will be included on the **Bead Rank** report during export. The user can select individual columns by placing a check next to the item. Once all items have been selected, click **Save Settings**.

## LSA - Epitope Settings



**Auto Epitope Analysis:** If this box is checked, the software will perform epitope analysis automatically when opening a batch for the first time or when saving a sample during analysis. This feature is found in the **Epitope Settings** tab. Once the **Auto Epitope Analysis** is selected, the user can choose appropriate parameters to analyze the data.

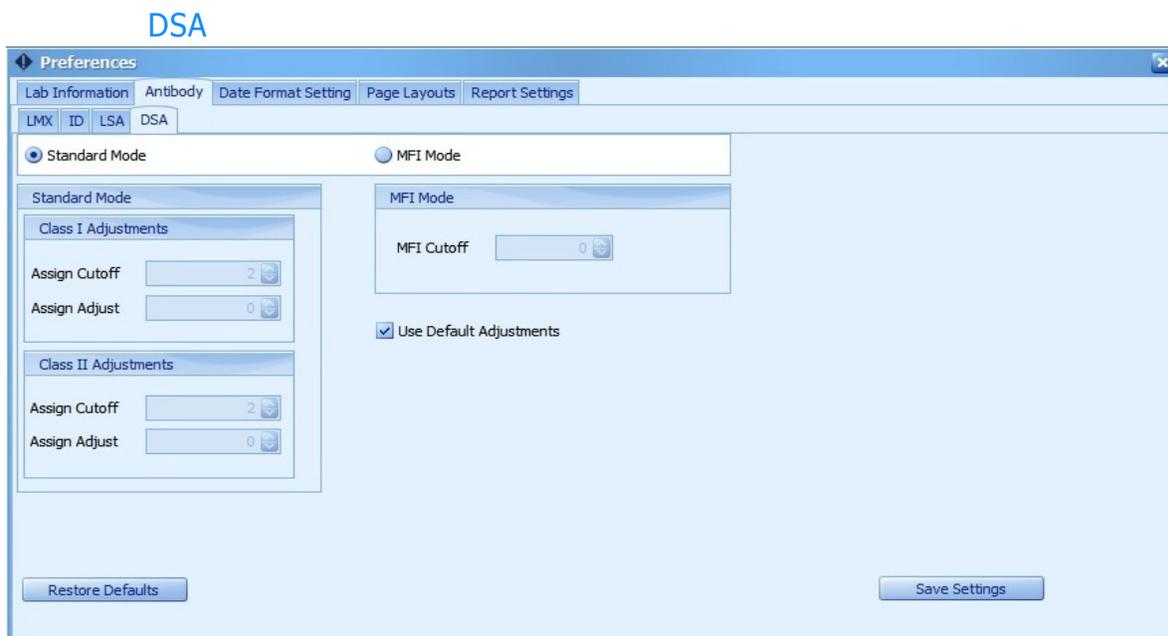
## LSA - C3d



**I) Class I and Class II Adjustments:** The user can override default adjustments with customized values to be used by the software during batch import.

**II) Negative Control Sample Name:** A negative control sample is required when running the C3d assay. The user must designate a Negative Control Sample Name that will be referenced for all C3d batches upon import.

If the **Negative Control Sample Name** in the batch does not match what is listed in **Preferences**, the user will be prompted to select a negative control upon import.



**I) Use Default Adjustments:** When this box is checked, lot specific default values will be used. Unchecking this box allows the user to use Class I and Class II Adjustments.

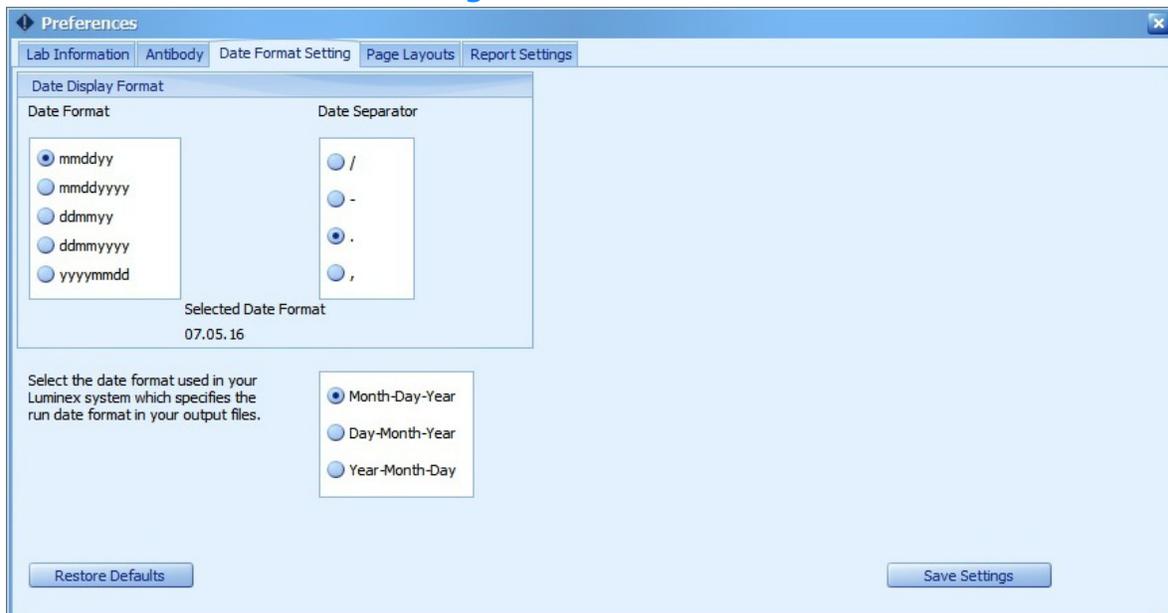
## **II) Class I and Class II Adjustments**

**i) Assign Cutoff:** This value indicates the number of calculations, against different controls, that must be positive for the sample to be assigned as positive.

**ii) Assign Adjust:** This value is used by the software to determine if a bead value is positive. When a calculation is greater than or equal to the Assign Adjust, that value is considered positive. Therefore, by raising the Assign Adjust, the assay sensitivity decreases.

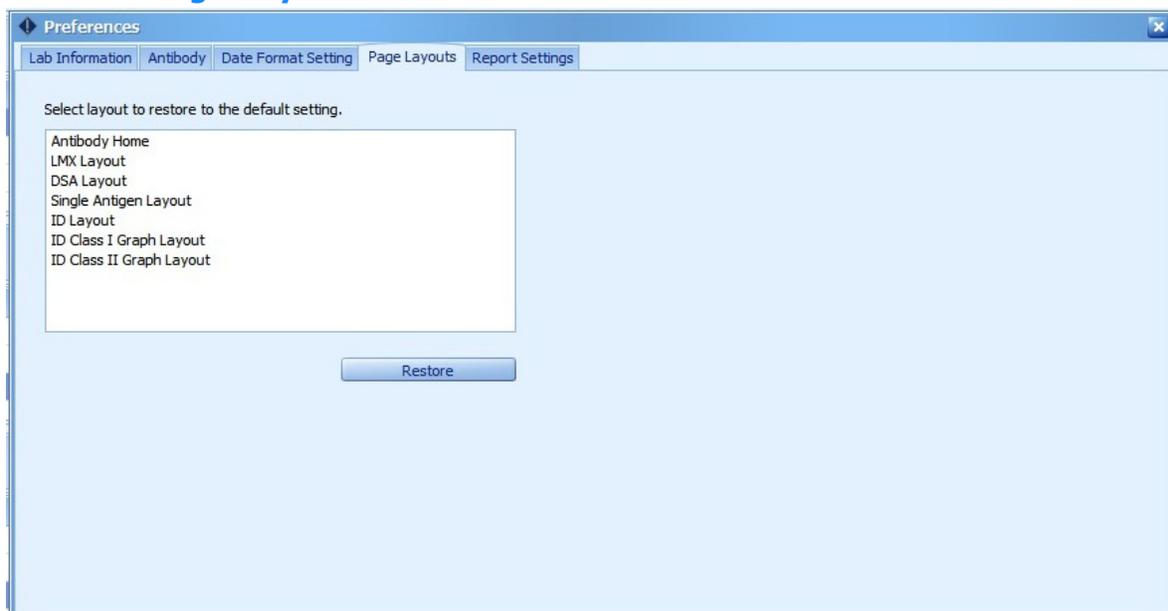
**III) Import Mode:** This allows the user to choose to apply either the Standard Assignment (**Standard Mode**) adjustments (Assign Cutoff and Assign Adjust) or to set cutoffs based on an MFI value (**MFI Mode**) upon import.

## Date Format Settings Tab



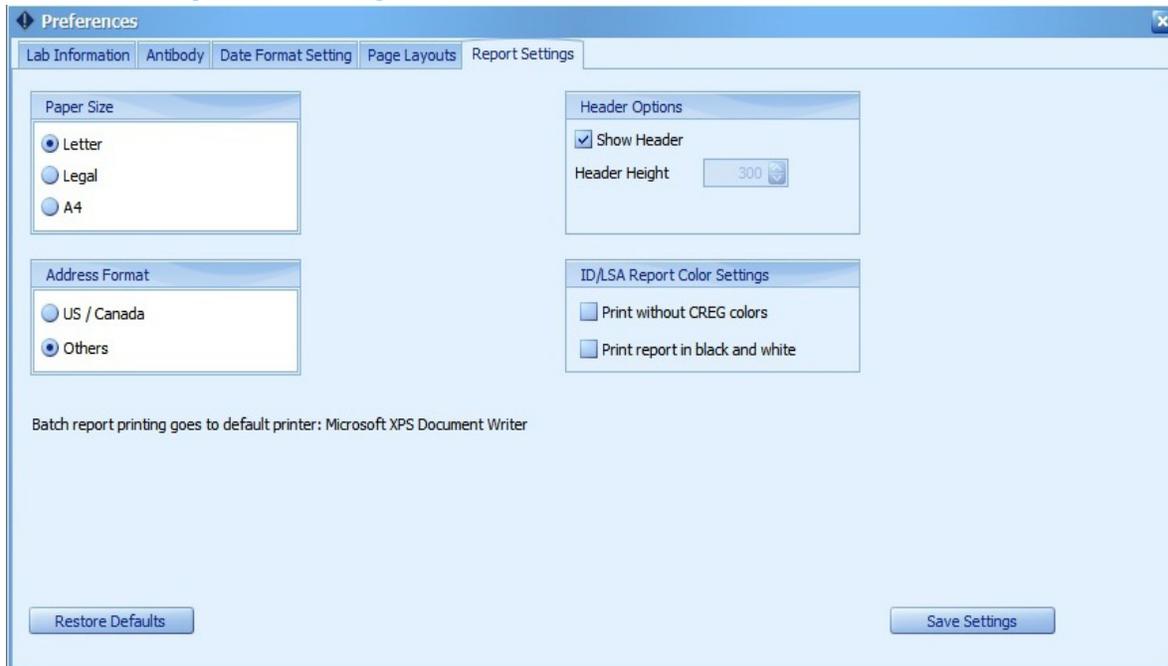
This tab allows the user to change the date format that appears in the reports and user interfaces. It is necessary to select the date format that aligns with the run date format in the output files generated by the Luminex.

## Page Layouts Tab



This tab allows the user to restore a specific page layout to its default settings. Select the layout and click restore.

## Report Settings Tab



This tab allows the user to choose paper size and address format. Settings will be applied to all reports.

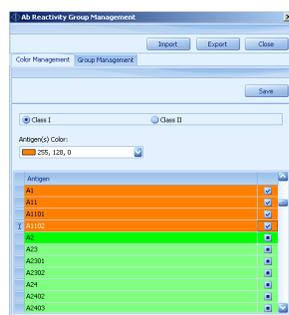
## Antibody Reactivity Groups

This menu item allows the user to create user defined antigen groups.

### To Import/Export Group Data:

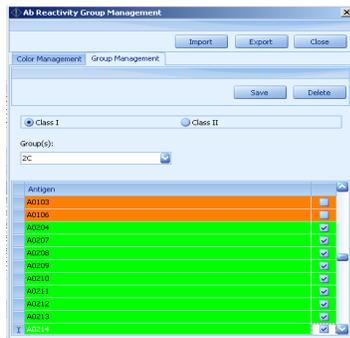
- 1) An already existing *.xml file* can be imported by clicking **Import**. This file is available on LIFECODES section of the Immucor website.
- 2) Once a category of groups is created, an *.xml file* can be exported by clicking **Export**.

### I) Color Management



- 1) Under the **Color Management** tab, choose either Class I or Class II.
- 2) Choose a color from the **Antigen(s) Color** drop down menu.
- 3) Place a check mark next to all the antigens to be colored one color.
- 4) Click **Save**.

## II) Group Management



1) Under the **Group Management** tab, choose either **Class I** or **Class II**.

2) Choose an existing group from the drop down menu if edits are needed or choose **Add New**.

3) If creating a new group, type the name of the group in the box and click **OK**.

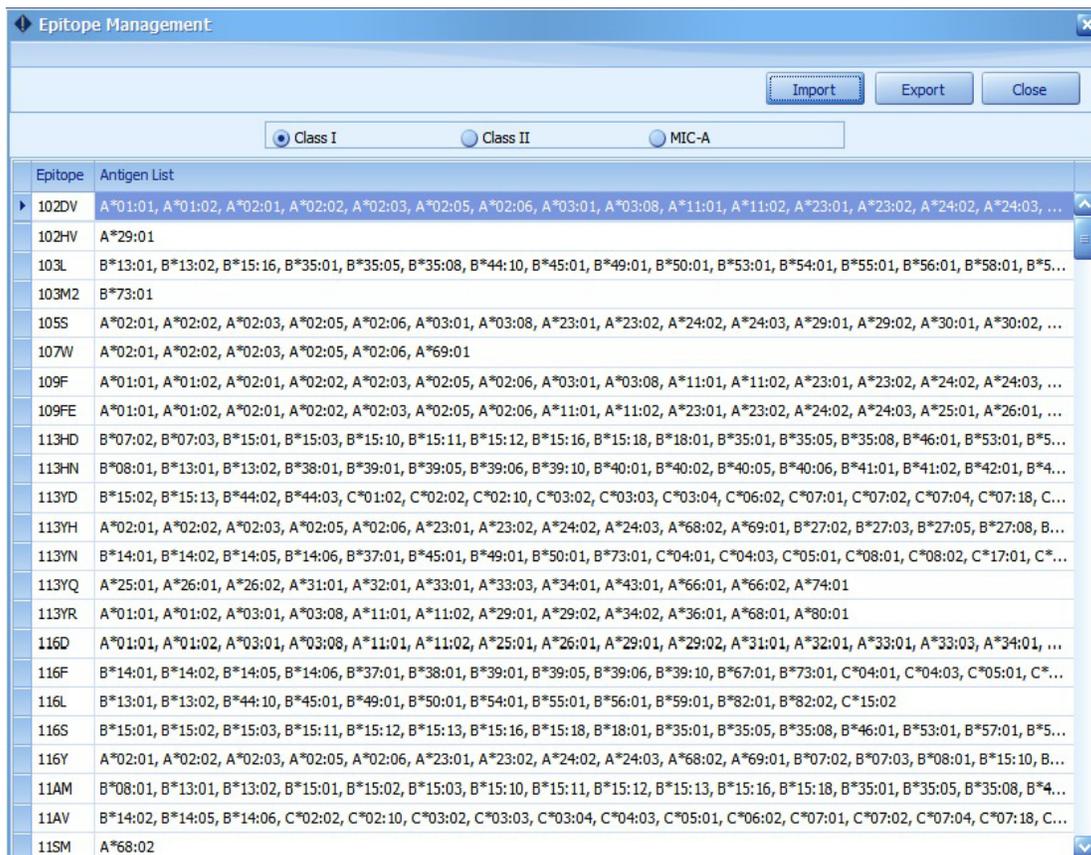
4) Place a check mark next to all antigens that need to be added to the newly created group or

the group being edited.

5) Click **Save**.

## Epitope Management

This menu item allows the user to import or export epitope information. The files containing the epitope information are CSV files. Separate files must be imported under their appropriate sections (Class I, Class II, and MIC-A).



## Tools



The **Tools** menu allows the user to manage certain properties in the software, such as the display of lots, screen assignments to display, and management of both users and instruments.

## Lot Availability

Lot ID	Expiration Date	Assay Name	Import Date	Available
02105C 01195B-SA1	12.31.15	02105C 01195B-SA1	07.01.16	<input checked="" type="checkbox"/>
3003153 3003124-LMX	11.15.16	3003153 3003124-LMX	07.01.16	<input checked="" type="checkbox"/>
3003157 3003076-LM1	10.15.16	3003157 3003076-LM1	07.01.16	<input checked="" type="checkbox"/>
3003072 3003007-LM2Q	10.15.16	3003072 3003007-LM2Q	07.01.16	<input checked="" type="checkbox"/>
11053A 09173N-SA2	09.30.14	11053A 09173N-SA2	07.01.16	<input checked="" type="checkbox"/>
3001302 3001288-LMX	09.15.14	3001302 3001288-LMX	07.01.16	<input checked="" type="checkbox"/>
08245C 08155T-C3dSA1	08.31.16	08245C 08155T-C3dSA1	07.01.16	<input checked="" type="checkbox"/>
08245C 08155T-SA1	08.31.16	08245C 08155T-SA1	07.01.16	<input checked="" type="checkbox"/>
09115A 08205C-C3dSA2	08.31.16	09115A 08205C-C3dSA2	07.01.16	<input checked="" type="checkbox"/>
09115A 08205C-SA2	08.31.16	09115A 08205C-SA2	07.01.16	<input checked="" type="checkbox"/>
09203A 06143B-SA1	08.31.14	09203A 06143B-SA1	07.01.16	<input checked="" type="checkbox"/>
07303Y 08072A-SAM	07.31.14	07303Y 08072A-SAM	07.01.16	<input checked="" type="checkbox"/>
3002867 3002816-LMD	07.15.16	3002867 3002816-LMD	07.01.16	<input checked="" type="checkbox"/>
3001209 3001164-LM1	07.15.14	3001209 3001164-LM1	07.01.16	<input checked="" type="checkbox"/>
3001075 3001038-LM2Q	06.15.14	3001075 3001038-LM2Q	07.01.16	<input checked="" type="checkbox"/>

The **Lot Availability** window displays all templates and expiration dates imported into the database. The user is able to choose which lots to make available by checking the box next to the lot under the Available column. If a lot is checked as **Available** then this lot can be used to import data and to create a batch.

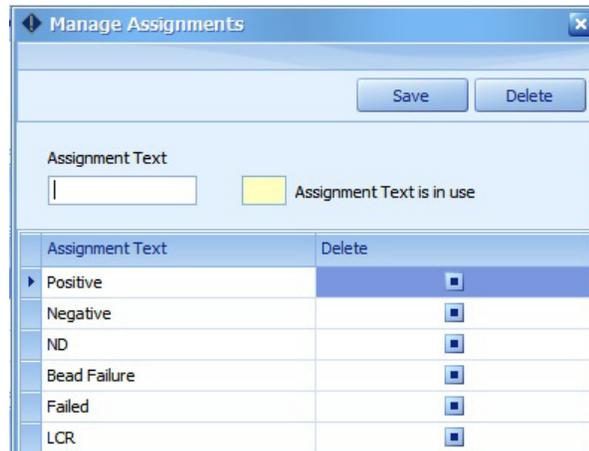
To search for a particular lot, type a portion of the lot ID in the **Lot Search** box.

Left-click any of the headers, **Lot ID**, **Expiration Date**, **Assay Name** to sort the column.

## Manage Assignments

The **Manage Assignments** window allows the user to create assignments for use when analyzing LMX and DSA data. **Positive**, **Negative**, and **Bead Failure** are automatically assigned to samples. **Not Determined (ND)**, **Failed** and **LCR** are default assignments that must be manually assigned when reviewing data. Other user defined assignments may be created or deleted in this management window.

### Creating Assignment Text:



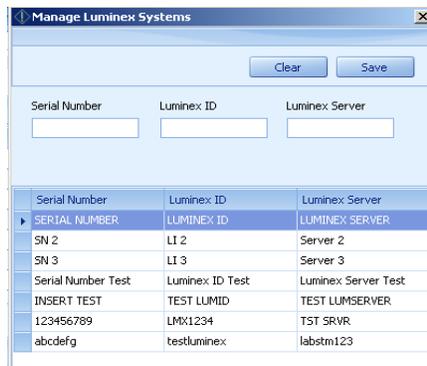
Assignment Text	Delete
Positive	<input type="checkbox"/>
Negative	<input type="checkbox"/>
ND	<input type="checkbox"/>
Bead Failure	<input type="checkbox"/>
Failed	<input type="checkbox"/>
LCR	<input type="checkbox"/>

1) Type the desired text in the **Assignment Text** field.

2) Click **Save**.

3) The new assignment will now display in the drop down menu of Class I and II Assignments when reviewing LMX and DSA data. Once an **Assignment Text** is in use (highlighted), the text cannot be cleared or edited.

## Manage Luminex Systems



Serial Number	Luminex ID	Luminex Server
SERIAL NUMBER	LUMINEX ID	LUMINEX SERVER
SN 2	LI 2	Server 2
SN 3	LI 3	Server 3
Serial Number Test	Luminex ID Test	Luminex Server Test
INSERT TEST	TEST LUMID	TEST LUMSERVER
123456789	LMX1234	TST SRWR
abcdefg	testluminex	labstm123

The user may enter multiple Luminex instruments when in the **Manage Luminex Systems** window. **Serial Number**, **Luminex ID**, and **Luminex Server** should be entered and then saved.

## Manage Users

The MATCH IT! software allows users to have unique log-ins.

### To create a user:

Note: The first time the software is installed, the login information is

**username: supervisor**

**password: lifecodes**

1) Type a **User Name**, **First Name**, and **Last Name**.

The screenshot shows the 'Manage Users' window. At the top, there is a tab labeled 'User(s) User: Supervisor'. Below this is a 'Role:' label and an 'Add' button. The form contains four input fields: 'User Name', 'First Name:', 'Last Name:', and 'Role' (a dropdown menu). Below the form is a table with the following data:

User Name	First Name	Last Name	Role	Enabled		
Supervisor	Lab	Supervisor	Lab Supervisor	<input checked="" type="checkbox"/>	Reset Password	Update
Technician	Lab	Technician	Technician	<input checked="" type="checkbox"/>	Reset Password	Update
User	Lab	User	User	<input checked="" type="checkbox"/>	Reset Password	Update

2) Choose the role: **Lab Supervisor**, **Technician**, or **User**.

A **User** does not have the ability to **Save**, **Complete** or **Approve** samples and is in a read-only mode.

A **Technician** is able to make changes, add comments, **Save** and **Complete** samples, but is not able to **Approve** samples.

A **Lab Supervisor** can create accounts. Additionally, a **Lab Supervisor** is able to perform all the roles of a **Technician** in addition to the ability to **Approve** samples and run **Audit Reports**.

3) Click **Add**.

### **To Change Password:**

1) Open the software and login with desired user.

2) Go to the **User: (User Name)** tab under **Manage Users** and type the old password and then the new password.

3) Click **Change Password**.

### **To Reset Password:**

1) Open the software and login as a Lab Supervisor

2) Open Manage Users window and select **Reset Password** next to the desired user.

Note: The password will set to *lifecodes*.

### **Available Assays**

This menu item allows the user to choose what to display on the **Antibody** tab. For example, if the user does not wish to display **LMX** batches, uncheck the **LMX** choice found under **Antibody**.

## Manage User Defined Exports

This menu item allows the user to manage custom exports that were created in the software.

## System Information

This menu item shows the system information for the user's particular setup. The information can also be exported.

If the software is in admin mode and Lifecodes Services is installed, it can be stopped and started in this window

## Exports/Reports



The **Exports/Reports** menu item allows the user to export results and create reports.

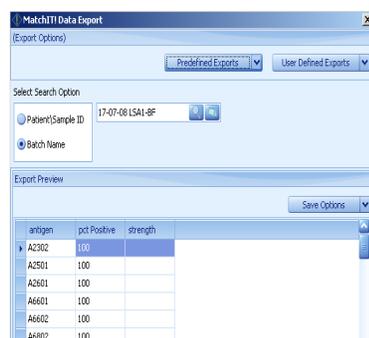
## Export Design Wizard

The wizard will help the user to create a user defined export for all tests.

- 1) Choose a test to create an export.
- 2) Customize the export columns to include in the final export.
- 3) Choose a field delimiter for your final export.
- 4) Name the export.

## Export Results

### To Export Results:



1) Select a Search Option, i.e. **Patient/Sample ID** or **Batch Name**.

2) Type the full or partial **Patient/Sample ID** or **Batch Name** into the cell. Click the magnifying glass. The search results will appear.

3) Select the appropriate **Patient/Sample ID** or **Batch Name** from the search results.

4) Select an export type:

**a) Predefined Exports:**

**Antibody Tail Export** includes antigens with their % Positive score and Strength. Antigens display based on the % Positive setting in the Tail Parameters. For example if the % positive is set to 75%, only those antigens 75% and above will display in the export.

**Antibody Tail ID** includes Batch Name, Sample ID, Lot ID, Run Date, PRA, Tail Assignments, and any user comments on individual samples.

**b) User Defined Exports:**

The user has the ability to create custom Exports to include all appropriate data. This is done through the Export Wizard as explained above.

If a **Patient/Sample ID Search** was performed, a list of **Batch IDs** will appear. Choose the appropriate batch. A preview of the **Export** will display.

If a **Batch Name Search** was performed, a list of **Batch IDs** will appear that contain all or part of the search text entered. Choose the appropriate batch. A preview of the **Export** will display.

5) Click the drop-down next to **Save Options** and choose the file type.

Note: The **Export button** on the home screen will display the same window



## Batch Reports

1) Click the magnifying glass to display a calendar.

2) Choose the date or range of dates when the batch was imported.

3) Batches will display in the **Batch** column. Double click the batch of choice. All samples within the batch will display in the **Sample** column.

4) Use the arrows to move the desired samples to the **Print** (right) column, which will include them in the batch reporting.

5) Once all desired samples have been moved to the **Print** (right) column, choose the appropriate **Test** tab and **Reporting Option** for the test.

Note (LMX/DSA): If individual sample reports are preferred, under **Reporting Options per Test** in the **LMX/DSA** tab, check **Single Sample per Report**.

6) Select **Send to Printer**, **Save to PDF**, **Save to Excel**, or **Save to RTF**. Multiple options may be chosen. If **Save to PDF**, **Save to Excel**, or **Save to RTF** is chosen browse to choose a **Save File Path**.

7) Click the **Print** icon. Dialog box will appear when printing is complete or reports have been generated.

Note: If an Audit Report is desired, click **Audit Report**. This report is only available in PDF format.

Note: The **Batch Reporting** button on the homepage will display the same window.

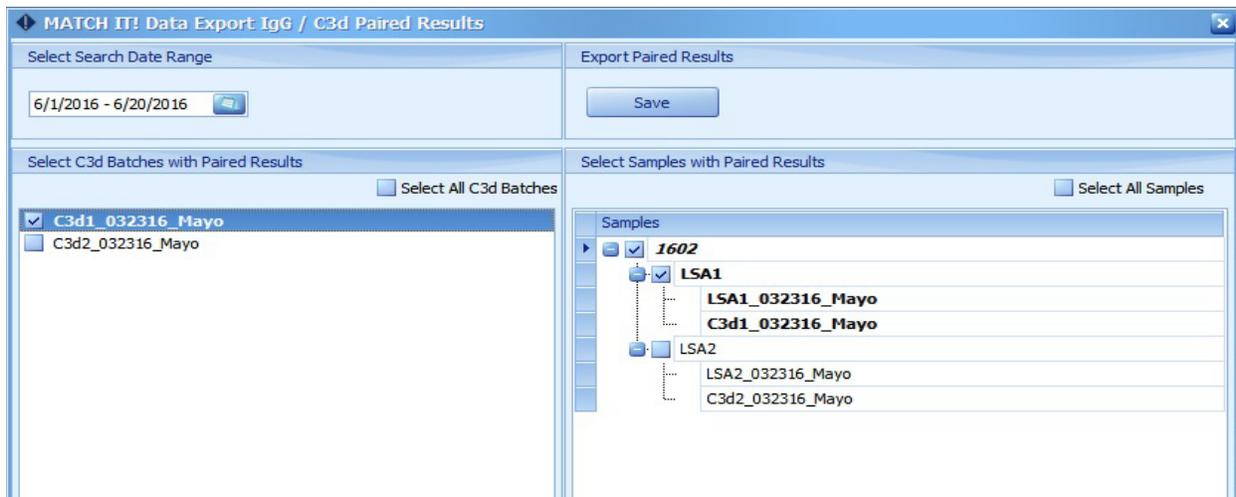


### Export IgG-C3d Paired Results

1) Click the Calendar Icon to select a run-date or range of run-dates to be displayed.

2) From the selected date range, a list of C3d Batches containing samples paired in Patient View will appear in the left window.

3) The user can select individual batches or Select All C3d batches by clicking the appropriate box.



4) Samples paired through **Patient View** from the selected batch(es) will populate the window on the right and will be sorted by name.

a) The User can **Expand** or **Collapse** the batch information displayed for all samples sample by clicking the appropriate button.

b) The user can **Expand** or **Collapse** the batch information displayed for an individual sample by toggling the box next to the sample name

- 5) The user can select individual samples to export by marking the box next to the sample name. If all samples are required for export the user mark the **Select All Samples** box.
- 6) To Export the results, click the **Export Paired Results** Button. The user can then save the exported data to any desired location.

Note: Files exported will be in CSV format.

## CHAPTER 3: AUTOMATED BATCH SETUP

This chapter describes how to set up a batch. Detailed instructions are described including creating a sample list, choosing a Luminex connection, and creating the entire batch for submission to the chosen Luminex.

### Lot Information Import

#### Importing Template files into Luminex

Before creating a batch, the information necessary for identifying the appropriate beads to count must be imported into the Luminex software. The information is provided in lot-specific template files. Files with the extension .lxt are designed for use with the Luminex xPONENT software. Templates can be downloaded from the Immucor website.

#### **To import an LXT file into Luminex xPONENT**

- 1) Select the **Protocols** Tab at the top of the Luminex xPONENT screen.
- 2) Click on the **Import** button on the bottom of the screen.
- 3) Navigate to the location of the LXT file(s). Choose the appropriate file to be imported. Only one file may be chosen at a time.
- 4) A message will appear for each successful file import.

#### Importing EDS files into MATCH IT!

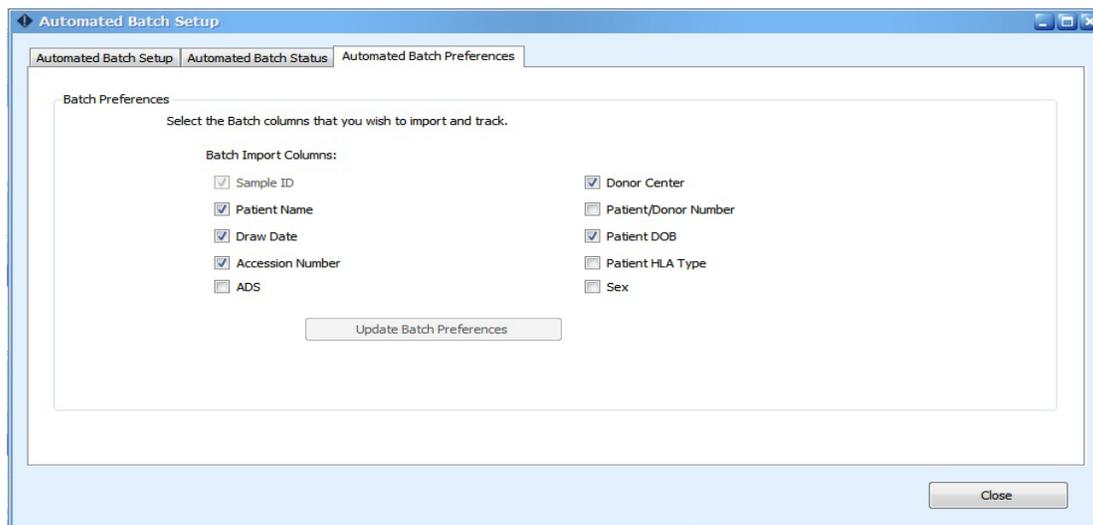


*Refer to Chapter 2: Lot Information Import*

## Automated Batch Setup

### Setting Automated Batch Preferences

This tab customizes the information to be either entered manually or imported from a sample list. To customize which import columns to include in a batch:

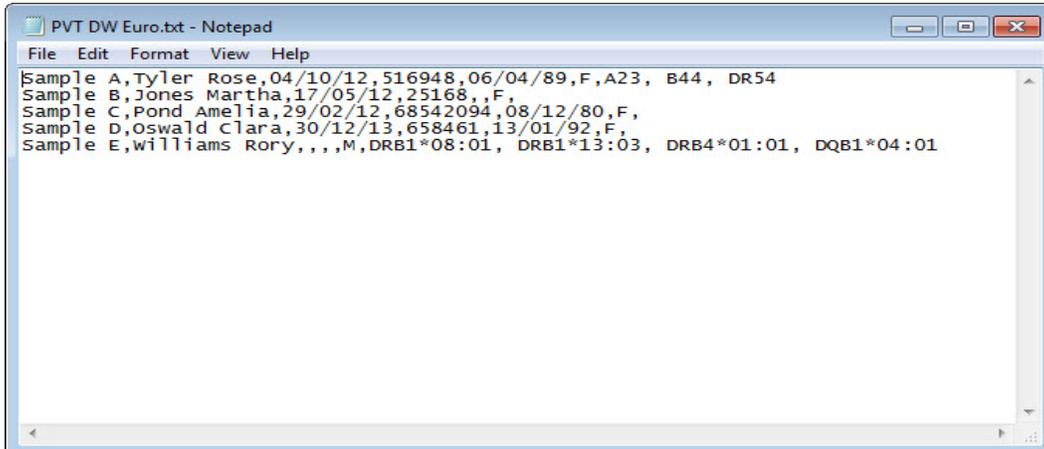


- 1) Click **Auto Batch Setup** on the **Antibody** screen.
- 2) Go to the **Automated Batch Preferences** tab.
- 3) Place a check in the box next to each item to be included as an import column.
- 4) Save by clicking **Update Batch Preferences**. Once **Batch Import** columns are selected, they will appear as columns under the **Automated Batch Setup** tab.

### Creating a Sample List (Optional)

A sample list is a file containing a comma separated list of the data selected on the **Automated Batch Preferences** tab. A **Sample ID** needs to be present in each **Sample List**. All other fields are optional. To create a **Sample List**:

- 1) Open a blank Notepad document.
- 2) Enter all column information. Each piece of information must be delimited by a comma regardless of whether the information is present or not.



Do not hit return after the last sample is entered.

### 3) Save the file

Note: Enter the Sample HLA Type in the same serological format used in the LIFECODES worksheets. In order for antigens to be excluded, they must match an antigen listed on the product worksheet. For example, if A1 is entered, it will be excluded. Entries such as A01, A01/02, etc. will not be excluded.

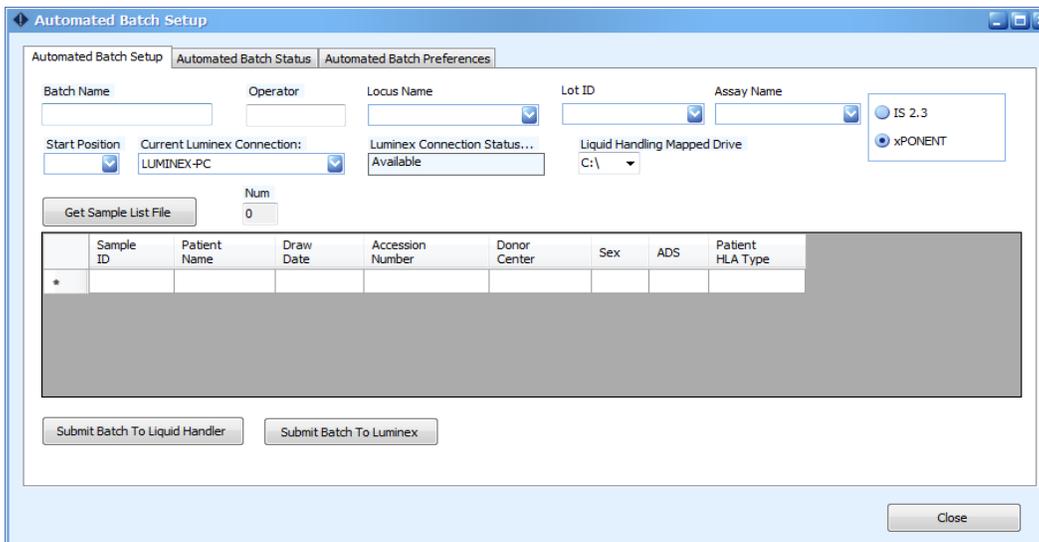
Antibodies can be entered in either serological or allelic format (A\*01:01). Each pair of antibodies must be separated by commas. This allows those antigens to be excluded during the analysis of the HLA antibody.

Commas must be entered between antigens. Draw Date and Date of Birth must be in the format selected in Preferences

Note: When creating sample lists for LSA-C3d, the name used for the Negative Control sample must match exactly the name listed under C3d settings. If this condition is not met, auto-import of this batch will fail.

## Creating a Batch

In order to create an automated batch, the EDS file for the particular product and lot must be imported into the LIFECODES MATCH IT! software and the correct Luminex Template must be imported into the Luminex Software. Refer to *"Importing Template Files into Luminex"*.



To create a batch:

- 1) Click **Automated Batch Setup** on the **Antibody** Screen.
- 2) Go to the **Automated Batch Setup** tab.
- 3) From the dropdown list under **Current Luminex Connection**, choose the Luminex instrument to which the batch will be submitted and verify that **Luminex Connection Status** is **Available**. If the name of the computer to which the instrument is attached does not display in the list, it may be typed in.

Note: xPONENT software must be running in order for the connection to be made.

- 4) Enter a Batch Name.

Note: Batch Names cannot be reused and cannot exceed 30 characters including spaces.

- 5) Enter user initials in **Operator**.
- 6) Choose a **Test Type**: LMX, Class I ID, etc.
- 7) Choose the appropriate **Lot ID**. If the template is imported into xPONENT, **Assay Name** will automatically populate with the Lot ID.
- 8) Enter a **Start Position** (well location on plate).

- 9) To load a pre-saved sample list, click **Get Sample List File** and choose desired file. The user may type directly into the columns as well.

Note: Sample List file format must match columns selected in Preferences.

- 10) To submit the batch to Luminex, click **Submit Batch to Luminex**.

At this point, the batch will be ready for selection in the Luminex Software.

FOR RESEARCH USE ONLY

Note: To submit a batch to an Automated Liquid Handler, choose the Liquid Handling Mapped Drive and then click **Submit Batch to Liquid Handler**. A dialog box will appear. Choose **Yes** if **Pos/Neg Control Override** is selected in Preferences.

This process generates two files—a configuration file and a sample list file that are used by the liquid handler to submit a batch to the Luminex Instrument.

Note: Specialized Luminex Templates have been developed by LIFECODES for use with liquid handlers. These templates can be found on the website but are not necessary when using the xPONENT.

## Running a Batch in Luminex

### Running a Single Batch in Luminex xPONENT

- 1) Open the xPONENT software and sign in as *admin*.
- 2) Select the **Batches** Tab at the top of the screen.



- 3) All batches that have not been acquired will be listed under **Pending Batches**
- 4) Select a batch by clicking on it. To Review batch contents select **Plate Layout**. To run click the **Run** button at the bottom of the screen.

### Running a Multibatch in Luminex xPONENT



- 1) In the batches tab, select Create a New Multi-Batch
- 2) Select the first batch to be included and click **OK**.
- 3) To add another batch, click on the well where that corresponds with the first sample in the batch and select the **Add** button at the bottom of the screen. To delete batches select the batch and click **Remove**.
- 4) Repeat step 3 until all desired batches have been added.
- 5) Verify that the plate is a direct representation of the Multi-Batch screen in the software.
- 6) Click **Run** to process immediately or **Save** to process at a later time.

Note: The first batch in a multi-batch will, by default be added to well A1. If this is not the location of the first batch in your multi-batch, Add the second batch to the correct location according to the instructions above then

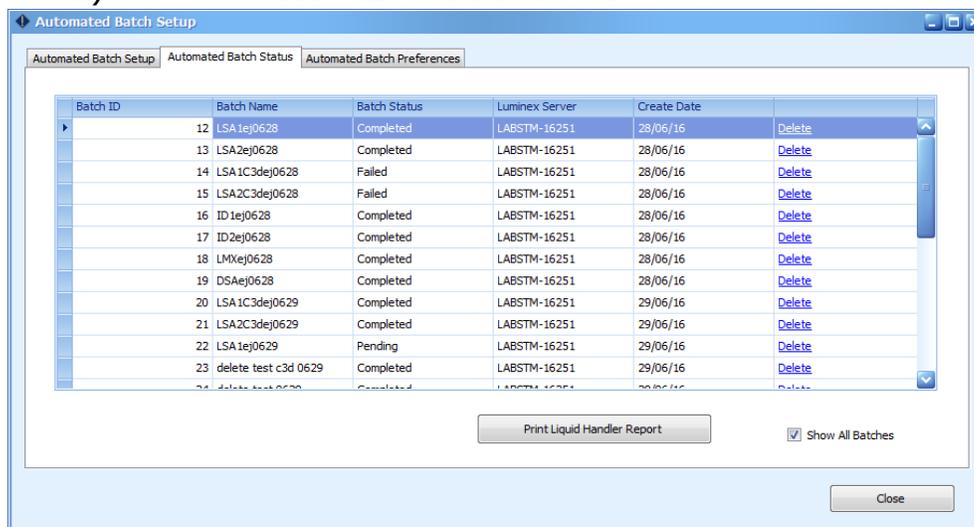
FOR RESEARCH USE ONLY

Remove the first batch. You can now add this batch back to the correct location following the steps above.

## Batch Status

The status of a batch can be checked in the MATCH IT! software.

- 1) Click **Automated Batch Setup** from the homepage.
- 2) Choose the **Automated Batch Status** tab.



3) Pending batches (those not yet acquired in the Luminex xPONENT software) will be displayed. To see completed batches as well, check **Show All Batches**. A pending batch may be deleted by clicking **Delete**.

Note: Manually importing failed batches will cause the status to change to completed.

4) Upon completion of a Batch acquisition in Luminex, the batch will be automatically imported into MATCH IT! It is necessary to refresh the home screen to view newly imported automated batches.

# CHAPTER 4: LIFECODES LMX ANALYSIS

This chapter contains information on the tools available to analyze LMX results.

## Importing LMX Results into MATCH IT!

If an Automated Batch was not created and data needs to be manually imported into the software, the appropriate EDS file must first be imported followed by the CSV file.

### Importing EDS files



Refer to Chapter 2: Lot Information Import

### Manually Importing CSV Files



Refer to Chapter 2: Batch Import

## Opening a Batch

### Direct Selection

1) Double click the batch name found on the **Antibody** Home tab under **LMX**.

2) The batch results are displayed in an **LMX Analysis** tab. All sample results appear in the middle section of the tab. Individual sample IDs within the selected batch are listed in the left section of the tab under the batch name.

LMX Analysis

Batch Name: LMX\_032216\_AOJD      Assign Cutoff: 1, 1  
Run Date: 03.22.16      Assign Adjust: 0, 0  
Lot Number: 3003153 3003124-LMX      Supplemental Assign Cutoff: 2, 2  
Expiration Date: 11.15.16      Supplemental Assign Adjust: 0, 0  
Reviewed By:

CON Ranges  
CON 1: 28 - 422    CON 2: 23 - 689    CON 3: 33 - 3118

Save Assignments    Complete    Approve

Sample: 1601    Well Position: 25(1 A4)    MFI Cutoff: 0    Locked    VBAF    Bead Counts

Patient: 1601

Draw Date:    Class I Assignment: Positive    Class II Assignment: Positive

	CI-01	CI-02	CI-03	CI-04	CI-05	CI-06	CI-07	CII-01	CII-02	CII-03	CII-04	CII-05	Pos Ctrl / CONs
Raw	7534	6379	12440	1439	14794	699	19107	4534	2061	685	21234	18515	20524
Adj Val1	29.28	24.44	51.58	1.7	63.06	-1.39	82.12	15.81	0.55	-2.68	91.54	77.03	221
Adj Val2	36.24	30.37	62.57	3.02	76.16	-0.49	99.02	19.95	1.94	-1.82	110.21	93.22	185
Adj Val3	6.66	5.48	12.64	-1.34	16.2	-2.1	21.21	2.85	-2.95	-2.77	23.98	19.34	786
Score	3	3	3	2	3	0	3	3	2	0	3	3	

## Date Range Selection

Rather than opening an individual batch from the **Antibody** tab, the user can open view several batches by selecting a range of dates, which will result in all batches run in that range being displayed.

1) Right click the symbol shown below.



2) A pair of calendars with a start and end date will open. Select the desired range and click **OK**.

3) The batch results are displayed in an **LMX Analysis** tab. All sample results for the highlighted batch appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.

## LMX Analysis

### Navigating to a Particular Sample

To view a particular sample in the batch, left click the sample name in the left hand panel. The software will jump to this sample and it will be highlighted in red.

Raw	CI-01	CI-02	CI-03	CI-04	CI-05	CI-06	CI-07	CII-01	CII-02	CII-03	CII-04	CII-05	Pos Ctrl / CONS
Adj Val1	93.42	109.25	76.77	125.13	35.92	13.69	88.37	1.89	0.2	-1.16	16.04	1.77	117
Adj Val2	101.48	118.51	83.23	135.41	39.12	15.41	95.75	2.55	0.49	-0.54	17.63	2.32	108
Adj Val3	29.86	35.31	24.01	40.2	10.66	3.1	27.85	-0.72	-2.57	-2.1	3.83	-1.37	349
Score	3	3	3	3	3	3	3	2	2	0	3	2	



## Displaying Bead Counts

To display the bead counts for a sample, click the down arrow next to **Bead** in the sample header.

	CI-01	CI-02	CI-03	CI-04	CI-05	CI-06	CI-07	CII-01	CII-02	CII-03	CII-04	CII-05
Raw	45	5	5	0	0	10	21	6	0	0	11	0
Adj Val 1	0	0	0	0	0	0	0	0	0	0	0	0
Adj Val 2	0	0	0	0	0	0	0	0	0	0	0	0
Adj Val 3	0	0	0	0	0	0	0	0	0	0	0	0
Score	0	0	0	0	0	0	0	0	0	0	0	0

	CI-01	CI-02	CI-03	CI-04	CI-05	CI-06	CI-07	CII-01	CII-02	CII-03	CII-04	CII-05
Raw	196	226	170	114	156	254	124	278	433	278	321	460
Adj Val 1	-3.05	-2.98	-2.9	-3.52	-3.21	-3.53	-3.73	-3.53	-4.65	-3.48	-1.79	-3.42
Adj Val 2	-3.62	-3.76	-3.37	-3.6	-3.24	-4.37	-4.03	-3.82	-5.8	-3.88	-2.5	-4.48

## Calculations and Displayed Values

To determine the **Adjusted Value** for a bead, the individual bead MFI is divided by the MFI for each **Negative Control Bead (CON1, CON2, CON3)**. From these quotients, the **Background Adjustment Factor (BAF)** for the appropriate bead/CON combination is subtracted. The BAF is a pre-determined MFI ratio for each bead/CON combination to compensate for background noise due to bead variation. See the lot-specific Recording Sheet provided with the kit for BAF values.

$$\frac{\text{Individual Bead MFI}}{\text{CON1}} - \text{BAF} = \text{Adjusted Ratio 1}$$

$$\frac{\text{Individual Bead MFI}}{\text{CON2}} - \text{BAF} = \text{Adjusted Ratio 2}$$

$$\frac{\text{Individual Bead MFI}}{\text{CON3}} - \text{BAF} = \text{Adjusted Ratio 3}$$

- For I-01 and II-01, a positive value for any one of the calculations indicates a positive bead reaction.
- For all remaining beads, a positive value for any two of the calculations indicates a positive bead reaction.
- A negative value for all three calculations indicates a negative bead reaction.
- The **Score** shown in the **Results Table** is the number of **Adjusted Ratios** that exceed the **Assign Adjust** value. By default, the **Assign Adjust** values are set to zero. *Refer to Chapter 2: LMX.*

## Tools for Making a Positive or Negative Assignment

### By Standard Mode

- A sample is considered to be positive for class I HLA-specific antibodies if at least one of the seven (7) class I HLA beads is positive.
- A sample is considered to be positive for class II HLA-specific antibodies if at least one of the five (5) class II HLA beads is positive.
- A sample is considered to be negative for HLA-specific IgG antibodies if all the HLA beads are found to be negative.

### By MFI Cutoff

Beads can be assigned as positive or negative by manually assigning an MFI cutoff. This can be set per sample by using the check box available in each sample window or by changing Preferences to use **MFI Mode**. Refer to Chapter 2: LMX.

### Overriding an Assignment

While the software performs analysis according to the product insert, all results should be reviewed. During this review process, an assignment can be changed manually by clicking the arrow on the right side of the Assignment text boxes and selecting one of the choices that appears.



The screenshot shows a software window for a sample. The sample ID is 1601, and the well position is 25(1A4). There are checkboxes for 'MFI Cutoff', 'Locked', and 'VBAF'. A 'Bead Counts' dropdown menu is visible. The 'Class I Assignment' and 'Class II Assignment' are both set to 'Positive'. A vertical label 'Sample' is on the right side of the window.

### Overriding Default Parameters

The default parameters (**Assign Adjust** and **Assign Cutoff**) should only be altered by personnel knowledgeable in the field of HLA Antibody Analysis. Changing these values will result in altered specificity and sensitivity of the assay and can only be done in Preferences prior to importing a batch. Refer to Chapter 2: LMX.

### Optional VBAF Analysis

The **Variable Background Adjustment Factor (VBAF)** is calculated as the difference between the observed MFI for a CON bead and a predetermined average (AVG) value based on a set of negative sera. The VBAF is then subtracted from the MFI value of the CON and the Class 1 & Class II beads. VBAF makes the assay less sensitive when the negative control bead values are low and more sensitive when the negative control bead values are high. Once this feature is enabled, the calculation can be applied to an entire batch (in the **Options** tab of the **LMX Analysis** window), or

to individual samples (using the VBAF checkbox in each sample window).  
*By default this feature is inactivated.*

The VBAF is designed to be used by personnel knowledgeable in the field of HLA Antibody analysis when the samples being analyzed have negative control bead values that do not conform to expected values.

To calculate Adjusted Values using VBAF:

- 1) Determine the lot specific trimmed median for CON1 from the EDS file.
- 2) Subtract the lot specific trimmed median from CON1 to get the VBAF
- 3) Divide the VBAF by 256.
- 4) Subtract the VBAF from the Raw MFI and then divide by the trimmed median.
- 5) To get the Adjusted Value, subtract the quotient in step 3 and the BAF from the quotient in step 4.

$$\frac{\text{Raw MFI} - \text{VBAF}}{\text{AVGCON1}} - \text{BAFCON1} - \frac{\text{VBAF}}{256} = \text{Adjusted Ratio 1 (VBAF)}$$

$$\frac{\text{Raw MFI} - \text{VBAF}}{\text{AVGCON2}} - \text{BAFCON2} - \frac{\text{VBAF}}{256} = \text{Adjusted Ratio 2 (VBAF)}$$

$$\frac{\text{Raw MFI} - \text{VBAF}}{\text{AVGCON3}} - \text{BAFCON3} - \frac{\text{VBAF}}{256} = \text{Adjusted Ratio 3 (VBAF)}$$

### Applying VBAF to an Entire Batch

To apply the VBAF calculation to the entire batch, select **View VBAF Calc** from the **Options** tab.

### Applying VBAF to a Single Sample

To apply the VBAF calculation to a single sample, select the VBAF checkbox in the header of the individual samples.

## Batch Failures

### Bead Count Failure

If a sample fails to meet the minimum bead count for a Class I or Class II bead, the Class I or Class II result, respectively, will be reported as Bead Failure. To override the failure, review the bead count and then choose the appropriate assignment from the drop-down menu.

If a CON bead fails to meet the minimum bead count, the software will report Bead Failure for both Class I and Class II.

## Positive or Negative Control Failure (When Using a Liquid Handler)

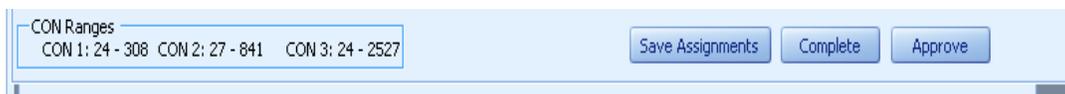
The software can be set so that the results for the entire batch are tied to the performance of the Positive and Negative control when a liquid handler is used. All samples will be listed as failed if either the Positive or Negative Control samples fail.

- A Negative Control is considered as failed if any bead fails to meet the minimum bead count, or if the Negative Control has a positive assignment for Class I or Class II.
- A Positive Control is considered as failed if any bead fails to meet the minimum bead count, or if either of the Class I or Class II assignment is negative.

The source of the failure is listed in the **LMX** header. Bead failures will only be listed within the panel not in the header. The feature that ties the performance of the batch to the performance of the negative and positive controls can be enabled or disabled in **Lab Settings** feature. *Refer to Chapter 2: LMX.*

## Approving Analysis Results

### Saving, Completing, and Approving an Assignment



The **Save Assignments** button saves any assignment edits that have been made. Changes can be made and re-saved.

The **Complete** button locks all the samples in the batch and signifies all samples have been analyzed and are ready for sign-off. When a batch has been completed and locked, only a Technician or Lab Supervisor may unlock the samples by clicking **Complete** again. Only a Lab Supervisor can unlock a single sample by clicking the **Locked** box. Completing the results lists the batch as **Completed** on the home page.

The **Approve** button signifies that analysis of the samples is finished. Only a Lab Supervisor can approve or unapprove a batch. To unapprove, click **Approve** again. Lab Supervisors can also unlock individual samples by clicking the **Locked** box in the sample window. Approving the results lists the batch as **Approved** on the home page.

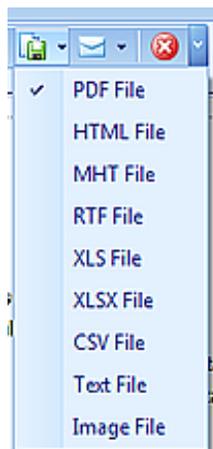
## Reporting and Printing

### Generating a Standard Report

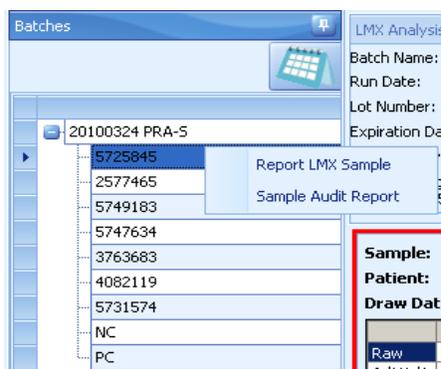
- 1) Once the results have been approved, a standard report may be run. The report for the batch can be ordered by **Sample** or **Well Location**.



- 2) The report is created by clicking the **Generate LMX Report** button.
- 3) Once a report appears on the screen, the user can print or save it.



### Printing an Individual Sample Report or Audit Report



- 1) Select the sample ID in the **Batches** panel.
- 2) Right click the sample ID to access the report options: **Report LMX Sample** or **Sample Audit Report**. A **Sample Audit Report** will only be generated if changes to the sample have been made. If there are no changes, then no report will appear.
- 3) Once a report appears on the screen, click the **Print** icon in the upper toolbar.

## Batch Reporting



*Refer to Chapter 2: Batch Reports*

## Exporting Summary Results



*Refer to Chapter 2: Export Results*

# CHAPTER 5: LIFECODES ID ANALYSIS

This chapter contains information on the tools available to analyze LIFECODES ID results.

## Importing ID Results into MATCH IT!

If an Automated Batch was not created and data needs to be manually imported into the software, the appropriate EDS file must first be imported followed by the CSV file.

### Importing EDS files



*Refer to Chapter 2: Lot Information Import*

### Manually Importing CSV Files



*Refer to Chapter 2: Batch Import*

## Opening a Batch

### Direct Selection

- 1) Double click the batch name found on the **Antibody** tab under **ID**.
- 2) The batch name will display on a tab above the Sample Navigation ribbon. All sample results appear in the middle section of the tab. Individual sample IDs within the selected batch are listed in the left section of the tab under the batch name.

## Date Range Selection

Rather than opening an individual batch from the **Antibody** tab, the user can open view several batches by selecting a range of dates, which will result in all batches run in that range being displayed.

1) Right click the symbol shown below.



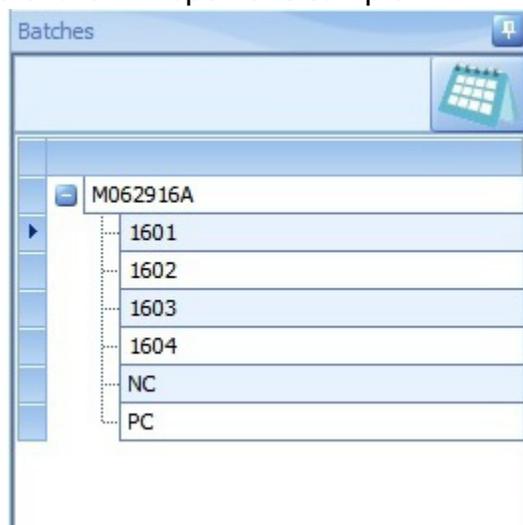
2) A pair of calendars with a start and end date will open. Select the desired range and click OK.

3) The batch results are displayed in an **ID Analysis** tab. All sample results for the highlighted batch appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.

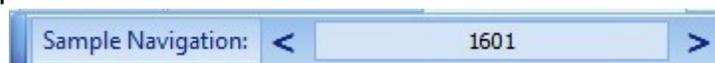
## ID Analysis

### Navigating to a Particular Sample

To view a particular sample in the batch, left click the sample ID in the window. The software will open this sample.



The sample navigation arrows can also be used to move from sample to sample.



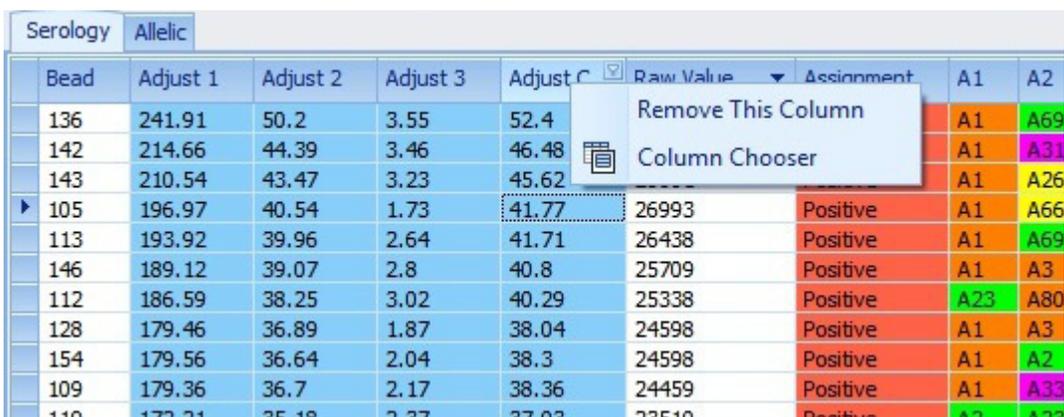
## Tabs in the Analysis Screen

Once a Sample is selected, the Standard Calculation tab will display the bead ranking grids. The user can select between Serology and Allelic phenotype displays by clicking on the tabs at the top of the grid.

Note: Only the data from the first tab can be used to view graphs, add to tail, highlight, etc.

## Column Customization

Columns can be customized to meet the user's needs by right clicking a column header. The customization will be saved for the user for future data review.



Bead	Adjust 1	Adjust 2	Adjust 3	Adjust 4	Raw Value	Assignment	A1	A2
136	241.91	50.2	3.55	52.4			A1	A69
142	214.66	44.39	3.46	46.48			A1	A31
143	210.54	43.47	3.23	45.62			A1	A26
105	196.97	40.54	1.73	41.77	26993	Positive	A1	A66
113	193.92	39.96	2.64	41.71	26438	Positive	A1	A69
146	189.12	39.07	2.8	40.8	25709	Positive	A1	A3
112	186.59	38.25	3.02	40.29	25338	Positive	A23	A80
128	179.46	36.89	1.87	38.04	24598	Positive	A1	A3
154	179.56	36.64	2.04	38.3	24598	Positive	A1	A2
109	179.36	36.7	2.17	38.36	24459	Positive	A1	A33
110	172.21	35.18	2.37	37.03	23510	Positive	A2	A28

## Changing Sort Order

The sample by default will display beads in descending order of **Raw MFI**. This can be changed by left clicking a column header. Once the column is clicked, a downward or upward triangle will appear showing the direction of order; descending or ascending in value, respectively.

## Column Removal/Addition and Column Width

To remove a column, right click the column and choose **Remove This Column**.

To add a column that has been previously removed, right click the column and choose **Column Chooser**. The **Customization** window will appear displaying the columns that have been removed. Click on the desired header and drag it to the desired position in the Standard Calculation window.

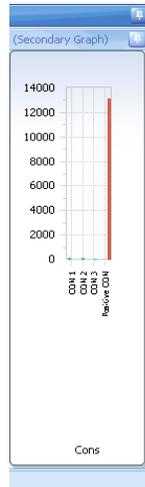
## Displaying Selected Bead Values

Specific beads containing particular information can be viewed.



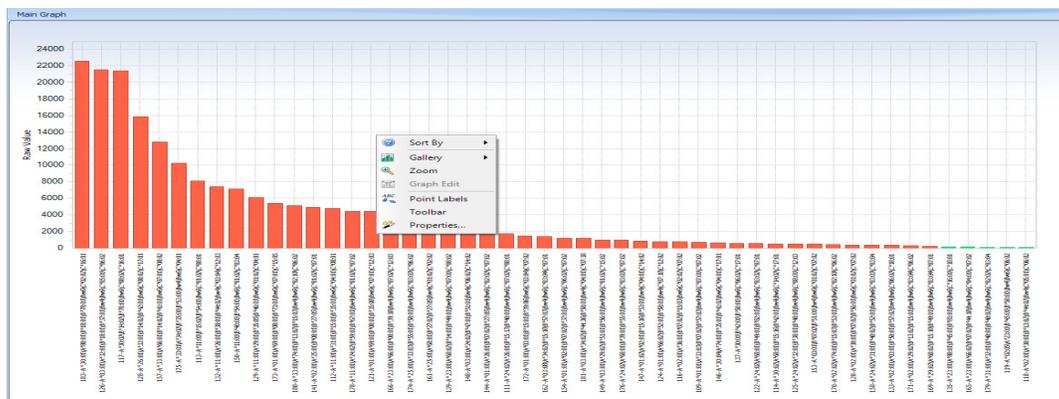
## Control Graph

A graph of **Raw MFI vs. Controls (Positive control and 3 negative CONS)** is displayed next to the Antigen Graph only when **Raw MFI vs. Bead (Antigens)** is chosen as the main graph.



## Additional Graphing Features

- To change the y-axis legend, click any of the column headers in the bead ranking view, i.e. **Raw Value**, **Adjust 1**, **Adjust 2**, **Adjust 3**, or **Adjust C**.
- To change the bead order (antigen order) of the x-axis, right click anywhere within the graphing area and choose **Sort By**. A selection of antigen sorting options will appear.



- To change the graph type, i.e. from a bar graph to a line graph, right click anywhere within the graphing area and choose **Gallery**. A selection of graph types will appear.
- To zoom, right click anywhere within the graphing area and choose **Zoom**. Use the mouse to make a box around the area to zoom.

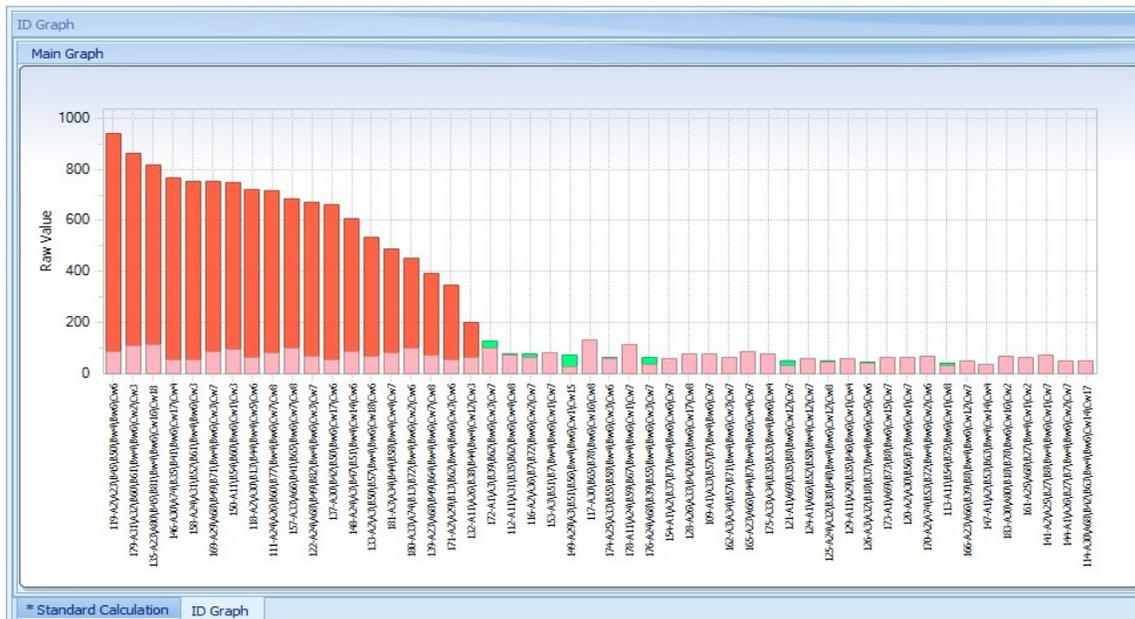
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- If a **Group** or **History** is selected, the graph will highlight the bars for the beads containing an antigen in the selected **Group**. The blue bars represent beads containing antigens within the selected **Group**.
- To overlay a particular sample, i.e. the negative control, onto each sample graph, right select the sample of choice from the batch window and right click to choose **Set as Negative Control**. Now when viewing any of the sample graphs within the batch, the set negative control sample will display with a pink overlay.

The screenshot shows the 'Batches' window with a list of samples. The 'NC' sample is selected. To the right, the 'Standard Calculation' table displays bead counts for various samples.

Bead	Bead Count	Ac
165	79	
132	80	
144	64	
137	64	
148	67	
164	60	
155	73	
130	79	
134	66	
163	83	
127	64	
157	70	

A 'Set as Negative Control' button is overlaid on the bottom right of the table.



Note: The user may select different samples within the batch to be designated as the Negative Control. Once this option has been turned on for a batch it cannot be turned off.

## Calculations and Displayed Values

To determine the adjusted value for a bead, divide the individual bead median MFI by the MFI for each Negative Control Bead (CON1, CON2, CON3). From these values, subtract the Background Adjustment Factor (BAF) for the appropriate bead/CON combination. The BAF is a pre-determined MFI ratio for each bead/CON combination to compensate for background noise due to bead variation and can be found on the lot-specific Recording Sheet provided with the kit.

$$\frac{\text{Individual Bead MFI}}{\text{CON1 MFI}} - \text{BAF} = \text{Adjust 1}$$

$$\frac{\text{Individual Bead MFI}}{\text{CON2 MFI}} - \text{BAF} = \text{Adjust 2}$$

$$\frac{\text{Individual Bead MFI}}{\text{CON3 MFI}} - \text{BAF} = \text{Adjust 3}$$

The Class I & II ID kits also employ a fourth negative control calculation, "CalcCON", based on performance of the non-reacting antigen-containing beads.

$$\frac{\text{Individual Bead MFI}}{\text{CalcCON}} - \text{BAF} = \text{Adjust C}$$

$$\text{CalcCON} = \text{MFI lowest ranked antigen bead} + 20$$

By default, a positive value for two or more of the four calculations indicates a positive bead reaction. This setting can be changed by the user.

### For LIFECODES Class I ID:

The percent Percent Reactive Antibodies (PRA) is calculated by:

$$\% \text{ PRA} = \frac{\text{Number of positive bead reactions}}{\text{Number of beads in the assay (not including control beads)}} \times 100$$

### For LIFECODES Class II IDv2:

$$\% \text{ PRA} = \frac{(\# \text{ of pos DR-enriched beads}) + (\# \text{ of neg DR-enriched beads that also contain a pos DQ antigen})}{\text{Total number of DR-enriched beads (not including control beads)}} \times 100$$

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## Tools for Making a Positive or Negative Assignment

Adjustments	Cutoffs	Control Values	Comments	Quick Print
Assign Adjust: 0.00	Assign Cutoff: 2 MFI Cutoff: 0 Use MFI Cutoff: <input type="checkbox"/>	CON 1: 62 Cal Con 76 CON 2: 54 Positive CON 22952 CON 3: 48 PRA 90	Update By: Lab Super... Comments: [a]	Bead Rank Graph

A bead is assigned as positive or negative based on user defined analysis parameters or by manual MFI cutoffs.

### By Standard Mode

If preferences have not already been set for these parameters or an override is necessary for a particular sample, they can be changed in the **Reactivity Adjustments** tab.

- **Assign Adjust** sets the positive threshold for all adjusted values. Once the value box is selected, the up and down arrows can be clicked to the desired value or the up and down arrow keys may be used. A value can also be typed directly into the white box. The default setting is 0.
- **Assign Cutoff** is a score of 1 to 4. It indicates the number of calculations, against different controls, that must be positive for the sample to be assigned as positive. This allows the user to show samples positive with only 1 out of 4 controls positive, 2 out of 4 controls positive, 3 out of 4 controls positive, or all 4 controls positive. The default setting is 2.

If the parameters are changed, the user must save the change prior to manual tail analysis. To save the changes Click **Save**.

If **AutoTail** is checked then the tail is automatically calculated on save.

Note: If epitopes are assigned and reactivity adjustment changes are made using **Assign Adjust** or **Assign Cutoff**, the epitope assignment will clear. To assign epitopes using the new cutoffs, click **Epitope Analysis** or if **Auto Epitope Analysis** is turned on, the epitopes will recalculate once the sample is saved.

### By MFI Cutoff

Beads can be assigned as positive or negative by manually assigning an MFI cutoff.

- 1) Under the **Reactivity Adjustments** tab, click the box next to **Use MFI Cutoff**.
- 2) The MFI value box is now available. Select the value box. The up and down arrows can be clicked to the desired value or the up and down arrow

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keys may be used. A value can also be typed directly into the white box. Once the value is entered, click the graph to view the new cutoff.

3) Click **Save**.

Note: To apply an MFI cutoff to all samples for Class I or Class II on import, a user may select MFI mode in the **ID** tab of **Preferences** window. MFI cutoffs can be set individually for Class I and Class II. The up and down arrow keys may be used. A value can also be typed directly in the white box. The user must then select the box that indicates that the value should be applied to data upon import.

Note: If epitopes are assigned and reactivity adjustment changes are made using **MFI mode**, epitope assignments will clear. To assign epitopes using the new cutoffs, click **Epitope Analysis** or if **Auto Epitope Analysis** is turned on, the epitopes will recalculate once the sample is saved.

## Batch Failures

### Bead Count Failure

- If a sample fails to meet the minimum bead count for a particular result, the bead will be flagged as *Bead Failure(s)*. To override the failure, double click the message and select the failed beads to include in the analysis



- If a CON bead fails to meet the minimum bead count, the software will report all beads as failed. To override the failure, click the message.



- A message box will appear to confirm the override.

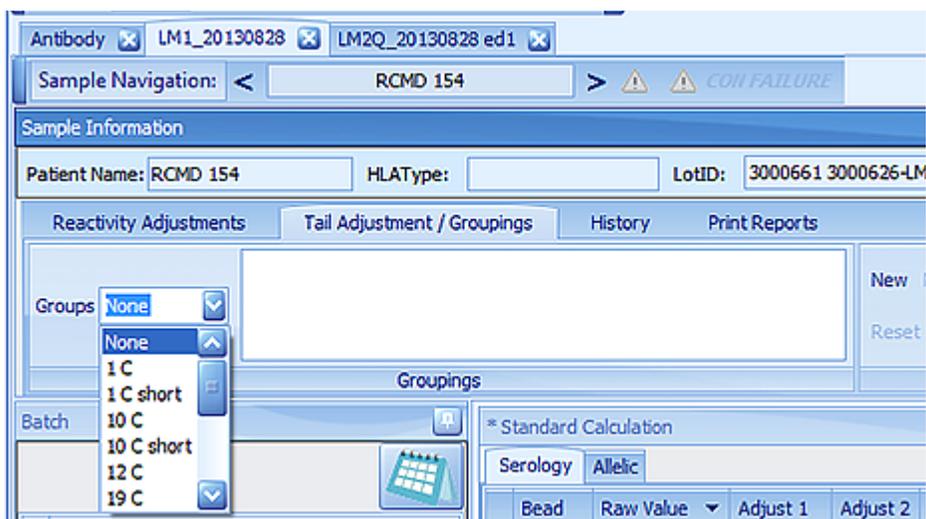
The source of all failures is listed in the ID Analysis header. By clicking the *Bead Failure(s)* message, the user has the option to include failed beads in the analysis.

Note: If a sample has both CON failures and bead failures, the CON failure must be overridden before the failed beads can be included.

## Visual Tools for Review

### Groupings

The **Groups** drop-down box is a list of user defined HLA Cross Reactive Groups (CREGs). By selecting a particular group, the antigens present within the particular group will be highlighted in the bead ranking.



### Color-Coded Antigen(s)

The user can color code antigens or groups of antigens to provide easier viewing. This feature is intended as a visual aid. The *.xml* file provided on the Immucor website contains color-coded antigens but they may be changed. *Refer to Chapter 2: Antibody Reactivity Groups*

### Epitope Analysis

Epitope Analysis can be run at a sample level. If epitopes are not calculated upon import click the **Epitope Analysis** button to assign available epitopes. Epitopes will be calculated based on Positive beads (epitopes are not calculated on assigned antigens).

To determine the epitope assignments, the software will perform the following procedure:

- 1) The software pulls epitope values from the database for antigens on positive beads.
- 2) The software calculates true positives, true negatives, false positives, false negatives, percent positive, chi squared and R-Value for each epitope.
- 3) The software compares the percent positive to the minimum value set in **Preferences** (default is 50%). Epitopes with a percent positive greater than the minimum are collected and sorted by the selected **Epitope Option** (default is **R-Value**). *Refer to Chapter 2: ID - Epitope Settings.*

4) The software adds the top epitope from this list to a list of selected epitopes. The beads containing that epitope/antigen relationship are removed from consideration.

Note: In the case of two epitopes having the same R-Value, the software chooses the top alphanumeric value for removal.

5) The process starts over with the remaining epitopes.

6) Once all of the epitopes are identified, the software will look at each epitope individually and add it to every bead that contains antigens that have a relationship with the current epitope.

Note: The **Epitope Analysis** feature will not work if **Use Serology** is checked in **Preferences**.

## Tail Analysis

Tail Analysis is by default a serology tail analysis. The user can change to a 4-digit tail analysis in **Preferences**.

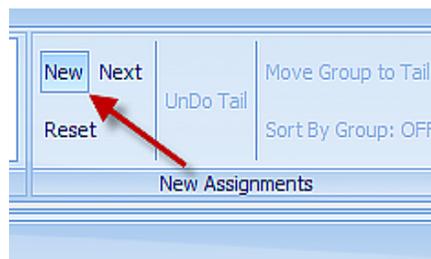
When **Exclude Patient Type** is turned **ON** on in the **Reactivity Adjustment** tab (if not already selected under **Preferences**) excluded antigens will be listed under the **Excluded Antigens** window in **ID Tail** and not available for Tail Analysis.

### Automatic Tail

The software will assign a tail automatically if **Perform Auto Tail Analysis** is chosen as a preference or if **Do Auto Tail** is checked in the **Sample Information** key. The tail will then be automatically assigned when imported.

### Manual Tail

- 1) Tail preferences should first be set in the preference window.
- 2) Go to the **Tail Adjustment/Groupings** tab.
- 3) Click **New**.



The antigens listed are those that meet the **Tail Parameters**. Refer to *Chapter 2: ID - Settings*.

The following statistics are displayed:

- a) # of true positives (++)
- b) # of false positives (+ -)
- c) # of false negatives (- +)
- d) # of true negatives (--)
- e) Chi<sup>2</sup>
- f) R Value
- g) % Positive
- h) Strength Index (Avg. MFI of all beads containing the antigen)

The screenshot shows a data table with columns: Assignment, A1, A2, B1, B2, Bw4, Bw6, C1, C2, Raw Value, and Epitope. The data is color-coded by assignment (Positive/Negative) and bead type. To the right, the 'Remaining Antigens' window displays a table with columns: Antigen, ++, +, -+, --, Chi, and R-Val. The table lists various antigens and their corresponding counts and statistical values.

The data can be sorted by any of the headers in the **ID Tail** window. Click the desired header and the data will sort in descending or ascending order. The default ranking is descending by RVal. A sort order change here does not impact the AutoTail sorting or the function of the **Next** button. Default sort order can only be changed in **Preferences**.

The screenshot shows the 'ID Tail' window with a data table similar to the one above. To the right, the 'Remaining Antigens' window displays a table with columns: Antigen, ++, +, -+, --, Chi, and R-Val. The table lists various antigens and their corresponding counts and statistical values.

A particular group can be highlighted within the **Available Tail Antigens** by selecting the appropriate group in the dropdown menu found in the **Tail Adjustment/Grouping** tab. The antigen(s) included in the group that meet the **Tail Parameters** set will be highlighted in gray under **Remain-**

**ing Antigens.** To bring the antigens within the selected group to the top of the **Remaining Antigens**, turn **Sort by Group** ON.

Note: If **Exclude Antigens** were not entered into the sample list, they can still be excluded from the tail analysis.

To add or exclude antigens to/from the tail, right Click an antigen within the grid and choose **Exclude Antigen "X" from Analysis**.



To add an antigen to the tail, double click the antigen found in the **Remaining Antigens** window or double click the antigen in the **Bead Ranking** grid. The antigen is added to the tail. The remaining antigens, not included within the tail, are then re-calculated and listed for further selection.

Note: The following **Tail Actions** can also be used when adding to the tail:

- **Next** moves the top-ranking antigen into the tail.
- Right click within the grid and choose **Move Antigen X to Tail Antigens Grid**.
- **Move Group to Tail** will move all antigens within the selected Group into the tail.
- **Undo Tail** will remove the most recent tail addition.
- **Reset** returns the tail to the last saved tail.
- **New** returns any antigens moved to the tail to the antigen list and allows the user to start again.

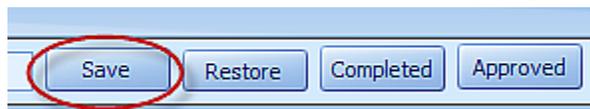
4) Continue loading tail until complete or until all antigens desired are added to the tail. Antigens will be bold and italicized in the bead ranking screen.

Remaining Antigens						
Antigen	++	+	-+	--	Chi	R-Val
Cw3	5	2	3	13	5.96	0.5
B60	2	5	0	16	5.01	0.4
B61	2	5	0	16	5.01	0.4
B49	2	5	0	16	5.01	0.4
B41	1	6	0	16	2.39	0.3
B44	1	6	0	16	2.39	0.3
A32	1	6	0	16	2.39	0.3
A6601	1	6	0	16	2.39	0.3
A31	2	5	1	15	2.14	0.3
Cw17	1	6	1	15	0.40	0.1
A26	1	6	1	15	0.40	0.1
B71	1	6	1	15	0.40	0.1

Tail Antigens						
Antigen	++	+	-+	--	Chi	R-Val
A23	2	17	3	28	0.01	0.0
A2	3	14	5	23	0.00	0.0
A24	4	10	5	18	0.22	0.0
A30	3	7	2	16	1.56	0.2

5) Click **Save** before moving to the next sample.



## Creating a History

The user has the option of creating a snapshot of the **History** for a particular sample. In the **History** tab, a user has the ability to load antigens to create a reactivity group specific to the sample. This will enable a user to monitor changes in antibody status across kits and over time.

### New History

1) Go to the **History** tab.



2) Click **New**.

3) The previously assigned antigens (either automatically or manually) will be checked and highlighted in the window which appears. Additional antigens may be added to the history by checking the box next to the antigen

Note: This will not change the saved tail results.

- 4) Click **Save**.
- 5) Name the **Antigen History Group** and press OK to save.

#### Applying a Previously Created History to a New Sample

A previously created **History** can be viewed with a new sample.

- 1) Go to the **History** tab of the new sample.
- 2) Click **Find**.
- 3) Type either the name of the **Antigen History Group** or a key component of the name, i.e. first letter.
- 4) The history of the sample will display.

#### View Current Assigned History for a Sample

- 1) Go to the **History** tab of the new sample.
- 2) Select the history from the dropdown.
- 3) The saved history snapshot will be highlighted in the bead ranking grid and in the graph.

#### Delete History

- 1) Go to the **History** tab of the sample.
- 2) Select a history from the dropdown or use **Find** to search for a history.
- 3) The history snapshot will be loaded.
- 4) Click **Delete**, then confirm deletion.

### Approving Analysis Results



#### Approving Results

When **Save** is clicked, the analysis for the sample is saved but can be analyzed again.

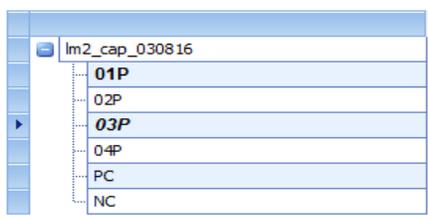
When **Restore** is clicked, the sample will revert to the most recently saved data/assignments.

Once analysis is complete and no additional changes need to be made for a particular sample, click **Complete**. Only a Technician or Lab Supervisor may make changes to a sample by clicking **Complete** again. When all samples in a batch have been designated as **Complete**, the batch status

will be listed as **Completed** on the home page and signify they are ready for **Approval**.

Once the analysis of completed results has been reviewed, click **Approved**. Once clicked, changes can no longer be made except by a Lab Supervisor by clicking **Approved** again. When all samples within a batch are designated as **Approved**, the batch status will list the batch as **Approved** on the home page.

Within the Batch List completed samples will be highlighted with bold text; completed and approved samples will be bold and italicized.

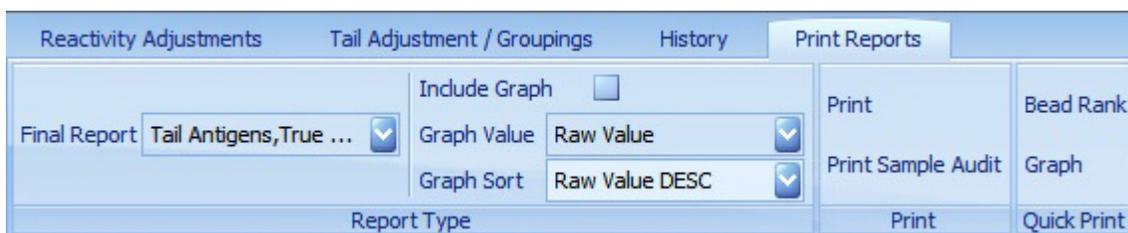


Batch ID	Sample ID	Status
lm2_cap_030816	01P	<b><i>Completed</i></b>
	02P	Completed
	03P	<b><i>Completed</i></b>
	04P	Completed
	PC	Completed
	NC	Completed

## Reporting and Printing

After the sample has been analyzed, (automatically or by using the manual tail analysis features) the user has the ability to customize a report.

### Customizing a Final Report



Reactivity Adjustments	Tail Adjustment / Groupings	History	Print Reports	
Final Report	Include Graph <input type="checkbox"/>		Print	Bead Rank
Tail Antigens, True ...	Graph Value Raw Value		Print Sample Audit	Graph
	Graph Sort Raw Value DESC		Print	Quick Print
Report Type				

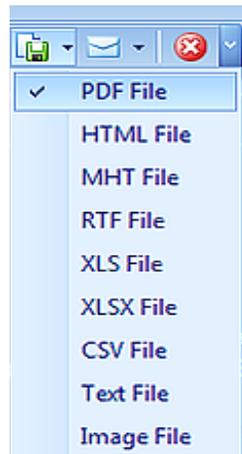
- 1) When the results are ready to be reported, go to **Print Reports** tab.
- 2) Click the drop down arrow next to **Final Report** and select the items to include in the **Final Report**.
- 3) A graph can be included in the report as well by checking the box next to **Include Graph**. **Graph Value** (y-axis) and **Graph Sort** (x-axis) may also be customized by clicking the drop down arrow and selecting the appropriate choice.
- 3) Once a report appears on the screen, click the **Print** icon in the upper toolbar.

## Quick Print

Either a **Bead Rank** report or **Graph** can be printed by clicking **Quick Print** on the **Print Reports** Banner. Selecting **Bead Rank** report will generate a list of antigens sorted exactly as it is sorted in the ID Analysis window. Selecting Graph will generate a graph with x-axis and y-axis legends matching those displayed in the ID Graph window.

## Exporting Reports

- 1) Generate a report from the **Print Reports** tab in the **ID Analysis** tab.
- 2) Once a report appears on the screen, click the **Export Report** icon in the upper right toolbar.
- 3) The dialog box that appears provides several different options for exporting/saving the report.



## Batch Reporting



*Refer to Chapter 2: Batch Reports*

## Exporting Summary Results



*Refer to Chapter 2: Export Results*

# CHAPTER 6: LIFECODES LSA ANALYSIS

This chapter contains information on the tools available to analyze LIFECODES Single Antigen Class I and II, C3d, and LIFECODES LSA MIC (MIC-A).

## Importing LSA Results into MATCH IT!

If an Automated Batch was not created and data needs to be manually imported into the software, the appropriate EDS file must first be imported followed by the CSV file.

### Importing EDS files



*Refer to Chapter 2: Lot Information Import*

### Manually Importing CSV Files



*Refer to Chapter 2: Batch Import*

## Opening a Batch

### Direct Selection

1) Double click the batch name found on the **Antibody** tab under **LSA**.

Note: C3d batches will display in bold type on the home screen.

2) The batch name will display on a tab above the Sample Navigation ribbon. All sample results appear in the middle section of the tab. Individual sample IDs within the selected batch are listed in the left section of the tab under the batch name.

## Date Range Selection

Rather than selecting an individual batch, a range of dates can be selected, which will result in all batches run in that range being selected.

1) Right click the antibody symbol as shown below.



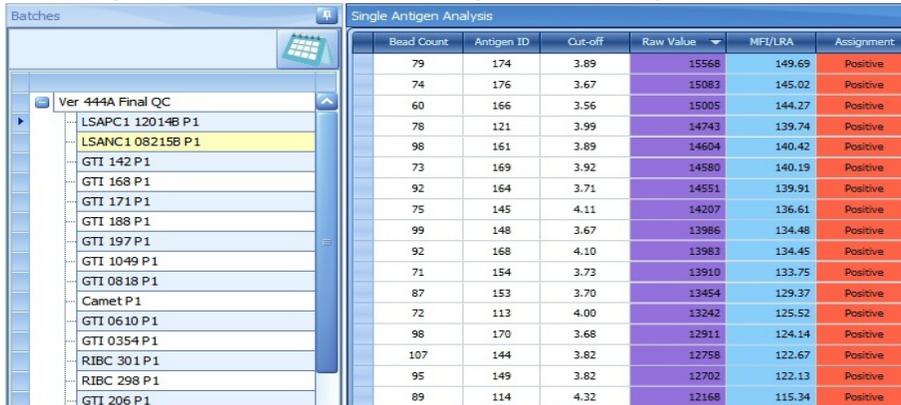
2) A pair of calendars with a start and end date will open. Select the desired range and click OK.

3) The batch results are displayed in an **LSA Analysis** tab. All sample results appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.

## LSA Analysis

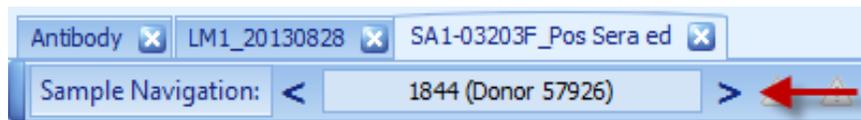
### Navigating to a Particular Sample

To go to a particular sample in the batch, left click the sample ID in the left hand panel. The software will open this sample.



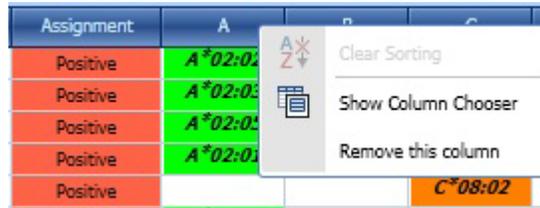
Batches	Single Antigen Analysis					
	Bead Count	Antigen ID	Cut-off	Raw Value	MFI/LRA	Assignment
Ver 444A Final QC	79	174	3.89	15568	149.69	Positive
LSAPC1 12014B P1	74	176	3.67	15083	145.02	Positive
LSANC1 08215B P1	60	166	3.56	15005	144.27	Positive
GTI 142 P1	78	121	3.99	14743	139.74	Positive
GTI 168 P1	98	161	3.89	14604	140.42	Positive
GTI 171 P1	73	169	3.92	14580	140.19	Positive
GTI 188 P1	92	164	3.71	14551	139.91	Positive
GTI 197 P1	75	145	4.11	14207	136.61	Positive
GTI 1049 P1	99	148	3.67	13986	134.48	Positive
GTI 0818 P1	92	168	4.10	13983	134.45	Positive
Camet P1	71	154	3.73	13910	133.75	Positive
GTI 0610 P1	87	153	3.70	13454	129.37	Positive
GTI 0354 P1	72	113	4.00	13242	125.52	Positive
RIBC 301 P1	98	170	3.68	12911	124.14	Positive
RIBC 298 P1	107	144	3.82	12758	122.67	Positive
GTI 206 P1	95	149	3.82	12702	122.13	Positive
	89	114	4.32	12168	115.34	Positive

The navigation arrows can also be used to move from sample to sample.



## Column Customization

Columns located in any of the Calculation tabs can be customized to meet the user's needs.



## Changing Sort Order

The sample by default will display beads in descending order of **Raw MFI**. This can be changed by left clicking a column header. Once the column is clicked, a downward or upward triangle will appear showing the direction of order; descending or ascending in value, respectively.

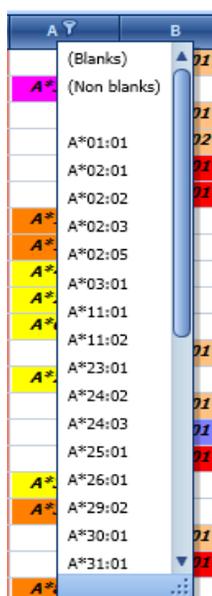
## Column Removal/Addition and Column Width

To remove a column, right click the column and choose **Remove This Column**.

To add a column that has been previously removed, right click the column and choose **Show Column Chooser**. The **Customization** window will appear displaying the columns that have been removed. Click on the desired header and drag it to the desired position in the Standard Calculation window.

## Column Filtering

Specific beads containing particular information can be viewed.



- 1) Hover over a column. A small pin will appear in the upper right corner of the chosen column.
- 2) Left click the column header pin. All values or text within that chosen column will be listed.
- 3) Choose any one of the values or text items displayed. When chosen, only the bead(s) that includes that value or text within that column will display.

Note: All of the sub-windows and columns may be resized by placing cursor on the line to be moved and dragging the mouse. The column order can be changed by placing the cursor on the desired header and dragging it to the desired location.

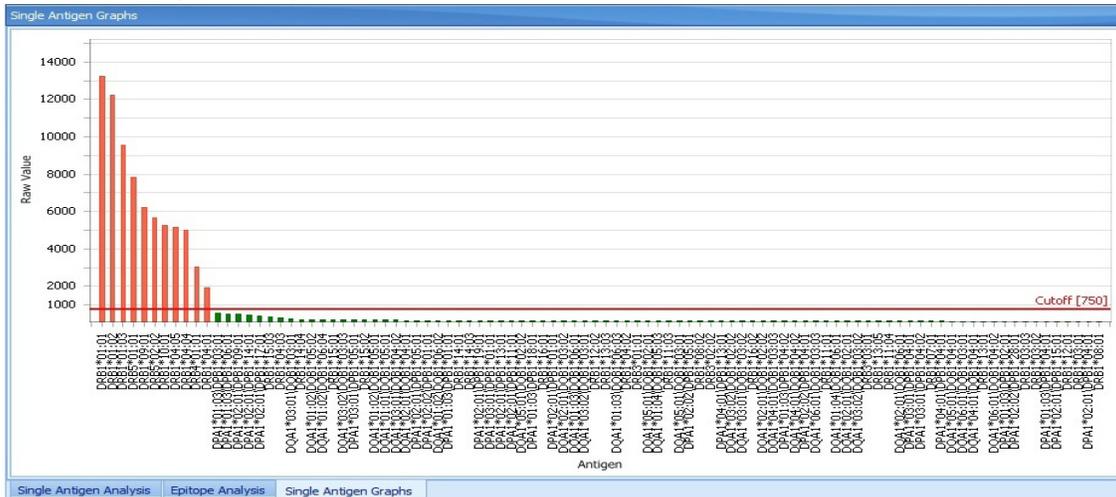
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## Automatic Assignments

The software will automatically assign antibody specificities for antigens that are 100% positive. The automatic assignments will appear in the **Single Antigen Results** window.

## Graphical Displays

### Antigen Graph



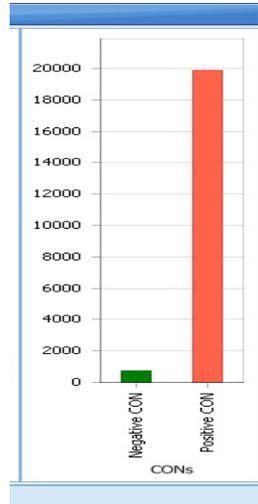
A graph of **Raw MFI** vs. **Bead** enables the user to visualize the strength of each bead relative to the sample and the assignment for each bead; red is a positive assignment, green is a negative assignment. There are two views for the graph:

The **Standard Mode** displays a graph with the positive and negative assignments for beads based on the parameters set.

The **MFI Cutoff** displays a graph with positive and negative assignments for beads based on the MFI value the user sets as the cutoff.

## Control Graph

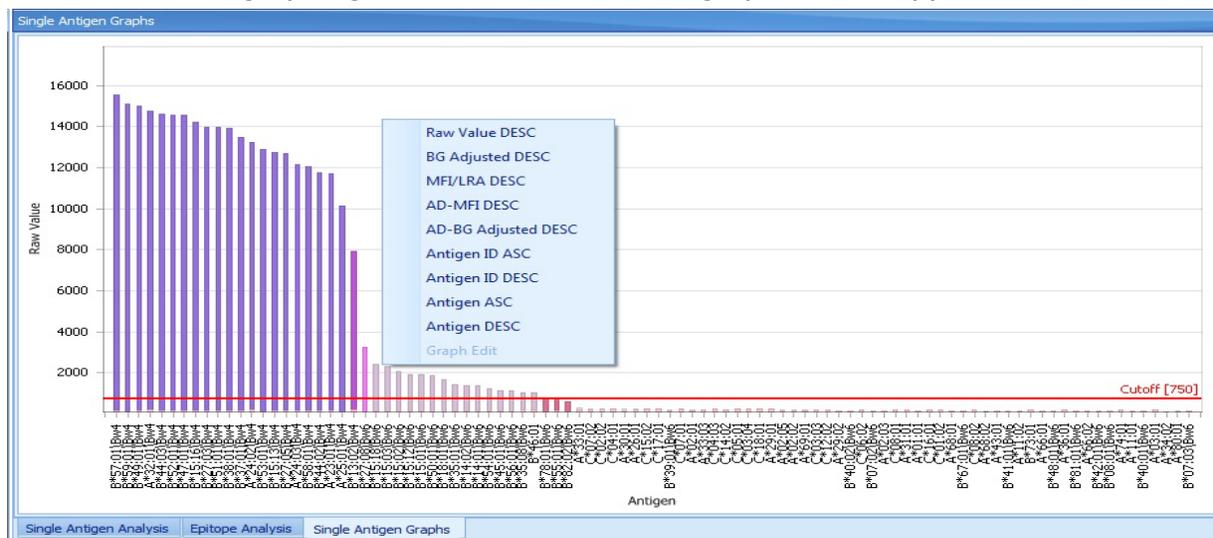
A graph of **Raw MFI** vs. **Controls (Positive and Negative CONs)** is displayed next to the Antigen Graph only when Raw MFI vs. Bead (Antigens) is chosen as the main graph.



## Additional Graphing Features

To change the y-axis legend, click any of the column headers from the LSA Analysis window.

To change x-axis legend (bead/antigen order), right click anywhere within the graphing area and a list of sorting options will appear.

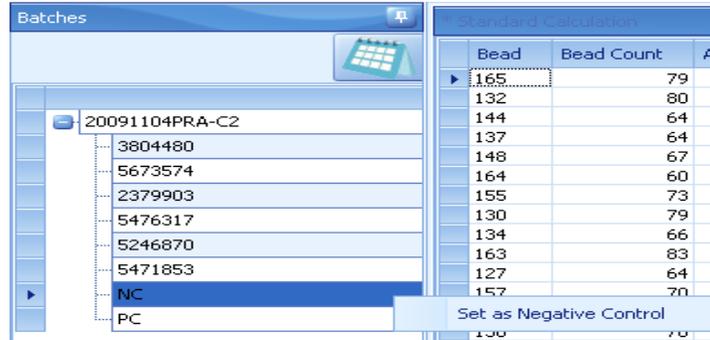


To zoom, click anywhere in the graph and use the scroll wheel on the mouse to zoom in and out.

If a **Group** or **History** is selected, the graph will highlight the bars for the beads containing an antigen in the selected Group. The blue bars represent beads containing antigens within the selected Group.

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To overlay a particular sample, i.e. the negative control, onto each sample graph, select the sample of choice and right click to choose **Set as Negative Control**. Now when viewing any of the sample graphs within the batch, the sample and the set negative control sample will display. This feature is only available for LSA Legacy and MIC-A.



Note: The user may select one of the samples within the batch to be designated as the Negative Control. Once this option has been turned on for a batch it cannot be turned off. This feature is only available for LSA Legacy and MIC-A. C3d will always have a negative control overlay. LSA will have a negative control overlay if one was selected on import. In this case, the assigned sample cannot be changed. The batch would have to be reimported in order to change the assigned Negative Control.

## Calculations and Displayed Values

### Calculations for LSA

To determine if a bead is positive, first establish if the raw MFI for each antigen bound bead is above the **MFI Threshold** found on the lot-specific Recording Sheet provided with the kit. If an antigen bound bead is above the **MFI Threshold**, divide the raw MFI by the MFI of the **Lowest Ranked Antigen (LRA)** of its respective locus to generate the MFI/LRA ratio. The LRA for each locus is the MFI value of the lowest ranked antigen bead for that locus.

$$\frac{\text{Individual Bead MFI}}{\text{LRA MFI for locus "1"}} = \text{MFI/LRA for antigen "x" from locus "1"}$$

$$\frac{\text{Individual Bead MFI}}{\text{LRA MFI for locus "2"}} = \text{MFI/LRA for antigen "y" from locus "2"}$$

$$\frac{\text{Individual Bead MFI}}{\text{LRA MFI for locus "3"}} = \text{MFI/LRA for antigen "z" from locus "3"}$$

Refer to the lot-specific Recording Sheet provided with the kit for the list of antigens present on each bead and the cut-off for estimating the positive/negative result with each antigen bound bead. An antigen bound bead is

considered positive if the MFI value is above the **MFI Threshold** and the **MFI/LRA** ratio is above the cutoff value. Higher or lower sensitivities can be obtained by adjusting the **MFI Threshold** and **Cut-off**.

### Calculations for C3d

The Negative Control Sample (NC) Raw MFI serves as the Background MFI for C3d calculations

To determine the adjusted value for a bead, subtract the Negative Control sample MFI from the RAW MFI to generate the **Background Adjusted MFI Value (BG Adjusted)** for each individual bead.

$$\text{BG Adjusted} = \text{Individual Bead MFI} - \text{MFI of NC bead}$$

Divide the **BG Adjusted** by the MFI of the **Calculated Control (CalcCON)** of its respective locus to generate the **Background Corrected Ratio (BCR)**. The CalcCON for each locus is the Raw MFI value of the lowest ranked antigen bead for that locus.

$$\frac{\text{BG Adjusted}}{\text{CalcCON MFI for locus "1"}} = \text{BCR for antigen "x" from locus "1"}$$

$$\frac{\text{BG Adjusted}}{\text{CalcCON MFI for locus "2"}} = \text{BCR for antigen "y" from locus "2"}$$

$$\frac{\text{BG Adjusted}}{\text{CalcCON MFI for locus "3"}} = \text{BCR for antigen "z" from locus "3"}$$

To calculate the **Relative Strength (R Strength)** of an antigen, divide the BG Adjusted values of the individual bead by the corresponding MFI value of the bead in the LSA Negative Control (NC) serum

$$\frac{\text{BG Adjusted MFI of Antigen}}{\text{Raw Value MFI of Antigen in NC}} = \text{R Strength}$$

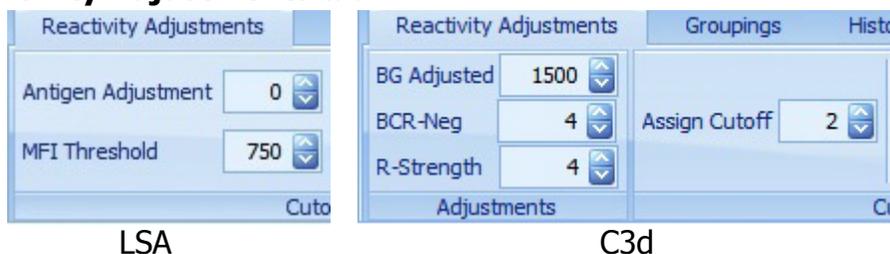
Higher or lower sensitivities can be obtained by adjusting the cutoff.

## Tools for Making a Positive or Negative Assignment

A bead is assigned as positive or negative based on user defined analysis parameters or by MFI cutoffs.

### By Standard Mode

If preferences have not already been set for these parameters or an override is necessary for a particular sample, they can be changed in the **Reactivity Adjustments** tab.



The **Antigen Adjustment** value is a software tool that the user can implement in order to adjust the cutoff value that determines whether or not the MFI/LRA ratio for a specific sample is assigned as positive or negative. The Antigen Adjustment value can also be assigned in Preferences so that it applies to every batch on import. *Refer to Chapter 2: LSA*

### By MFI Cutoff

MFI Cutoff can also be used from the **Reactivity Adjustments** tab by clicking the box and setting the cutoff to the desired value. This change will be applied only to the current sample.



### Additional Calculations

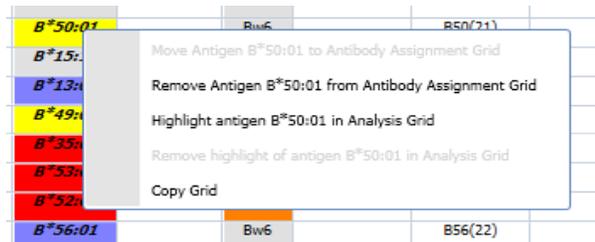
To determine the adjusted value for a bead, subtract the Negative Control sample MFI from the RAW MFI to generate the **Background Adjusted MFI Value (BG Adjusted)** for each individual bead.

$$\text{BG Adjusted} = \text{Individual Bead MFI} - \text{MFI of NC bead}$$

To determine the **AD-BG Adjusted**, divide the **BG Adjusted** by the relative amount of antigen on each bead as found in the lot-specific Recording Sheet.

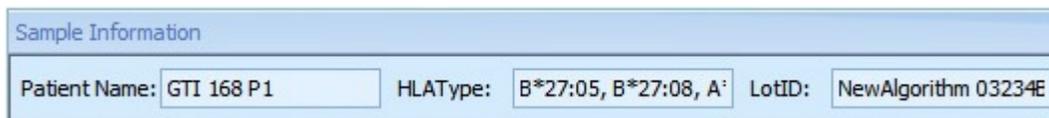
To determine the **Adjusted MFI (AD-MFI)**, divide the raw MFI by the relative amount of antigen on each bead as found in the lot-specific Recording Sheet.

### Move/Remove/Exclude Antigens to/from the Assignment



The user may right click an antigen within the assignment grid and choose to **Move** or **Remove Antigens from Antibody Assignments**.

If **Sample Antigens** were entered into the sample list, they will be displayed in the **Sample Information** tab.



When **Exclude Patient Type** is turned **ON** in the **Reactivity Adjustments** tab (if not already selected under **Preferences**) excluded antigens will be listed under the **Groupings** tab.



### By LSA Legacy

To determine the adjusted value for a bead, first subtract the Background MFI from the RAW MFI to generate the **Background Corrected MFI (BCM)** for each individual bead.

$$\text{BCM} = \text{MFI} - \text{Background MFI}$$

The **Background MFI** is the background noise due to bead variation and can be found on the lot-specific Recording Sheet provided with the kit.

Divide the **BCM** by the MFI of the **Calculated Control (CalcCON)** of its respective locus to generate the **Background Corrected Ratio (BCR)**. The CalcCON for each locus is the Raw MFI value of the lowest ranked antigen bead for that locus.

$$\frac{\text{BCM}}{\text{CalcCON MFI for locus "1"}} = \text{BCR for antigen "x" from locus "1"}$$

$$\frac{\text{BCM}}{\text{CalcCON MFI for locus "2"}} = \text{BCR for antigen "y" from locus "2"}$$

$$\frac{\text{BCM}}{\text{CalcCON MFI for locus "3"}} = \text{BCR for antigen "z" from locus "3"}$$

To generate the **Antigen Density Background Corrected Ratio (AD-BCR)**, normalize BCR by dividing this number by the relative amount of antigen on each bead.

The bead is considered positive if two or more of the adjusted values are above the cutoff values. Higher or lower sensitivities can be obtained by adjusting the cutoff.

Note: For LSA MIC-A, there is only one CalcCON which is defined as the Raw MFI value of the lowest ranked antigen bead.

### Weak Antigen Assignments (LSA Legacy Only)

To change the assignment of all **Weak** beads to **Positive** and have all such Antigens listed in **Antibody Assignments**, check **Include Weak** in the **Single Antigen Results** window

To change the assignment of all **Weak** beads to **Negative**, check **Exclude Weak** in the **Single Antigen Results** window.

Once Include Weak or Exclude Weak is used no changes to the Antibody Assignments can be made.

## Visual Tools for Review

### Groupings

The **Groups** drop-down box is a list of user defined HLA Groups. By selecting a particular group, the antigens present within the particular group will be highlighted.

The screenshot shows a software interface with a 'Groups' dropdown menu on the left and a table of antigen analysis results on the right. The dropdown menu is open, showing options: None, 1 C, 1 C short, 10 C, 10 C short, 12 C, and 19 C. The table below has columns: Bead Count, Antigen ID, Cut-off, Raw Value, and MFI/LRA. The 'Raw Value' column is highlighted in purple, and the 'MFI/LRA' column is highlighted in red.

Bead Count	Antigen ID	Cut-off	Raw Value	MFI/LRA
79	174	3.89	15568	149.69

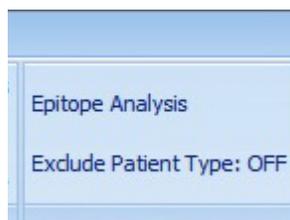
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## Color-Coded Antigen(s)

The user can color-code antigens or groups of antigens to provide easier viewing. This feature is intended as a visual aid.

## Epitope Analysis

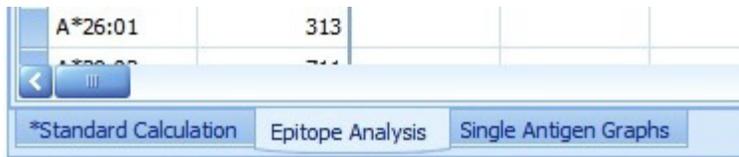
Epitope Analysis can be run at a sample level. If epitopes are not calculated upon import click the **Epitope Analysis** button to assign available epitopes.



To determine the epitope assignments, the software will perform the following procedure:

- 1) The software pulls epitope values from the database for antigens on positive beads.
  - 2) The software calculates true positives, true negatives, false positives, false negatives, percent positive, chi squared and R-Value for each epitope.
  - 3) The software compares the percent positive to the minimum value set in **Preferences** (default is 50%). Epitopes with a percent positive greater than the minimum are collected and sorted by the selected **Epitope Option** (default is **R-Value**). *Refer to Chapter 2: ID - Epitope Settings.*
  - 4) The software adds the top epitope from this list to a list of selected epitopes. The beads containing that epitope/antigen relationship are removed from consideration.
- Note: In the case of two epitopes having the same R-Value, the software chooses the top alphanumeric value for removal.
- 5) The process starts over with the remaining epitopes.
  - 6) Once all of the epitopes are identified, the software will look at each epitope individually and add it to every bead that contains antigens that have a relationship with the current epitope.

Epitopes can also be calculated in the **Epitope Analysis** tab located at the bottom of the analysis screen.

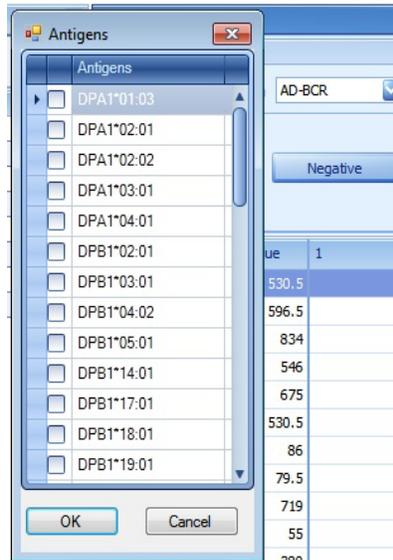


In the **Epitope Analysis** Tab, the user can refine the list of epitopes displayed by excluding antigens based on BCM, BCR, AD-BCR, or MFI values.

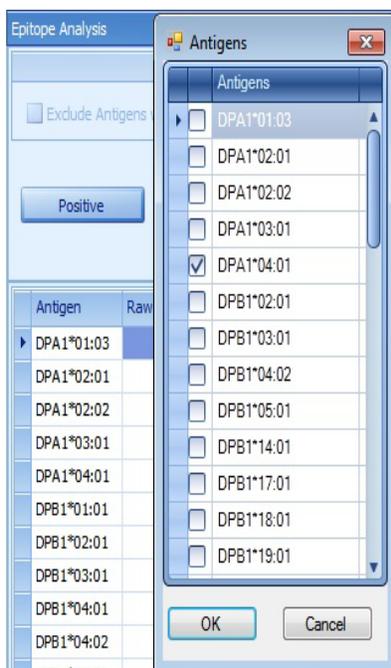


Antigens excluded by these parameters will be listed in the **Excluded Antigens** window.

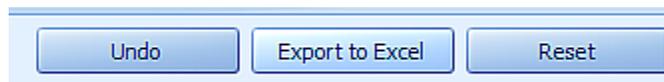
Antigens that are known or predictive Negatives can be selected from the **Negative** drop-down. These Antigens will be removed from the grid and will be added to the **Excluded Antigen(s)** list.



Antigens that are known or predictive Positives can be selected from the **Positive** drop-down list. When an Antigen is assigned as Positive, it will change to bold text and the associated epitope will be highlighted in the grid.



The user can use the **Undo** and **Reset** buttons at any time during analysis.



When Analysis is complete the results can be exported to an Excel worksheet using the **Export to Excel** button.

Note: If epitopes are assigned and changes are made to **Reactivity Adjustments** then epitope assignments will clear. To assign epitopes using the new cutoffs, click **Epitope Analysis** or, if **Auto Epitope Analysis** is selected in Preferences, they will recalculate when the sample is saved.

## Batch Failures

### Bead Count Failure

The source of all failures is listed in the **LSA Analysis** header. By clicking the failure message, the user has the option to include failed beads in the analysis.



If a CON bead fails to meet the minimum bead count, the software will report all beads as failed. To override the failure, click the message. A message box will appear to confirm the override.

If a sample fails to meet the minimum bead count for a particular result, the bead will be flagged as FAILED. To override the failure, double click the message and select the failed beads to include in the analysis.



Note: If a sample has both CON failures and bead failures, the CON failure must be overridden before the failed beads can be included.

## Creating a History

The user has the option of creating a snapshot of the **History** for a particular sample. In the **History** tab, a user has the ability to load antigens to create a reactivity group specific to the sample. This will enable a user to monitor changes in antibody status across kits and over time.

### New History

1) Go to the **History** tab.



2) Click **New**.

3) The previously assigned antigens (either automatically or manually) will be checked and highlighted in the window which appears. Additional antigens may be added to the history by checking the box next to the antigen

Note: This will not change the saved assignments.

4) Click **Save**.

5) Confirm the decision to make a history snapshot of the results and name the **Antigen History Group**.

### Applying a Previously Created History to a New Sample

A previously created History can be viewed with a new sample.

1) Go to the **History** tab of the new sample.

2) Click **Find**.

3) Type either the name of the **Antigen History Group** or a key component of the name, i.e. first letter.

4) The history of the sample will display.

### View Current Assigned History for a Sample

1) Go to the **History** tab of the new sample.

2) Select the history from the drop-down.

3) The saved history snapshot will be highlighted in the bead ranking grid and in the graph.

### Delete History

1) Go to the **History** tab of the sample.

2) Select a history from the dropdown or use **Find** to search for a history.

3) The history snapshot will be loaded.

4) Click **Delete**, then confirm deletion.

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## Approving Analysis Results

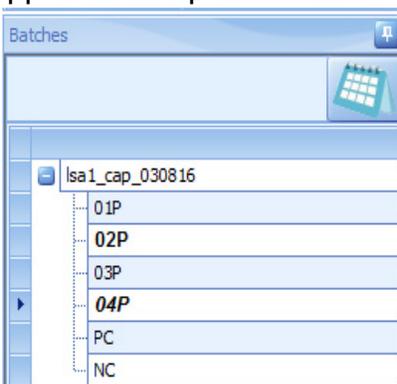
When **Save** is clicked, the analysis for the sample is saved but can be analyzed again.

When **Restore** is clicked, the sample will revert to the most recently saved data/assignments.

Once analysis is complete and no additional changes need to be made for a particular sample, click **Completed**. Only a Technician or Lab Supervisor may make changes to a sample by clicking **Completed** again. Once all samples in a batch have been completed, the batch will be listed as **Completed** on the home page and signify they are ready for sign-off.

Once the analysis of completed results has been reviewed, click **Approved**. Once clicked, changes can no longer be made except by a Lab Supervisor by clicking **Approved** again. Approving results will list the batch as **Approved** on the home page.

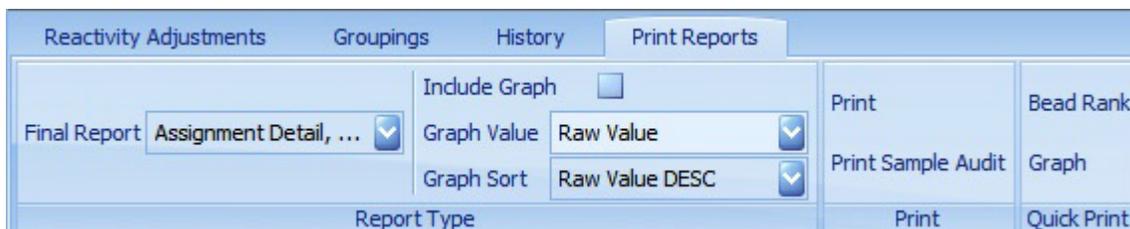
Within the Batch List completed samples will be highlighted with bold text; completed and approved samples will be bold and italicized.



## Reporting and Printing

After the sample has been analyzed, (automatically or manually) the user has the ability to customize a report.

### Customizing a Final Report



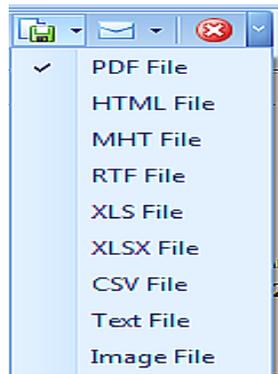
- 1) When the results are ready to be reported, go to **Print Reports** tab.
- 2) Click the drop down arrow next to **Final Report** and select the items to include in the Final Report.
- 3) A graph can be included in the report as well by checking the box next to **Include Graph**. **Graph Value** (y-axis) and **Graph Sort** (x-axis) may also be customized by clicking the drop down arrow and selecting the appropriate choice.
- 3) Once a report appears on the screen, click the **Print** icon in the upper toolbar.

## Quick Print

Either a **Bead Rank** report or **Graph** can be printed by clicking **Quick Print** on the **Print Reports** Banner. Selecting **Bead Rank** report will generate a list of antigens sorted exactly as it is sorted in the Single Antigen Analysis window. Selecting Graph will generate a graph with x-axis and y-axis legends matching those displayed in the **LSA Graph** window.

## Exporting Reports

- 1) Generate a report from the **Print Reports** tab in the **LSA Analysis** window.
- 2) Once a report appears on the screen, click the **Export Report** icon in the upper right toolbar.
- 3) The dialog box that appears provides several different options for exporting/saving the report.



## Batch Reporting



*Refer to Chapter 2: Batch Reports*

## Exporting Summary Results



*Refer to Chapter 2: Export Results*

# CHAPTER 7: LIFECODES DSA ANALYSIS

This chapter contains information on the tools available to analyze LIFECODES Donor Specific Antigen results (DSA).

## Importing DSA Results into MATCH IT!

If an Automated Batch was not created and data needs to be manually imported into the software, the appropriate EDS file must first be imported followed by the CSV file.

### Importing EDS files



*Refer to Chapter 2: Lot Information Import*

### Manually Importing CSV Files



*Refer to Chapter 2: Batch Import*

## Opening a Batch

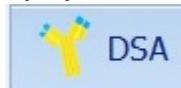
### Direct Selection

- 1) Double click the batch name found on the **Antibody** tab under **DSA**.
- 2) The batch results are displayed in a **DSA Analysis** tab. All sample results appear in the middle section of the tab. Individual sample IDs within the selected batch are listed in the left section of the tab under the batch name.

### Date Range Selection

Rather than selecting an individual batch, a range of dates can be selected, which will result in all batches run in that range being selected.

- 1) Right click the antibody symbol as shown below.



- 2) A pair of calendars with a start and end date will open. Select the desired range and click **OK**.

3) The batch results are displayed in a **DSA Analysis** tab. All sample results for the highlighted batch appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.

## DSA Analysis

### Navigating to a Particular Sample

To go to a particular sample in the batch, left click the sample name in the left hand panel. The software will jump to this sample and it will be highlighted in red.

The screenshot shows the 'DSA Analysis' window. On the left, a tree view lists 'DSA Analysis 1' with sub-items 'LCR', '1', '2', '3', '4', 'NC', and 'PC'. The main area displays batch information: 'Batch Name: DSA Analysis 1', 'Run Date: 03/09/16', 'Lot Number: 3002867 3002816-LMD', 'Class I BAFs: 14.8630 \* CON1^0.7800, 18.2000 \* CON2^0.7370, 6.4100 \* CON3^0.8170', and 'Class II BAFs: 14.6960 \* CON1^0.7020, 20.7280 \* CON2^0.6400, 9.2200 \* CON3^0.6960'. Below this is a red header for the selected sample: 'Sample: LCR', 'Well Position: 25(1 A4)', 'Patient: LCR', 'Draw Date: [blank]', 'Class I Assignment: Failed', and 'Class II Assignment: Failed'. A table at the bottom shows data for 'Raw', 'Adj 1', 'Adj 2', 'Adj 3', and 'Score' across columns 'I', 'II', 'CONs', and 'Pos Ctrl/ Lys Ctrl'.

	I	II	CONs	Pos Ctrl/ Lys Ctrl
Raw	0	5446		6157
Adj 1	-9306.06	613.27	3850	0
Adj 2	-4487.6	2970.37	1760	
Adj 3	0	0	0	
Score	0	2		

### Changing the Sort Order

The samples within a batch are loaded in order of their location in the batch. By selecting the Sort tab located in the upper right, the results can be ordered by **Sample ID**, **Well Location** (default), **CON1**, **CON2**, **CON3**, or **Pos Ctrl**.

The screenshot shows the 'Sort' dropdown menu with the following options: 'Well Location' (selected), 'Sample ID', 'Pos Ctrl', 'CON1', 'CON2', and 'CON3'.

### Displaying Bead Counts

To display the bead counts for a sample, click the down arrow next to **Bead** in the sample header.

The screenshot shows a software interface with two sample wells. The top well, 28(1D4), is assigned 'Positive' for both Class I and Class II. The bottom well, 29(1E4), is assigned 'Negative' for Class I and 'Positive' for Class II. A 'Bead Counts' dropdown menu is open, displaying the following values: 78: 74, CON1: 64, CON2: 73, CON3: 60, I: 77, II: 62, and Pos Ctrl: 74. The main table shows raw and adjusted MFI values for Class I and II beads, along with control (CON) values.

	I	II	CONs	Po
Raw	2320	1908		21
Adj 1	1673.76	1469.81	126	31
Adj 2	1416.5	1292.52	200	
Adj 3	1845.77	1547.39	194	
Score	3	3		

## Calculations and Displayed Values

To determine the adjusted values for a capture bead, the MFI value of each capture bead is compared to three cutoff values (background adjustment factors; BAFs). The three cutoff values are calculated from the background measured on the three CON beads in each test well. Each CON bead has an equation for calculating the cutoff value for the Class I HLA capture bead and a separate equation for calculating the cutoff value for the Class II HLA capture bead. The two equations for each CON bead are lot-specific and can be found on the Recording Sheet. The cutoff value calculated for a CON bead is subtracted from the MFI value of the capture bead. The process is repeated for each of the remaining two CON beads to obtain three results (Adjusted MFI Values).

**Example:** Class I HLA BAF for CON1 =  $49.465(\text{CON1})^{0.5312}$

Class I HLA BAF for CON2 =  $34.622(\text{CON2})^{0.5673}$

Class I HLA BAF for CON3 =  $29.615(\text{CON3})^{0.6532}$

**Example:** Class I HLA Capture Bead MFI - (BAF for CON1) = Adjusted MFI 1

Class I HLA Capture Bead MFI - (BAF for CON2) = Adjusted MFI 2

Class I HLA Capture Bead MFI - (BAF for CON3) = Adjusted MFI 3

## Tools for Making a Positive or Negative Assignment

### By Standard Mode

- A sample is considered positive for donor specific antibodies if two or more **Adjusted MFI** values are positive.
- A sample is considered negative for donor specific antibodies if two or more **Adjusted MFI** values are negative.

### By MFI Cutoff

Beads can be assigned as positive or negative by manually assigning an MFI cutoff. This can be set per sample by using the check box available in each sample window or by changing Preferences to use **MFI Mode**. Refer to Chapter 2: DSA.

### Overriding an Assignment

While the software performs analysis according to the product insert, all results should be reviewed. During this review process, an assignment can be changed manually by clicking the arrow on the right side of the text box and selecting one of the choices that appears.

The screenshot shows a software window with a red header. The header contains fields for 'Sample: 1', 'Patient: 1', 'Draw Date:', 'Well Position: 25 (1 B4)', 'Locked' (checkbox), 'MFI Cutoff' (input field with '0'), and 'Bead Counts' (dropdown). Below the header, there are two dropdown menus: 'Class I Assignment: Positive' and 'Class II Assignment: Negative'. A dropdown menu is open for 'Class I Assignment', showing options: Positive, Negative, ND, Bead Failure, Failed, and LCR. Below the dropdowns is a table with columns for Class I and Class II results, CONs, and Pos Ctrl/ Lys Ctrl.

	I	II	CONs	Pos Ctrl/ Lys Ctrl
Raw	3146	248		21394
Adj 1	2787.92	-9.74	59	61
Adj 2	2784.97	-29.67	58	
Adj 3	2938.09	69.23	71	
Score	3	1		

### Overriding Default Parameters

The default parameters (**Assign Adjust** and **Assign Cutoff**) should only be altered by personnel knowledgeable in the field of HLA Antibody Analysis. Changing these values will result in altered specificity and sensitivity of the assay and can only be done in Preferences prior to importing a batch. Refer to Chapter 2: DSA.

## Batch Failures

### Bead Count Failure

If a sample fails to meet the minimum bead count for a Class I or Class II bead, the Class I or Class II result, respectively, will be reported as bead failure. To override the failure, review the bead count and then choose the appropriate assignment from the drop-down menu.

If a CON bead fails to meet the minimum bead count, the software will report bead failure for both Class I and Class II.

### Positive or Negative Control Failure

- A Negative Control is considered as failed if any bead fails to meet the minimum bead count, or if the Negative Control has a positive assignment for Class I or Class II.
- A Positive Control is considered as failed if any bead fails to meet the minimum bead count, or if either of the Class I or Class II assignment is negative.

The source of the failure is listed in the **DSA** header.

## Approving Analysis Results

The **Save Assignments** button saves any assignment edits that have been made. Changes can be made and re-saved.

The **Complete** button locks all the samples in the batch and signifies all samples have been analyzed and are ready for sign off. When a batch has been completed and locked, only a Technician or Lab Supervisor may unlock the samples by clicking **Complete** again. Completing the results lists the batch as **Completed** on the home page.

The **Approve** button signifies the samples are finished. When a batch has been approved, only a Lab Supervisor may unapprove the samples by clicking **Approve** again. Approving the results lists the batch as **Approved** on the home page.

The screenshot shows a software interface for 'DSA Analysis'. It contains the following fields and buttons:

<b>Batch Name:</b>	DSA Analysis 1	<b>Assign Cutoff:</b>	3, 3	<b>For Research Use Only</b>
<b>Run Date:</b>	03/09/16	<b>Assign Adjust:</b>	0, 0	
<b>Lot Number:</b>	3002867 3002816-LMD	<b>Expiration Date:</b>	07/15/16	
<b>Class I BAFs:</b>	14.8630 * CON1^0.7800, 18.2000 * CON2^0.7370, 6.4100 * CON3^0.8170			
<b>Class II BAFs:</b>	14.6960 * CON1^0.7020, 20.7280 * CON2^0.6400, 9.2200 * CON3^0.6960			
<b>Reviewed By:</b>		<b>Comments:</b>	<input type="text"/>	

At the bottom right, there are three buttons: **Save Assignments**, **Complete**, and **Approve**.

## Reporting and Printing

### Generating a Standard Report

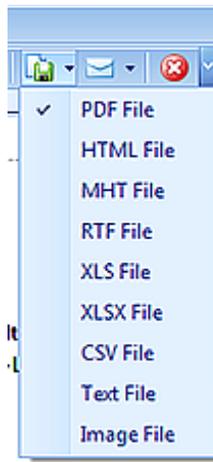
1) Once the results have been accepted, a report can be generated. The report for the batch can be ordered by **Sample** or **Well Location**.

The screenshot shows a dialog box for generating a report. It has the following elements:

- Buttons: **Reports**, **Export**, **Sort**
- Label: **Sort By:**
- Radio buttons:  **Sample**,  **Well Location**
- Button: **Generate DSA Report**

2) The report is created by pressing the **Generate DSA Report** button.

3) Once a report appears on the screen, the user can print or save it.



## Printing an Individual Sample Report or Audit Report

2667569-LCR	CON Ranges	CON 1: 0 - 0	CO
JDJ-KGS	Adj 3	17275.5	
4167695-LCR	Score	3	
CSH-LAH			
3793978-LCR			
CJS-JCS			
4611265-LCR			
ANY-KYS			
5053415-LCR			
JBH-HTO			
4170007-LCR			

1) Select the sample ID in the **Batch** panel.

2) Right click the sample ID to access the report options: **Report Sample** or **Sample Audit Report**. A **Sample Audit Report** will only be generated if changes to the sample have been made. If no changes then no report will appear.

3) Once a report appears on the screen, click the **Print** icon in the upper toolbar.

## Batch Reporting



*Refer to Chapter 2: Batch Reports*

## Exporting Summary Results

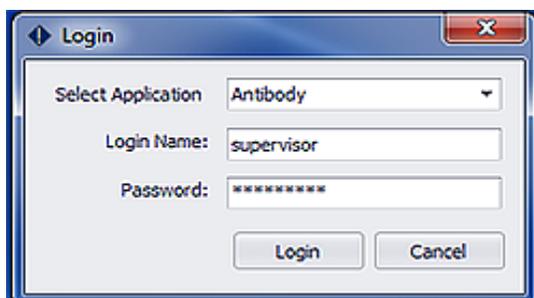


*Refer to Chapter 2: Export Results*

## CHAPTER 8: DATABASE MANAGEMENT

This chapter provides information regarding managing databases; including creating, deleting, backing up and storing databases.

To open the database management window you must first click on the **Start** button located at the lower left of the computer screen.



1) Go to **All Programs** and then select **Lifecodes**.

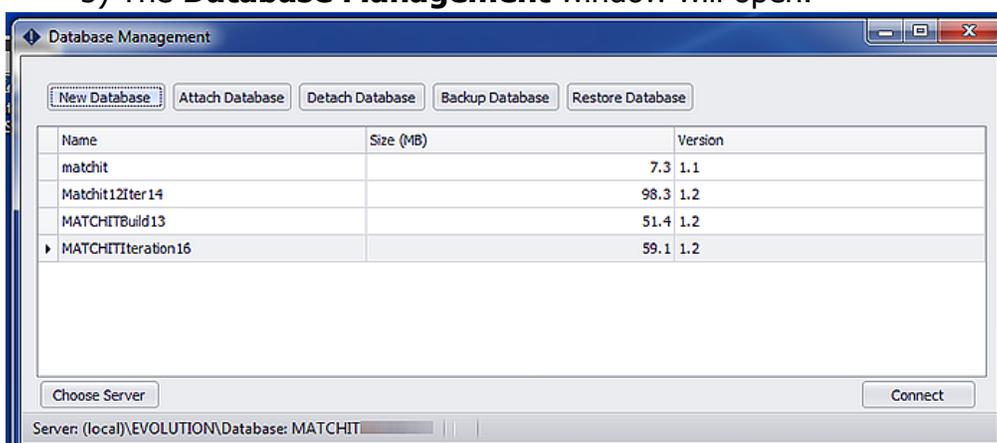
2) Select **Database Management**.

3) Select **Antibody** from the **Application** dropdown.

4) Sign in using the same Login and Password that are used to

access the MATCH IT! Antibody analysis software (Login Name: supervisor, Password: lifecodes) and click **Login**.

5) The **Database Management** window will open.



### Creating a New Database

To create a new database, select **New Database**. A prompt for a name will appear. A database name must start with a letter. Once named, click **OK**.

### Connecting to a Database

To choose the database to be used, first highlight the database and then select **Connect**.

## Deleting a Database

To delete a database, highlight the database to be deleted and select **Delete Database**. A prompt will appear asking if the database should be deleted. Select **Yes** to delete the database. Once a database is deleted, it cannot be retrieved and all data is lost.

If the current database in use needs to be deleted, the user must connect to another database. Once a new connection has been established, the former database in use can be deleted.

## Attaching a Database

To attach a database, select **Attach Database**. A dialog box will appear where the user selects the database to be attached. This feature is only available on the PC housing the database.

## Detaching a Database

Detaching a database removes it from the server list, but does not delete the database. It can be attached later if needed. To detach a database, highlight the database and select **Detach Database**. The database that is currently in use cannot be detached. This feature is only available on the PC housing the database.

## Backing Up a Database

To backup a database, select **Backup Database**. Next, navigate to the location where the backup is to be kept.

If the software is running on Windows 7, Backup files should be stored at C:\ProgramData\Lifecodes\Backup.

## Restoring a Database

To restore a database, select **Restore Database**. Next, select the location where the backup to be restored is kept.

If the software is running on Windows 7, Backup files should be stored at C:\ProgramData\Lifecodes\Backup.

This feature is only available on the PC housing the database.

## Choosing a Server

In order to connect to a SQL database on another computer, select **Choose Server**. From here, the SQL Instance and database can be selected. If the SQL instance does not appear in the drop down, it can be entered manually.

# CHAPTER 9: PATIENT VIEW

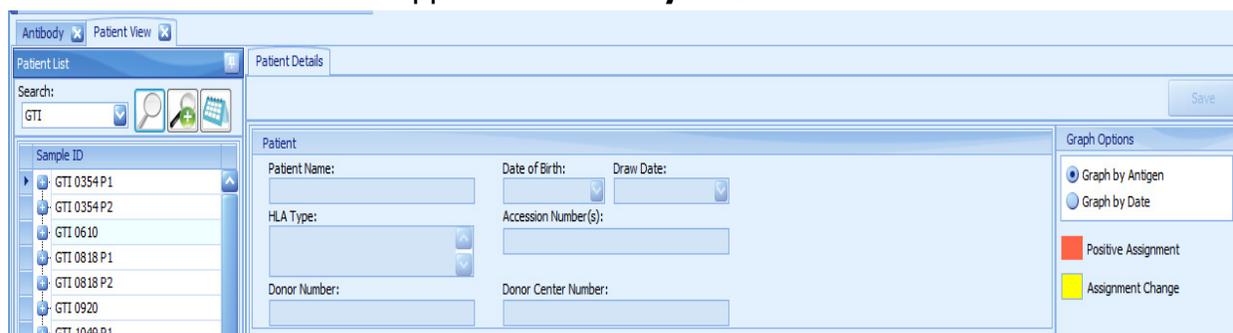


This chapter contains information regarding viewing data for a particular sample. All batches can be displayed, graphically compared from one batch to another, and antibody history viewed.

## Sample Search

### By Sample ID or Patient Name

Type the sample ID or patient name into the search box and click the magnifying glass. As the ID is typed into the box, the auto-complete feature will activate. All batches containing that sample ID will display. Click the batch for it to appear in **Antibody Batch Results**.



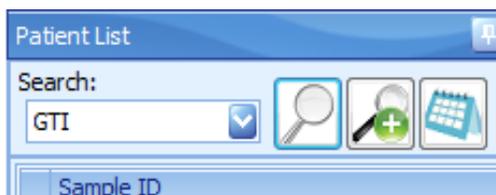
### By Run Date

Click the calendar and choose a range of dates or specific date. All samples from batches run within the range or date will display. Click the batch for it to appear in **Antibody Batch Results**.

### Advanced Sample Search

Selecting the Advanced Sample Search button will allow the user to search for samples by multiple identifiers.

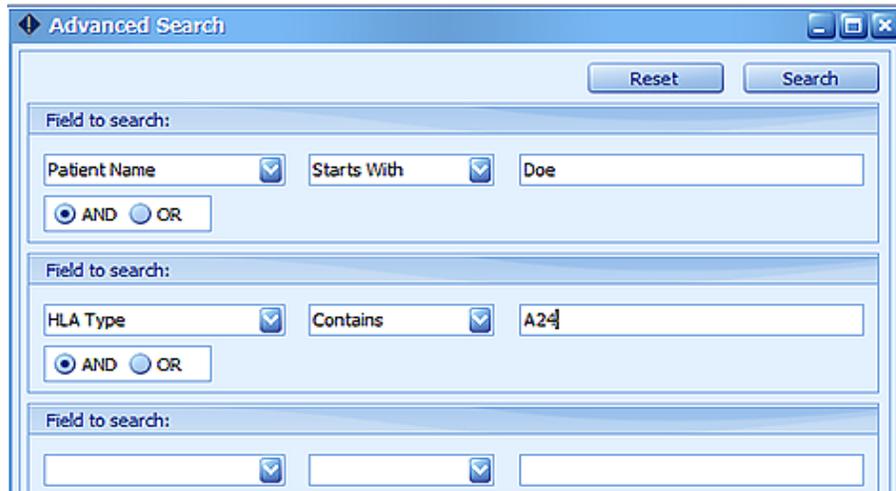
To use this feature, first select the **Advanced Search** button from the Advanced Search Window. Then click the first drop-down to search by Assignment, Patient Name, Donor Center, Donor Number, or HLA Type.



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Select the appropriate qualifier (Equals, Starts With, Contains) from the second drop-down.

Enter the specific search term in the window. Up to three fields can be included in a single search.



Once all desired fields have been chosen, click **Search**.

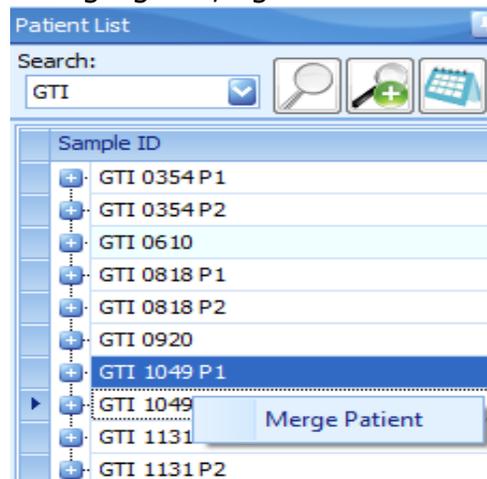
All Samples that fulfill the search requirements will be listed on the left under **Patient List**.

### Merge Sample IDs/Patient Names

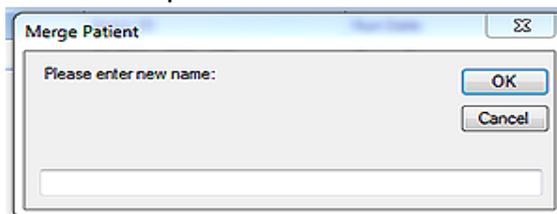
1) To merge sample IDs or patient names, first find the sample ID or patient name by searching by date.

2) Highlight the first ID. Hold the CTRL key as the other IDs are selected.

Once all IDs are highlighted, right click and choose **Merge Patient**.



3) Name the new Sample.

A dialog box titled "Merge Patient" with a close button (X) in the top right corner. The main text says "Please enter new name:". Below this text is a text input field. To the right of the input field are two buttons: "OK" and "Cancel".

Now the sample ID or patient name can be found as they were originally named as well as found under the new merged name and highlighted in light blue.

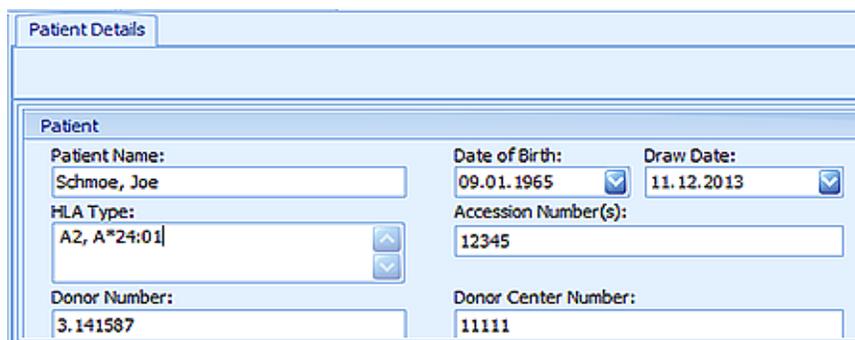
Note: New sample IDs or patient names can be added to already existing merges by selecting the new sample and the merged sample, right clicking and selecting **Add to Existing Merged Patient**. Two merged sample IDs can also be merged together in the same fashion.

To unmerge, right click on a merged sample ID or patient name and select **Unmerge**. This will return the sample IDs to their originally imported state.

## Viewing Antibody Batch Results

### Patient Information

If Patient Name, Date of Birth, Draw Date, HLA Type, Accession Number, Donor Number, or Donor Center Number were included in the auto-batch set-up (refer to *Chapter 3: Automated Batch Setup*), they will be displayed in the **Patient Details** tab of **Patient View** for each individual sample.

A screenshot of the "Patient Details" tab in a software interface. The form contains several fields: "Patient Name" with the value "Schmoe, Joe"; "Date of Birth" with the value "09.01.1965" and a calendar icon; "Draw Date" with the value "11.12.2013" and a calendar icon; "HLA Type" with the value "A2, A\*24:01" and up/down arrow icons; "Accession Number(s)" with the value "12345"; "Donor Number" with the value "3.141587"; and "Donor Center Number" with the value "11111".

The user can also manually enter this data in to any one of these fields.

### Manually Entering Patient Data

1. Select the batch from the **Patient List** window.
2. Enter the patient details.
3. Click **Save**.

Note: The user will be prompted to save **Patient Details** for the single batch or for all batches containing the sample. If the user chooses to save for all batches, the draw date, if entered, will be applied only to the selected batch.

## Entering HLA Type

Patient HLA Type can be manually entered in the **Patient Details** tab. Once saved it will display in **Patient Information** in the Analysis screen and on reports generated for that sample.

If a user wants to exclude the patient HLA type then antigens entered into this field must match an antigen listed on a product worksheet and be separated by commas.

Example:

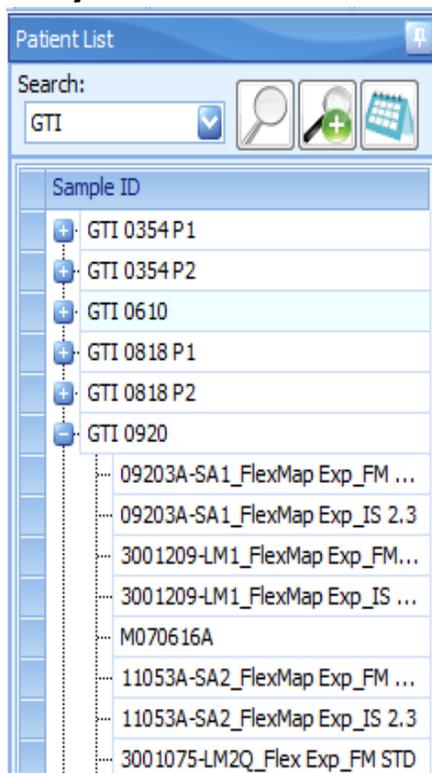
A2, A24, B56, B51

or

A\*02:01, A\*24:02, B\*56:01, B\*51:01

## Displaying Batches

1) To view all batches containing a specific sample, double-click the sample name or click the **+** icon. All batches containing that sample will display under the **Antibody Batch Results** tab.



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2) Click any of the batches listed for the selected sample for all results to appear in **Antibody Batch Results**.

Antibody Batch Results		Antibody History		Select COV		Select All			
Test Type									
CLASS I ID									
Test Type	Lot ID	Sample ID	Batch ID	Run Date	Draw Date	PRA	Final Results		
CLASS I ID	3003157 3003076-LM1	1603	LM1_032216_AOJD	03/22/16			98		
CLASS II ID									
Test Type	Lot ID	Sample ID	Batch ID	Run Date	Draw Date	PRA	Final Results		
CLASS II ID	3003072 3003007-LM2Q	1603	LM2Q_032216_AOJD	03/22/16			80		
LMX									
Test Type	Lot ID	Sample ID	Batch ID	Run Date	Draw Date	Class I Result	Class II Result	Hi BG Class I	Hi BG Class II
LMX	3003153 3003124-LMX	1603	LMX_032216_AOJD	03/22/16		Positive	Positive	Positive	Positive
SINGLE ANTIGEN I									
Test Type	Lot ID	Sample ID	Batch ID	Run Date	Draw Date	PRA	Final Results		
SINGLE ANTIGEN I	08245C 08155T-SA1	1603	LSA1_032316_Mayo	03/23/16			35		
SINGLE ANTIGEN I	<b>08245C 08155T-C3dSA1</b>	<b>1603</b>	<b>C3d1_032316_Mayo</b>	<b>03/23/16</b>			<b>5</b>		
SINGLE ANTIGEN II									
Test Type	Lot ID	Sample ID	Batch ID	Run Date	Draw Date	PRA	Final Results		
SINGLE ANTIGEN II	09115A 08205C-SA2	1603	LSA2_032316_Mayo	03/23/16			0		
SINGLE ANTIGEN II	09115A 08205C-C3dSA2	1603	C3d2_032316_Mayo	03/23/16			<b>1</b>		
SINGLE ANTIGEN II	09115A 08205C-C3dSA2	1603	C3d 2 Bead Failure	03/23/16			0		

3) The antigen specificities for the chosen batch will display once the batch is selected.

Note: C3d batches will display in bold type.

If two batches have been run for a chosen assay and both batches are selected by holding down the CTRL key, any differences of antigen assignments between the batches will be highlighted.

- Red and checked antigens are positive in all batches.
- Yellow and checked antigens are positive in only one of the selected batches.

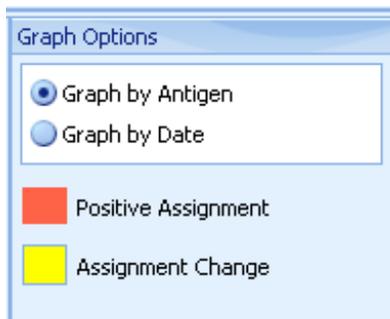
Note: Double click the batch to open the sample for analysis.

4) If an antibody history was created previously for a particular sample (*refer to Chapter 5: Creating a History*), the history will display in the **Antibody History** tab. Edits to the history can be made here as well.

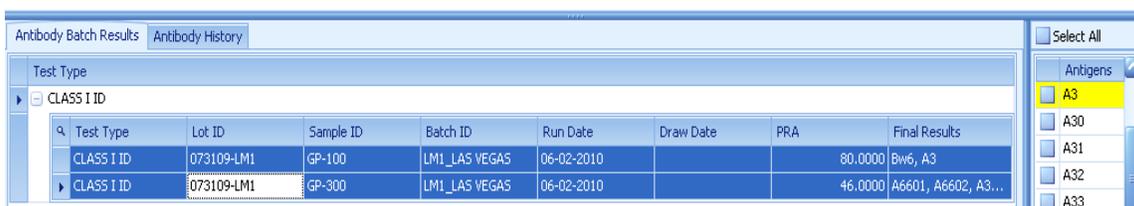
## Graphing Antigens across Several Batches

A graph can be created with combined results from multiple batches.

- 1) Choose to either **Graph by Antigen** or **Graph by Date**.



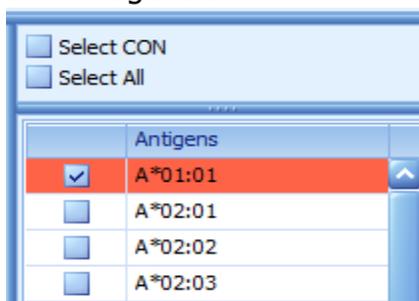
- 2) In the **Antibody Batch Results** window, select each batch to be included in the graph by holding down the CTRL key.



The 'Antibody Batch Results' window shows a table with columns: Test Type, Lot ID, Sample ID, Batch ID, Run Date, Draw Date, PRA, and Final Results. Two rows are highlighted. On the right, an 'Antigens' list has 'A3' selected.

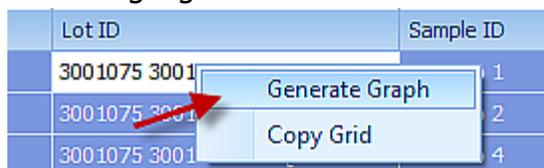
Test Type	Lot ID	Sample ID	Batch ID	Run Date	Draw Date	PRA	Final Results
CLASS I ID	073109-LM1	GP-100	LM1_LAS VEGAS	06-02-2010		80.0000	Bw6, A3
CLASS I ID	073109-LM1	GP-300	LM1_LAS VEGAS	06-02-2010		46.0000	A6601, A6602, A3...

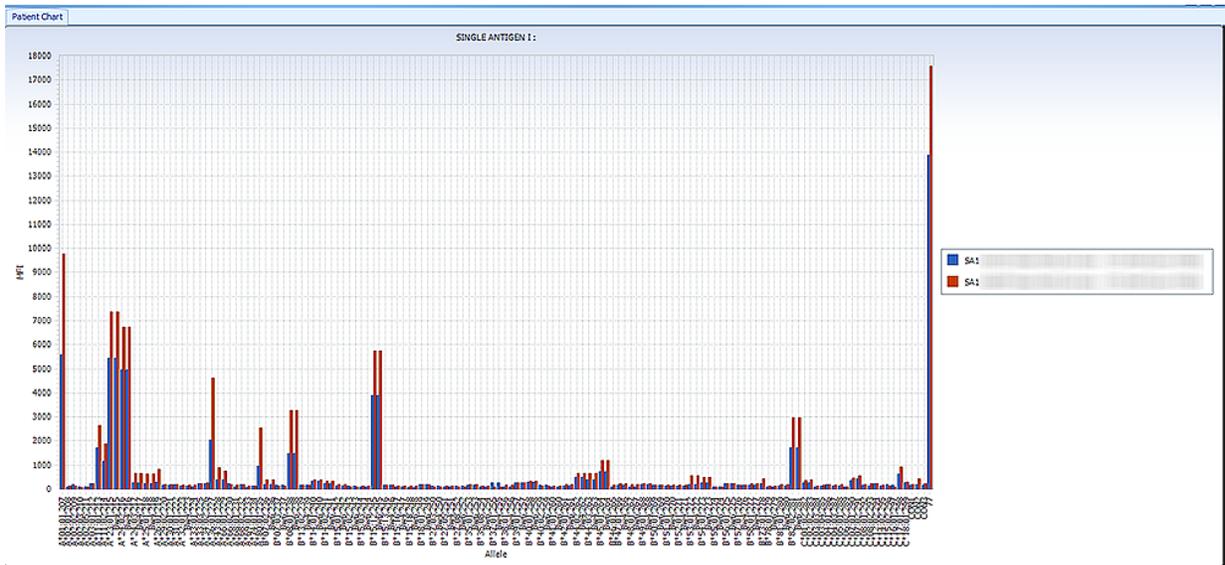
- 3) Assigned antigens to be graphed will appear in the **Antigen** column on the right. Additional antigens can be added by selecting manually.



- 4) To include the CON value in the graph mark the box for **CON**. To include all Antigens in a graph mark the box for **Select All**.

- 5) Right click the highlighted batches and choose **Generate Graph**.

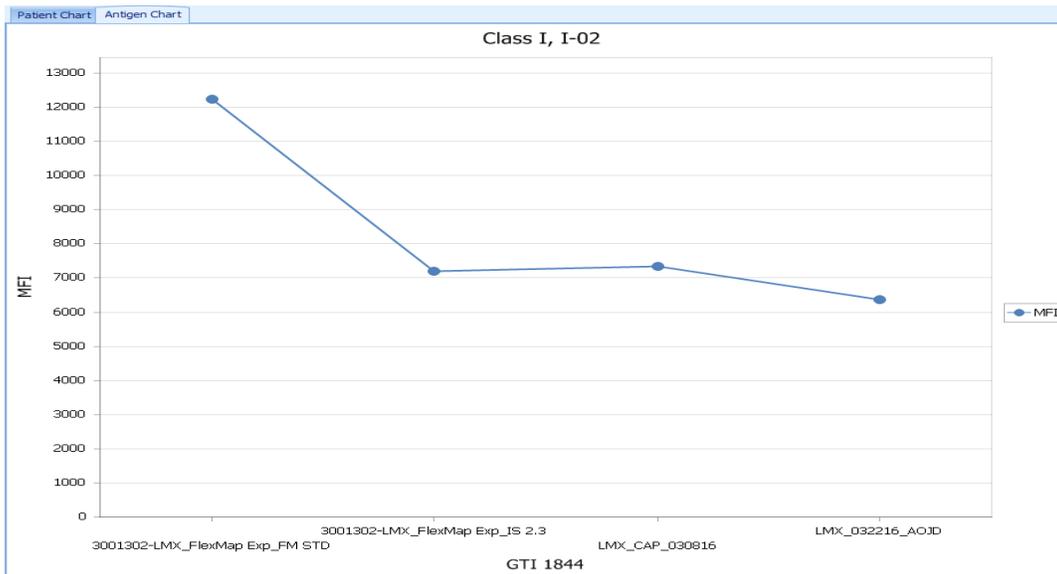




By default the graph will be a bar graph with **Antigens** listed on the X-axis and **MFI** on the y-axis.

To modify the style of graph or to graph by an assay-specific calculated value (ADJ1, BCM, etc) right click anywhere in the graph and select from the menu that appears.

Note: Clicking on an antigen opens the **Antigen Graph**.



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## LSA IgG and C3d Features

### Creating LSA IgG-C3d Paired Data Sets

- 1) Search for the sample by name or by run date in the **Patient List** search window
- 2) Click any of the batches listed for the selected sample for all results to appear in **Antibody Batch Results**. C3d batches will display in bold type.
- 3) Select the data set to be paired from the batches listed. Hold down the CTRL key to highlight both LSA and the C3d.
- 4) Right-click and select **Assign IgG-C3d Pair** from the pop-up.

Test Type	Lot ID	Sample ID	Batch ID	Run Date	Draw Date	PRA	Final Results
SINGLE ANTI...	03054B 0115...	AR443230	checkout LSA 2	08.21.14			32 DPB1*03:01,...
▶ SINGLE ANT...	<b>03054B 011...</b>	<b>AR443230</b>	<b>Checkout C...</b>	<b>09.09.14</b>			<b>14 DPB1*03:01...</b>

Generate Graph

Copy Grid

**Assign IgG C3d Pair**

Export Antigens

Generate Report ▶

Note: Assigned pairs will be highlighted. The first assigned pair for a sample will be highlighted in light blue. The second assigned pair for a sample will be highlighted in red. Any subsequent paired data sets will be highlighted in yellow.

Test Type	Lot ID	Sample ID	Batch ID	Run Date	Draw Date	PRA
<b>SINGLE ANT...</b>	<b>04234B TST...</b>	<b>AR412339</b>	<b>CheckOut C...</b>	<b>09.05.14</b>		<b>7</b>
▶ SINGLE ANTI...	09203A 0614...	AR412339	Checkout LS...	08.21.14		3

NGLE ANTIGEN II

Test Type	Lot ID	Sample ID	Batch ID	Run Date	Draw Date	PRA
SINGLE ANTI...	03054B 0115...	AR405752	checkout LSA 2	08.21.14		26
SINGLE ANTI...	03054B 0115...	AR412339	checkout LSA 2	08.21.14		32
<b>SINGLE ANT...</b>	<b>03054B 011...</b>	<b>AR405752</b>	<b>Checkout C...</b>	<b>09.09.14</b>		<b>13</b>
▶ <b>SINGLE ANT...</b>	<b>03054B 011...</b>	<b>AR412339</b>	<b>Checkout C...</b>	<b>09.09.14</b>		<b>30</b>

Note: IgG-C3d pairs must be assigned in order to use the **Export IgG-C3d pair** function in **Exports/Reports**.

### Export Antigens

Right clicking on a sample will allow the user to export antigens for that sample. To export antigens by batch, refer to *Chapter 2: Export IgG-C3d Paired Results*.

## Graphing LSA IgG-C3d Paired Data

The MATCH IT! software graphing tool allows the user to generate a graph that gives a direct comparison between LSA IgG and C3d results.

1) Select LSA IgG and C3d data to be graphed. Click on the LSA-IgG sample to select. Hold down the CTRL key and click on the C3d sample.

Test Type	Lot ID	Sample ID	Batch ID	Run Date	Draw Date	PRA	Final Res
SINGLE ANT...	042348 TST	AR412220	Checkout C...	09.05.14			7 A*02:02
SINGLE ANT...			Checkout LS...	08.21.14			3 A*23:01
SINGLE ANT...			checkout LSA 2	08.21.14			26 DPB1*03
SINGLE ANT...			checkout LSA 2	08.21.14			32 DQB1*02

2) Right-Click and select **Generate Graph**. All assigned antigens from the antigen window will appear as data points on the graph.

Note: IgG vs C3d Graphs will display Background Corrected MFI in the y-axis and antigens in the x-axis.

## Generating LSA IgG-C3d Reports

The user can generate a report with LSA IgG data and C3d data from the Sample view screen.

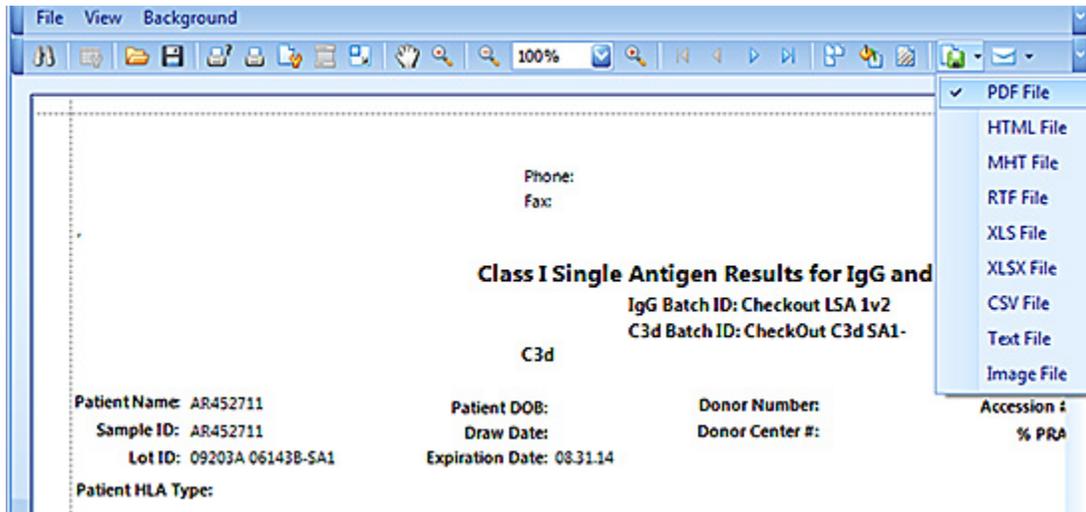
1) Select LSA IgG and C3d data to be reported Click on the LSA-IgG sample to select. Hold down the CTRL key and click on the C3d sample.

2) Right-Click and select **Generate Graph** from the menu. Select whether or not to include a graph in the report from the sub-menu.

Test Type	Lot ID	Sample ID	Batch ID	Run Date	Draw Date	PRA	Final Results
SINGLE ANTI...	03203F 0228...	AR420178	Checkout LS...	08.21.2014			2 B*15:12, B*8...
SINGLE ANT...	042348 TST	AR420178	Checkout C...	09.05.2014			14 A*02:01, A*...

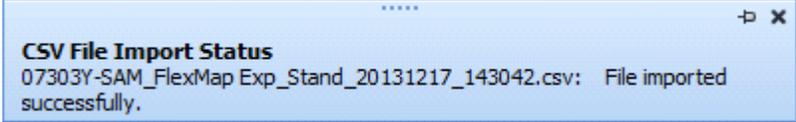
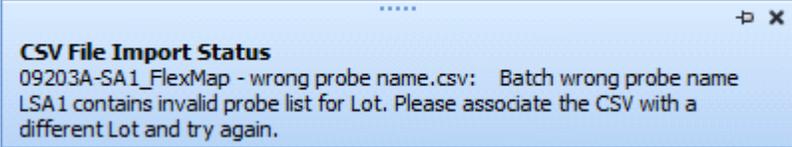
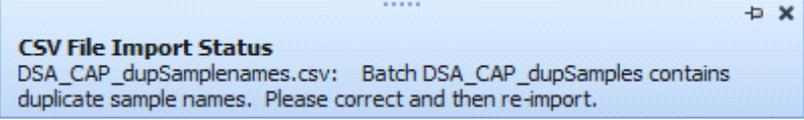
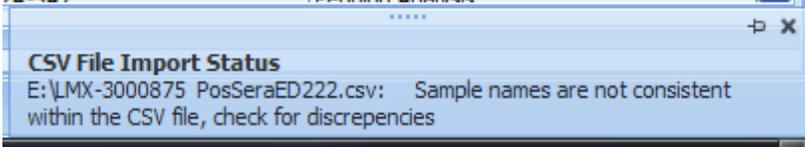
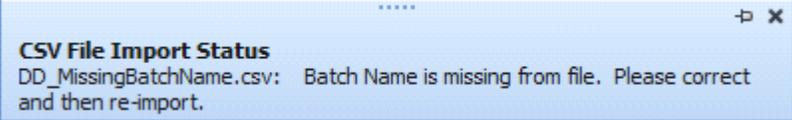
3) The LSA IgG-C3d report will populate a new window.

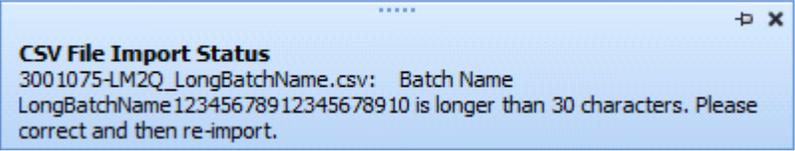
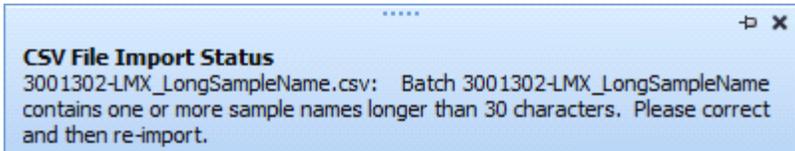
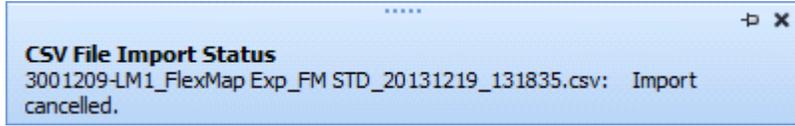
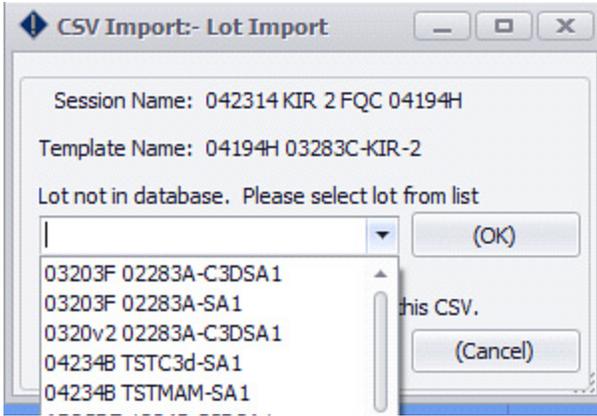
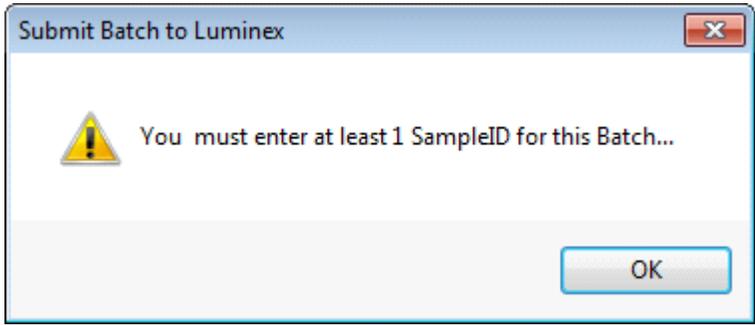
4) Once a report appears on the screen, click the **Export Report** icon in the upper right toolbar. The dialog box that appears provides several different options for exporting/saving the report.

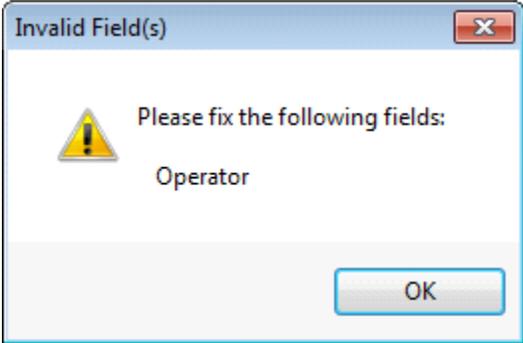
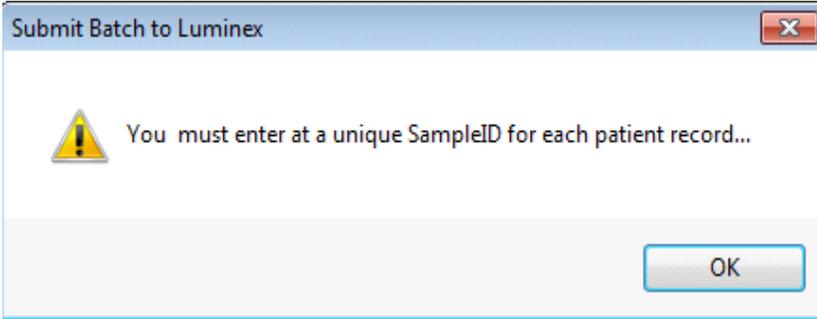
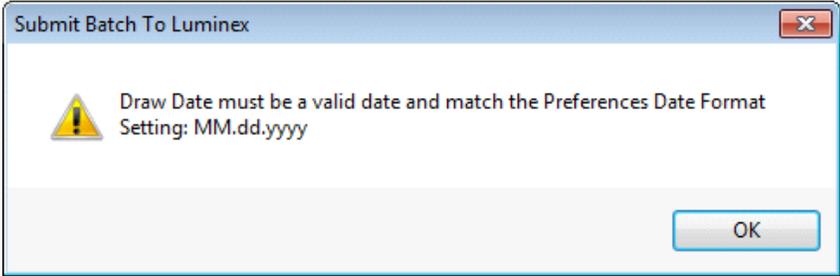
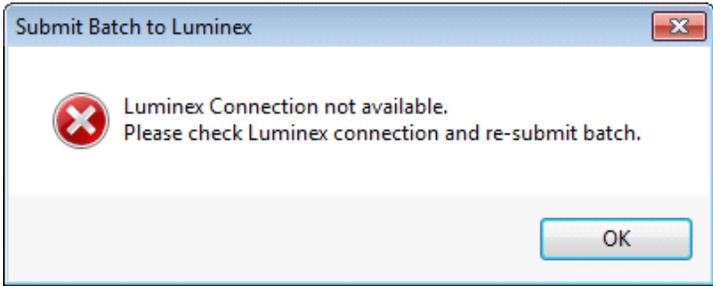


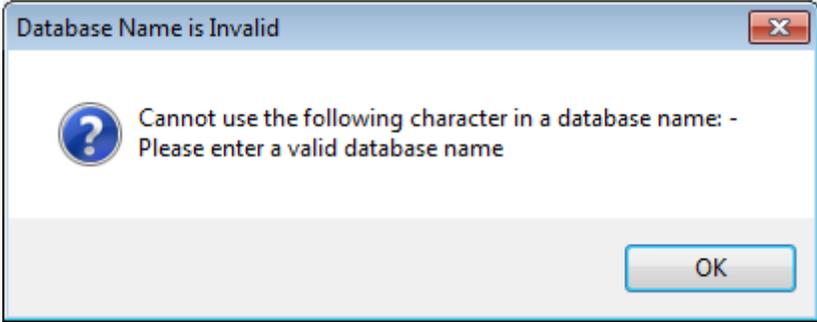
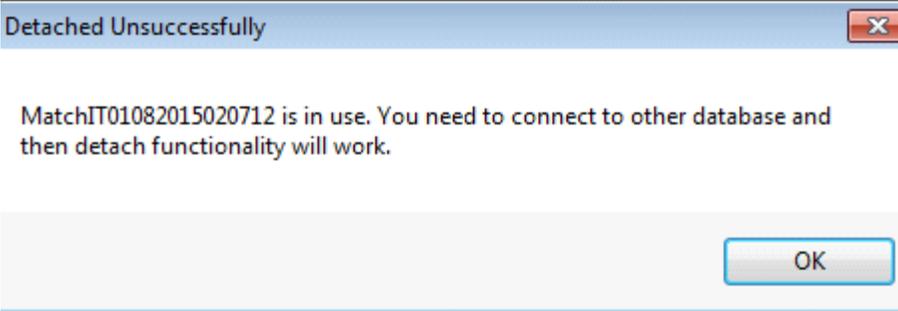
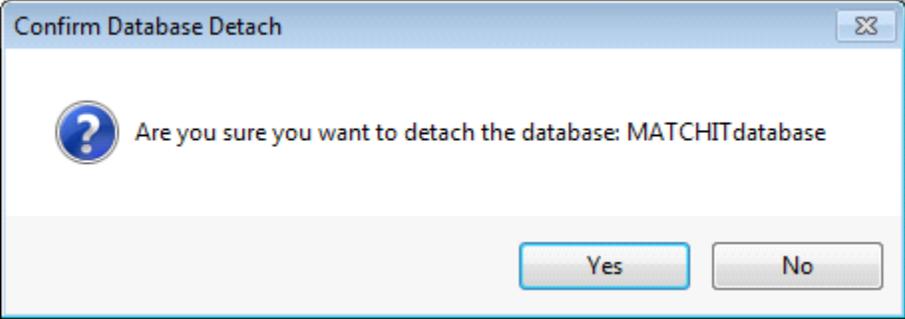
5) Select and save to the desired location.

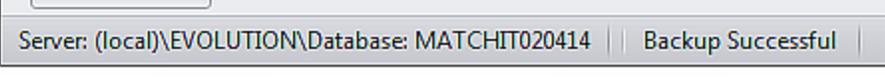
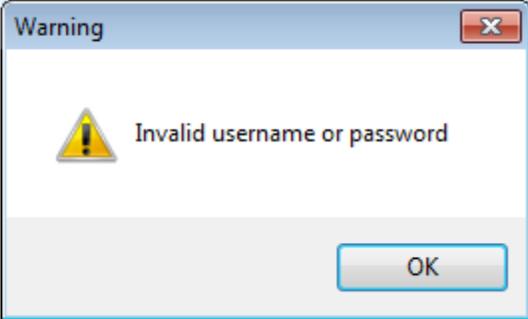
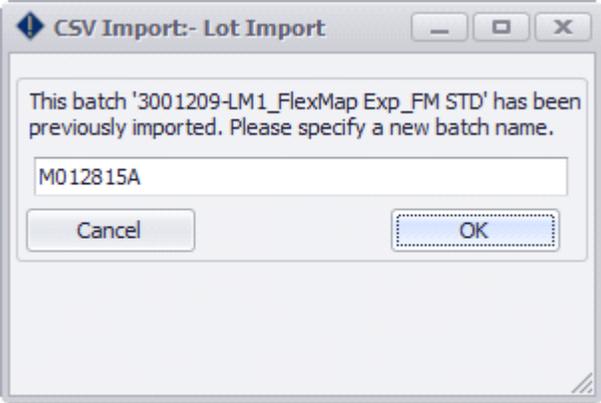
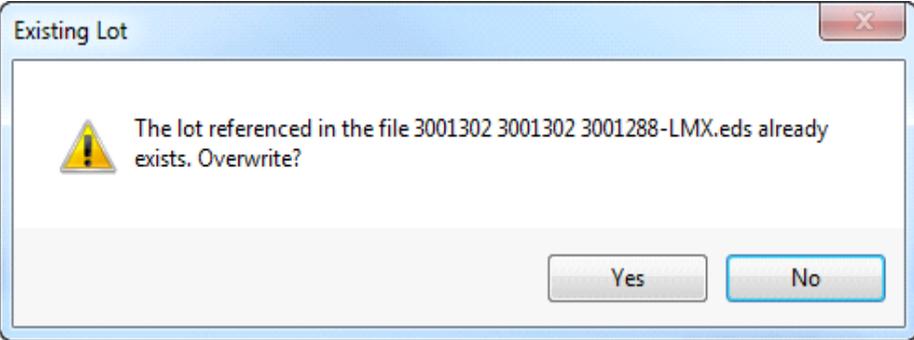
# APPENDIX A: ERROR CONDITIONS

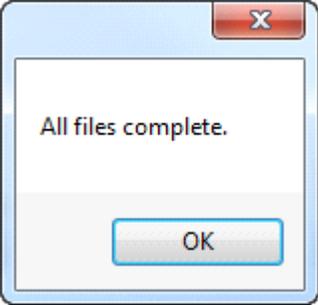
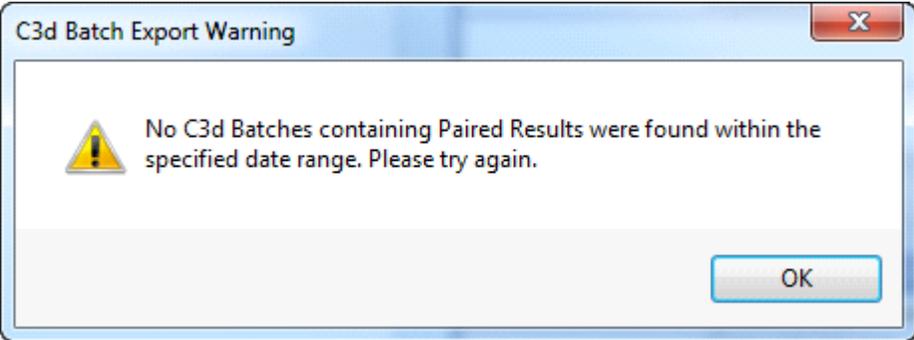
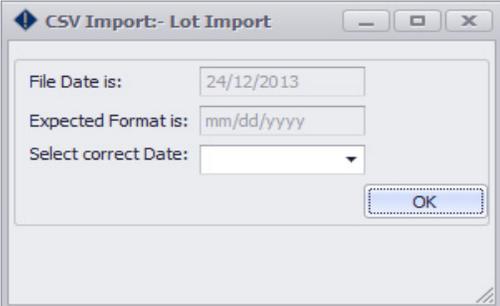
Error Condition	Message
CSV file successfully imported	 <p><b>CSV File Import Status</b> 07303Y-SAM_FlexMap Exp_Stand_20131217_143042.csv: File imported successfully.</p>
Lot selected for import is not correct and has invalid probes	 <p><b>CSV File Import Status</b> 09203A-SA1_FlexMap - wrong probe name.csv: Batch wrong probe name LSA1 contains invalid probe list for Lot. Please associate the CSV with a different Lot and try again.</p>
CSV file contains duplicate sample names	 <p><b>CSV File Import Status</b> DSA_CAP_dupSamplenames.csv: Batch DSA_CAP_dupSamples contains duplicate sample names. Please correct and then re-import.</p>
CSV file contains invalid or inconsistent sample names	 <p><b>CSV File Import Status</b> E:\LMX-3000875 PosSeraED222.csv: Sample names are not consistent within the CSV file, check for discrepancies</p>
CSV file is missing batch name	 <p><b>CSV File Import Status</b> DD_MissingBatchName.csv: Batch Name is missing from file. Please correct and then re-import.</p>

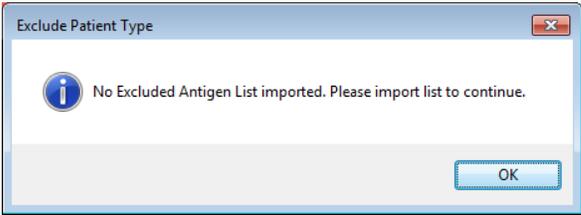
Error Condition	Message
CSV file contains Batch name is longer than 30 characters	 <p><b>CSV File Import Status</b>          3001075-LM2Q_LongBatchName.csv: Batch Name          LongBatchName12345678912345678910 is longer than 30 characters. Please          correct and then re-import.</p>
CSV file contains sample name(s) is longer than 30 char- acters	 <p><b>CSV File Import Status</b>          3001302-LMX_LongSampleName.csv: Batch 3001302-LMX_LongSampleName          contains one or more sample names longer than 30 characters. Please correct          and then re-import.</p>
Batch import can- celed	 <p><b>CSV File Import Status</b>          3001209-LM1_FlexMap Exp_FM STD_20131219_131835.csv: Import          cancelled.</p>
Lot could not be found in database	 <p><b>CSV Import:- Lot Import</b></p> <p>Session Name: 042314 KIR 2 FQC 04194H          Template Name: 04194H 03283C-KIR-2</p> <p>Lot not in database. Please select lot from list</p> <p>03203F 02283A-C3DSA1          03203F 02283A-SA1          0320v2 02283A-C3DSA1          04234B TSTC3d-SA1          04234B TSTMAM-SA1</p> <p>(OK) (Cancel)</p>
No samples are entered	 <p><b>Submit Batch to Luminex</b></p> <p> You must enter at least 1 SampleID for this Batch...</p> <p>OK</p>

Error Condition	Message
Missing fields	
Duplicate sample names	
Invalid date format	
Luminex connection not available	

Error Condition	Message
Invalid database name	
Successful database creation	
Detach in-use database	
Detach database Confirmation	
Detach database successful message	

Error Condition	Message
Database backup successful message	 <p>Server: (local)\EVOLUTION\Database: MATCHIT020414   Backup Successful</p>
Invalid login	 <p>Warning</p> <p>Invalid username or password</p> <p>OK</p>
Batch has already been imported into database.	 <p>CSV Import:- Lot Import</p> <p>This batch '3001209-LM1_FlexMap Exp_FM STD' has been previously imported. Please specify a new batch name.</p> <p>M012815A</p> <p>Cancel OK</p>
EDS file already exists in database	 <p>Existing Lot</p> <p>The lot referenced in the file 3001302 3001302 3001288-LMX.eds already exists. Overwrite?</p> <p>Yes No</p>

Error Condition	Message
EDS file(s) imported successfully.	
No paired C3d samples found within specified date range.	
Bead Failure	
CON Failure	
Batch date doesn't match date preference on import.	

Error Condition	Message
Excluded Antigen List has not been imported	

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Aucun revendeur, distributeur, agent ou employé de Immucor GTI Diagnostics, Inc. n'est autorisé à faire des modifications ou des additions au présent contrat. Pour toute utilisation du logiciel en Amérique du Nord et en Amérique Latine, le présent contrat sera régi par les lois du Commonwealth du Delaware. Pour tous les autres pays, le présent contrat sera régi par les lois du pays dans lequel le logiciel a été acheté. Clients: Si vous avez des questions sur le présent contrat ou sur les politiques d'utilisation des logiciels Immucor GTI Diagnostics, Inc. , écrivez à: Inside Sales and Service, Immucor GTI Diagnostics, Inc. ,20925 Crossroads Circle, Waukesha, WI 53186, USA.

## **CONVENIO PARA USO DE SOFTWARE DE IMMUCOR GTI DIAGNOSTICS, INC.**

SI USTED NO ESTÁ DE ACUERDO CON ESTOS TÉRMINOS Y CONDICIONES, NO INSTALE EL SOFTWARE Y DEVUELVA ESTE PAQUETE COMPLETO DENTRO DE LOS 30 DÍAS DESPUÉS DE LA VENTA, JUNTO CON SU NOTA, PARA EL REEMBOLSO TOTAL DE SU DINERO.

### **1. USO**

Usted (persona física, o moral, laboratorio, o institucion) podrá usar el MATCH IT!, Antibody Analysis Software de Immucor GTI Diagnostics, Inc. (el "Software"), en la cantidad establecida, siempre que reúna las condiciones que siguen. Además, usted podrá hacer una (1) copia de archivar del Software.

Para Modernizaciones y Sustitutos Mejores:

Si se trata de un Software de modernización o sustituto mejor, se le autoriza para que use el Software sólo en caso de que sea usuario autorizado de un producto de aprobación según lo determinado por Immucor GTI Diagnostics, Inc. y siempre que usted (i) o suprima el producto de aprobación o instale el producto nuevo en la misma computadora o red, tal como el producto de aprobación, y (ii) no transfiera el producto de aprobación a ninguna otra persona.

### **2. RESTRICCIONES**

Salvo lo que se estipule expresamente en la Cláusula 1, usted no podrá alterar, fusionar, modificar o adaptar el Software de ninguna manera, incluso la ingeniería inversa, el desensamblaje o la descompilación. Usted no podrá vender, distribuir, prestar, arrendar, alquilar, otorgar licencia o transferir de manera distinta el Software o cualquier copia del mismo; excepto que sí podrá transferir el Software de manera definitiva (incluso todas las versiones anteriores), a reserva de que transfiera el Convenio para Uso de Software y toda la documentación y soportes magnéticos, y no retenga copia alguna. Si el

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Software es un software de demostración y evaluación ("D y E"), no podrá transferir el Software con propósito comercial. En caso que adquiriera el Software precargado en computadora como parte de su compra de la computadora ("Software del Fabricante"), entonces no podrá transferir ese Software del Fabricante por un valor aparte del de la computadora.

Si está haciendo uso del Software en cualquier país de la Comunidad Europea, la prohibición de alterar, fusionar, modificar o adaptar el Software no afecta a sus derechos bajo ninguna legislación que aplique las Directrices del Consejo de la C.E. sobre la Protección Legal de Programas Informáticos. Si busca información de interfase en los términos del Artículo 6.1.b de esas Directrices, debiera inicialmente consultar Immucor GTI Diagnostics, Inc., 20925 Crossroads Circle, Waukesha, WI 53186, USA.

### **3. DERECHOS DE PROPIEDAD INTELECTUAL**

Immucor GTI Diagnostics, Inc. o sus proveedores son titulares de todos los derechos de propiedad intelectual del Software y de la documentación del usuario, y están protegidos por leyes sobre propiedad intelectual vigentes (incluso por leyes sobre patentes, marcas registradas y derechos de autor), así como por disposiciones de tratados internacionales. Immucor GTI Diagnostics, Inc. se reserva todos los derechos que no se hayan cedido expresamente.

### **4. GARANTÍA LIMITADA**

Durante noventa (90) días a partir de la fecha de su compra, Immucor GTI Diagnostics, Inc. le garantiza que (i) el Software se ajusta sólidamente a la documentación aplicable del usuario y (ii) los soportes magnéticos sobre los que está distribuido el Software y la documentación del usuario (si la hay) son libres de defectos en materiales y mano de obra. A su opción, Immucor GTI Diagnostics, Inc. le hará la devolución del importe que usted haya pagado por el Software o le proporcionará los artículos correctos, sin costo, siempre que el o los artículos defectuosos sean retornados a Immucor GTI Diagnostics, Inc. dentro de los noventa (90) días después de la fecha de compra. Cualquier maltrato o modificación no autorizada del Software anulará esta garantía limitada.

Como excepción a lo estipulado en la presente, Immucor GTI Diagnostics, Inc. no hace garantía, declaración de hecho o promesa, ya sea expresa o tácita, reglamentaria o de otro carácter, con respecto al Software, documentación del usuario o apoyo técnico inherente, incluso respecto a su calidad, funcionamiento, comerciabilidad o idoneidad para un propósito especial.

La garantía y recursos estipulados en la presente cláusula son exclusivos y en sustitución de todos los demás, verbales o escritos, expresos o tácitos. Esta garantía le otorga derechos jurídicos específicos, y quizá usted también disponga de otros derechos que varían de una jurisdicción a otra.

### **5. LIMITACIÓN DE RESPONSABILIDAD CIVIL**

Toda vez que el software es inherentemente complejo y no pueda ser libre de errores por entero, es responsabilidad de usted verificar su trabajo y hacer el copiado preventivo. En ningún caso, Immucor GTI Diagnostics, Inc. o cualquiera de sus licenciantes será responsable por daños y perjuicios indirectos, especiales, incidentales, extracontractuales, económicos, de cobertura o consecuentes derivados del uso o la inhabilidad de uso de productos y servicios de Immucor GTI Diagnostics, Inc. (o de cualquiera de sus licenciantes), entre los cuales figuran los

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Immucor GTI Diagnostics, Inc. será superior al monto desembolsado por usted en la compra del Software, del cual derivara aquella reclamación. Esta limitación sobre daños pecuniarios no será aplicable a reclamaciones relativas a la pérdida de la vida o la lesión corporal que surja de productos que se les dé tratamiento de bienes de consumo conforme a la ley aplicable. Algunos estados, provincias y demás jurisdicciones no permiten la exclusión o limitación de garantías implícitas o de restricción de responsabilidad civil por daños y perjuicios incidentales o consecuentes, de tal manera que la exclusión o limitación de más arriba quizá no le sea a usted pertinente. Sin embargo, en las jurisdicciones competentes, Immucor GTI Diagnostics, Inc. hace valer sus límites de responsabilidad con arreglo a las estipulaciones de este Convenio, hasta el alcance legal permisible.

## **6. DERECHOS RESTRINGIDOS DEL GOBIERNO DE LOS EE.UU.**

El Software y/o la documentación del usuario se proporcionan con DERECHOS RESTRINGIDOS Y LIMITADOS. El uso, reproducción o divulgación por parte del Gobierno de los EE.UU. se sujeta a restricciones como se consagra en la FAR 53.027- 14 (Junio de 1987). Alterna con [f](g)(3) (Junio de 1987), FAR 53.027-19 (Junio de 1987) o DFARS 53.027-7013 (c)(^)(ii) (Junio de 1988), según proceda. La contratista/fabricante es Immucor GTI Diagnostics, Inc. 20925 Crossroads Circle, Waukesha, WI 53186 EE.UU.. En caso que el Gobierno procure obtener el Software de acuerdo con prácticas comerciales ordinarias, este Convenio para Uso de Software, en lugar de las cláusulas reglamentarias anotadas arriba, normará las condiciones de la licencia del Gobierno.

## **7. CONDICIÓN GENERAL**

Ningún intermediario, distribuidor, agente o empleado de Immucor GTI Diagnostics, Inc. está autorizado para hacer modificación o adición alguna a este Convenio. Para efectos del uso del Software en América del Norte y América Latina, este Convenio se regirá por las leyes del Estado de Delaware. Para todos los demás países, este Convenio se regirá por las leyes del país en el que fuera adquirido el Software. Para clientes: Si llegaran a tener alguna pregunta respecto a este Convenio o a las normas del uso de software de Immucor GTI Diagnostics, Inc., escriban a Servicio y Ventas, Immucor GTI Diagnostics, Inc. , 20925 Crossroads Circle, Waukesha, WI 53186.