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User Manual

HLA FUSION™ SOFTWARE

Version 4.0

Catalog #: FUSPGR

IVD

ONE LAMBDA
A Thermo Fisher Scientific Brand

ThermoFisher SCIENTIFIC

All of One Lambda software products are designed to assist personnel experienced in HLA analysis by suggesting typing results. However, any clinical or diagnostic results must be carefully reviewed by a person qualified in HLA typing to assure correctness. This software may be used to aid in suggesting results, but should not be used as the sole method for determining reportable results. This software is meant as a laboratory aid, not as a source of definitive results. The software design does not mitigate hazards associated with the software. The laboratory director or technologist trained in histocompatibility testing is required to review all data to detect any problems with the software. Please note that this document was prepared in advance of the HLA Fusion software release. Therefore, you may notice slight differences in the content of the actual application screens.

IVD For In Vitro Diagnostic Use.

CE

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A Thermo Fisher Scientific Brand

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Introduction

What is HLA Fusion™ Software?

HLA Fusion Software is a companion to One Lambda's molecular typing and antibody screening products. This software runs in both stand-alone (on a single computer) and network environments.

The features of this software allow you to do the following:

- Import raw data from the LABScan 100 flow analyzer
- Manually enter reaction patterns for Micro SSP and LABScan 3D, FlowPRA, LAT and LCT products
- Read ELISA results for LAT products
- Analyze the raw data and review the results in graphical form
- Adjust cut-off values to clarify the results
- Easily update product information, (i.e., new product and lot information)
- Search for specific data and create standard or custom reports

Note: Make sure you have downloaded the most up to date Nomenclature and/or Serology Equivalent files before you import catalogs or attempt to analyze sessions/samples.

Also, please make sure your collation of SQL Server matches the collation of client instances, (a *collation* encodes the rules governing the proper use of characters for a language or an alphabet). If you are not certain, please verify with your system/database administrator.

Product Documentation and Update Files

*The HLA Fusion help contains the most current HLA Fusion information and procedures. It is accessible from within the Fusion software application by pressing the **F1** key or by selecting **Help : HLA Fusion Help**. The most recent copy of the HLA Fusion help file can also be downloaded from the OLI download website. Simply download the latest help file and copy it into your local Fusion installation help folder, replacing the existing file ending in extension .CHM.*

While this document, the HLA Fusion User Manual, is kept as current as possible, it must be delivered well in advance of the software in order to allow for translations.

Generally, product update information, such as new features and issue resolution is located in the *HLA Fusion Release Notes*. If a software release is minor and the release notes are not updated, a README file is provided with a list of changes to the software and pertinent information that is not yet included in the user's manual.

In addition, you can always access the most current product update information from the **Help > Product Update Notes** menu option within the HLA Fusion Software application, or from the OLI download site.

Program Updates

Note: For best results, always make sure you are using the latest version of HLA Fusion™ Software.

HLA Fusion will automatically (if configured) detect if there is a software update/patch available and inform you of the availability. You may also obtain updates of HLA Fusion by request. Please contact your One Lambda, Inc. representative for a copy of the software, or see the Technical Support section below for more contact information. Product information updates, (catalog files, etc.) for HLA Fusion are available through your One Lambda Inc. representative, or from the One Lambda website:

http://download.onelambda.com

Limitations of the Program

All One Lambda software products are designed to assist personnel experienced in HLA analysis by suggesting typing and antibody screening results. However, results must be carefully reviewed by a person qualified in HLA typing or antibody screening to assure correctness. This software may be used to aid in suggesting results, but should not be used as the sole method for determining reportable results. This software is meant as a laboratory aid, not as a source of definitive results.

For the reliability of patient information stored in the database, users must ensure that the identifier for each patient is unique and that each sample identifier is unique. The storage capacity of HLA Fusion is limited by your version of Microsoft SQL Server. Please see the Fusion Database Utility Users Guide, or the Microsoft website, (www.microsoft.com) for more information about the storage capacity of the various versions of SQL Server.

HLA Fusion assumes that data for each required input is in standard format that has not been modified. Raw data files must be in a Comma Separated Values (CSV) file format and must follow these guidelines:

- The data file is a CSV generated by LABScan 100, using software versions 2.3 or xPONENT 3.1 or xPONENT 4.2.
- All HD products must be acquired on software version 2.3, or xPONENT 3.1 or xPONENT 4.2.
- The data file name,(also known as a Session ID) must be 40 characters or less in length and include the .csv file extension.
- The data is generated based on original, unmodified templates provided by One Lambda, Inc.
- The user is responsible for final assignments and must review all suggested results.

Technical Support

For technical support or to report software problems, contact your One Lambda representative. From the United States, call 800-822-8824, or in the Greater Los Angeles Area, call 818-702-0042. Contact us by e-mail at: techsupport@onelambda.com

For system requirements, see the *HLA Fusion Software Installation Guide*.

Scope of this Manual

This manual provides information on how to import raw data, make changes in cut-off values and other configuration and control adjustments as necessary for analysis, as well as how to track and report analysis results. It is very important to recognize that the QC, (Quality Control) data used with this program and the defaults set in this program are based on One Lambda's experience with the product in a tightly-controlled research and development environment. Thus, a laboratory performing HLA typing or antibody screening in another environment may need to reset cut-off values to meet specific laboratory requirements.

From the Main Menu of HLA Fusion, you can access the three major components of the program:

- Analyze Data
- Reports
- Manage Records
- Manage Samples

In addition, you may also access the following features:

- Patient Information
- Utilities
- Help
- Exit

This manual helps you start using One Lambda's HLA Fusion. It includes an overview of the system and then takes you into the process of analyzing data.

See the *HLA Fusion Software Installation Guide* for installation instructions.

Navigation

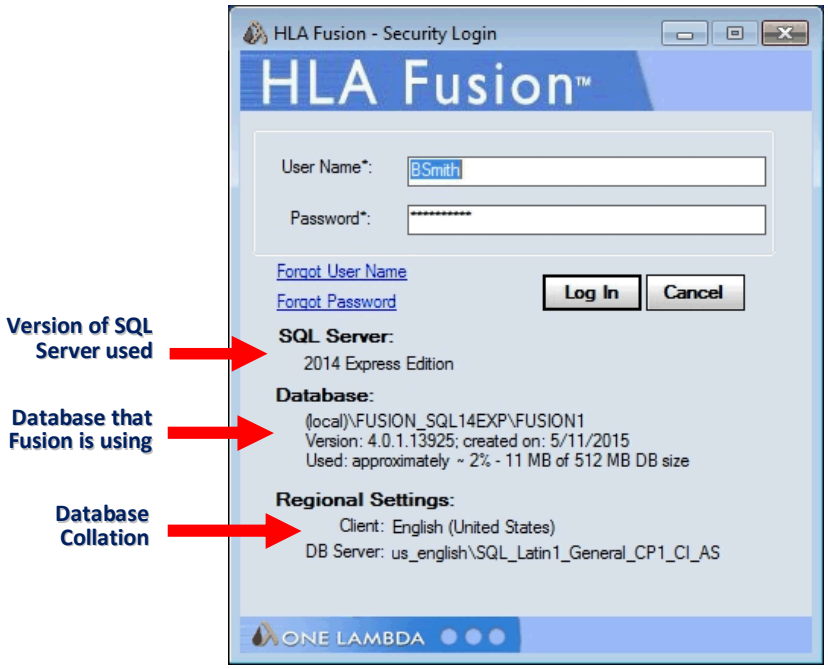
This section describes the various ways to access the HLA Fusion software menus and functions, as well as how to use the Navigator tool to access and move between sessions and samples.

Logging on to Fusion

1. Double-click the HLA Fusion Icon on your computer desktop. You can also open the program from the Windows menu: **Start > Programs > One Lambda > HLA Fusion.**

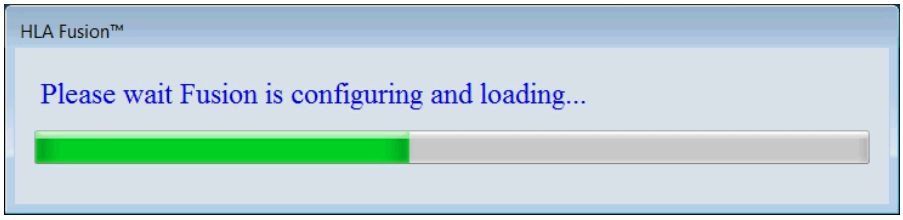
   The Security Login dialog box is displayed.

The Fusion Security Login Screen



Enter your HLA Fusion **User Name** and **Password**.

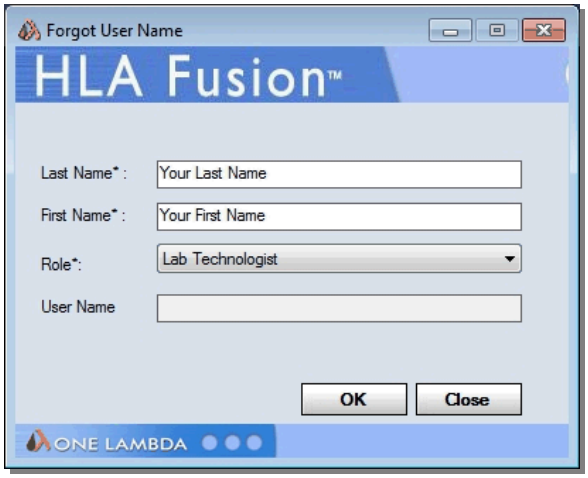
Click the **Log In** Log In button to open the program. A message asks you to wait.



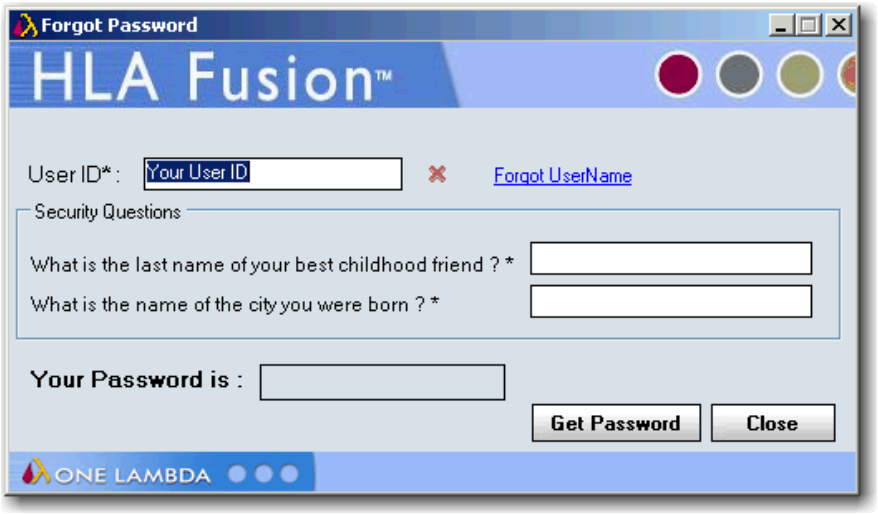
Note: The **Database** field displays the database to which you are currently connected.

Retrieving a Forgotten User Name or Password

- If you forget your HLA Fusion User Name, click the **Forgot User Name** link, enter your first and last name and select your lab role, (supervisor or technician). The system displays the user name matching the data you provide:



- If you forget your HLA Fusion password, click the **Forgot Password** link and answer the two security questions you were asked when you set up your user profile.
- The password is displayed when the questions are answered correctly.

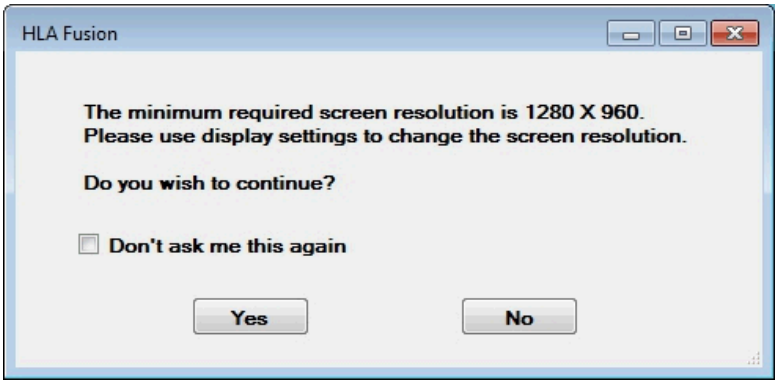


Key System Settings

Screen Resolution

HLA Fusion software requires a screen resolution of **1280 x 960**. The software displays a message if your current resolution is less than the expected settings.

Note: You can choose to suppress this message through the **Edit** link on the **General Configurations** section of the Home page.



Minimum Screen Resolution

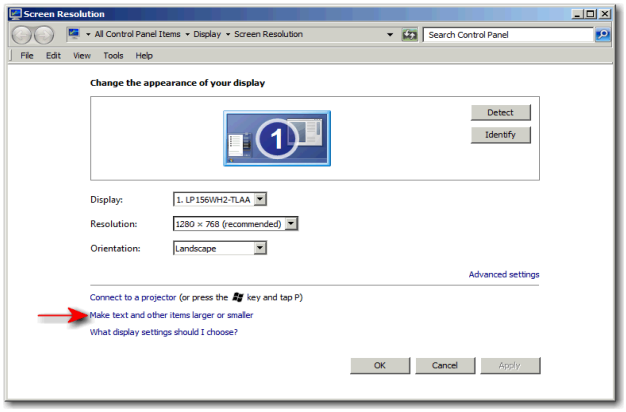
You can select **Yes** to have the continue to start the application. Or, you can select **No** to exit the program.

In addition, if your computer is running Microsoft® Windows 7® or Windows 8®, the text display size setting must be set to **Smaller - 100% (default)**. Take these steps if you need to adjust this setting:

1. Right-click on the computer desktop. Select the **Screen Resolution** option.

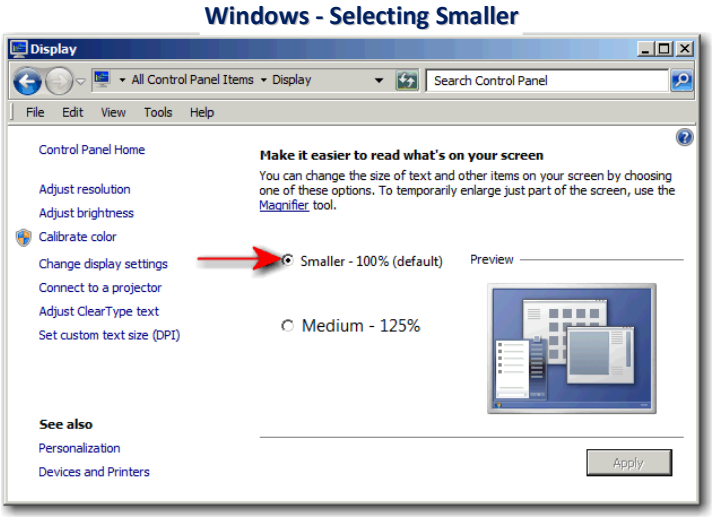
   The **Screen Resolution** window displays.

Windows 7 Screen Resolution window



Select the **Make text and other items larger or smaller,** (*see previous*).

2. Select Smaller sized text.



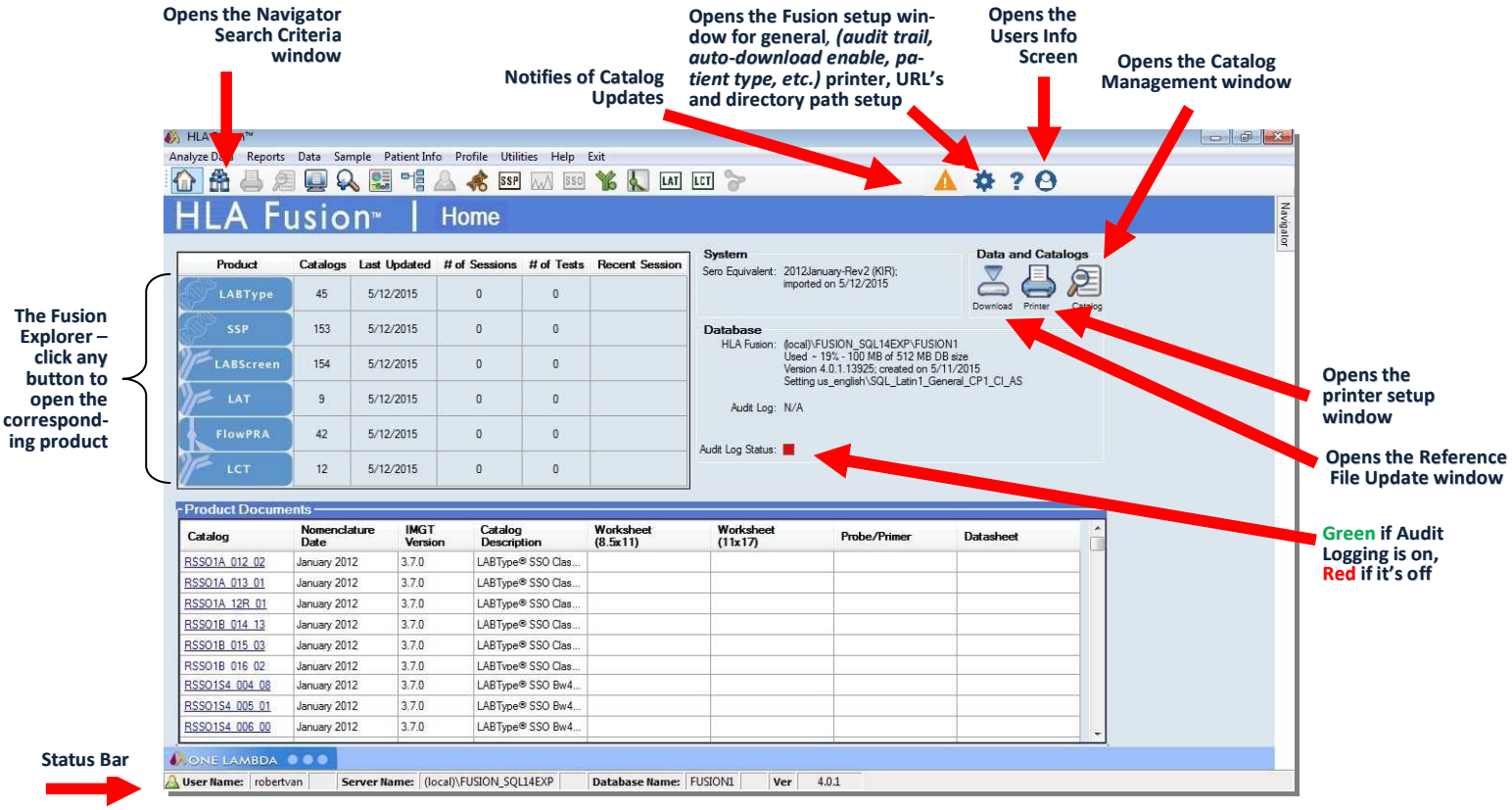
File Permissions

All HLA Fusion users must have read and write permissions to the following directories and files:

- `C:\Program Files (x86)\One Lamda\`
- `OneLambda.Fusion.Interface.exe.config`
- `ReportMap.xml`
- `C:\OLI Fusion\`(and all the sub directories and the files in these directories)

User Interface

Fusion Home Pages



This user interface option gives you access to the individual product home pages, import data and view analysis windows. It also allows you to view or access system or product data, reference file downloads and configuration settings.

This interface is what you will see when you first log in to HLA Fusion if the default configuration is set.

Note: If the current page does not show updated information upon modifications or downloads, go back to the main Home page, then return to the product home page to see the changes.

To display the home page for one of the products listed in the bottom left area of the page, click the button or menu option. For **LABScreen**:

- From the main Fusion home page, click the LABScreen button, **or** click the LABScreen button on the HLA Fusion toolbar at the top of the screen.

OR,

- Select **Analyze Data > LABScreen** from the Fusion Menu Bar.

Notice how the screen changes to fit the selected One Lambda product?

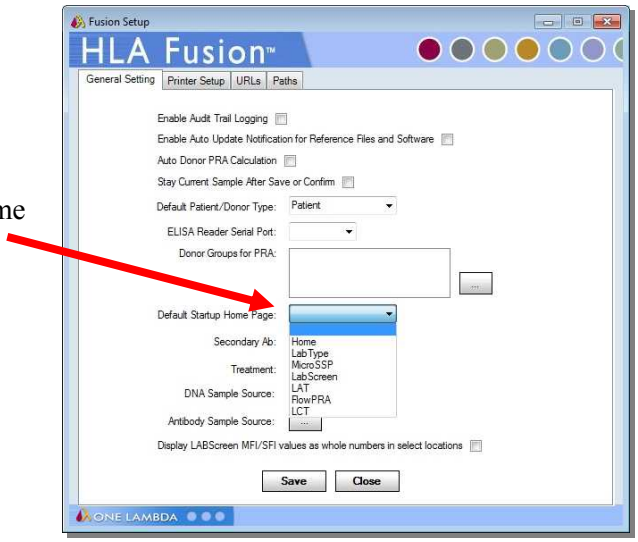
Note: Migrated and upgraded databases also use the same interface.

If you want to make one of the product home pages the default home page so that each time you login to HLA Fusion, that particular home page is displayed, do the following:

1. On the top second row of the screen, click the  button.

OR,

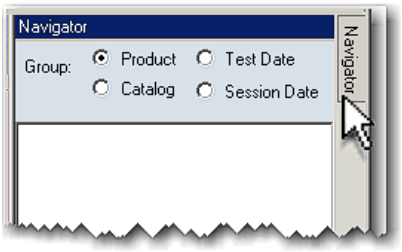
2. Click the word Utilities on the Fusion Taskbar.
3. On the **General Settings** tab, click the drop-down arrow and select from the drop-down list in the **Default Home Page** field to select your default home page.
4. Click **Save** and then **Close**.



Launching Navigator

If the Navigator tab is not already displayed on the right of the application window, click the **Show Navigator** toolbar button to activate the Navigator function,

Or,

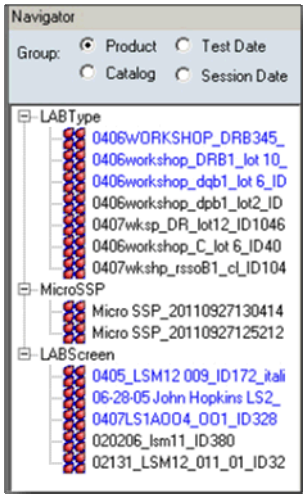


Move your cursor over the **Navigator** tab on the right border of the application window to slide the Navigator into view.

Navigator Tree

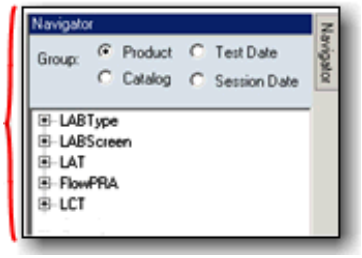
Using the **Navigator** tree, you can easily move between analysis products, sessions, samples and test dates.

The Fusion Navigator Tree



Note:	Double-click on a session, or click the + sign to the left of the **Catalog**, **Date** or **Product** module to display the list of sessions.

HLA Fusion Products



Sessions in the Navigator

Click a sample name to display it in the analysis window.

Results Grouping

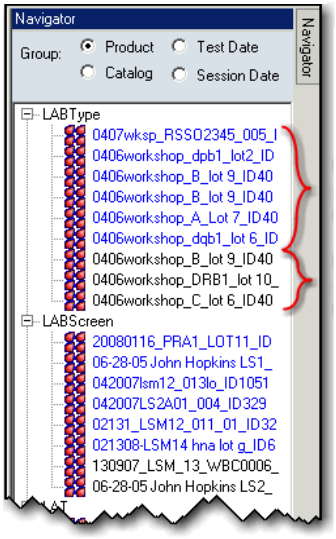
The sessions and samples displayed though the Navigator tool can be sorted by various criteria:

- **Product type**
- **Session Date**
- **Catalog**
- **Test Date**

The default is to group by **Product**. See the next few sections for details about the various display options.

Group by Product

Reviewed/Unreviewed Sessions



Sessions not yet analyzed are BLUE.

Analyzed sessions are BLACK.

The Navigator displays imported sessions for each product type, based on the date range and other criteria set in the **Find** option. If you are already in the analysis mode for a certain product, just the sessions that fit within the date range for that product will display.

Click the + sign next to the product type you are interested in to display its sessions.

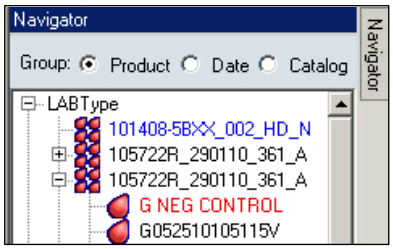
- The sessions displayed in **blue** are the ones that have not yet been analyzed. Once you analyze a session, its color on the Navigator list changes to **black**.

- Click a session name to display the samples within that session. For LABType and LABScreen, the system also performs a batch analysis and displays the results in the Session Summary.

  If a session sample is listed in **Red**, it means the sample failed in the Analysis.

- Click a Sample Name to display it in an analysis window.

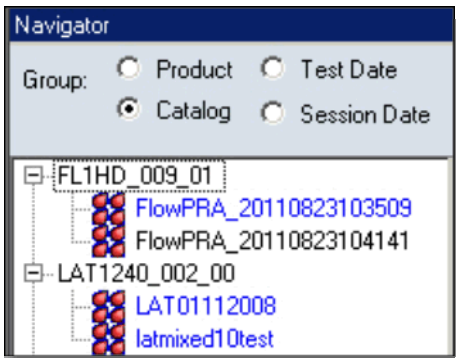
Sample Failed in Batch Analysis



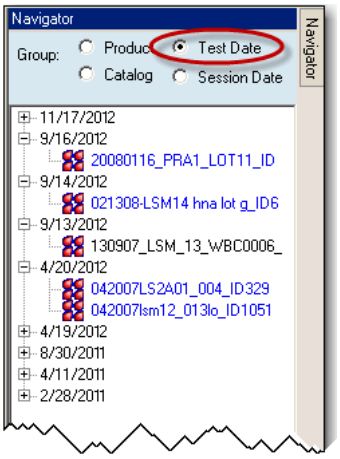
Group by Catalog

When you select the **Catalog** group option in the Navigator, sessions are displayed in alphanumeric order by **Catalog Name**.

Group by Catalog



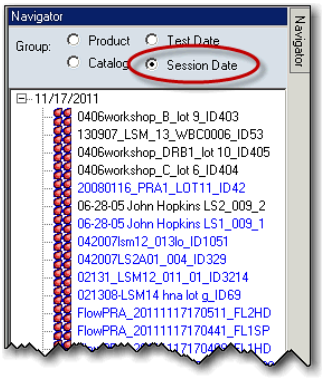
Group by Test Date



When you select the **Test Date** group option, sessions are displayed in chronological order by their test dates.

Otherwise, the use of this tool is the same as described previously in Group by Product.

Group by Session Date

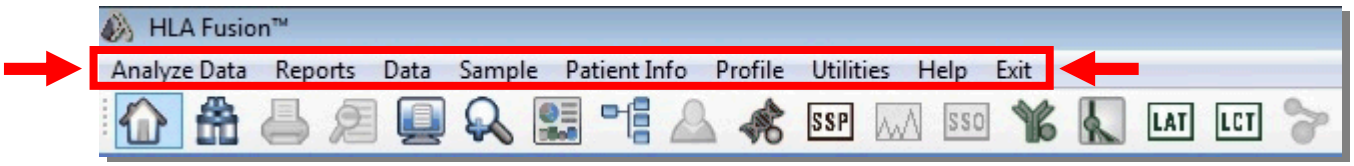


When you select the **Session Date** option, sessions are displayed in order of their creation dates.

Otherwise, the use of this tool is the same as described above in Group by Product

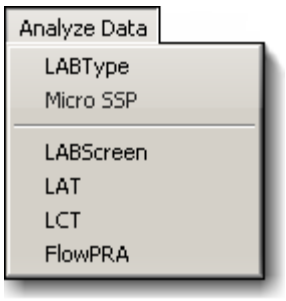
Accessing HLA Fusion™ Software Functions

Main Menu Options



Options on the Fusion Menu Bar

You can access HLA Fusion functionality at any time from the toolbar's Main Menu, which is displayed at the top of all HLA Fusion application windows. See the following sections for a list of the options available under each main menu item.



Menu Bar: Analyze Data

Analyze Data

Each option under this menu item is either a molecular or antibody product for which you can import CSV files, or manually enter reactions and analyze data. For details, see the individual product analysis sections in this user manual.

Reports

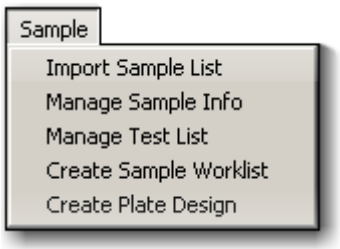
When you select this menu item, the **Reports Page** is displayed, allowing you to create reports of your analysis data.

Data

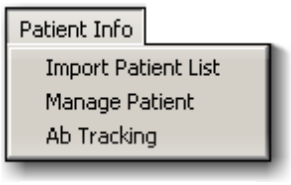
When you select this menu item, a **Data Window** is displayed that allows you to manage, (i.e., delete, archive, activate or move) sessions and samples, map session alleles to a new IMGT V3 nomenclature, and view/print log files of session data.

Sample

Options under this menu item pertain to importing, creating, managing, and exporting sample information. This is also the menu to use for managing Luminex test lists and for creating sample work lists and plate designs.



Menu Bar: Sample



Menu Bar: Patient Info

Patient Info

Options under this menu item pertain to importing patient/donor lists, managing individual patient/donor information and tracking patient antibody data.

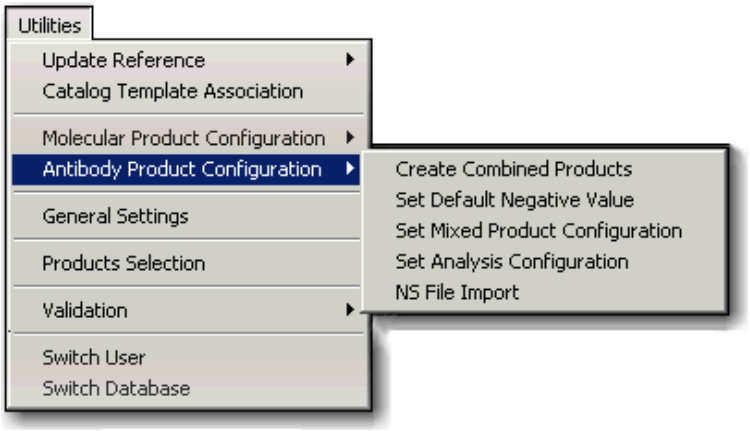
Profile

Menu Bar: Profile

There are options under this menu item for creating and managing your own user profile, lists of system users and privileges and lab information. There is also an option for switching between the home page options depending on your system and navigation preference.

Utilities

The options under this menu item pertain to importing catalog, code and serology files, configuring the molecular and antibody products you analyze, setting up your HLA Fusion system, and system validation.

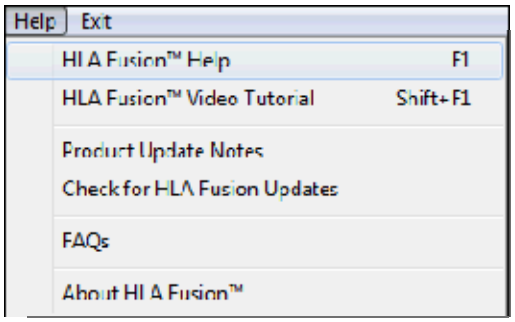


Menu Bar: Utilities

Help

This menu item allows you to access the following HLA Fusion Software information:

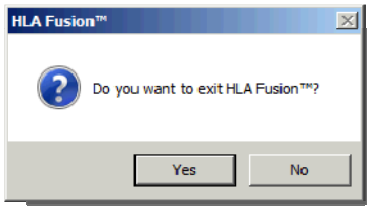
- Online help, which provides guidance in using HLA Fusion Software.
- Links to tutorial, “Show Me” videos.
- Notification of updates and a description of new features in the latest HLA Fusion software.



Menu Bar: Help

- Dynamically updated Frequently Asked Questions (FAQ's) about HLA Fusion software.
- The build and version number of the HLA Fusion Software application you are currently using.

Note: The online help can be accessed from anywhere within the HLA Fusion application when you press the F1 key on your keyboard. Occasionally, updates are made to the online help between releases of the HLA Fusion. To ensure you have the most current help file, check the OLI download site at:`download.onelambda.com/pub/tray_info/Windows/HLA_Fusion_Catalogs/Document/`



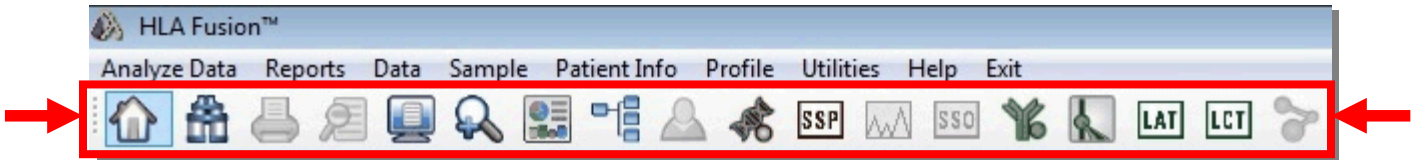
Exit Confirmation Message

Exit

When you select this menu item, a dialog box displays that allows you either to select **Yes** to exit and close the HLA Fusion application, or select **No** to keep the current session open.

Toolbar Buttons

HLA Fusion provides a toolbar, displayed just below the main menu bar options with access to commonly used functions.

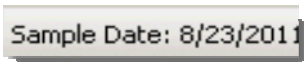


Fusion Toolbar buttons

- You can also hover your mouse over the buttons and a label will pop-up with the name of each button.
- Please note that some of these buttons are only available to use when you're on an Analysis Screen.

  The following table describes each toolbar button:

Button	Name
	Home
	Find
	Print
	Print Preview
	Print Screen
	Magnify
	Reports
	Show Navigator
	Patient
	Related Records
	Side by Side Comparison

Other Buttons and Controls	
 Product Data Analysis	
 Sample Navigation Tools *(Only visible during sample analysis).* The **<<Summary** link returns to the associated sample summary table.	
	Displays the date of the current sample in the analysis window.

Click the **Find**  button to open the HLA Fusion **Search Window** to look for records using various criteria.

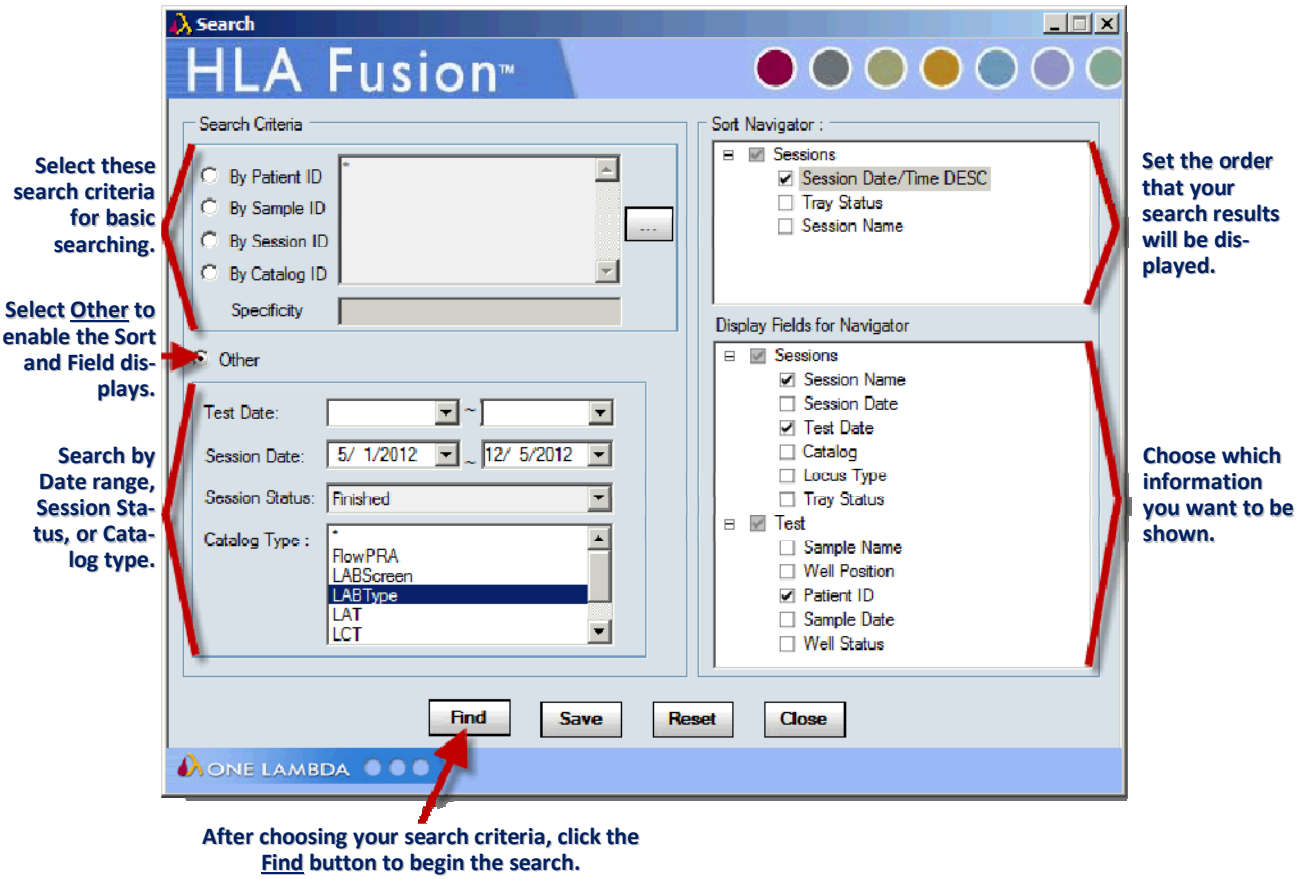
You can choose to search by **Patient ID**, **Sample ID**, **Session ID**, **Catalog ID,** (and specificity), or **Other**.

Other allows you to provide multiple search criteria including: **date range**, **session status**, and **catalog type**.

The **Find** dialog box also allows you to modify the Navigator Session sort and display criteria.

The **Side by Side Comparison** and **Related Records** buttons are visible only during sample analysis.

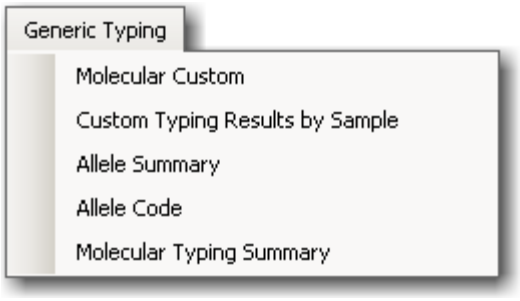
Fusion Search Screen



Note:	The date range set here, in the **Session Date** field, is used as the default date range throughout HLA Fusion, such as in the Navigator and Reports windows. Each time you change it, and click the **Find** button, the default changes for the rest of the application.

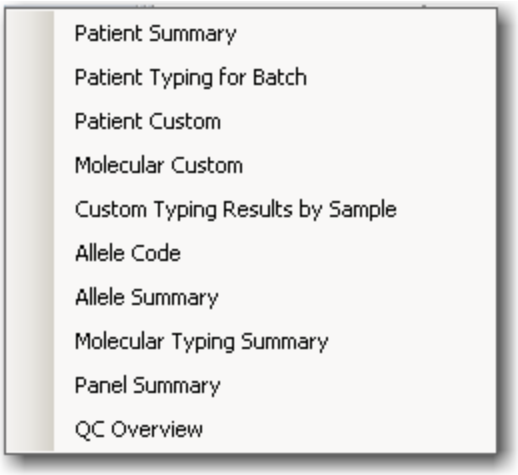
Print Report

From any **Analysis Screen**, you can click the **Print** button to display a list of the reports that you can print,(the reports listed are specific to the product you are currently analyzing, so what you see in the example here may be different). If you have set up a default printer, (configured through **Utilities > Printer Setup**) the selected report is automatically sent to the specified printer. Otherwise, a dialog box is displayed from which you can select a printer.



Example of Print Report Options

Preview Report



Example of Preview Report Options

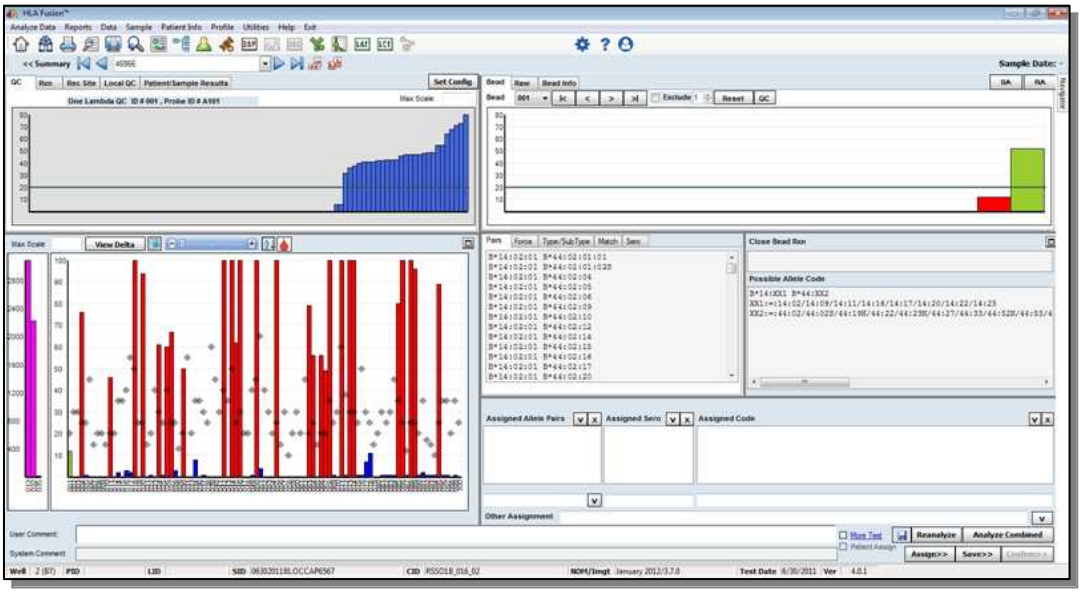
From any **Analysis Screen**, click the **Preview Report** button to display a list of reports you can check out before printing—reports listed are specific to the product you are currently analyzing. The reports are displayed in a preview window. Use the **Print** Print and **Export** Export buttons in the preview window to output the report in the selected format.

Click the **Close** button at the upper right of the screen to exit the preview window.

Print Screen

From any **Analysis Screen**, click the **Print Screen** button to open a new window containing a screen shot of the current analysis window. Click the **Print** button, (top, left corner) to send the screen shot directly to the printer.

To close this window, click the **Exit** button or the **Close** Close button.

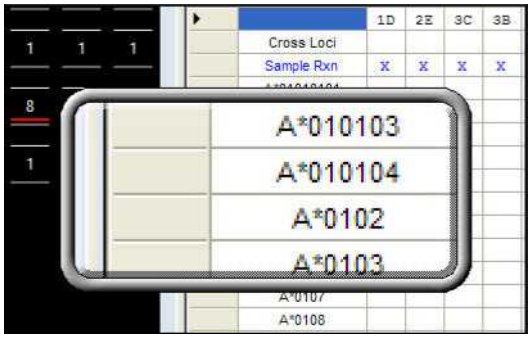


Example of Print Screen Results

Magnify

From any **Analysis Window**, click the **Magnify** button to activate the magnifying glass and enlarge any section of the window. Use your mouse to move the magnifier and use the arrow keys on your computer keyboard to increase or decrease the height and width of the magnified area.

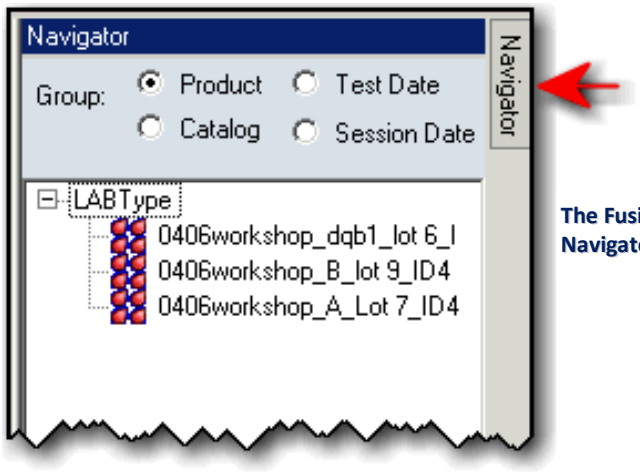
Click anywhere on the screen to deactivate the magnifying glass.



Magnify an Area

Show Navigator

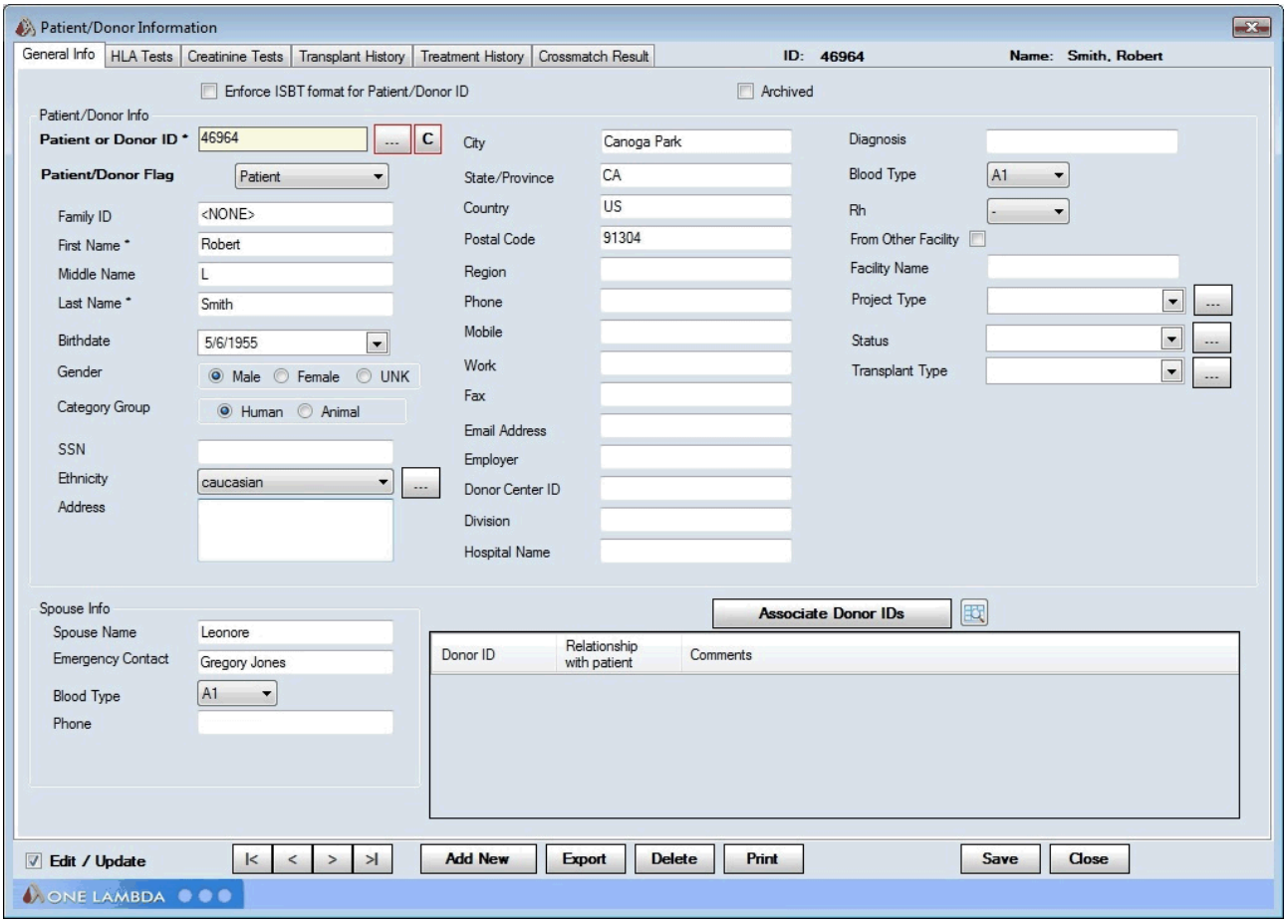
If the Fusion **Navigator**, (normally displayed on the right side of the application window) is not visible, click the **Show Navigator** button on the toolbar. Once the **Navigator** tab is displayed, move your cursor over it to slide the Navigator panel open.



The Fusion Navigator

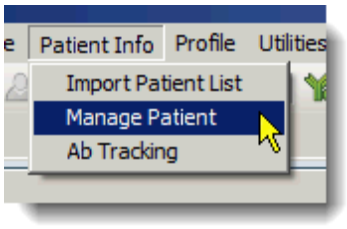
Patient/Donor Information

From any **Analysis Screen**, click the **Patient** button to display the **Patient/Donor Information Screen** where you can enter or edit information related to a patient or donor and associate it with the current sample.



Patient/Donor Information Screen

You can also open the Patient/Donor Information screen at any time by clicking **Patient Info** on the Fusion Menu Bar, followed by **Manage Patient**.



Related Records

A **Related Record** is a sample that is associated in some way with the current sample or patient.

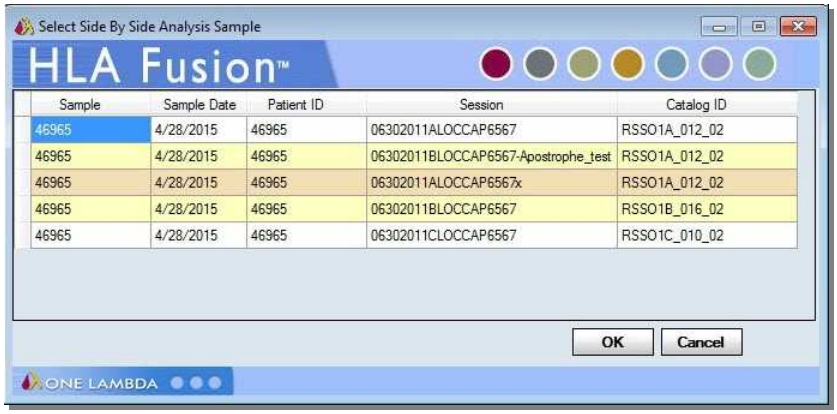
From any **Analysis Screen**, click the **Related Records** button to load all records related to the current sample into the drop-down list in the **Sample ID** field. Use the sample navigation arrows to display the analysis of each related record, one-by-one.

To exit from the Related Records mode and return to the previous analysis screen, click the **<<Summary** <<Summary link to the left of the **Sample ID** field at the top of the screen.

Note: This function can be also accessed by right-clicking a sample in the Fusion Navigator. Review the product-specific sections of this manual for more information about using this feature.

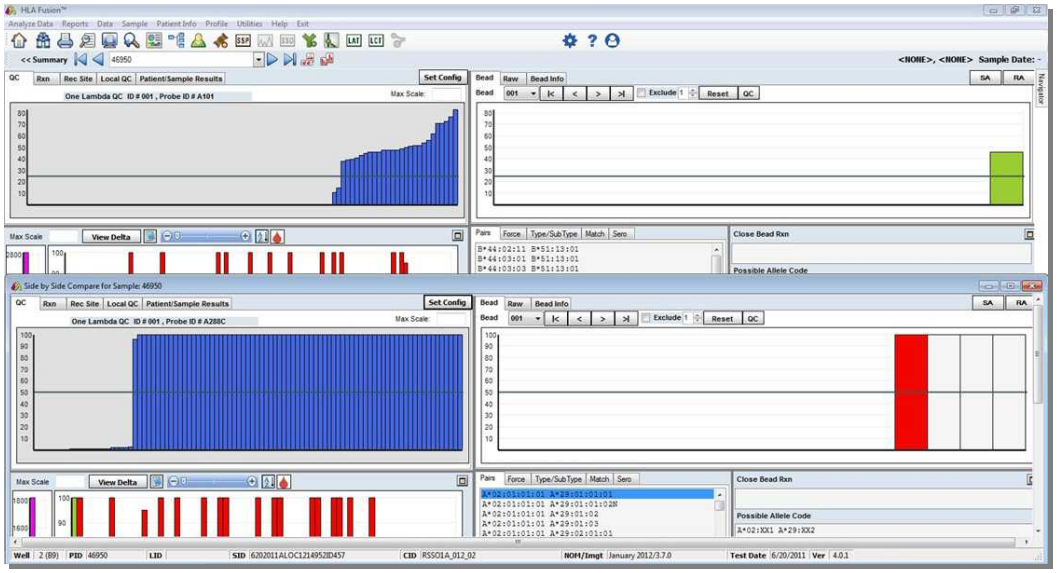
Side-by-Side Analysis

From any Analysis Screen click the **Side-by-Side Analysis** button on the Fusion toolbar to compare the current sample analysis, (with a **brown** background) with previous analysis sessions for the same Sample ID.



Begin Side-by-Side Analysis

- Select a previous sample analysis from the displayed list to compare to the current one. The two analysis windows are then displayed together for comparison.
- Each window can be resized and moved by dragging and dropping. Click again on the Side-by-Side Analysis button to cancel the comparison display.

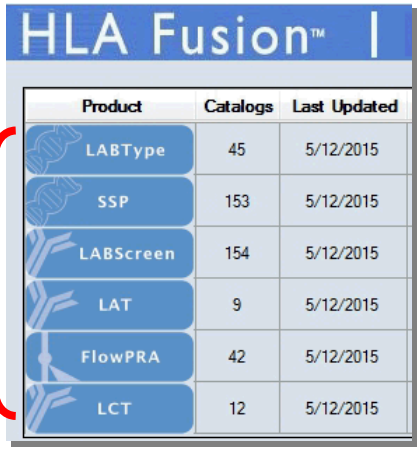


Side-by-Side Analysis View

Note: This function can also be accessed by right-clicking a sample in the Fusion Navigator.

Product Data Analysis

Product Group



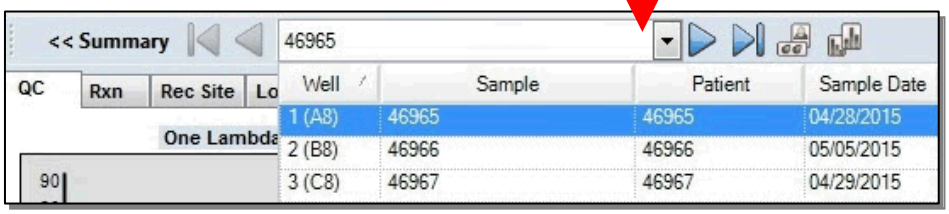
Click any of the **Product Data Analysis**  buttons on the Fusion toolbar to display that product's home page, import a session file, manually enter a session, or display and select from the Navigator List of previously imported sessions for that product.

- You can also click on any of the Fusion products located in the **Product Group** at the top upper left side of the Home screen to open a product's home page.

Sample Navigation

The **Sample Navigation** tools, (only accessible from an Analysis Screen) give you access to all the samples in the current session. You can select a different sample within the same session either by selecting from the drop-down list in the **Sample ID** field, or by clicking the forward/back arrow buttons next to the drop-down field.

The SampleID Drop-down



The Sample Navigator

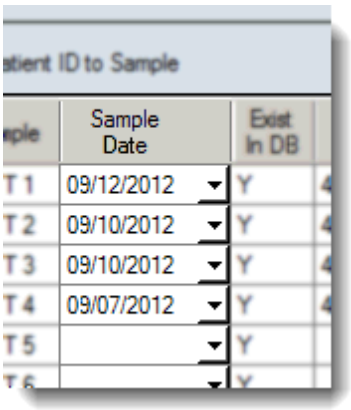
Clicking on the drop-down▼arrow displays all the samples within the current session, as shown below:

Well	Sample	Patient	Sample Date	Session	Catalog ID	Local ID	ImgtVer
2 (B1)	9027	042908		07-17-12 PP3914 BW4L6...	RSSO1S4_005_01		3.7.0
3 (C1)	9093			07-17-12 PP3914 BW4L6...	RSSO1S4_005_01		3.7.0
4 (D1)	9256			07-17-12 PP3914 BW4L6...	RSSO1S4_005_01		3.7.0
11 (C2)	E18149			07-17-12 PP3914 BW4L6...	RSSO1S4_005_01		3.7.0
14 (F2)	E21675			07-17-12 PP3914 BW4L6...	RSSO1S4_005_01		3.7.0
22 (F3)	KO			07-17-12 PP3914 BW4L6...	RSSO1S4_005_01		3.7.0
24 (H3)	PAST			07-17-12 PP3914 BW4L6...	RSSO1S4_005_01		3.7.0
25 (A4)	PORTER			07-17-12 PP3914 BW4L6...	RSSO1S4_005_01		3.7.0

Sample Drop-down

- Selecting a sample from this list in the Sample ID field makes that sample the active sample in the analysis window. Alternatively, you can use the forward ▶ or back ◀ arrow buttons to select different samples.
- Click this ⏮ button to go to the *first* sample. Click this ⏭ button to go to the *last* sample
- Clicking **<<Summary** takes you back to the session summary for the current sample.

Sample Date



Sample Date

For the sample currently being analyzed, the **Sample Date** field displays the date the sample was obtained.

The sample date can be set and auto-filled from the Session Import table.

LABType Analysis

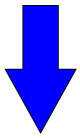
The HLA Fusion™ LABType® analysis module analyzes Luminex CSV output files for LABType products, including HD output files. Analysis results are based on catalog specifications, NMDP or Local codes and serology equivalent reference files. All of which can be downloaded and used with the Fusion software.

A few things should be completed or verified before you start an analysis session:

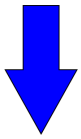
- Make sure you have the latest catalog files, as well as NMDP code, local code,(if used) or serology equivalent reference files before you analyze. You can download or update existing catalogs from the LABType Home Page.
- View and modify global product configuration settings prior to starting analysis. Global settings are displayed and be can be modified on the LABType Home Page, or through the Utilities menu. Global settings apply across all newly imported sessions.
- Save time importing CSV files by verifying that the default URL's and directory or folder paths are pointing to the locations where these files are commonly stored on your system or network. These settings can also be modified in the General Configurations section of the Fusion Explorer Home page.
- You can set HLA Fusion to remain on a sample that you've just saved or confirmed rather than automatically moving to the next sample by changing this setting in the General Configurations section of the Fusion Explorer Home page.

Note: Some of the above tasks require Supervisor User privileges. You may have to verify with your Supervisor that these tasks have been completed.

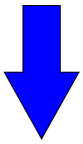
Overview of the LABType Analysis Process



After importing session(s), check the Summary Table for ***low*** Positive Control and ***low*** Bead Counts. Consider deleting those samples.



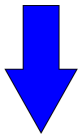
Check the lower left graph of the Analysis Screen for close reactions –just above or below the cut-off points. Also check the Control and Bead Analysis Tabs.



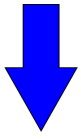
Use the Force tab to help review homozygous and rare allele results, (lower right quadrant).

Look at the reaction table to review allele reactivity patterns, (upper left quadrant).

Check the Close Reaction Box to further finalize assignments, (lower right quadrant).



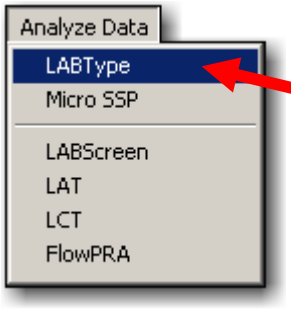
Make any necessary cut-off adjustments, (upper right or lower left quadrants).



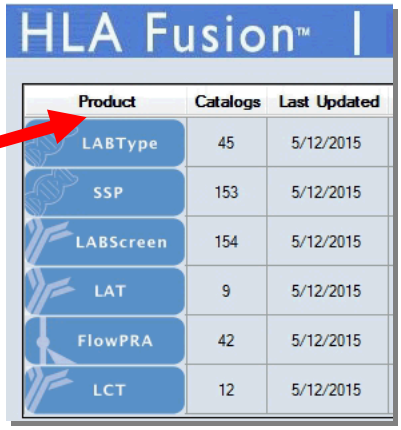
Make final allele pair, serology and/or coded assignments, (lower right quadrant).

Start LABType Analysis

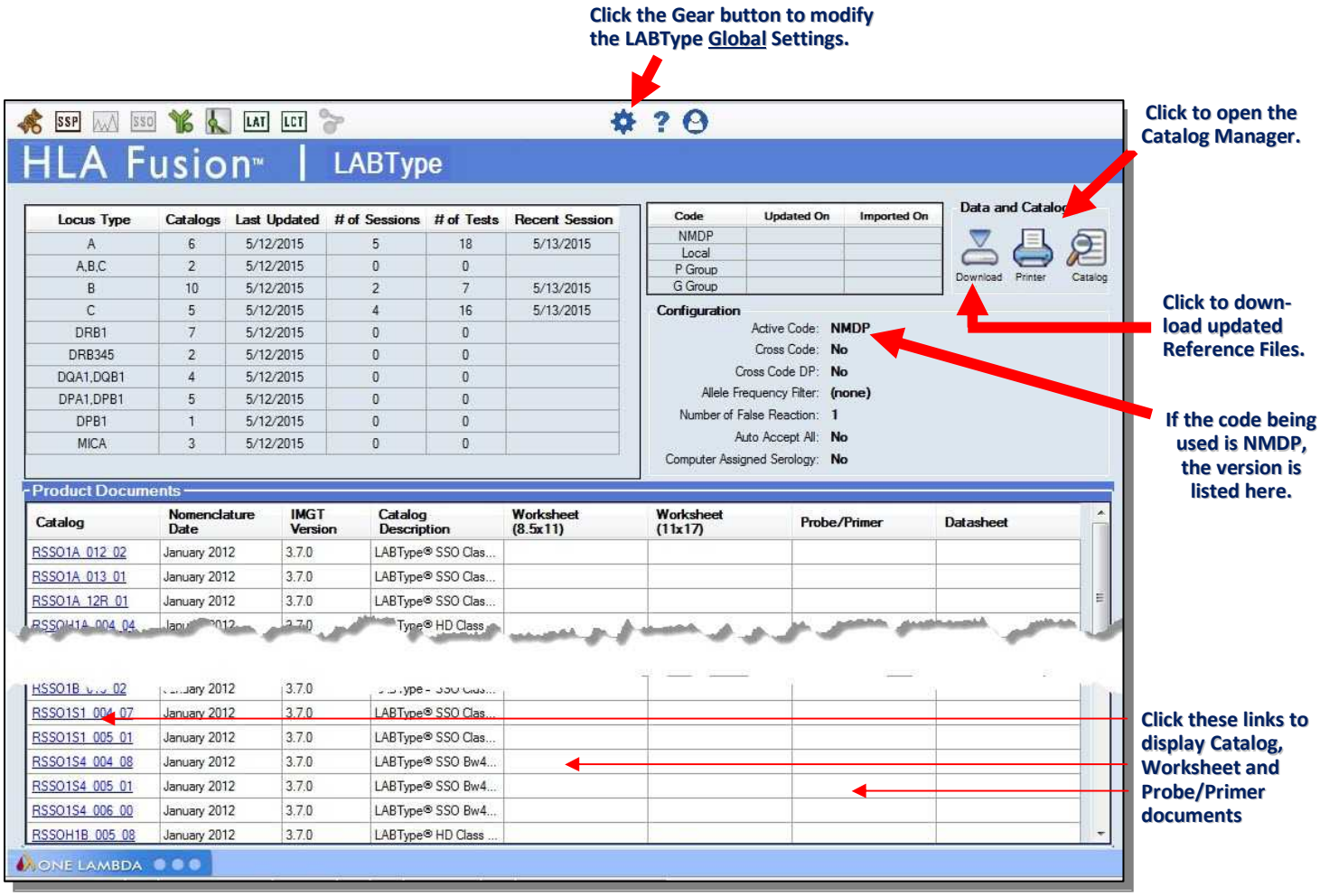
Importing LABType Session Data (Non HD)



- Click the **LABType** button on the Product Group Panel on the Home Screen, the **LABType** button on the Fusion toolbar, or click **Analyze Data** on the toolbar and select **LABType**.

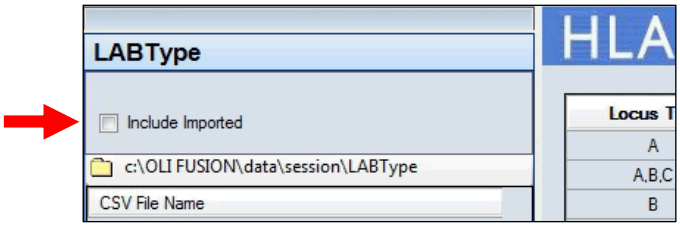


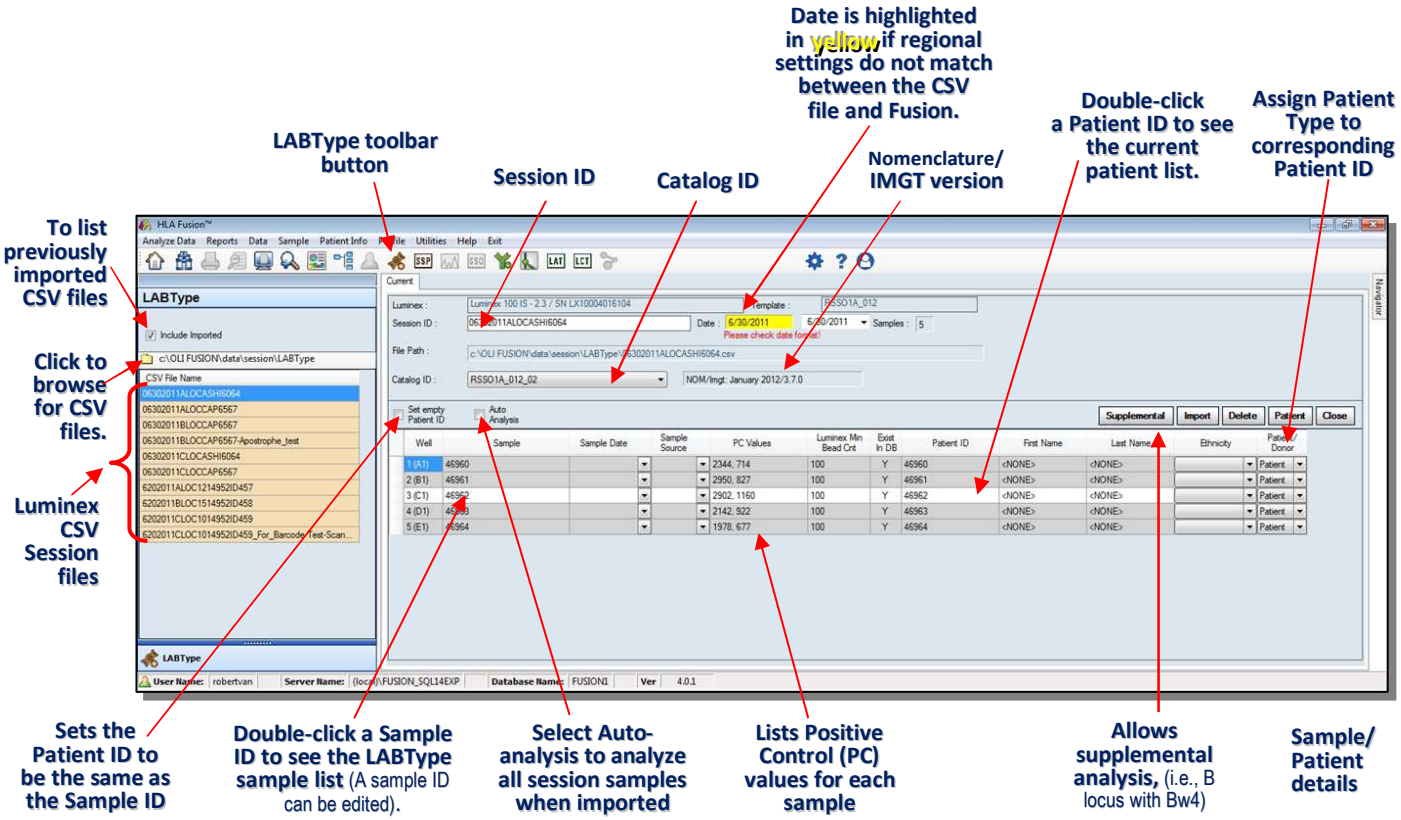
The LABType **Home Page** is now displayed:



Note: The Reference file Updates function does not work for NMDP or seroequivalent files.

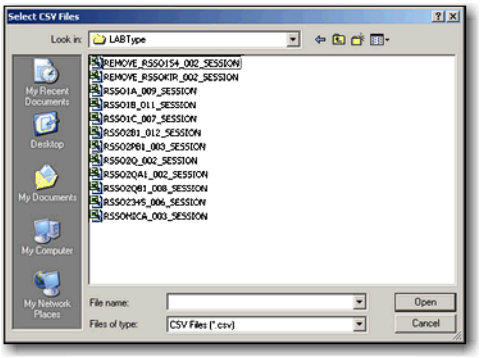
To open the **Session** screen, click the **"Include Imported"** checkbox on the upper left hand side of the LABType Home Page. The Session screen will then appear (below):





Note: Open worksheets and probe/primer sheets to verify the accuracy of revision numbers, (*these documents do not contain a revision number in their filename*).

2. Click the small **Folder** Icon and select a session(s) from the **Select CSV Files** screen.



Selecting/Importing CSV Files

Note: HLA Fusion converts Luminex-generated CSV file data, such as date and time, to the local regional code if a regional code is specified in the CSV file. (*A regional code cannot be specified for CSV files created with Luminex software version 2.2 or earlier.*) If the first date field is highlighted yellow, it indicates that Fusion detected a regional code mismatch. In this case, it is recommended that you use the drop-down selector in the second date field to choose the appropriate date, taking into consideration regional date format differences.

3. Select a file from the list of CSV files to import, or click the **Folder** icon above the list to browse to LABType CSV file(s) on your system/network. If samples in a session have a positive control value below the minimum setting, they are flagged so you can easily select and delete them from the session.

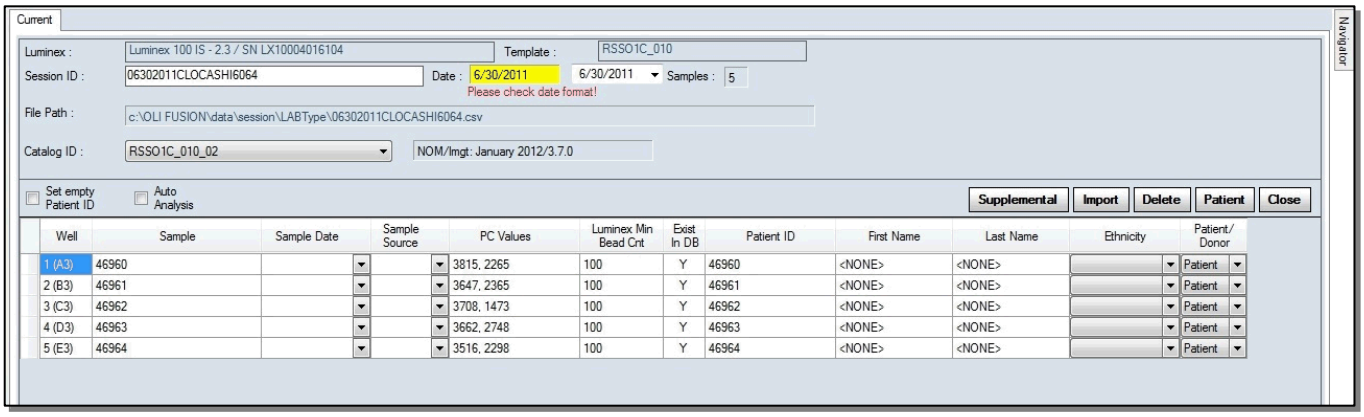
Note: You may see CSV files for products other than LABType, or other CSV files. This means that you must first click on a sub-folder for LABType, or that your LABType session files are not contained within the directory to which HLA Fusion is pointing.

4. HLA Fusion assigns a **Session ID**, (*the CSV filename*) automatically. Optionally, you can edit the Session ID field. The ID can be alphanumeric, (contain letters and numbers) and will be listed alphabetically with any other LABType session files in your database.

Session I.D. field

Note: A Session ID must be **unique** to the Fusion database. If the Session ID already exists, HLA Fusion prompts you to rename the session. It is also highly recommended that you do not use any special characters in this field since they may serve a specific purpose as field separators.

5. Click a CSV file to display its associated samples in the **Sample/Patient Details** table.

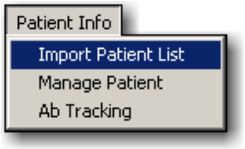


LABType Session - Patient/Sample Details table

Note: The **Supplemental** button can be used to add sessions that have already been analyzed, to the current one for a combined analysis, (e.g., B7 sessions with B locus sessions). This does not work for combinations of cross loci sessions, (such as A locus and B locus).

6. If a sample is already associated with a patient, the Patient ID and any existing or related patient information is displayed.

   To add patient information, do one of the following:



   - To add patient data which is already stored in the system, double-click in the Patient ID column of the Sample/Patient Details table, or
   - Click **Patient Info** on the Fusion Menu Bar and select **Import Patient List** to import the patient information file.
   - To manually add patient data, type data directly into the patient-related fields in the table.

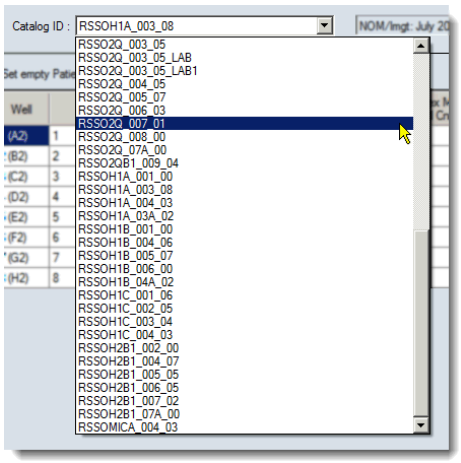
You can automatically assign the Sample ID to empty Patient ID fields by selecting the check box for ***Set empty Patient ID to Sample***.

7. Select a Catalog file. The catalog file selection method varies depending on the CSV file and the catalog files you may have previously imported for LABType.

Note: If you need to import more catalogs, click the **[Download]** link on the LABtype Home Page. The Catalog drop-down list may not be immediately updated if you downloaded the catalogs during the current import session. You may need to click the **Home** button and then click the **LABType** button again to return to the import process.

   - If the CSV file specifies a template name, (only applies to CSV files from Luminex 2.2 and later) and one of the available catalog files is associated with that template, then all new sessions with the same template will auto-select that catalog.

Catalog Listing



As shown here, you can also select a different catalog file from the one that Fusion has selected by using the drop-down list in the Catalog ID field and selecting any catalog file listed.

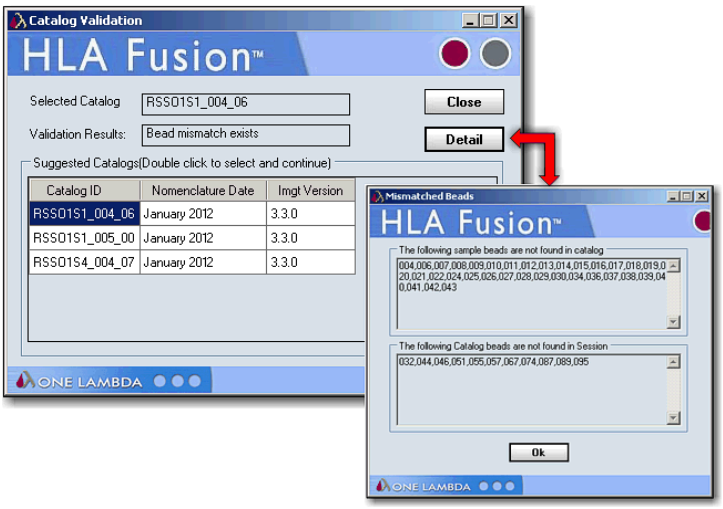
If there is no template match, the system then considers the closest bead match between the session and all available catalog files. If only one catalog file is a close match, it is automatically selected and you can check to see if there are any samples that have been flagged as having a low Positive Control, (PC) or low bead.

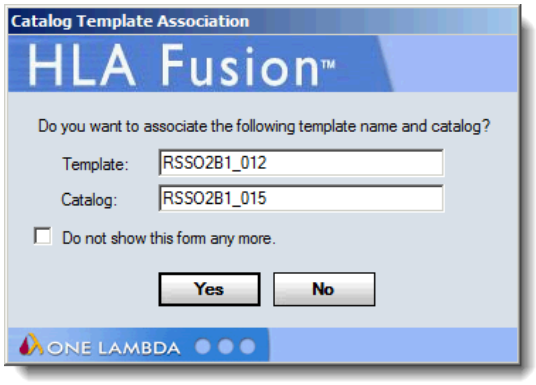
8. If there is more than one match, a catalog validation dialog box is displayed with the best bead matches. You can confirm the selected Catalog file by simply clicking the **Close** button. Or, you can double-click a catalog file name on the list of **Suggested Catalogs**.

Clicking the **Detail** Detail button on the **Catalog Validation** screen opens the **Mismatched Beads** window which lists which beads were not found in the Session and/or Catalog.

Click the **OK** OK button to close.

Catalog Validation





Catalog Association

Following Catalog File Validation, Fusion may ask you if you would like to associate that template name with the specified catalog file.

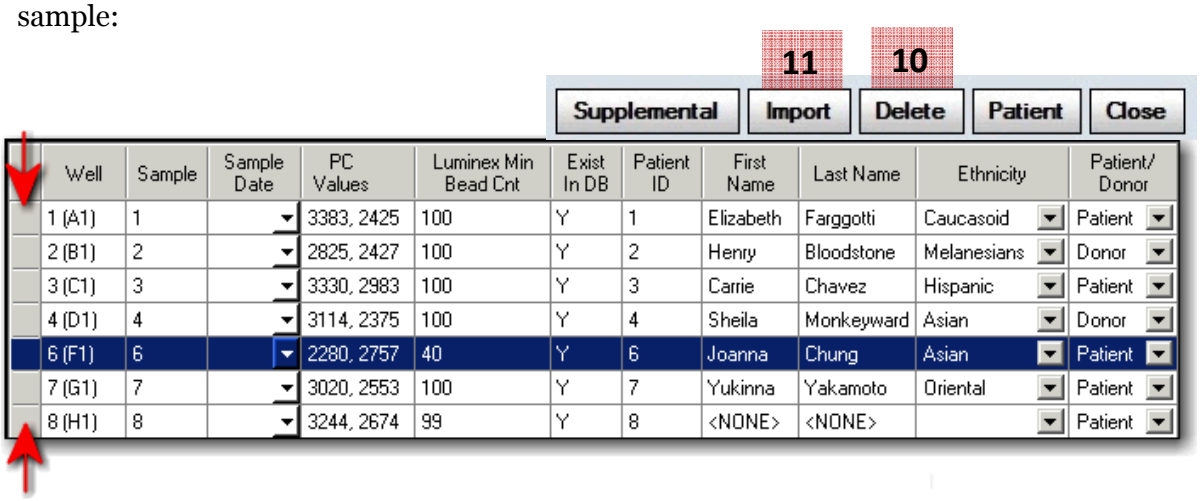
If you click **Yes** to associate the two, the system automatically selects this catalog file for future imports of any CSV files that reference this template.

Note: If the incorrect catalog and template are associated, review the section, *Associating Product Catalog Files and Luminex Templates,* for instructions on removing the association.

Check to see if there are any samples that have been flagged as having a low Positive Control (PC) or low Bead Count; the rows of low PC or Low Bead Count samples are highlighted Gray.

You may want to delete these samples because they often slow analysis. However, such removal means you can no longer track these samples. Take the following steps if you want to delete any of these samples:

9. Click in the border to the left of the Well position column to highlight the entire row for the sample:



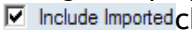
Well	Sample	Sample Date	PC Values	Luminex Min Bead Cnt	Exist In DB	Patient ID	First Name	Last Name	Ethnicity	Patient/ Donor
1 (A1)	1		3383, 2425	100	Y	1	Elizabeth	Farggotti	Caucasoid	Patient
2 (B1)	2		2825, 2427	100	Y	2	Henry	Bloodstone	Melanesians	Donor
3 (C1)	3		3330, 2983	100	Y	3	Carrie	Chavez	Hispanic	Patient
4 (D1)	4		3114, 2375	100	Y	4	Sheila	Monkeyward	Asian	Donor
6 (F1)	6		2280, 2757	40	Y	6	Joanna	Chung	Asian	Patient
7 (G1)	7		3020, 2553	100	Y	7	Yukinna	Yakamoto	Oriental	Patient
8 (H1)	8		3244, 2674	99	Y	8	<NONE>	<NONE>		Patient

10. To remove the sample and prevent it from being imported as part of the session, press the **Delete** button (upper right side of the screen).

11. When session and sample information is verified, click **Import**.

If you selected the **Auto Analysis** check box, the session is imported as well as analyzed when you click **Import** and it is displayed on the Fusion Navigator as an analyzed session.

You can continue importing Luminex Session Files, or you can click a session in the Navigator to start a Batch Analysis.

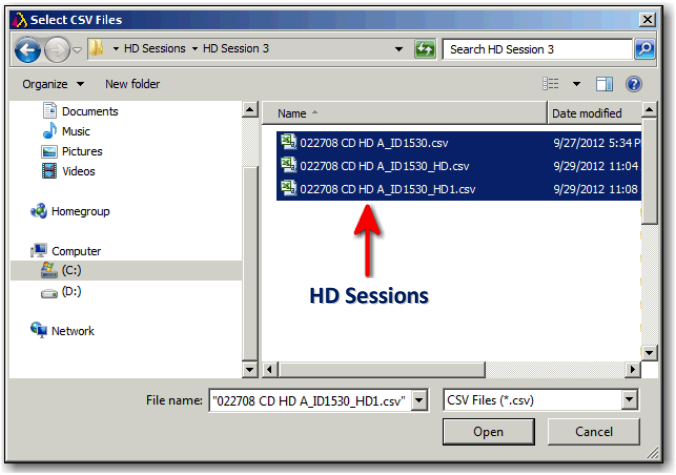
Note: Once a CSV file has been imported, it no longer displays on the Luminex Session Import list unless you select the **Include Imported** 

check box. This may be used to re-import a session under a new name and/or user.

Acquiring LABType Session Data (HD)

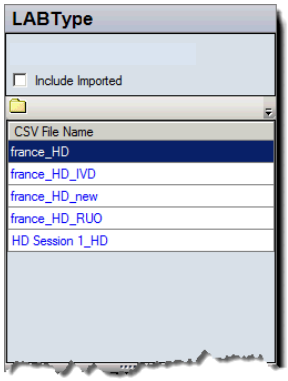
To display a listing of HD session(s) on the CSV File Name list:

Selecting HD Session Files



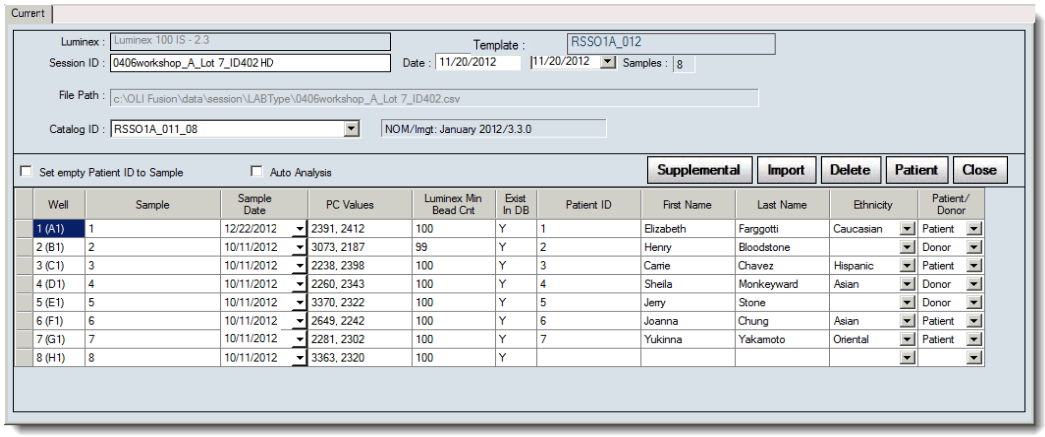
1. Click the **Folder** icon. The **Select CSV Files** screen opens. Note that you may need to open HD sessions from a location other than the default path for LABType files. After clicking the Folder icon, browse to the location where the LABType HD files are stored on your system/network.
2. Click the **Open** Open button.

Note: HLA Fusion converts Luminex-generated CSV file data, such as date and time, to the local regional code if a regional code is specified in the CSV file. (*A regional code cannot be specified for CSV files created with Luminex software versions 2.2 or earlier.*) If the first date field is highlighted yellow, it indicates a regional code mismatch. In this case, it is recommended that you use the drop-down selector in the **second date field** to choose the appropriate date, taking into consideration regional date format differences.



3. Select an HD session from the CSV File Name list to display its associated samples in the **Current Sample/Patient Details** table, as shown below.

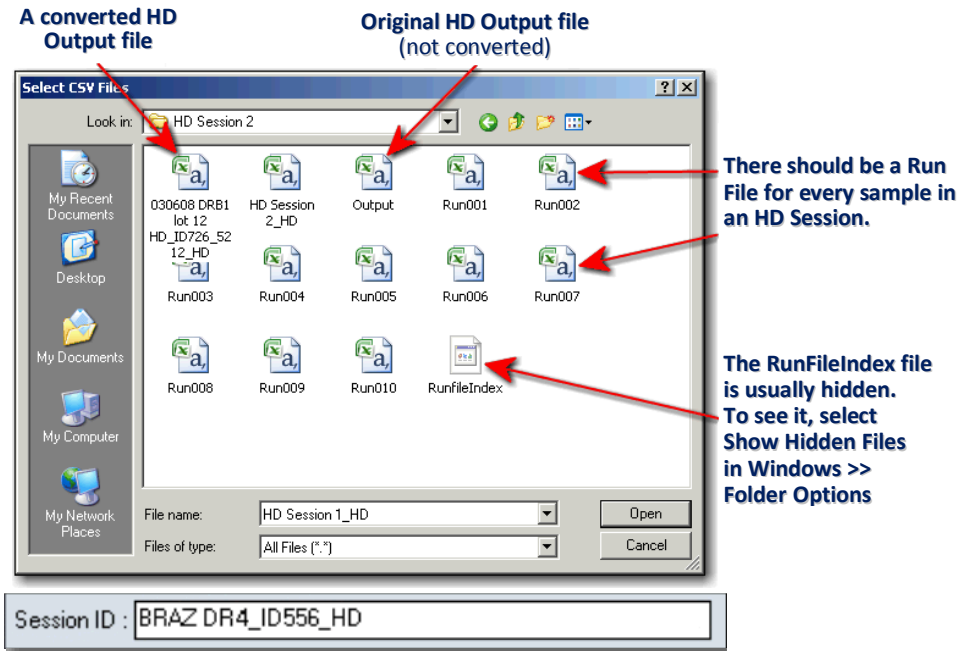
HD Samples in the current Sample/Patient Details table



Well	Sample	Sample Date	PC Values	Luminex Min Bead Cnt	Exist In DB	Patient ID	First Name	Last Name	Ethnicity	Patient/ Donor
1 (A1)	1	12/22/2012	2391, 2412	100	Y	1	Elizabeth	Farggotti	Caucasian	Patient
2 (B1)	2	10/11/2012	3073, 2187	99	Y	2	Henry	Bloodstone		Donor
3 (C1)	3	10/11/2012	2238, 2398	100	Y	3	Carrie	Chavez	Hispanic	Patient
4 (D1)	4	10/11/2012	2260, 2343	100	Y	4	Sheila	Monkeyward	Asian	Donor
5 (E1)	5	10/11/2012	3370, 2322	100	Y	5	Jerry	Stone		Donor
6 (F1)	6	10/11/2012	2649, 2242	100	Y	6	Joanna	Chung	Asian	Patient
7 (G1)	7	10/11/2012	2281, 2302	100	Y	7	Yukinna	Yakamoto	Oriental	Patient
8 (H1)	8	10/11/2012	3363, 2320	100	Y					

Caution: Luminex 2.2/2.3: Make sure you select the CSV file from the same directory that contains all the run files and the run-index file, (*generally a hidden file in the directory*) that were output from the Luminex machine into a session folder. Each sample in the session must correlate to a run file in this directory. This is essential if the HD CSV file is not yet converted; HLA Fusion automatically converts any unconverted HD files during import, ***if*** the unconverted output file resides in the same location as the run files and run-index file for that session.

xPONENT 3.1: The output file can be located anywhere. There is no run index file. But the run files must be together in a directory that is structured with the session directory, and underneath that, the run files.



HD Session Listing (Luminex 2.2/2.3)

Fusion assigns a Session ID by default. Optionally, you can change the Session ID. If the HD file has not been converted, it will be named *Output* until it is imported, at which point it will have the name of the original output session folder, (regardless of whether you rename the folder) followed by "**_HD**."

Note: A **Session ID** must be *unique* to the Fusion database. If the Session ID already exists, the software prompts you to rename the session. It is also highly recommended that you do not use any special characters in this field since they may serve a specific purpose as field separators.

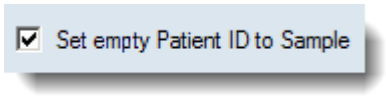
Note: To see the **RunFileIndex** file if using Windows XP, open Windows Explorer and Click the **Folders** button. Then, click **View** on the Windows **Title bar** and select **Folder Options** from the drop-down menu. Now, click the **View** tab and scroll down to **Hidden files and folders**. Select, **Show hidden files and folders**, and Exit. When viewing a selection of CSV files, change the **Files of type** to **All Files**, to reveal the RunFileIndex file. In Windows Vista and Windows 7, open Windows Explorer and select **Tools >> Folder Options**. Next, click on the **View tab** and select **Show hidden files, folders and drives**. If you rename a session, do not name it *output* as that is reserved for the original HD output file.

Note: The **Supplemental** button can be used to add other sessions to the current one, (e.g., supplementing B locus sessions with B7) for analysis. This does not work for combinations of different test types, (such as A locus and B locus).

If a sample is already associated with a patient, the Patient ID and any existing, related patient information, is displayed.

4. To add patient information, do one of the following:

   - To add existing data from the system, double-click in the **Patient ID** column of the **Sample/Patient Details** table, or click the **Patient List** button on the toolbar. The **Import Patient** window is displayed, allowing you to import the patient information file.
   - To manually add patient data, simply type data into the patient-related fields of the table.
   - You can assign the Sample ID to empty Patient ID fields by selecting the check box for **Set empty Patient ID to Sample**.



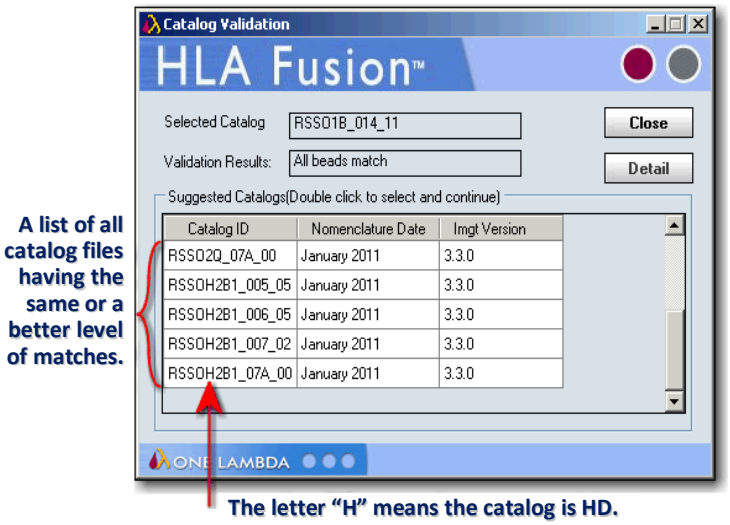
5. Select a catalog file. Your catalog selection method may be one of the following, depending on the CSV file and the catalog files you have imported for LABType:

Note: If there are no catalog files available for selection, or the one you want is not available, review the *Utilities* section of this manual for instructions on how to add new catalog files to the database.

- If the CSV file specifies a template name, (*only applies to CSV files from Luminex 2.2 and later*) and one of the available catalog files is associated with that template, then that catalog file is automatically selected. If you want to select a different catalog file, you can use the drop down list in the Catalog ID field to select from any other catalog files listed there.

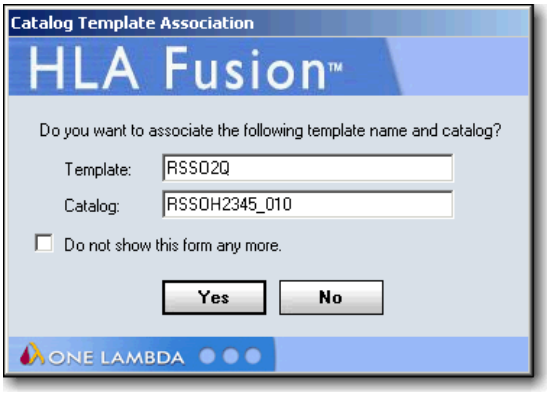
- If there is no template match, the system then considers the closest bead match between the session and all available catalog files. A catalog validation dialog box is displayed. You can confirm the selected catalog file simply by clicking the **Close** Close button. Or, double-click another catalog name on the list of Suggested Catalogs.

Note: The catalogs listed in the validation dialog box for HD sessions may also include non-HD catalogs. You can identify an HD catalog by the 'H' in the name (e.g., RSSOH2B1_003_05).



6. Following catalog file validation, the system may ask if you'd like to associate the template name with the specified catalog file. If you associate the two, all new sessions with the same template will automatically select this catalog.

Catalog Template Association



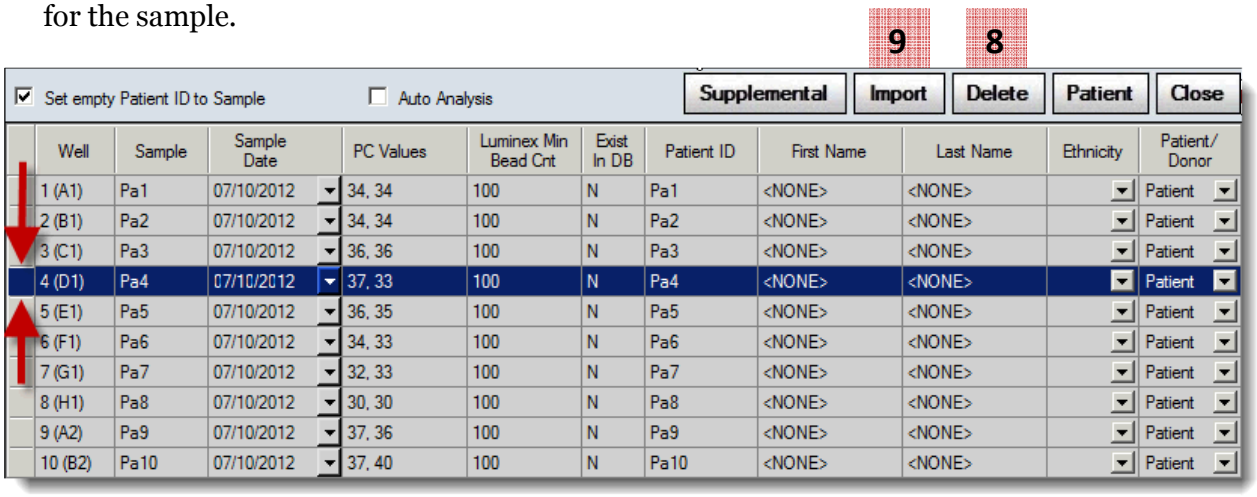
Note: If the incorrect catalog and template are associated as in the above example, review the section, *Associating Product Catalog Files and Luminex Templates* for instructions on removing the association.

Check to see if there are any samples that have been flagged as having a low Positive Control (PC) or low Bead Count; the rows of low PC or low bead count samples are highlighted **Gray**.

You may want to delete these samples because they often slow analysis. However, such removal means you can no longer track these samples.

Take the following steps if you want to delete any of these samples:

7. Click in the **Gray** border area to the left of the Well position column to highlight the entire row for the sample.

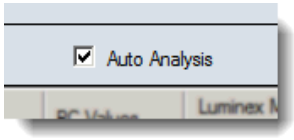


Well	Sample	Sample Date	PC Values	Luminex Min Bead Cnt	Exist In DB	Patient ID	First Name	Last Name	Ethnicity	Patient/ Donor
1 (A1)	Pa1	07/10/2012	34, 34	100	N	Pa1	<NONE>	<NONE>		Patient
2 (B1)	Pa2	07/10/2012	34, 34	100	N	Pa2	<NONE>	<NONE>		Patient
3 (C1)	Pa3	07/10/2012	36, 36	100	N	Pa3	<NONE>	<NONE>		Patient
4 (D1)	Pa4	07/10/2012	37, 33	100	N	Pa4	<NONE>	<NONE>		Patient
5 (E1)	Pa5	07/10/2012	36, 35	100	N	Pa5	<NONE>	<NONE>		Patient
6 (F1)	Pa6	07/10/2012	34, 33	100	N	Pa6	<NONE>	<NONE>		Patient
7 (G1)	Pa7	07/10/2012	32, 33	100	N	Pa7	<NONE>	<NONE>		Patient
8 (H1)	Pa8	07/10/2012	30, 30	100	N	Pa8	<NONE>	<NONE>		Patient
9 (A2)	Pa9	07/10/2012	37, 36	100	N	Pa9	<NONE>	<NONE>		Patient
10 (B2)	Pa10	07/10/2012	37, 40	100	N	Pa10	<NONE>	<NONE>		Patient

Highlight a Sample Row for Deletion

8. Press the **Delete** button (upper right of screen) to delete the sample and prevent it from being imported as part of the session.

9. When session and sample information have been verified, click the **Import**  button.



The session is now displayed in **Blue** at the top of the **Navigator** tree. If you selected the **Auto Analysis** check box, the session was imported and analyzed when you clicked the Import button.

The session is now displayed in the Navigator as an **Analyzed** session.

You can continue importing more Luminex files, or you can click on a Session in the **Navigator** to start **Batch Analysis**.

Note: Once a CSV file has been imported, it no longer displays on the Luminex session import list unless you select the **Include Imported CSV** check box.

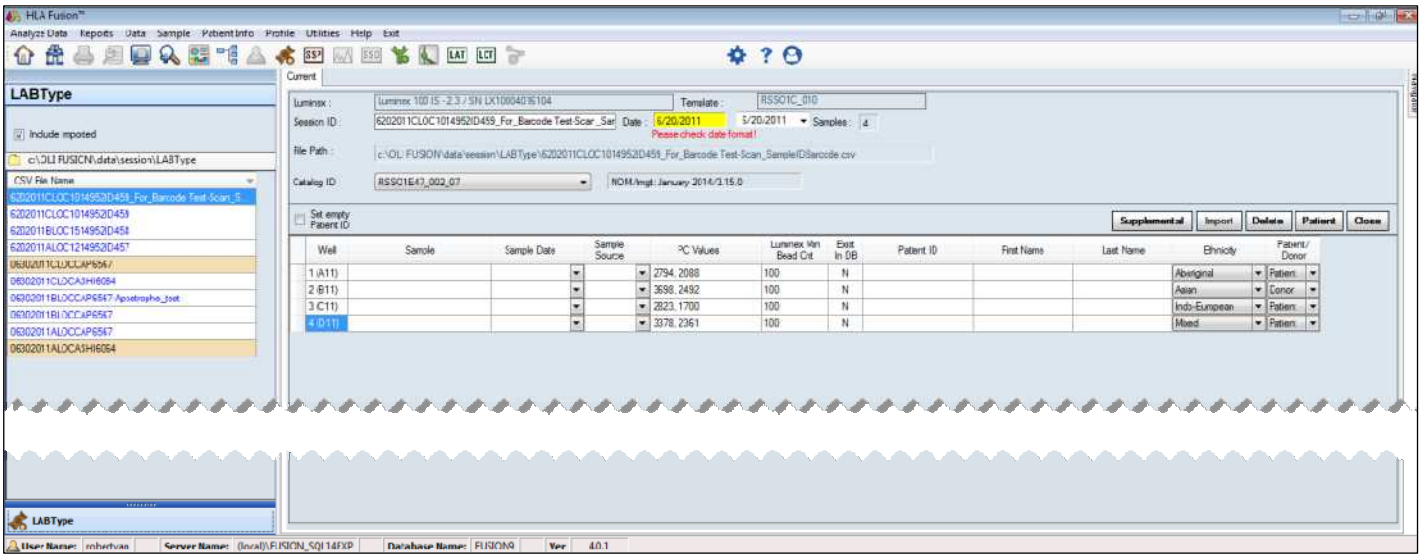
Analyzing Exon 4+ Sessions

HLA Fusion allows you to analyze Exon 4+ data with generic HD or non-HD LABType samples to provide higher resolution results. You can apply Exon 4+ resolution to locus A, B or C typing data.

Please follow these steps to analyze LABType samples with Exon 4+ resolution:

1. On the home screen, click either the **LABType** button or the product icon: 

The LABType home page is displayed.

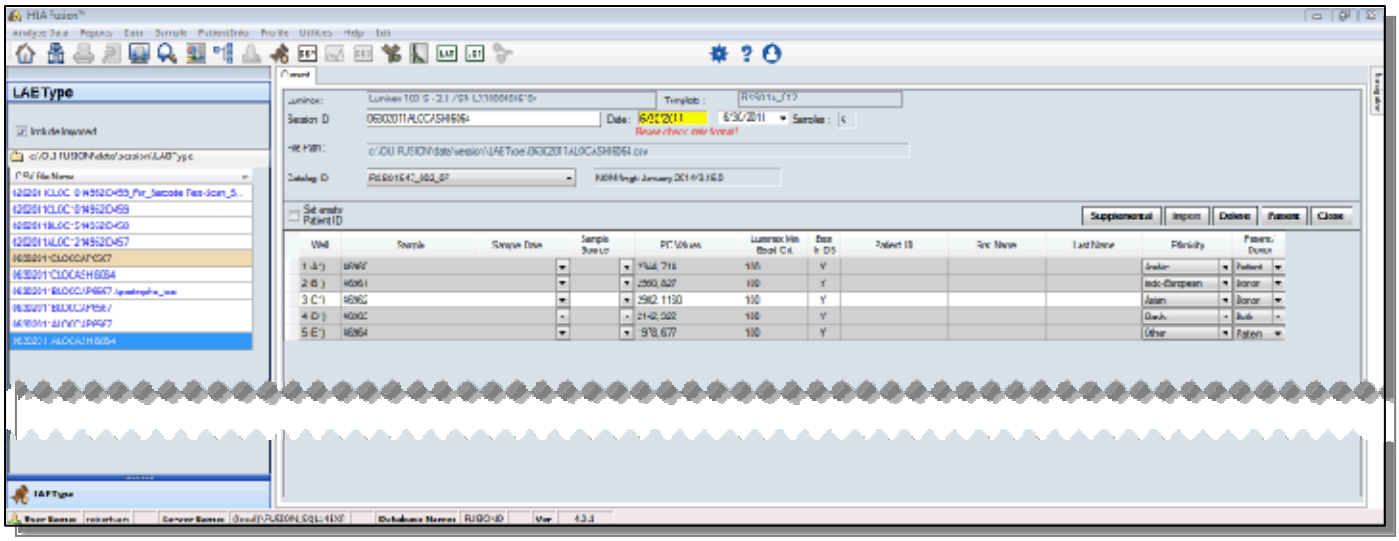


2. Click the **[Download]** link on the upper right side of the LABType home page and download the catalogs you need to analyze generic A, B, and/or C locus and Exon 4+ LABType samples, (e.g., **`RSSO1E_001_00.cat`**).

3. Select files from the list of CSV files on the left side of the LABType Home Page that you want to import for supplement with Exon 4+ data.

   - Or, click the **Folder** icon and browse to the LABType CSV file(s) on your system/network to locate and select CSV files.

The LABType Session/Patient Details Table is displayed.



4. **Import** the sessions containing samples you want to supplement with Exon 4+ data by following the same process you have used to previously import CSV files into Fusion.

5. Use the Fusion LABType analysis window to analyze the samples you want to use in analysis with Exon 4+.

6. Click the **LABType** button to return to the LABType home page.

7. Make sure you downloaded the Exon 4+ catalog(s) (e.g., **`RSSO1E_001_00.cat`**). If you have not yet done so, click the **[Download]** link on the upper right side of the LABType home page and download the necessary catalog(s).

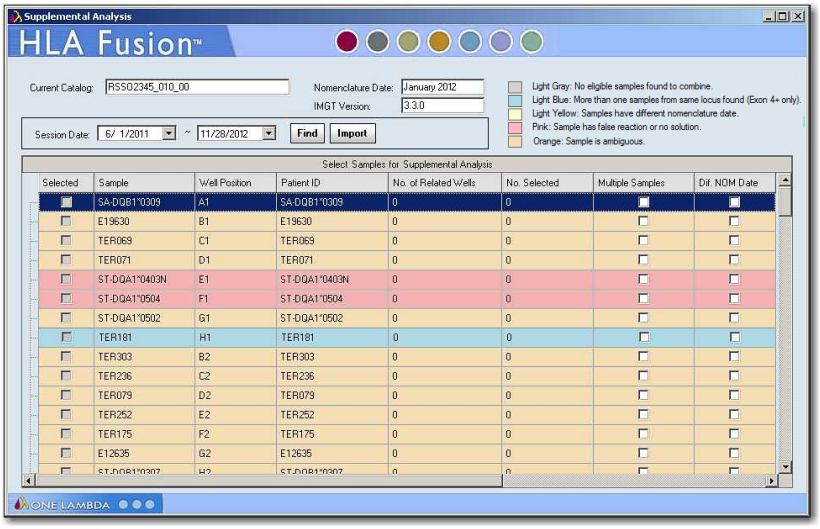
8. After the Exon 4+ catalog(s) have been added to your computer or network, select Exon 4+ sessions from the list of CSV files on the left side of the LABType home page.

    - Or, click the **Folder** icon above the list to browse to the LABType CSV file(s) on your computer or network to locate and select Exon 4+ CSV files.

9. This will display the Exon 4+ samples in the **Sessions Detail Table** on the right side of the LABType window.

10. Click the **Supplemental** button, (*please note that the Import button is not available for Exon 4+ sessions*). The Supplemental Analysis window is displayed.

Supplemental Session Selection (Exon 4+)



The supplemental screen displays the grid of all the possible samples that can be combined with the current session. The colors in the legend represent the following:

- Mismatch or false reaction. For Exon 4+ a false sample is disabled: **Pink**
- Sample is ambiguous: **Orange**
- Found more than one sample for a locus: **Light Blue**
- Nomenclature date different: **Light Yellow**
- No related test available to combine: Light **Gray**

Make sure the samples you want associated for the supplemental analysis are selected.

Note: Only one sample can be associated with each Exon 4+ per locus. If there is more than one generic sample available for association with the Exon 4+ of a particular locus, the system by default selects the most recently created sample. You can select an older sample if desired.

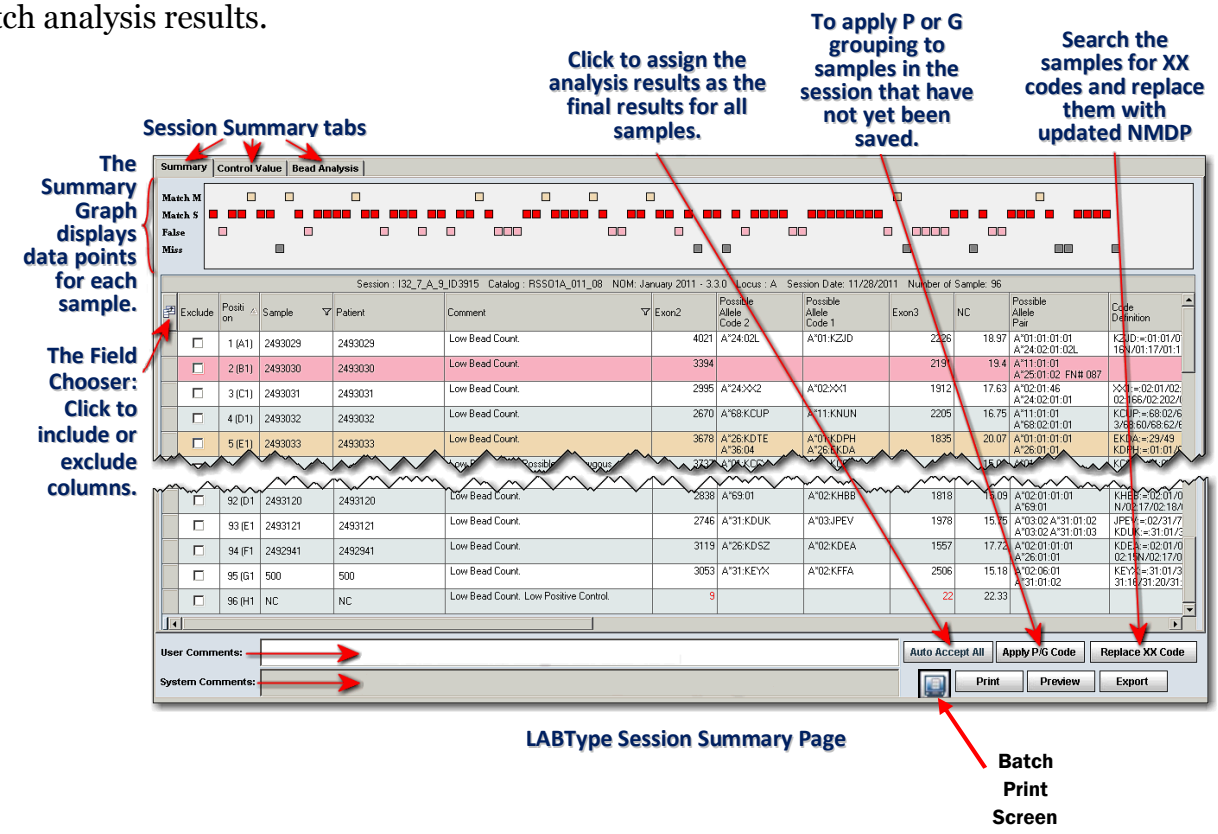
Micro SSP data can be combined with Exon 4+ data only *after* it has been combined with LABType data. LABType combined with Exon 4+ *cannot* be combined with Micro SSP data.

11. Click the **Import** Import button.

The supplemental session and all associated samples are displayed in the Fusion Navigator where you can select them to analyze in the LABType analysis window.

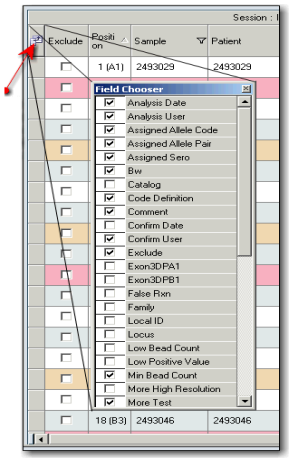
LABType Session Summary

The session summary page can be launched by clicking a session in the Navigation tree. It presents a preview of the analysis results, listing each sample in the session and corresponding batch analysis results.



The Session Summary Field Chooser

Click here to open the Field Chooser.



Click the **Field Chooser** button on the far left side of the table headings. The Field Chooser appears. This allows you to select or clear the check boxes next to column headings to include or exclude those columns from the Summary Table. Selecting or clearing check boxes in this window instantly updates the table.

You can also rearrange the order of the fields by using your mouse pointer to drag and drop any field name to a new location on the Field Chooser.

When you close the **Field Chooser**, a message displays to let you choose whether or not to save any changes you've made. If you click Yes, your changes are saved for all future LABType Session Summaries on this same computer until further modifications are made and saved.

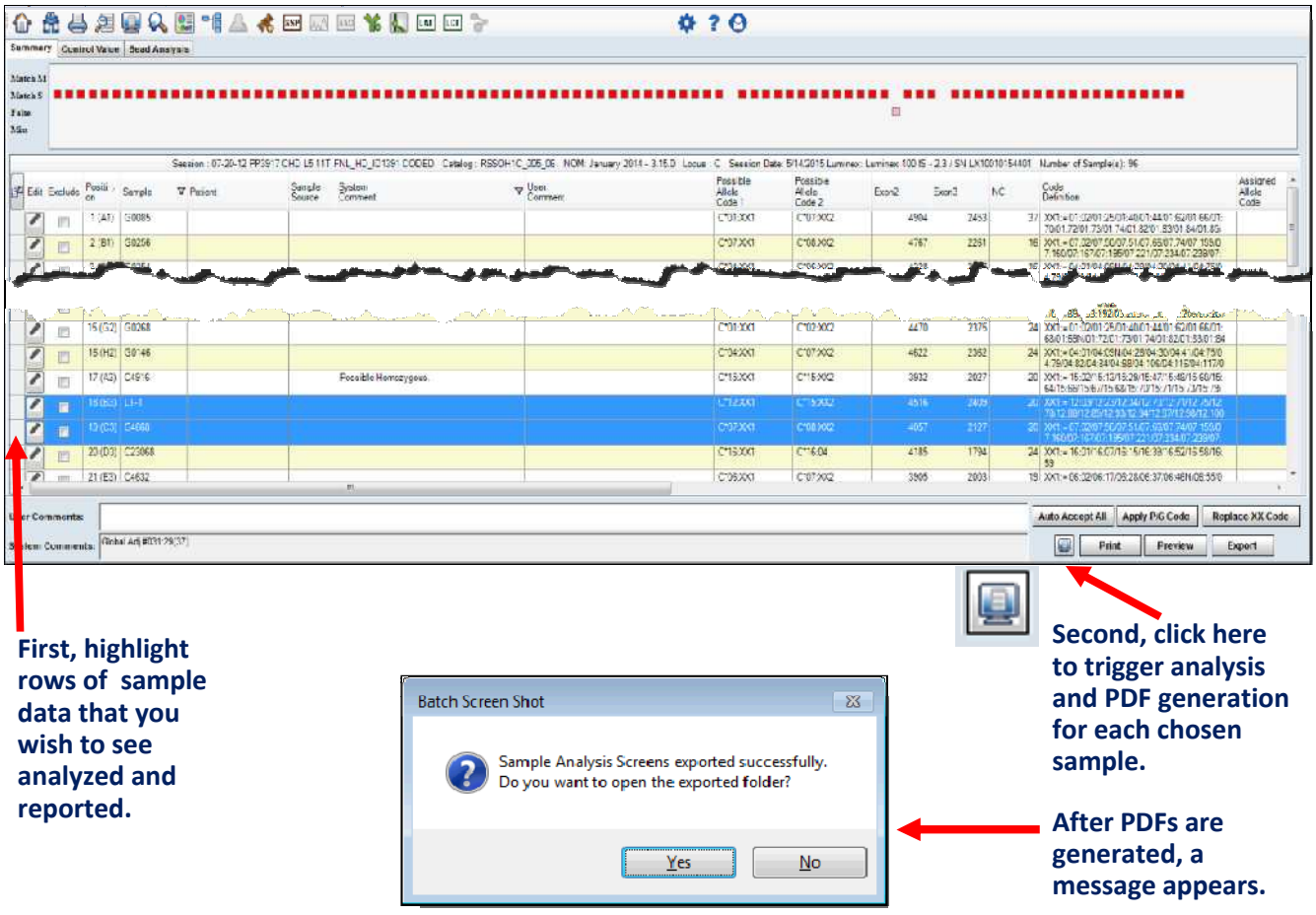
Note: If you do not see a particular field available in the field chooser and you are sure it should be there, go to `C:\HLA Fusion\temp` and delete the file named **`Labtype_Layout.xml`**.

The Batch Print Screen Function

The **Batch Print Screen** icon on the bottom right allows you to select multiple rows of sample data to analyze. Each analysis is performed as a graphic representation just like the LABType main screen with four quadrants. Each analysis is exported to a PDF file, one PDF file for each sample.

To use this feature, first use the mouse to select rows of sample data that are of interest by clicking down and dragging within the leftmost column directly under the Field Chooser button. A blue highlight will surround these chosen rows. Then click the **Batch Print Screen** icon near the lower rightmost corner of the screen. A series of analysis windows will flash by, and you will then be asked if you would like to examine the PDF files that were generated.

Batch Print Screen Row Selection

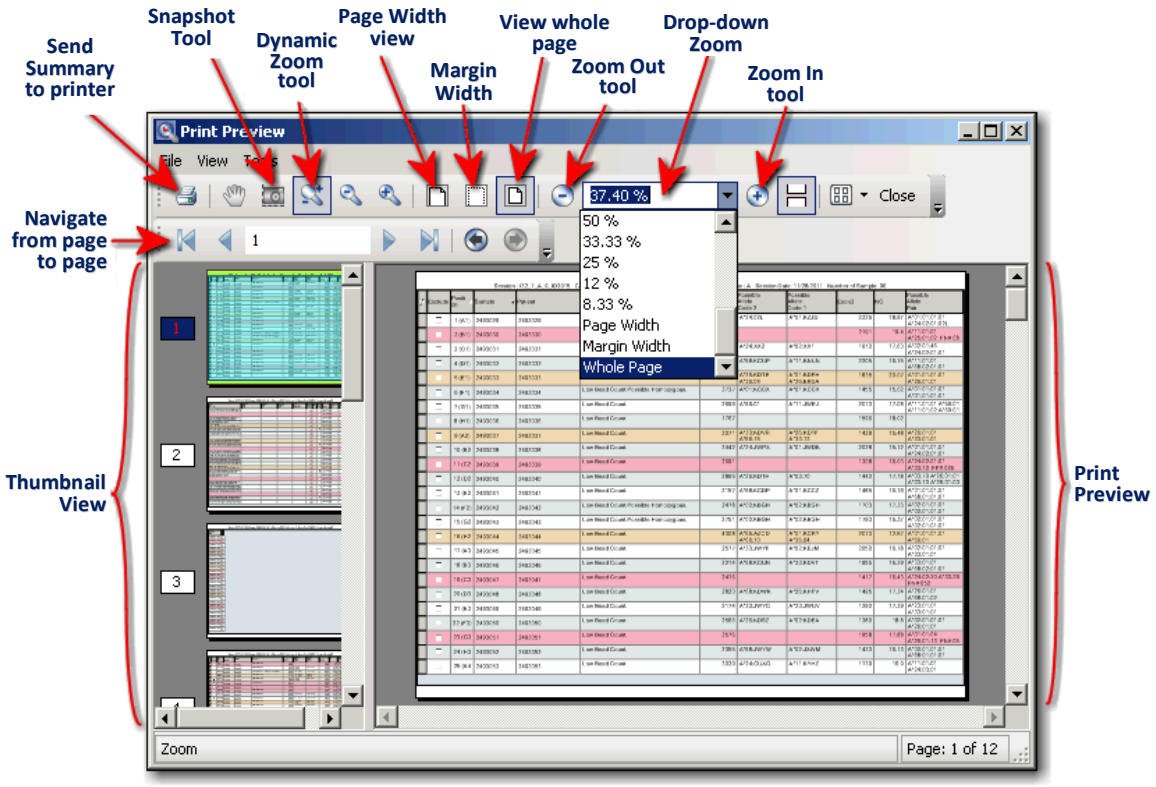


Export, Preview and Print Buttons

Clicking the **Export** Export button on the Fusion toolbar will format the Summary as a Microsoft Excel spreadsheet file. Fusion suggests a **Session Name** for the spreadsheet, but you can change it.

Clicking the **Print Preview** button on the Fusion toolbar not only opens a new window which shows you how a session will look when printed, but also allows you to select which pages and/or specific parts of pages you would like to print.

When you click the **Print** Print button, the Summary is sent directly to the printer.



The Print Preview Screen

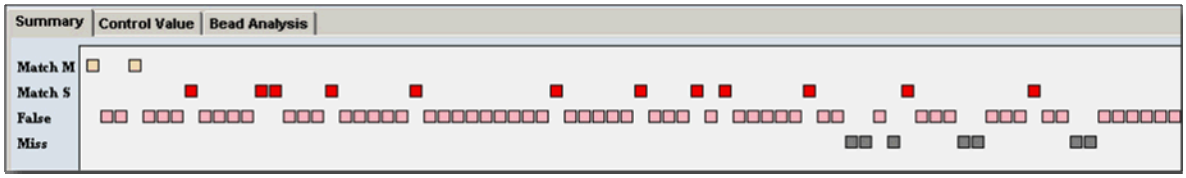
Clicking the **Print** button on the **Print Preview Screen** will send the images you've chosen directly to your printer.

LABType Session Summary Tabs

Summary Tab

The LABType **Session Summary Tab** displays a **Results Summary Graph**. The graph displays the quality of batch analysis results for each sample:

- **Match M** indicates multiple matched results (**Orange**)
- **Match S** indicates a single matched result (**Red**)
- **False** indicates a false reaction in results (**Pink**)
- **Miss** indicates that there are no suggested results (**Grey**)



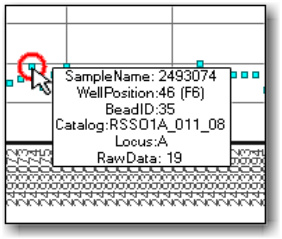
Results Summary Graph (Summary Tab)

- Click any of the squares in the Results Summary graph to display the corresponding sample analysis window.
- If the **Auto Accept All** button is enabled at the bottom of the Session Summary screen, you can click it to assign the possible results as final results for all samples - except those with ambiguous results.

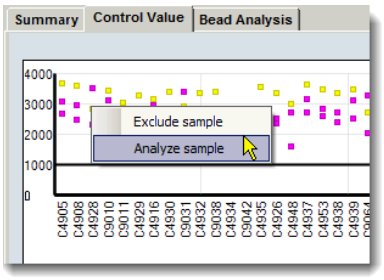
This feature is not activated unless you select it through the **Molecular Product Configuration>>Molecular Analysis Configuration** option in the **Utilities** menu.

Control Value Tab

This tab allows you to review the quality of the Control Values for each sample. This tab is divided into three graphs, all of which have the following elements in common:



- The X-axis indicates the samples, sorted by well position.
- The Y-axis indicates the raw data values specific to each graph, (e.g., positive or negative control values).
- From any graph, right-click to select either **Exclude Sample** or **Analyze Sample**.
- Double-click on any marker to go to the analysis screen for that sample.
- Hovering your cursor over any marker displays the sample's annotation.



The Positive Control Summary

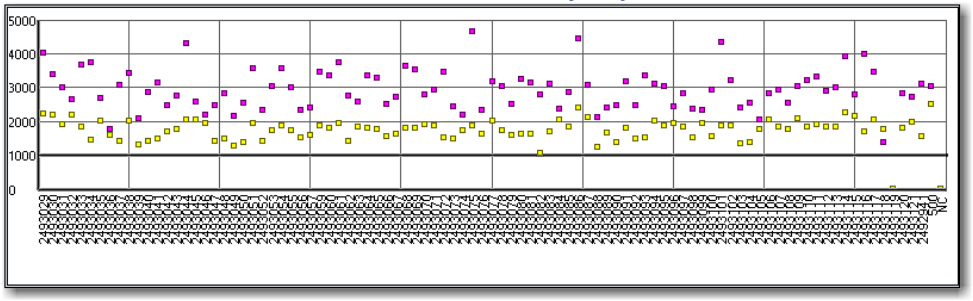
The **Positive Control Summary** graph, (top) displays the positive control value for each sample.

- The x-axis indicates the Sample ID names, sorted by well position.
- The y-axis indicates the positive control raw data values.

The horizontal bar indicates the configured value for the minimum positive control. This value can be configured through either the Utilities >Molecular Product Configuration menu, or by configuring sample-specific settings from the analysis window.

- Each exon is represented by a different color.
- Double-click on any marker to bring up the analysis window for the sample.

Positive Control Summary Graph

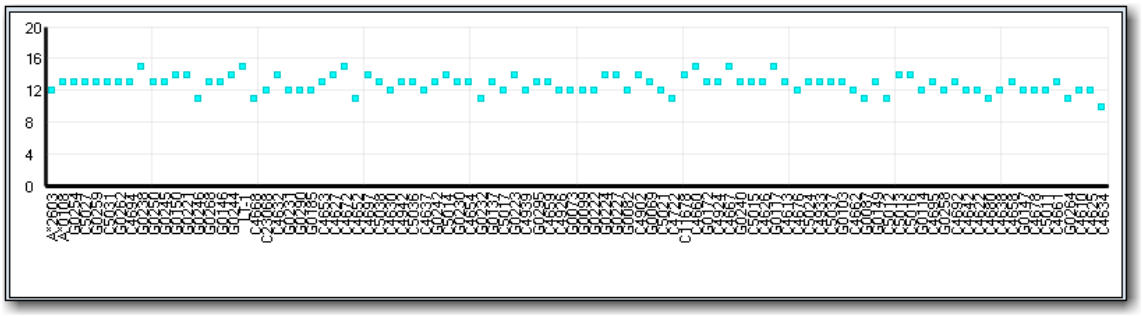


Negative Control Summary

The **Negative Control Summary** graph, (middle) displays the negative control values for each sample.

- The X-axis indicates the Sample ID names, sorted by well position.
- The Y-axis indicates the negative control raw data values.
- Double-click on any marker to bring up the analysis window for that sample.

Negative Control Summary Graph

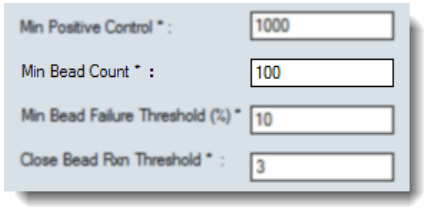


Bead Count Summary

The **Bead Count Summary** graph, (lower) displays the Lowest Bead Count per sample.

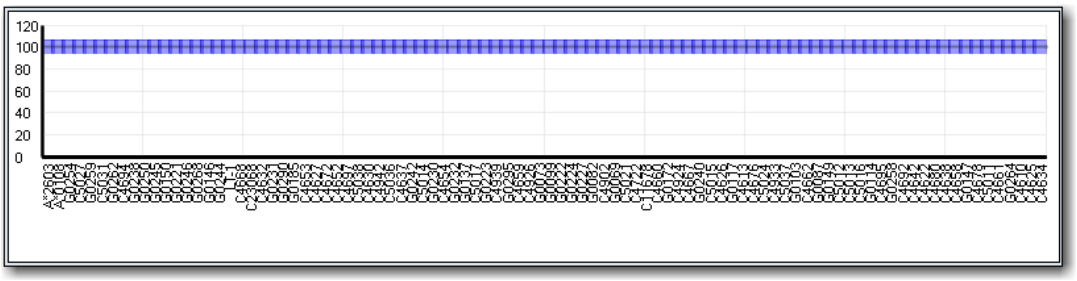
- The X-axis indicates the sample ID names, sorted by well position.
- The Y-axis indicates the negative control raw data values.

The horizontal bar indicates the configured value for the Minimum Bead Count. This value can be globally configured through the **Utilities >Molecular Product Configuration** menu.



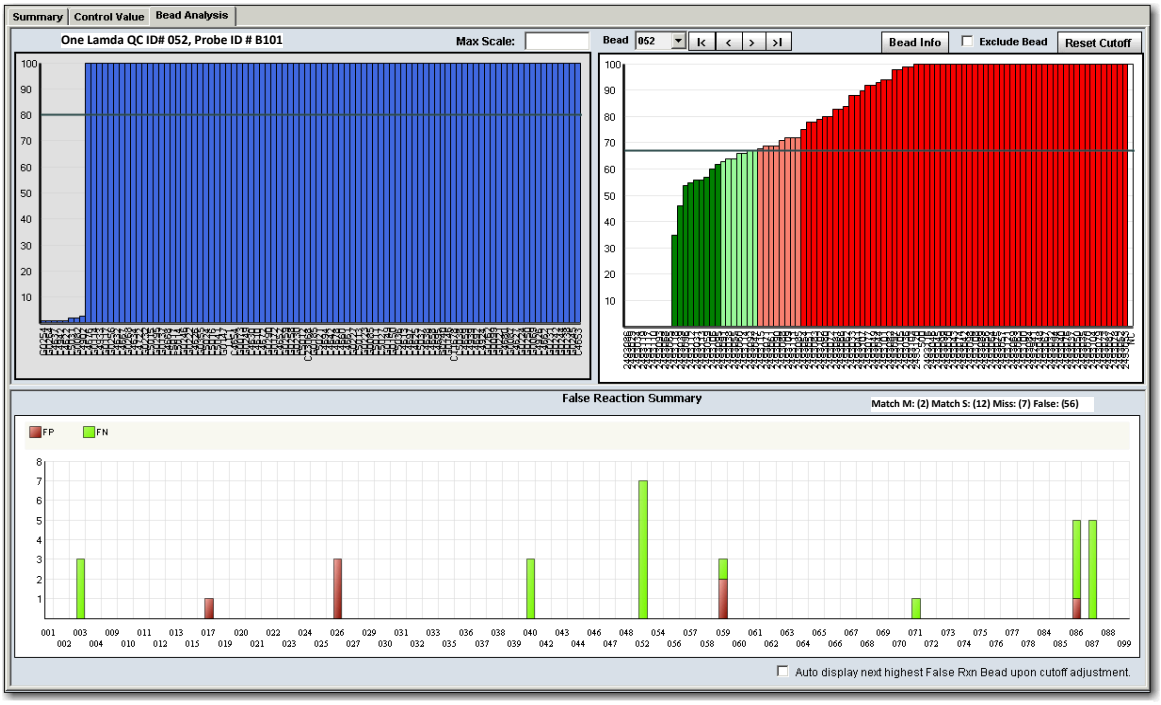
You can configure Sample-Specific settings directly from the Analysis Window. Double-click on any marker to bring up the Analysis Window for that sample.

Bead Count Summary Graph



The Bead Analysis Tab

This tab allows you to review the global session information for each bead. This tab displays three graphs, which are described in the following sections.

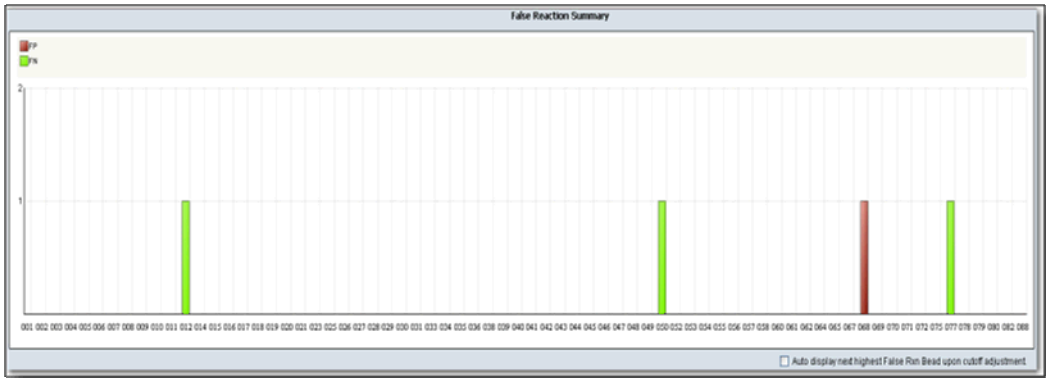


Bead Analysis Tab

False Reaction Summary

With the graph in the lower panel, you can review the number of False Reactions, (*both positive and negative*) associated with each bead in the entire session.

False Reaction Summary



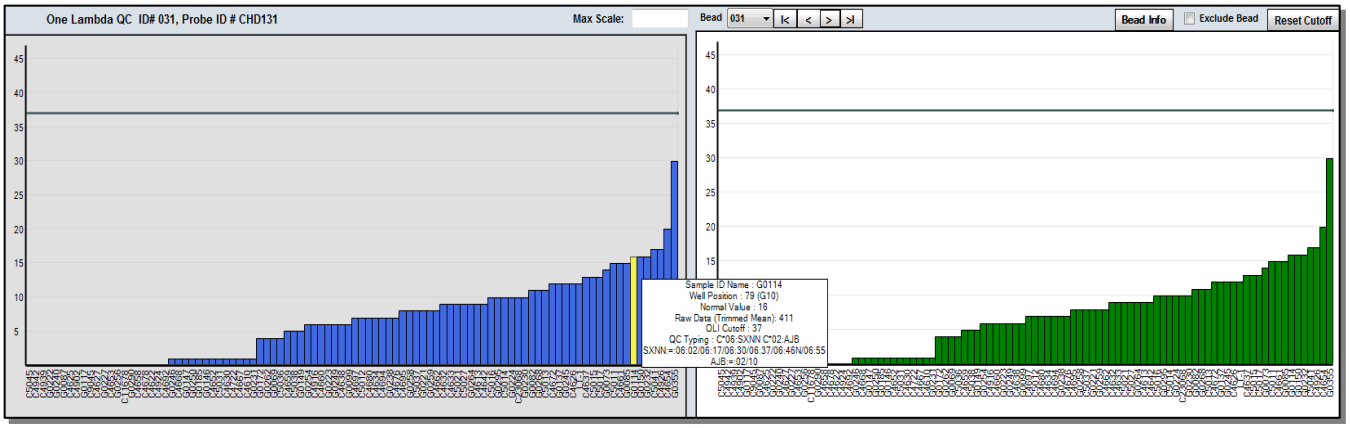
The color of the bar represents the type of false reaction that exists:

- **Green** = false negative
- **Red** = false positive

The height of the color bar indicates the number of false reactions to the indicated bead.

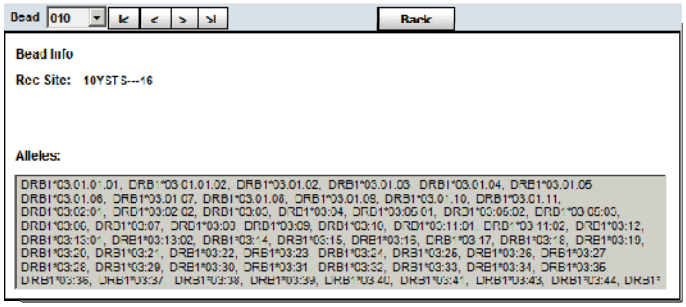
Double-clicking on one of the bars in this graph changes the corresponding QC and Bead graphs to that bead. Likewise, double-clicking one of the Bead ID's along the X axis changes the corresponding QC and Bead graphs to that bead.

The two graphs in the upper panel compare the bead profiles of the current session, (right graph) with a histogram of the same beads run on a One Lambda QC panel, (left graph). If a local QC is used for the session, the local QC histogram is displayed on the left.



QC Panel and Bead Profile Graph

- Hover your cursor over the bars on the histograms to display bead information.
- Right-click a bead profile to select either **Exclude Sample** or **Analyze Sample**.
- Double-click any bead to go directly to the Analysis Screen for that sample.
- Click the **Bead Info** Bead Info button to see the allele specificities for the current bead.

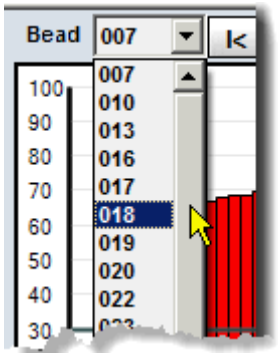


Bead Info Button – Allele Specificities

- You can also resize these graphs by placing your cursor in the area between the graphs until the cursor image changes to ↕. Then you can click and drag the cursor to resize the graphs.

- To scale the histograms on the QC Panel Graph, enter a value in the **Max Scale** text box and press the **Enter key** on your keyboard. This resets the upper Y-axis value of the bead profile histogram for both the QC and the current session.
- Using the **Bead Navigation** buttons, you can navigate between the beads.
- You can also select individual beads from the drop-down list.

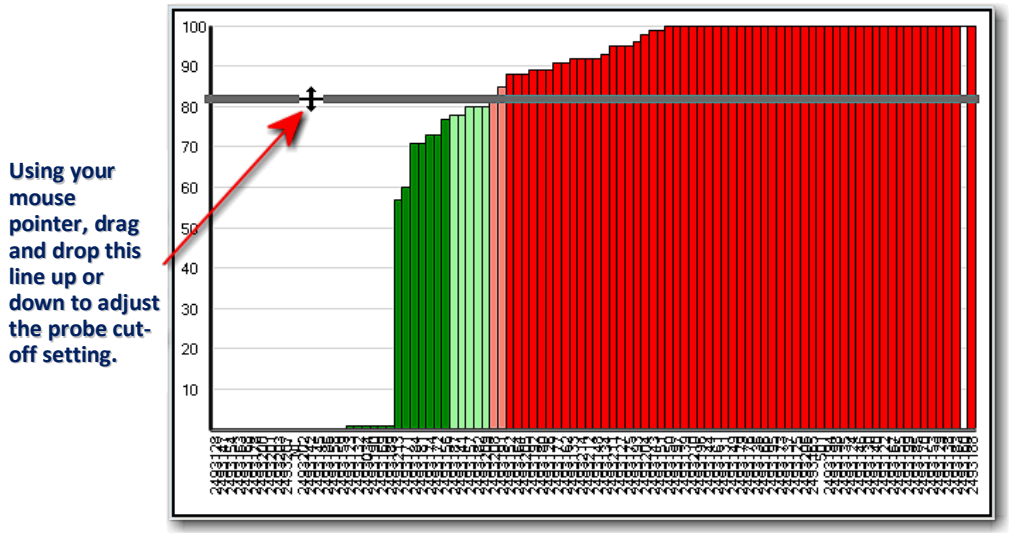
Bead drop-down list



- Check the **Exclude Bead** box to remove the current bead from the analysis session. The excluded bead is listed in the comment field with a notation that the bead has been excluded. In addition, excluded beads are displayed on the graphs during analysis as GRAY bars.
- Adjustments made to probe cut-off values in Bead Analysis affect all samples in this session. Pre-adjusting values to account for an individual lab's testing conditions can save time during analysis by changing all samples at once, (i.e., globally).

Make <u>global</u> cut-off adjustments by doing the following:

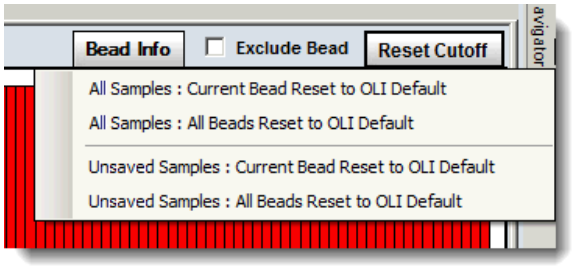
- Click and hold the horizontal adjust probe cutoff bar, and drag it up or down to a new cutoff setting.



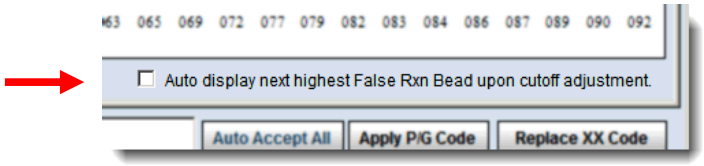
Adjusting the Cut-off Bar.

To reset the cut-off, click the **Reset Cutoff** Reset Cutoff button and select a reset option from the drop-down list.

Reset Cut-off Menu



- When adjusting the cut-off, you can determine which bead is displayed after the adjustment by either selecting or deselecting the following check box at the bottom right of the Bead Analysis window:



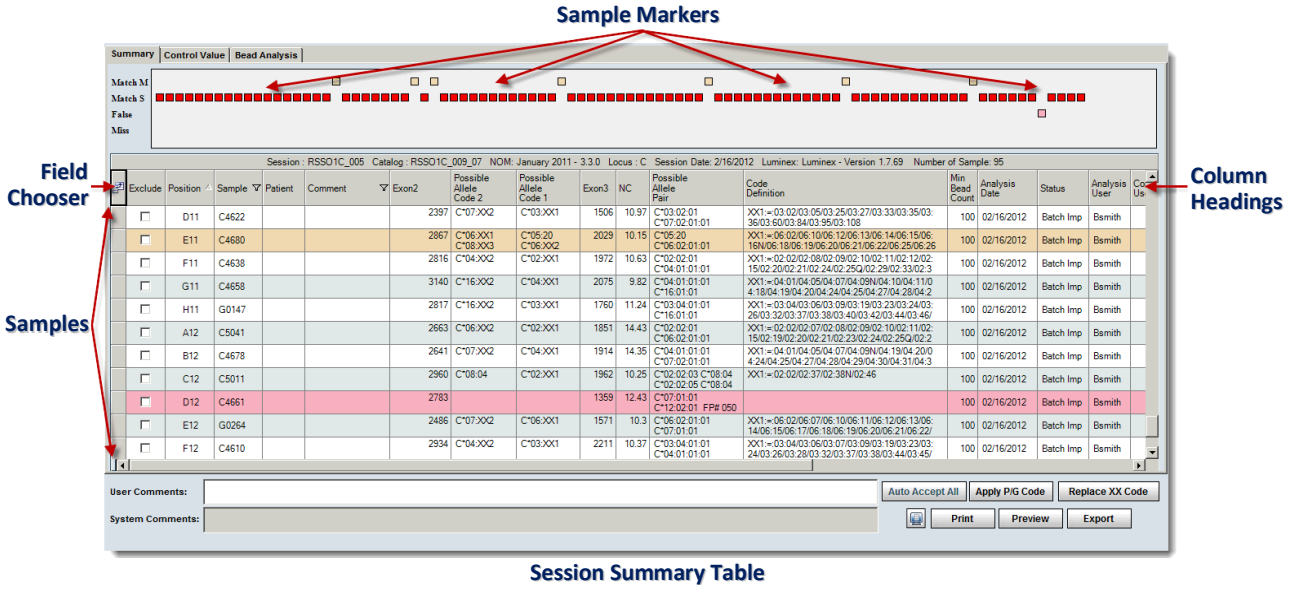
- If the check box is selected, the next highest False Reaction bead is displayed after the cut-off adjustment.
- If the check box is <u>not</u> selected, the bead displayed before the cutoff adjustment was made remains displayed.

There are two **Comments** fields at the bottom—a **User** one to record your own comments and a **System** field in which HLA Fusion records recent actions you've taken in the Summary Window, such as adjusting a cut-off. The system comments cannot be edited.

User and System Comments

General Session Summary Features

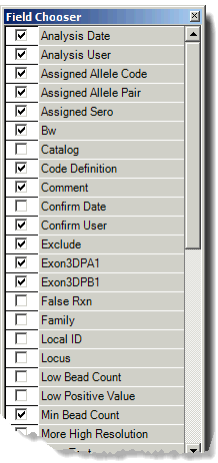
Aside from the functionality on the three LABType Session Summary tabs, there are other features that allow you to manipulate the summary table data.



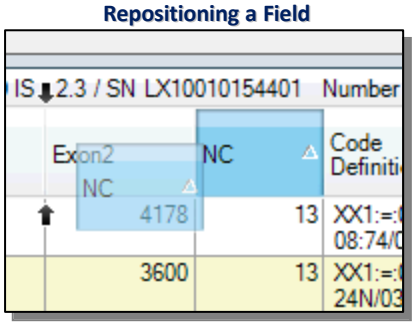
- You can double-click a sample in the Summary Table or single-click a sample marker on the Summary Graph to go directly to the Analysis Screen for that sample.
- Double-click in the User Comments field to add or edit your remarks. System-generated comments cannot be modified.
- Click the **Field Chooser** button to the left of the table headings. The Field Chooser is displayed. This allows you to select or clear the check boxes next to column headings and include or exclude those columns from the Summary Table.
- Selecting or clearing check boxes in this window instantly updates the table.

Note: If you do not see a particular field available through the field chooser and you are sure it should be there, go to C:\HLA Fusion\temp and delete the file named: **`Labtype_Layout.xml`**.

Field Chooser

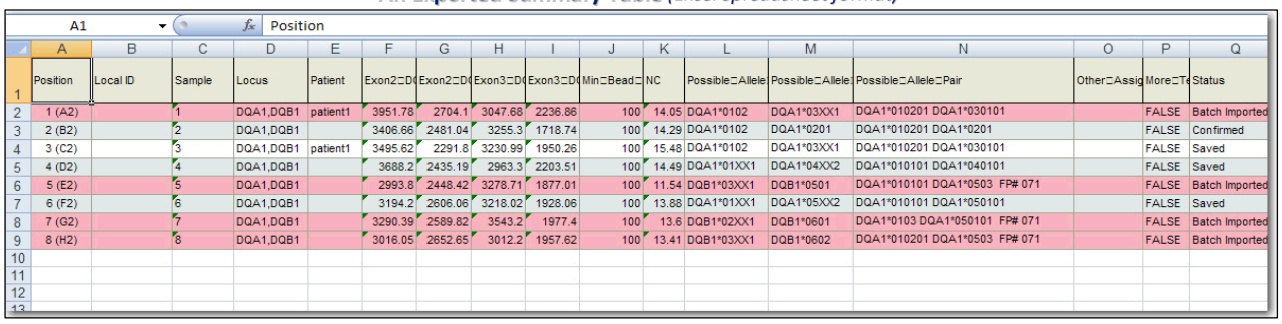


Repositioning a Field



- Click on any column header of the Summary Table to sort the table by that column. The **triangle**△ in the column header indicates the sorting order—up for ascending and down ▽ for descending.
- Columns can also be dragged and dropped to change their order.
- When you close the **Field Chooser**, a pop-up message displays to let you choose whether or not to save any changes you made. If you click **Yes**, your changes are saved for all future LABType session summaries on this same computer until further modifications are saved.
- Click the **Export** button to save the Summary Table on your computer or the network, (default location is C:\OLI FUSION\data\report). The file is saved in Excel (*.XLS) format.
- Click the **Print** Print button to immediately print out a report of the Summary Table.

An Exported Summary Table *(Excel Spreadsheet format)*

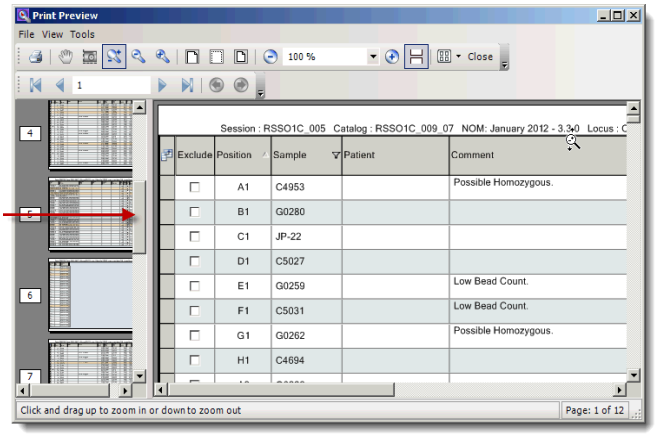


	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	Position	Local ID	Sample	Locus	Patient	Exon2	Exon2	Exon3	Exon3	Min Bead	NC	Possible Allele	Possible Allele	Possible Allele Pair	Other Assig	More T	Status
2	1 (A2)		1	DQA1,DQB1	patient1	3951.78	2704.1	3047.68	2236.86	100	14.05	DQA1*0102	DQA1*03XX1	DQA1*010201 DQA1*030101		FALSE	Batch Imported
3	2 (B2)		2	DQA1,DQB1		3406.66	2481.04	3255.3	1718.74	100	14.29	DQA1*0102	DQA1*0201	DQA1*010201 DQA1*0201		FALSE	Confirmed
4	3 (C2)		3	DQA1,DQB1	patient1	3495.62	2291.8	3230.99	1950.26	100	15.48	DQA1*0102	DQA1*03XX1	DQA1*010201 DQA1*030101		FALSE	Saved
5	4 (D2)		4	DQA1,DQB1		3688.2	2435.19	2963.3	2203.51	100	14.49	DQA1*01XX1	DQA1*04XX2	DQA1*010101 DQA1*040101		FALSE	Saved
6	5 (E2)		5	DQA1,DQB1		2993.8	2448.42	3278.71	1877.01	100	11.54	DQB1*03XX1	DQB1*0501	DQA1*010101 DQA1*0503 FP# 071		FALSE	Batch Imported
7	6 (F2)		6	DQA1,DQB1		3194.2	2606.06	3218.02	1928.06	100	13.88	DQA1*01XX1	DQA1*05XX2	DQA1*010101 DQA1*050101		FALSE	Saved
8	7 (G2)		7	DQA1,DQB1		3290.39	2589.82	3543.2	1977.4	100	13.6	DQB1*02XX1	DQB1*0601	DQA1*0103 DQA1*050101 FP# 071		FALSE	Batch Imported
9	8 (H2)		8	DQA1,DQB1		3016.05	2652.65	3012.2	1957.62	100	13.41	DQB1*03XX1	DQB1*0602	DQA1*010201 DQA1*0503 FP# 071		FALSE	Batch Imported
10																	
11																	
12																	

- Click the **Preview** Preview button to review a report of the Summary Table before printing or saving.

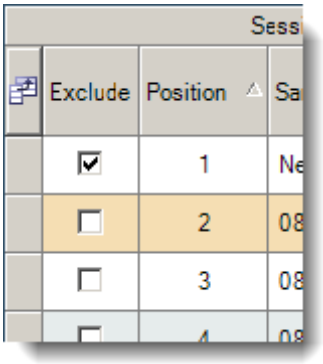
Print Preview Screen

Use slider to move from page to page



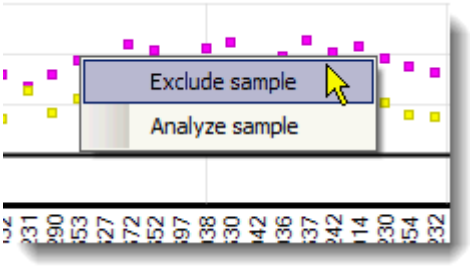
- In the Print Preview window, the left side displays symbols for each page of the report. Use the Slider to move from page to page, or click on a page icon to go to that page.
- Use your mouse **Scroll Wheel**, or click and move your mouse up and down to zoom in and out of each page in the Print Preview window.

Excluding a Sample from Analysis



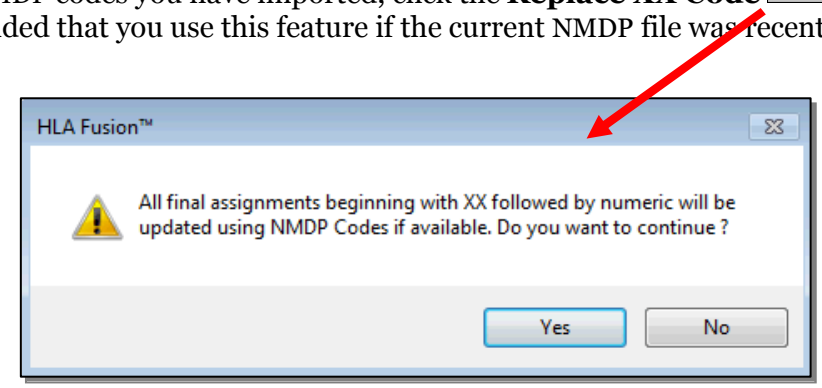
If you want to exclude a sample from an analysis session, select the **Exclude** check box next to that sample.

You can also right-click the sample on either of the graphs on the Control Value tab and select **Exclude Sample**.



This means the selected sample is not displayed in Fusion reports, or in Bead Analysis, Control Value data, or as results in the sample Analysis Window.

- The False Sample rows in the Summary table are highlighted in **Pink**; sample rows having multiple matches are highlighted **Orange**.
- If you want HLA Fusion to search the entire session for XX codes and replace them with the most current NMDP codes you have imported, click the **Replace XX Code** Replace XX Code button. It is recommended that you use this feature if the current NMDP file was recently imported.



Note: For individual samples, the replace code function can be performed by selecting the **Reanalyze** Reanalyze button from the analysis window.

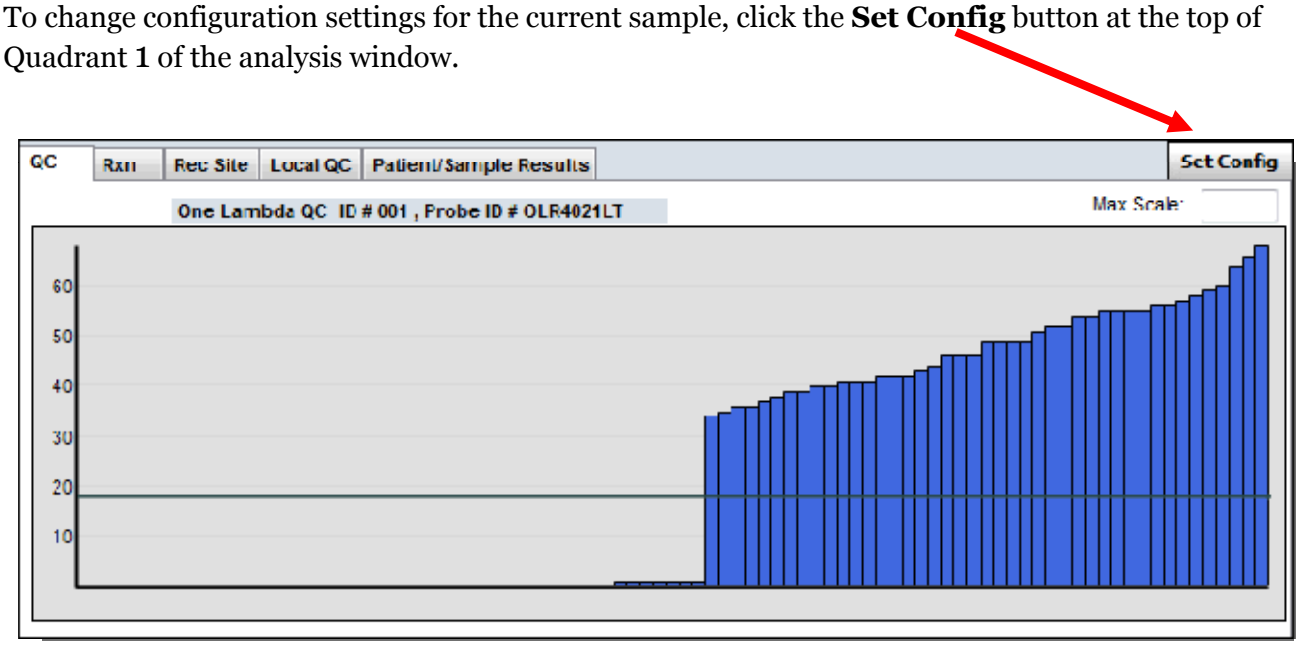
Configure LABType Analysis for the Current Sample

Global default LABType configurations can be set from the Utilities menu. In addition, configurations can also be set from within the LABType analysis window for the current sample.

Change Configuration for the Current Sample

Before starting analysis, you can change analysis options for the current sample by using the configuration menu as shown below. Changes to configuration settings *during analysis* affect the *current sample only*.

To change configuration settings for the current sample, click the **Set Config** button at the top of Quadrant 1 of the analysis window.

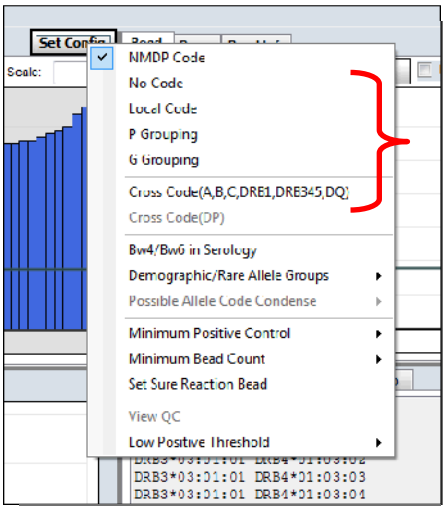


Set Config button on the QC Graph in Quadrant One

Assign Code

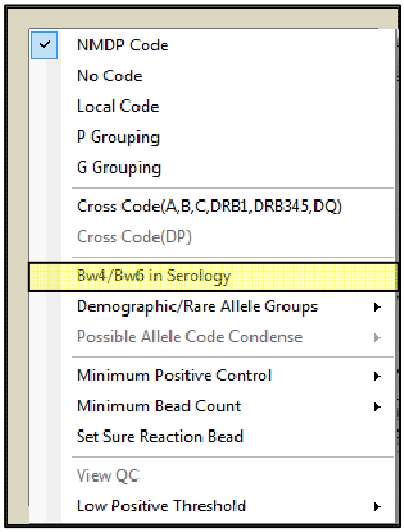
By default, Fusion assigns NMDP codes to the alleles. However, you can optionally change these codes to one of the following options:

Current Sample Configuration Options



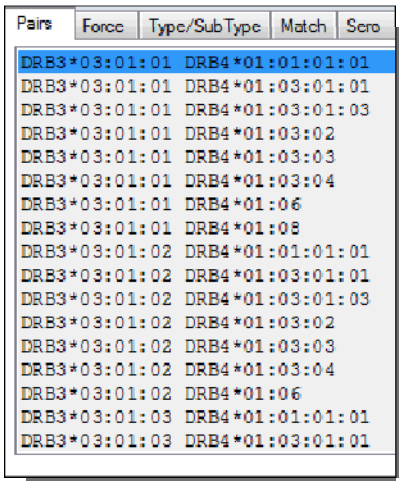
- **No Code** - the results, allele pairs assembled into a string with no formatted code, are simply condensed without applying a coded format.
- **Local Code** - assigns user-defined code definitions, (codes used by your Lab) for suggested code results.
- **P Grouping** - Codes allele strings in P Grouping as published by IMGT.
- **G Grouping** - Codes allele strings in G Grouping as published by IMGT.
- **Cross Code** - allows allele combinations that cross serological groups (e.g., **`EAPW = DRB1*04:03:01DRB1*04:03:03`**). By default, cross-coding is turned off so that allele pairs are condensed only within the same allele groups.

Bw4/Bw6 in Serology



Serology has identified many pairs of HLA-B alleles which appear to differ only at the Bw4/Bw6 region—the two mutually exclusive serological epitopes. If you select this option, Bw4/Bw6 is added to the serology results.

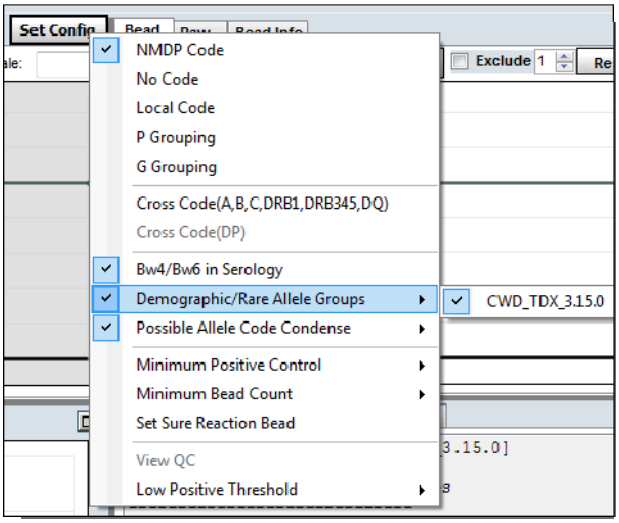
Bw4/Bw6 in Serology



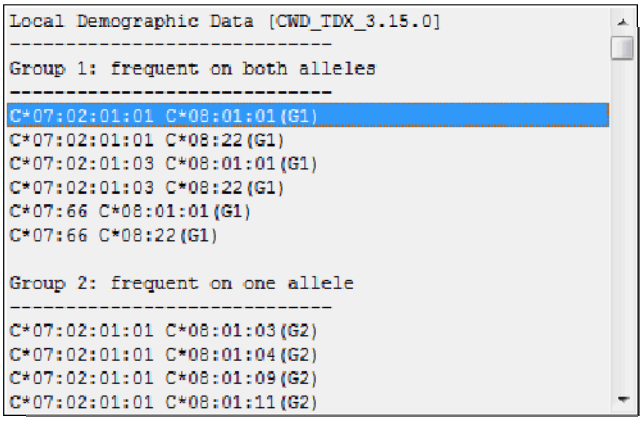
Demographic Information

The Demographic Information option allows you to organize alleles according to their frequency. Based on the demographic selection you make, HLA Fusion displays as many as three allele groups in the allele pairs list:

- **Group 1:** Frequent on *both alleles*
- **Group 2:** Frequent on *one or the other* of the alleles only
- **Group 3:** Frequent on *neither* allele



Demographic Configuration Option



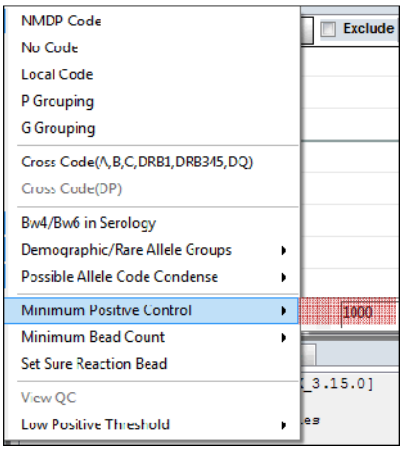
Demographic Frequency

Note: If the Demographic Information option is not available, (i.e., grayed-out) it means you need to import an allele frequency input file. On the Fusion Menu bar, select **Utilities**>**Update Reference**>**Allele Frequency**. Click the browse button and locate the Allele Frequency files. Click **Import Allele Frequency.**

Minimum Positive Control

The default Minimum Positive Control value assigned by the system is 1000. If desired, enter a new value in the Minimum Positive Control Value field and press the **Enter** key on your keyboard.

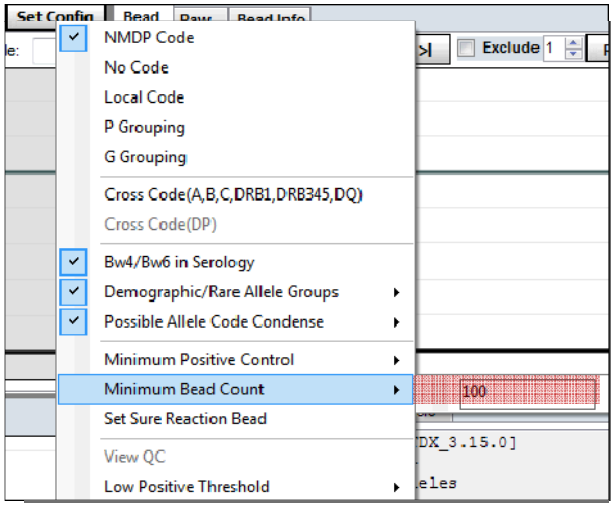
Set Minimum Positive Control



The sample is flagged in the System Comments as having a low Positive Control if any positive control trimmed mean in the current sample falls under the threshold you've set. On the analysis Bead Tab, the bead bars for samples below the threshold you've set are colored **GRAY**.

Minimum Bead Count

Set Minimum Bead Count



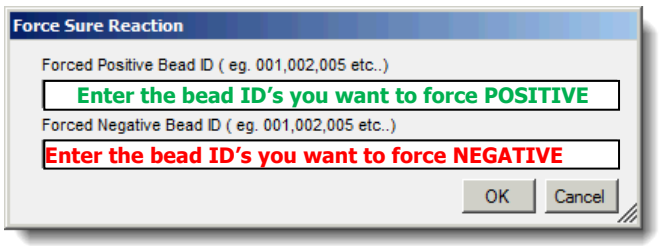
The default Minimum Bead Count value assigned by the system is 100. If desired, enter a new value in the **Minimum Bead Count Value** field. The sample is flagged in comments as having a low bead count if any bead count in the current sample falls below the threshold you set.

Set Sure Reaction Bead

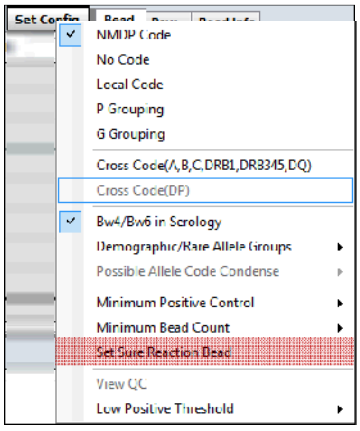
1. Click the **Set Config** button, (upper right) and select the **Set Sure Reaction Bead** option in the configuration menu to enter Bead IDs for which to force positive or negative values.

   The **Force Sure Reaction** dialog box is displayed.

2. Here you can enter bead IDs for which you want to force positive, (false positives are considered true positives) or negative, (false negatives are considered true negatives).

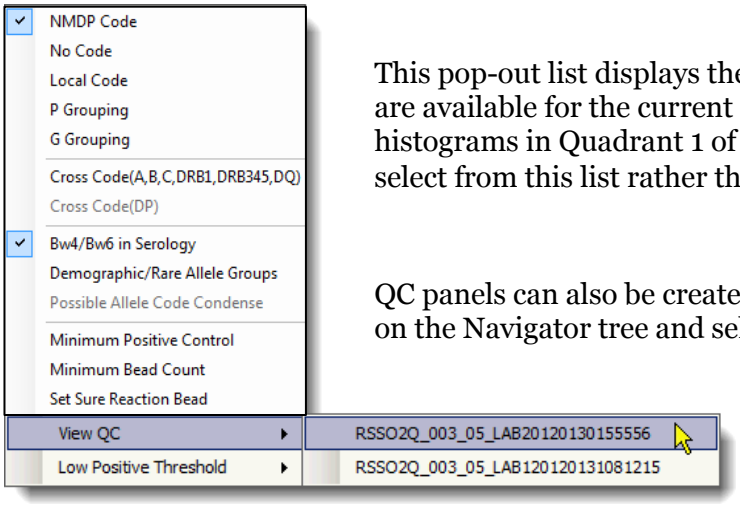


Force Sure Reaction



Set Sure Reaction

View QC

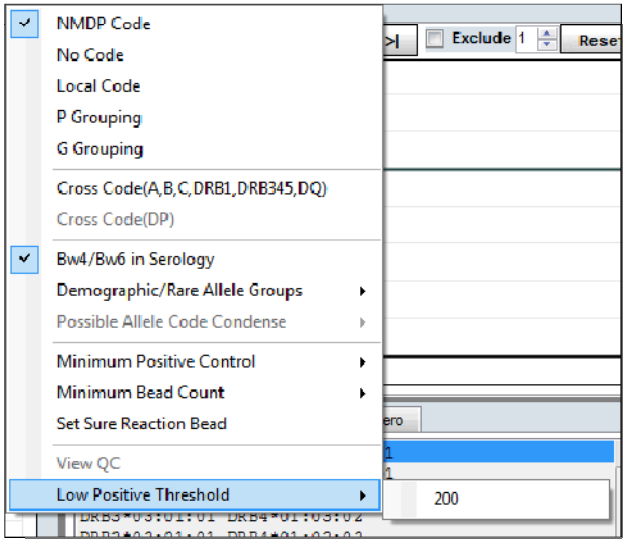


Configure Alternate QC Panels

This pop-out list displays the Alternate QC panels, (that you created) which are available for the current Catalog file which can be displayed as histograms in Quadrant 1 of the Analysis Window. When clicked, you can select from this list rather than use the OLI QC.

QC panels can also be created by right-clicking a saved LABType Session on the Navigator tree and selecting Create Local QC.

Low Positive Threshold Setting



Set Low Positive Threshold

The default Low Positive Threshold value assigned by HLA Fusion is 200.

If desired, click the **Set Config** Set Config button and enter a new value in the **Low Positive Threshold** field located at the bottom of the pop-out menu.

Samples below this value are graphed as **GRAY**, vertical bars in the upper right Quadrant, (2) of the Bead Analysis screen.

Using the LABType Data Analysis Window

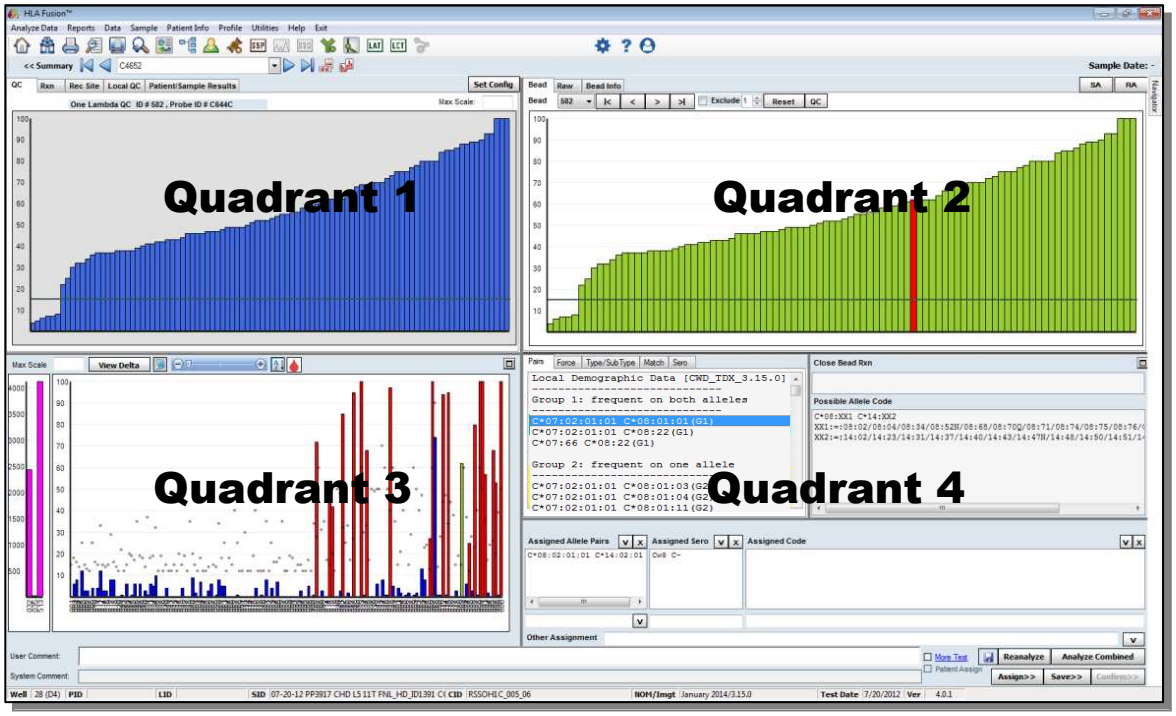
The LABType Data Analysis Window provides detailed analysis information for each sample in the session. You can review the allele assignments suggested by the program and modify and accept the typing assignments. HLA Fusion suggests possible typing results, but the final assignment must be made by you or your supervisor.

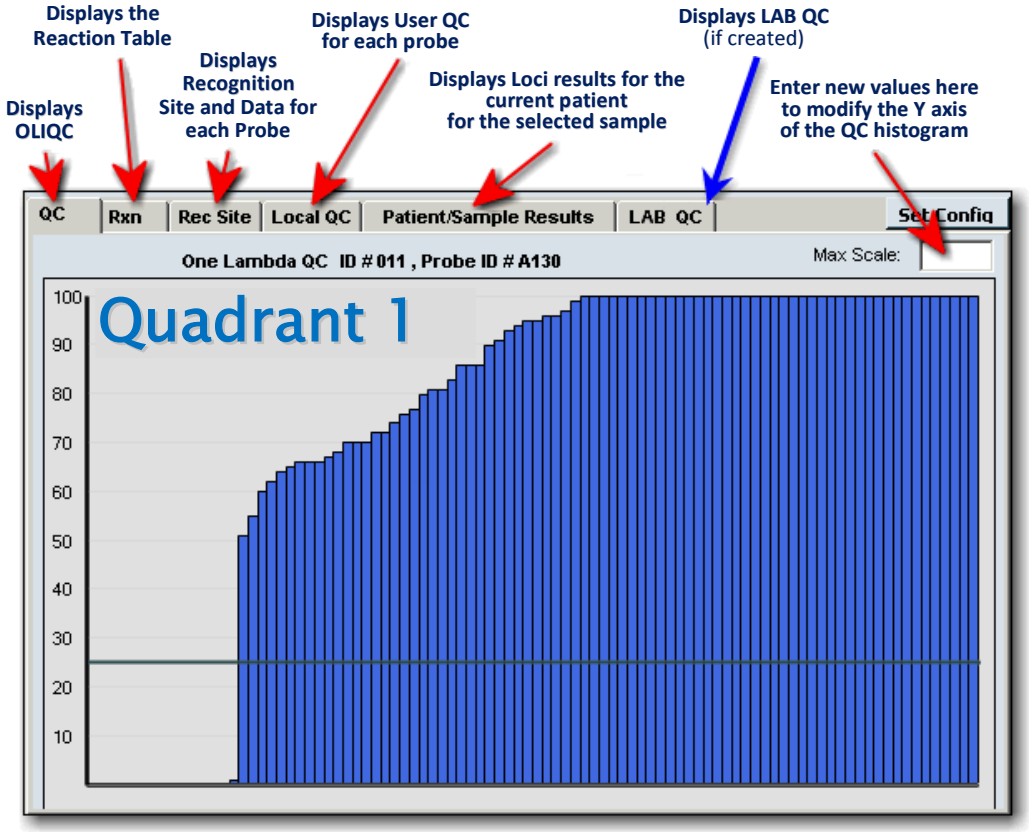
From the LABType Analysis Window you can do the following:

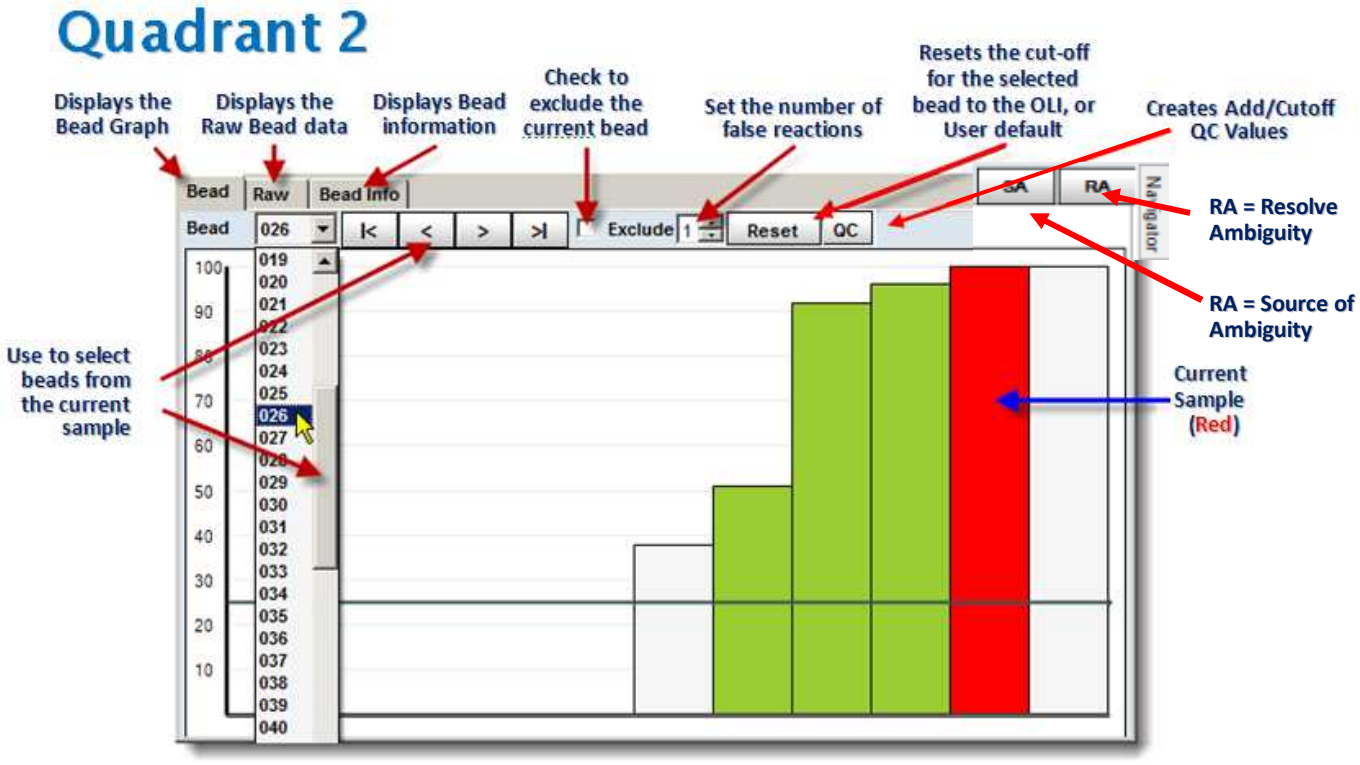
- Switch between code formats
- Apply Bw4/Bw6 to serology results
- Apply frequency filters
- Show the delta between the signal generated and the cutoff point for each bead
- Display reaction, recognition site, raw, and bead data
- Navigate between beads
- Exclude a bead from analysis
- Adjust cutoffs
- Assign non-coded allele pairs
- Assign a coded allele pair
- Assign serology equivalents
- Make manual assignments
- Remove assignments
- Save and confirm your analysis results
- Find the source of an ambiguity and ways to resolve it

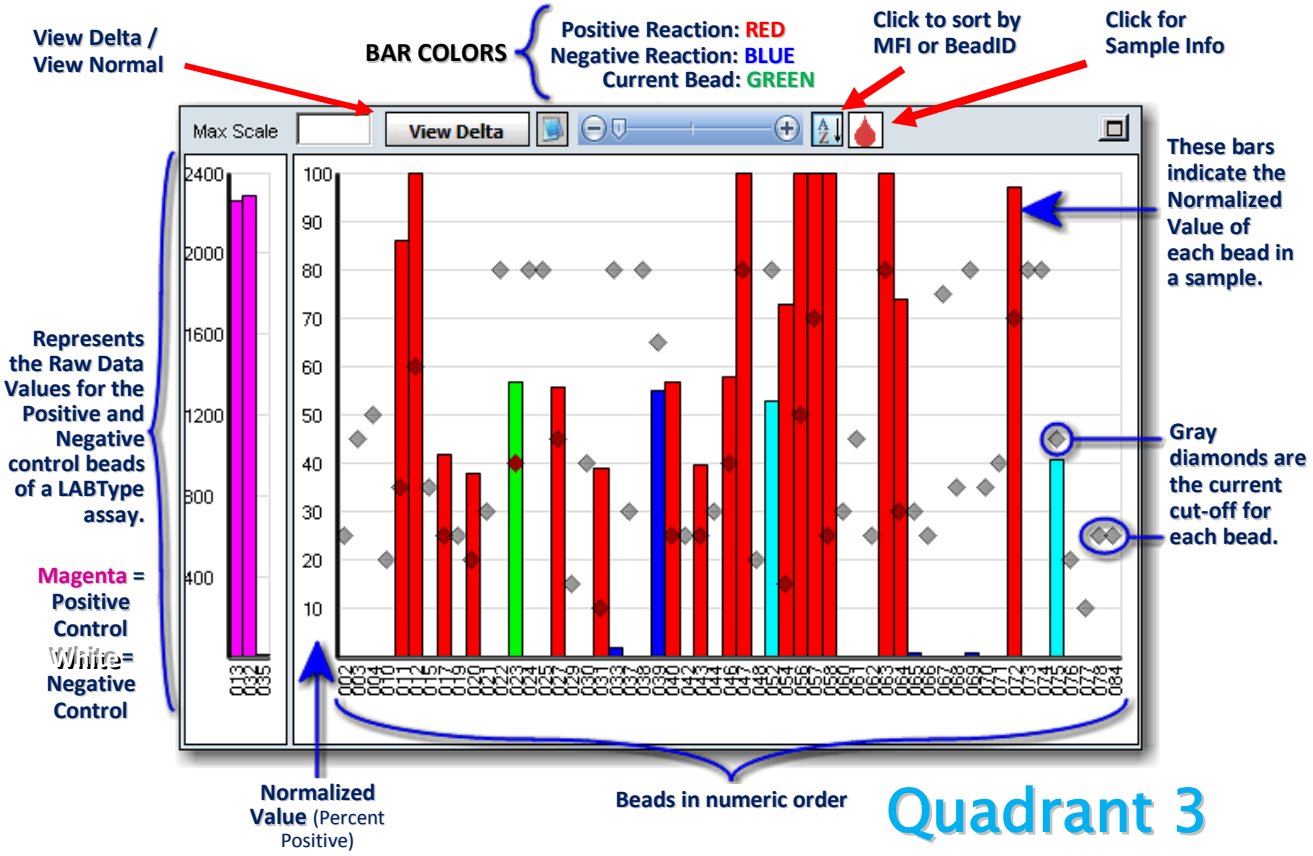
The LABType Analysis Window is divided into four main sections, or Quadrants, each providing specific data for analysis.

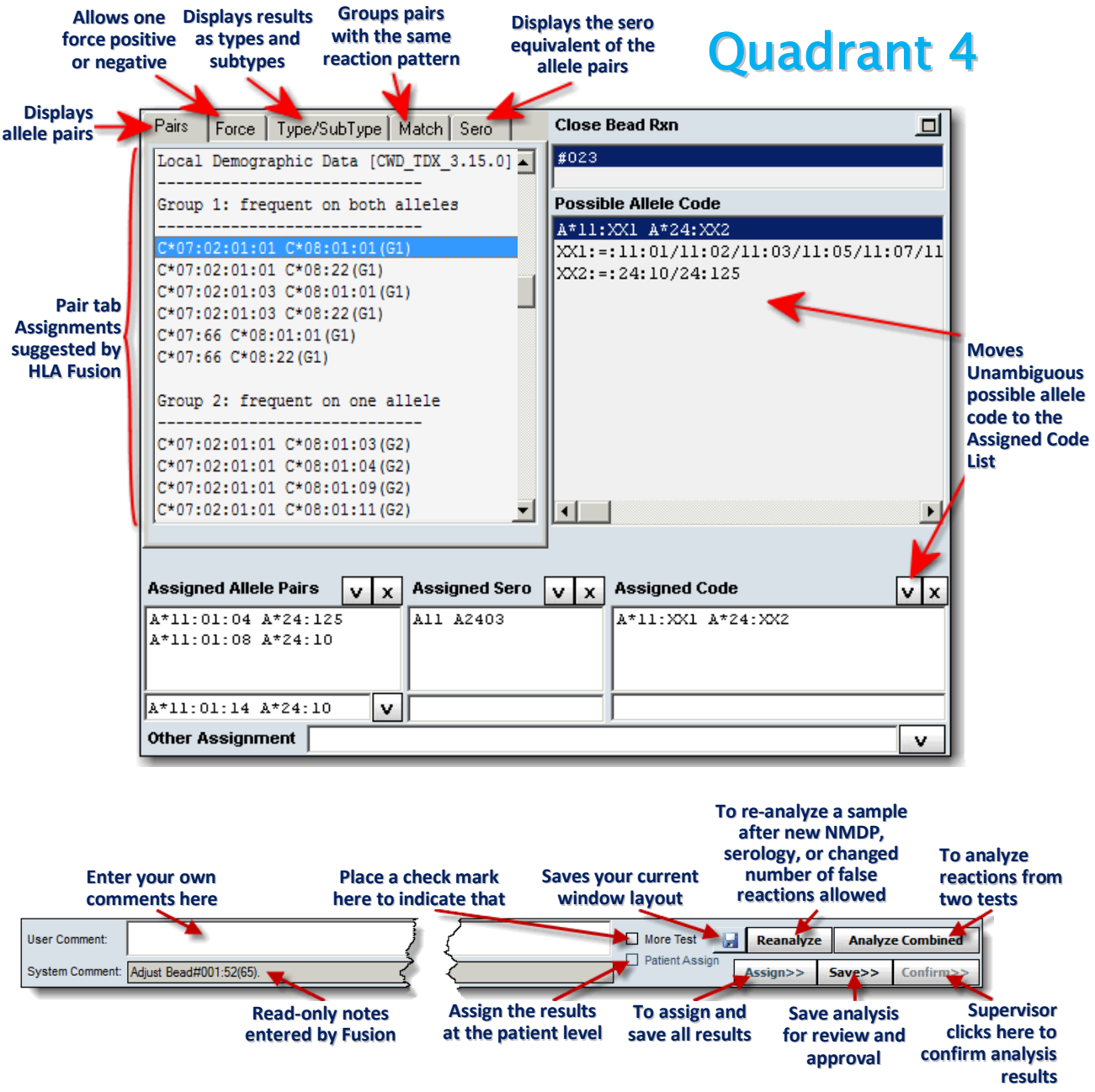
The LABType Sample Analysis Window






Quadrant 2
Displays the Bead Graph
Displays the Raw Bead data
Displays Bead information
Check to exclude the current bead
Set the number of false reactions
Resets the cut-off for the selected bead to the OLI, or User default
Creates Add/Cutoff QC Values
RA = Resolve Ambiguity
RA = Source of Ambiguity
Use to select beads from the current sample
Current Sample (Red)
Bead
Raw
Bead Info
Exclude
Reset
QC
SA
RA
Navigator


View Delta / View Normal
BAR COLORS
Positive Reaction: RED
Negative Reaction: BLUE
Current Bead: GREEN
Click to sort by MFI or BeadID
Click for Sample Info
Max Scale
View Delta
These bars indicate the Normalized Value of each bead in a sample.
Represents the Raw Data Values for the Positive and Negative control beads of a LABType assay.
Magenta = Positive Control
White = Negative Control
Gray diamonds are the current cut-off for each bead.
Normalized Value (Percent Positive)
Beads in numeric order
Quadrant 3



Each quadrant of the Analysis Window represents a different view of the same sample. The quadrants are all linked to one another: a change you make to Quadrant 2, (cutoff for example) affects the display in Quadrants 1, 3 and 4. Each quadrant can be re-sized, vertically and horizontally:

- Hover your cursor between the quadrants until the cursor image changes to ✢. Click and drag the graph to resize it.
- Or, click the Quadrant **Maximize** ☐ button to modify the quadrant display.

Keyboard Shortcuts for LABType Analysis Navigation

The following table defines some computer keyboard combinations you can use to quickly navigate through a LABType sample during analysis.

Keyboard Combo	To Do this...
Alt + **N**	**Navigate to the next bead**, (from bead analysis & sample analysis screens)
Alt + **P**	**Navigate to the previous bead**, (from the bead analysis & sample analysis screens)
Alt + **A**	**Assign and go to the next sample**, (from the sample analysis screen)

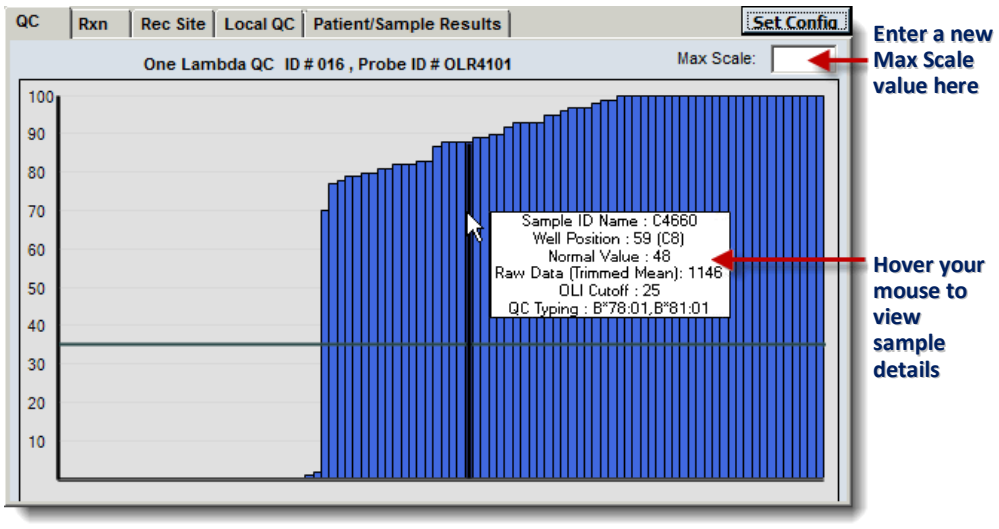
Quadrant 1 (QC Histogram)

There are several tabs in this quadrant, as explained in the following sections.

QC Tab

The **QC Tab** displays a histogram of the reaction profile for the current bead against all samples of the QC panel used in the analysis.

Each bar represents a QC sample, and its height represents the normalized reaction value.



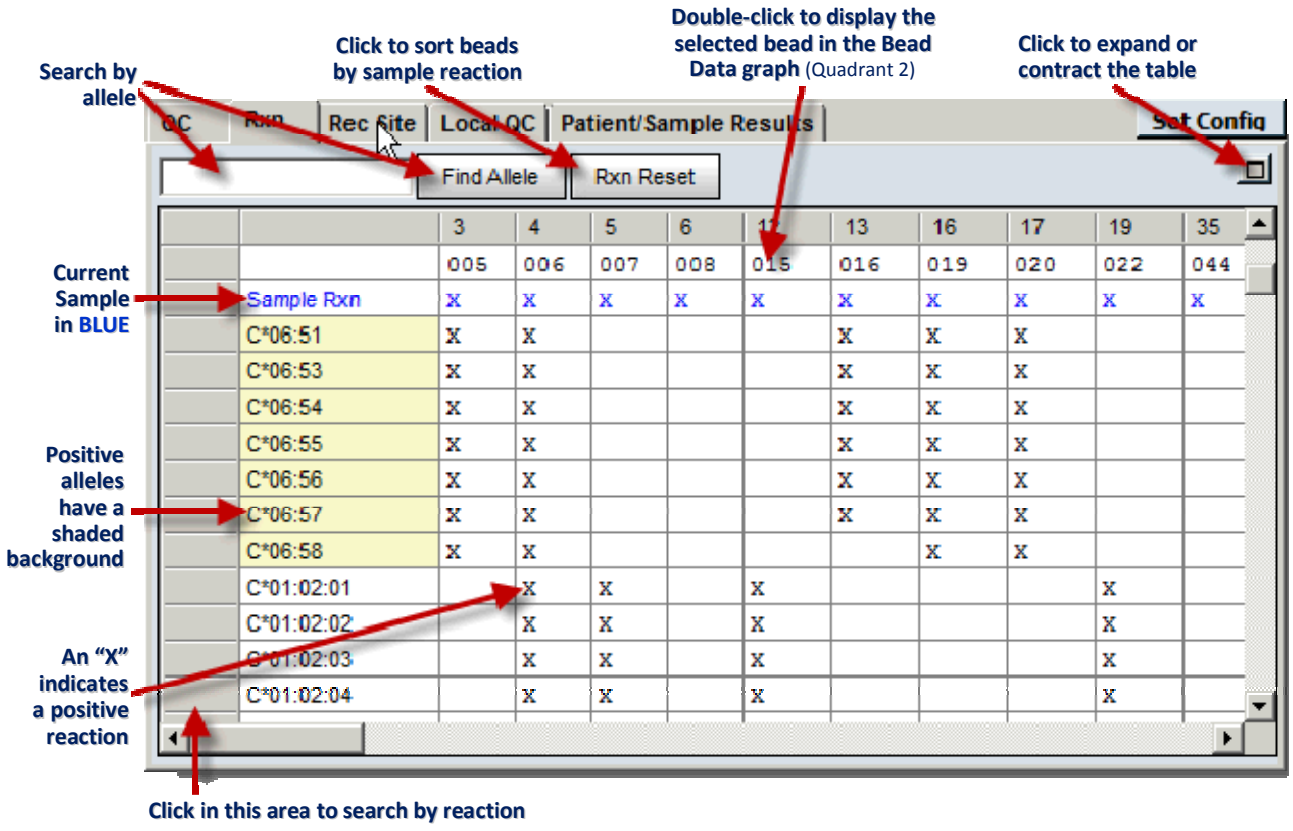
- Hover your cursor over any sample and the sample details are displayed, including typing results, (see graphic).
- To change the histogram scale, click inside the **Max Scale** box, type in new limits, and press the **Enter** key.

  The Max Scale feature defines the maximum Y-axis range. When you enter a new Max Scale value, the QC and bead data histograms automatically refresh to display the range from zero to the new maximum value.
- The cut-off line represents the One Lambda default cutoff value.

Rxn (Reaction)**Tab**

The **Reaction Pattern** tab displays the Positive reactions for each bead, (X-axis) versus every allele, (Y-axis) defined in the catalog file.

From the LABType Analysis Window in Quadrant **1**, click the **Rxn** tab to display the **Reaction Pattern Table**.

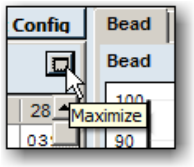


		3	4	5	6	12	13	16	17	19	35
		005	006	007	008	015	016	019	020	022	044
	Sample Rxn	X	X	X	X	X	X	X	X	X	X
	C*06:51	X	X				X	X	X		
	C*06:53	X	X				X	X	X		
	C*06:54	X	X				X	X	X		
	C*06:55	X	X				X	X	X		
	C*06:56	X	X				X	X	X		
	C*06:57	X	X				X	X	X		
	C*06:58	X	X					X	X		
	C*01:02:01		X	X		X				X	
	C*01:02:02		X	X		X				X	
	C*01:02:03		X	X		X				X	
	C*01:02:04		X	X		X				X	

The Default configuration:

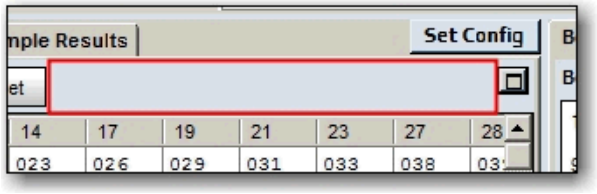
- Beads are sorted by sample reaction.
- The current sample appears on top line of the table in a **blue** font
- Positive alleles are listed below the sample row and have a shaded background.
- **Salmon** coloring indicates a false positive.
- **Green** indicates a false negative.

Positive reactions are displayed as an "**X**" on the table, (**Blue** for the current sample and **Black** for the rest). PC, NC, and excluded beads are displayed as a zero, "**O**" on the table.



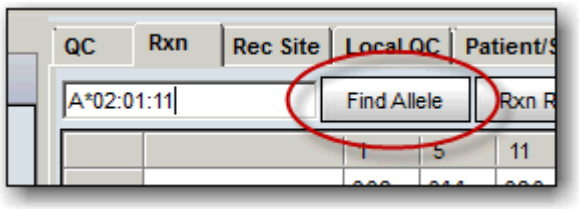
If you want to expand the table to its full size, click the **Maximize** button. To minimize the view, click the button again.

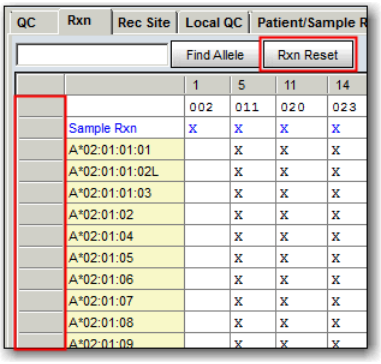
OR…



Double-click anywhere in the area just above the table, between the **Rxn Reset** and the **Max** buttons to expand the table. To size the table back to its original quadrant size, double-click in the same area again.

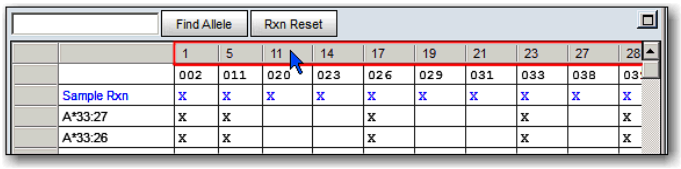
Type an allele into the field and click the **Find Allele** button to display the allele and its reaction pattern in the first row below the sample. Double-click on an allele name to bring that allele to the top of the table. You can bring all of a certain allele group to the top by entering an allele group (e.g., DRB1*03).

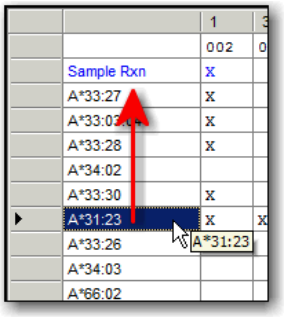




Click on the blank, gray row header to the left of an allele name or reaction to move all the beads with that reaction to the *left*. Click the **Rxn Reset** button to reset the table to its original configuration.

When a column header is clicked, the table is sorted by reaction criteria for that bead. The *first click* sorts in **ascending order** from top to bottom. The *second click* sorts in **descending order**.





Double-click on the allele column to bring the selected allele *up* to the top of the Reaction Pattern Table, just below the sample.

If you use the **Analyze Combined** 

button to analyze two or more analyses for the same sample, Bead IDs in additional analyses are differentiated from the current one in the Rxn Table by an underscore and a sequential number.

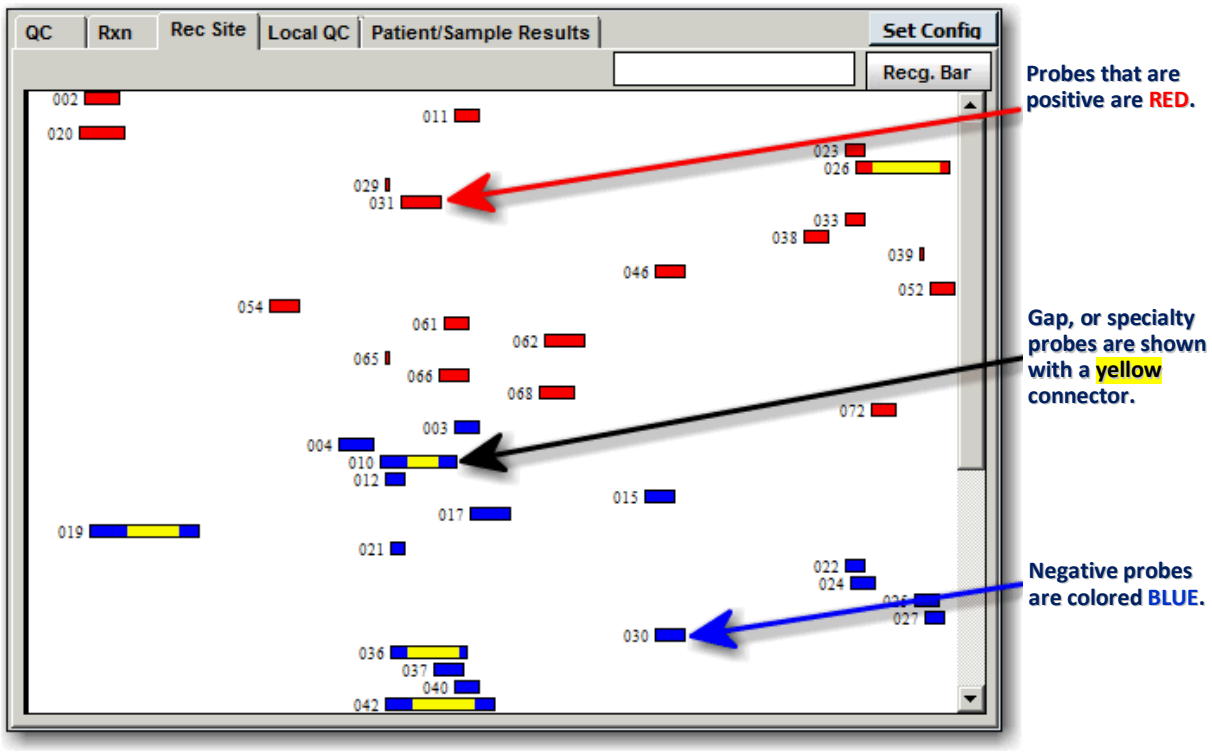
For example, if the current sample contains a bead with Bead ID002, and you analyzed it in combination with an additional analysis for the sample, that same bead for the second sample analysis is listed as 002_0 in the Rxn Table. The number following the underscore increments for additional samples you may add to the combined analysis (_1 for a third sample test, etc.).

Rec (Recognition) **Site Tab**

This graph maps the recognition sites of all probes in the sample and highlights those probes that pick up any of two user-selected alleles for comparison.

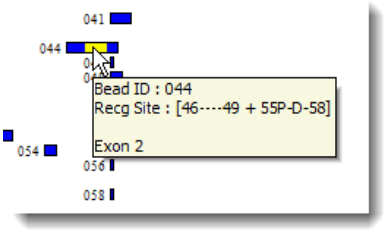
- **X-axis:** probe binding site in reference to the exons amplified in the test kit used, (starting with exon 2's on the left and going to exon 4's or higher on the right, if applicable to the sample).
- **Y-axis:** bead

From the LABType analysis window in **Quadrant 1**, click the **Rec Site** tab.



- Probes that are positive for the selected alleles are colored **Red** and are displayed at the top of the plot. Negatives are colored **Blue**, and are displayed below the positives.
- Probes are identified by a horizontal bar at the location of the recognition site. The probe position is labeled next to the bar.
- When you click a probe, the bead graph in Quadrant **2** updates and a pop-up information box displays the following fields:

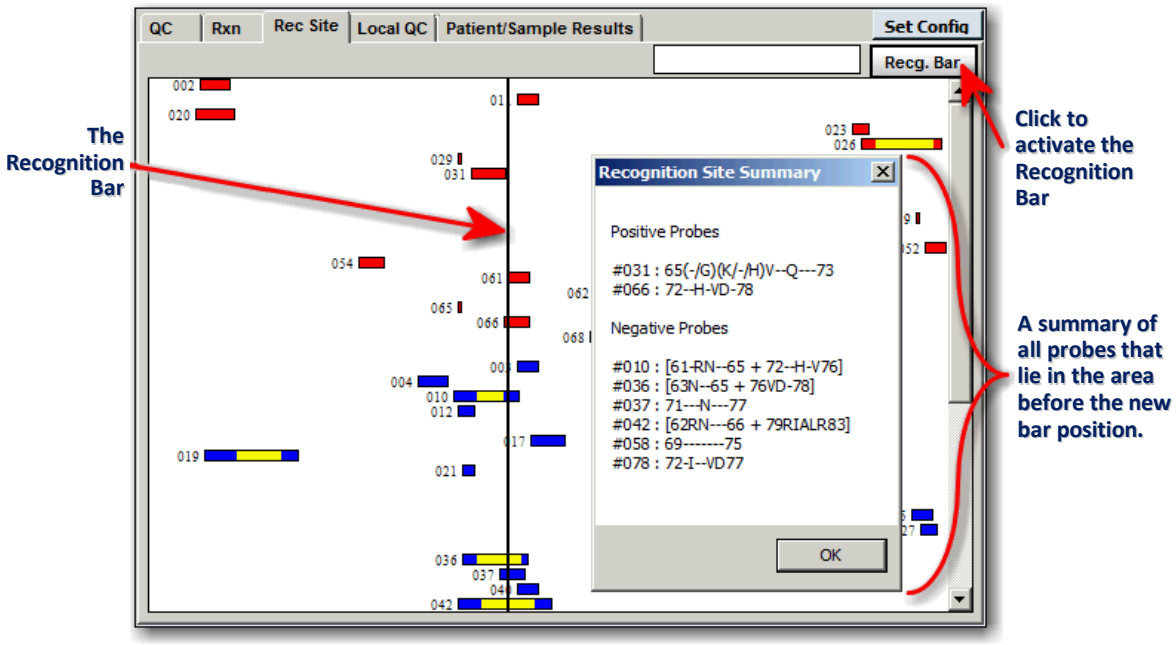
  1. Bead ID
  2. Recognition Site
  3. Exon number



- **Gap**, or *specialty probes* are indicated by a **yellow** connector that joins two recognition sites. The recognition site data that displays when you click a specialty probe is for <u>both</u> of the connected probes.

The Recognition Bar

Activate the **Recognition Bar** by clicking the **Recg. Bar** Recg. Bar button. Initially, the bar will appear on the left side of the graph. Drag the bar to the right with your mouse pointer. Once you release the bar the system will display the **Recognition Site Summary**, (Positive, Negative and Excluded probes) for wherever this bar is positioned in the window.

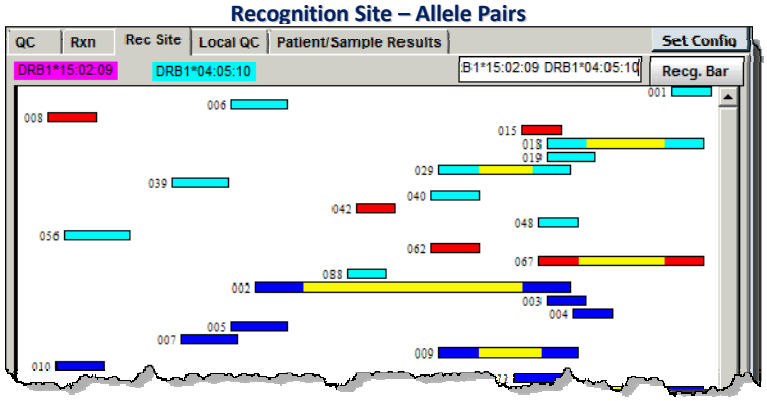


Probe Recognition Site Summary

Click the **OK** OK button to dismiss the Recognition Site Summary.

- You can enter up to two alleles, separated by space, in the **Allele Text Field** C*01:02:01 C*03:38:02, and press the **Enter** Enter key on your keyboard.
- Or, you can search alleles by double-clicking the allele pair on the **Possible Allele Pairs** results list, (in Quadrant 4).

Recognition Site – Allele Pairs

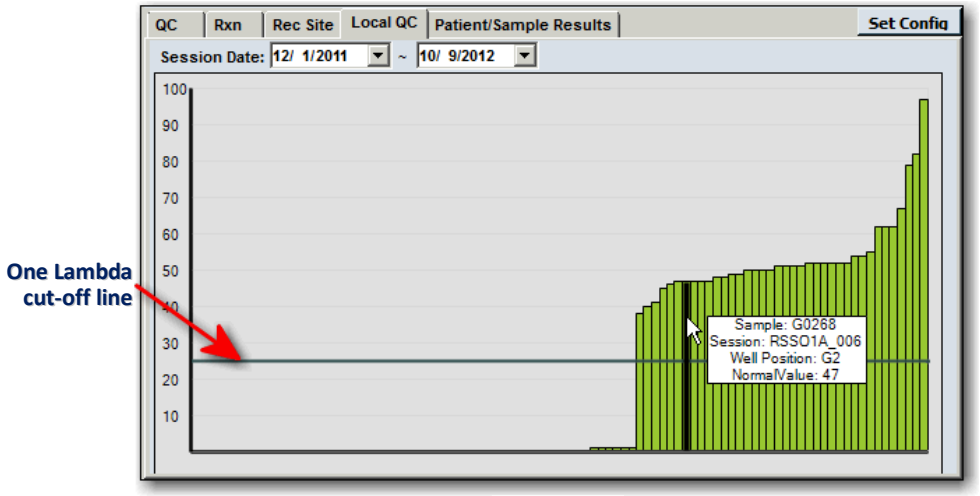


All probes that are reactive to the selected allele(s) are colored:

- Allele 1: **Magenta**
- Allele 2: **Cyan**

Local QC Tab

The **Local QC** tab displays a histogram of the reaction profile for the current bead against all samples this user has ever run for the same product, (same lot/revision) and over a specified date range.

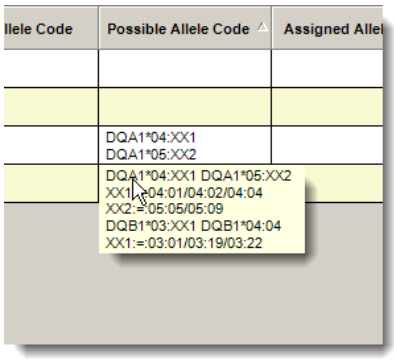


Local QC Tab

Each **Green** bar represents a QC sample and its height represents the normalized reaction value. This will serve as a user-created QC graph.

- Hover your cursor over any sample, and the sample details are displayed.
- The graph is continually updated as you analyze the product over time.
- The cut-off line represents the One Lambda default cut-off value.

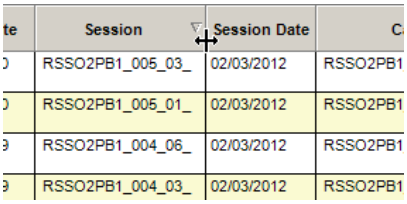
Patient/Sample Results Tab



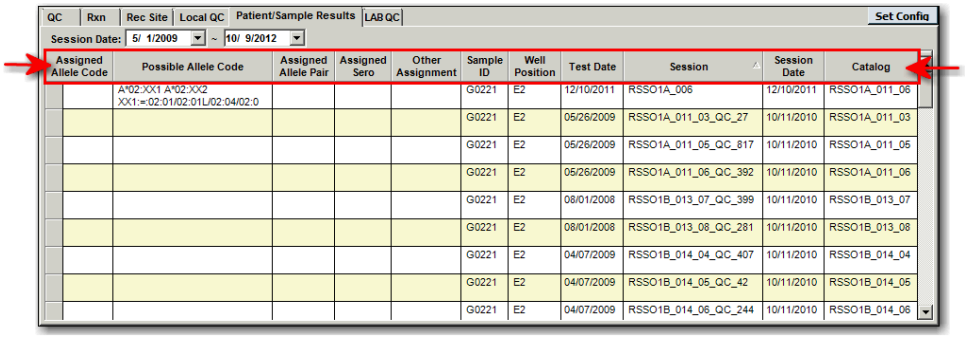
The **Patient/Sample Results** tab details all of the results for all the tests done on a Sample ID or Patient ID. As results are saved for each locus, either the serology result or the allele code for each loci appears in this all-loci section.

Click on any of the labeled **Gray** tabs along the top of the grid to sort the results in either ascending or descending order. The direction of the small triangles ▲indicates how the results have been sorted.

Hover your mouse over any **Possible Allele Code** to see the entire allele code.



You can use your mouse to widen the grid, or double-click *between* the tabs to automatically increase the column width to accommodate all the data presented.



Patient/Sample Results tab

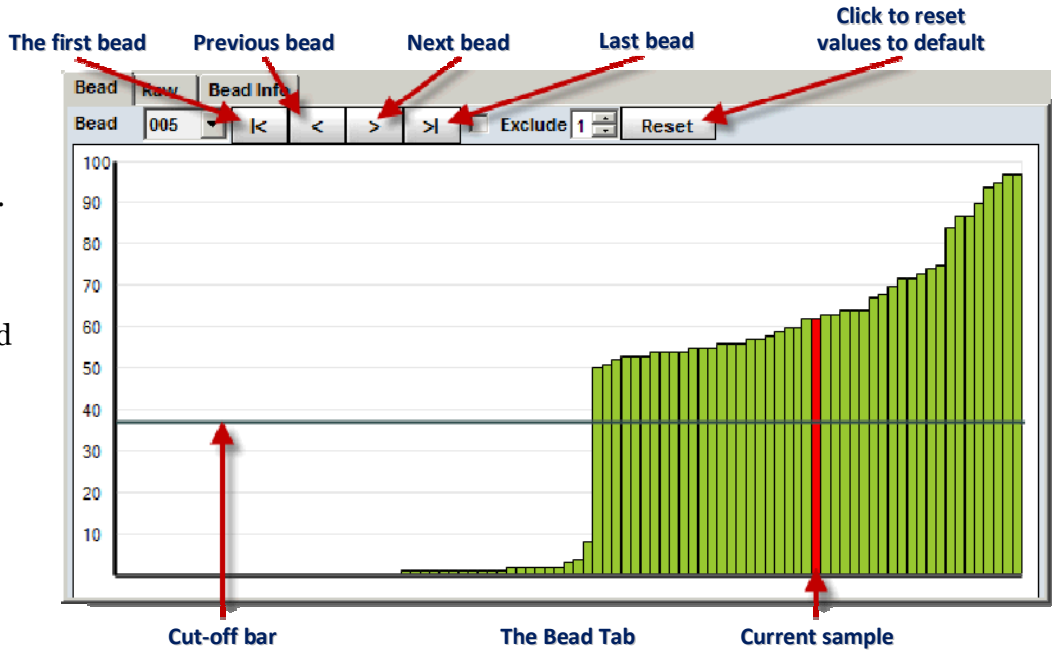
Quadrant 2(Bead Data)

There are three tabs in this quadrant which are explained in the following sections.

Bead Tab

The **Bead** Tab displays the histogram for the currently selected bead. Each bar represents a sample. The bar height represents the normalized reaction value for the selected bead in that sample.

The **Red** bar represents the currently selected sample.



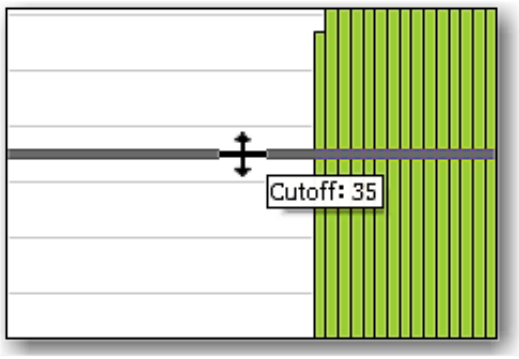
Double-click on a bar to navigate to the analysis of that selected sample.

You can click the arrow buttons to select a Bead Bar and display the selected bead in **Quadrant 2**.

Alternatively, you can also select the bead from the **Bead Navigator at the top.**

- **X-axis:** Samples sorted in order of reactivity, (weakest to strongest).
- **Y-axis:** Normalized value, (% positive).
- **Data points:** Bars represent the normalized value of a sample for the current bead.
- **The Bar Colors:** All bars are **Green**, except the *current sample*, which is **Red**.
- A white bar indicates samples with a low, (PC) positive control.
- **Cut-off line:** The cut-off line is located at the cut-off value for the current bead, (values above this line are considered positive).
- The cut-off line on this histogram can be modified. To adjust sample cut-off values, do this:

1. Click and hold the horizontal cut-off bar and drag it up or down to a new cut-off setting. The cut-off value is displayed next to the cursor and changes as you drag the bar up or down.

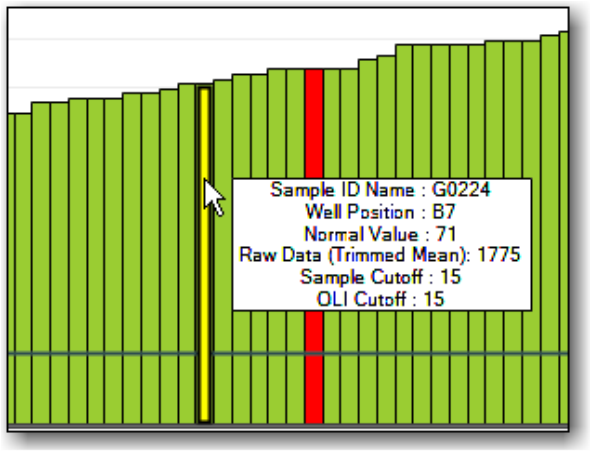


Adjusting the Cut-off Bar

2. To reset the cut off values to the default for the current sample, click the **Reset** 

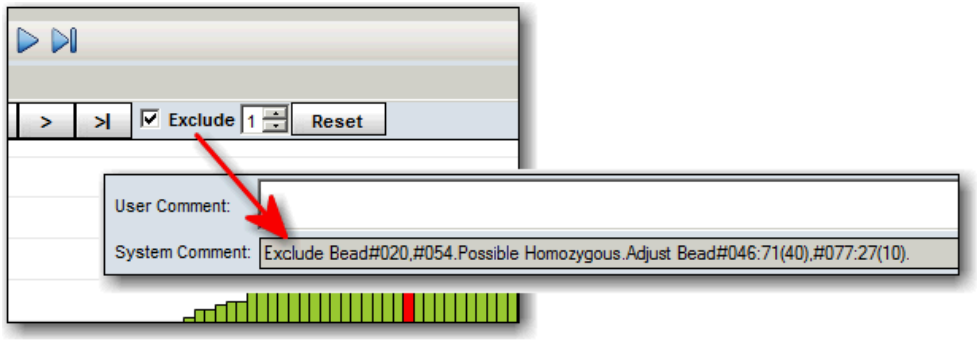
button and choose a default option.

- When a Sample Bar is double-clicked, the analysis module displays the results for the selected sample.
- Hover your cursor over any sample and the bar turns yellow and sample details are displayed.



Sample Detail

- If you wish to exclude a bead from analysis, check the **Exclude** box. When checked, the *current bead* is excluded from the analysis of the current sample. Analysis results are refreshed to reflect the change and a notation is added to the **System Comment** field: *Exclude Bead #[bead id]*.



Excluded Bead in System Comments

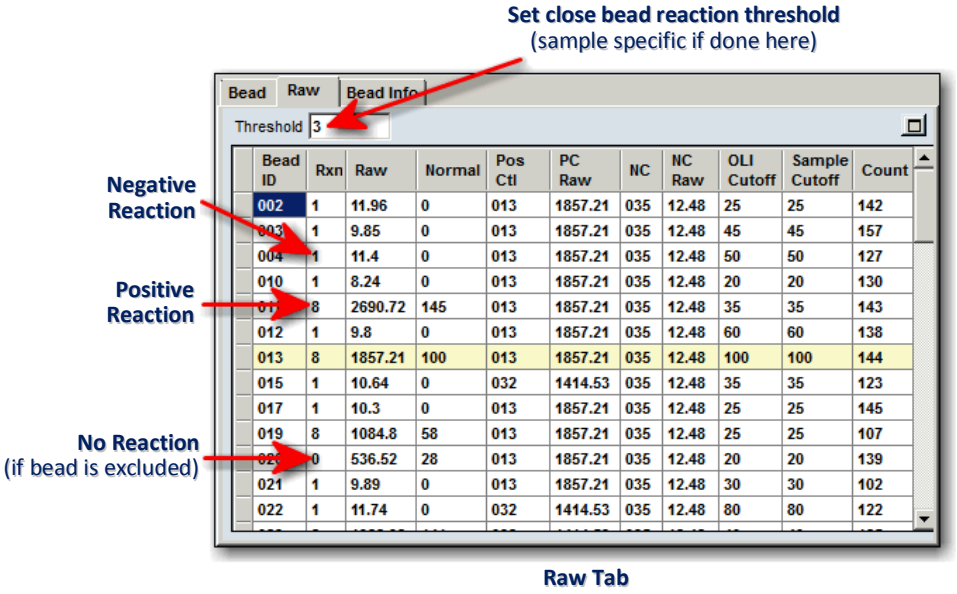
- If HLA Fusion cannot determine any results that exactly match the reaction pattern entered, it analyzes the reaction assuming that there is one false reaction in the sample. If a solution still cannot be found, the system continues to search through additional false reactions until the number of allowable false reactions has been reached, or a solution is found.

The false reaction setting must be between the minimum setting of **1** and the maximum setting of 4.

Note: Regardless of the maximum false reactions set here, the sample analysis stops at the first false reaction found.

Raw Tab

Displays the data for the current sample as a table of values. From the LABType analysis window in **Quadrant 2**, click the **Raw** tab to display the **Raw Data Table**.



Raw Tab

The columns in the Raw Data table display the following types of data:

- **Rxn**: (1=negative, 8=positive, 0=no reaction)
- **Raw**: raw data for the trimmed mean fluorescent
- **Normal**: normalized value
- **PosCtl**: positive control bead ID
- **OLI Cutoff**: default OLI positive threshold cut-off
- **Sample Cutoff**: sample positive threshold cut-off
- **Count**: bead count

The beads having reactions that fall within the range of the close bead threshold are highlighted in **Yellow**.

- These *close beads* are also listed in the **Close Bead** text box in Quadrant 4.

The Close Bead Threshold can be set for all newly imported LABType sessions by using the **Utilities > Molecular Product Configuration** menu.

This sets the range of close beads based on the normalized values, +/- from the current cut-off for the bead so that a bead can be considered a close bead and be highlighted yellow on the raw data table. The default value is 3. To change the threshold value, type in a new value in the **Threshold** box and press the **Enter** key.

The raw table is updated instantly and rows with a close bead reaction are highlighted in yellow.

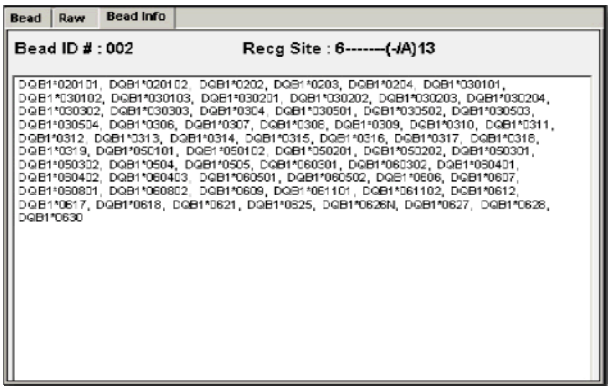
- Click the **Maximize** button to expand the **Raw Data Table**. Click the button again to minimize the Raw Data Table.
- Click on any column header to sort the Raw Data table by that column. Double click a Bead ID to select that bead on the Bead Tab.
- The count values and corresponding Bead IDs in **Red** are those beads that have a bead count *lower* than the low positive control threshold. The minimum Bead Count threshold may be set through the **Utilities > Molecular Product Configuration** menu, or by clicking **[Edit]** on the LABType Configuration portion of the LABType home page. The default threshold is **100**.

Bead ID	Rxn	Raw	Normal	Pos Ctl	PC Raw	NC	NC Raw	OLI Cutoff	Sample Cutoff	Count
002	1	10.22	0	013	2999.09	035	10.87	23	23	103
003	8	1328.81	44	013	2999.09	035	10.87	15	15	41
004	8	2205.25	73	013	2999.09	035	10.87	23	23	97
005	1	214.56	7	013	2999.09	035	10.87	20	20	69
006	8	3675.94	123	013	2999.09	035	10.87	30	30	99
007	8	2173.95	72	013	2999.09	035	10.87	25	25	134
008	1	14.38	0	032	2502.84	035	10.87	60	60	141
009	1	235.59	8	013	2999.09	035	10.87	20	20	101
010	1	77.78	3	032	2502.84	035	10.87	40	40	50
011	8	2603.98	87	013	2999.09	035	10.87	20	20	98
013	8	2999.09	100	013	2999.09	035	10.87	100	100	124
014	1	64.08	2	032	2502.84	035	10.87	13	13	105

Bead counts lower than low positive control threshold

Bead Info Tab

When you click the **Bead Info** tab, it displays the allele specificities of the most recently selected bead from the QC histogram or bead profile graph, as well as the recognition site of the probe.

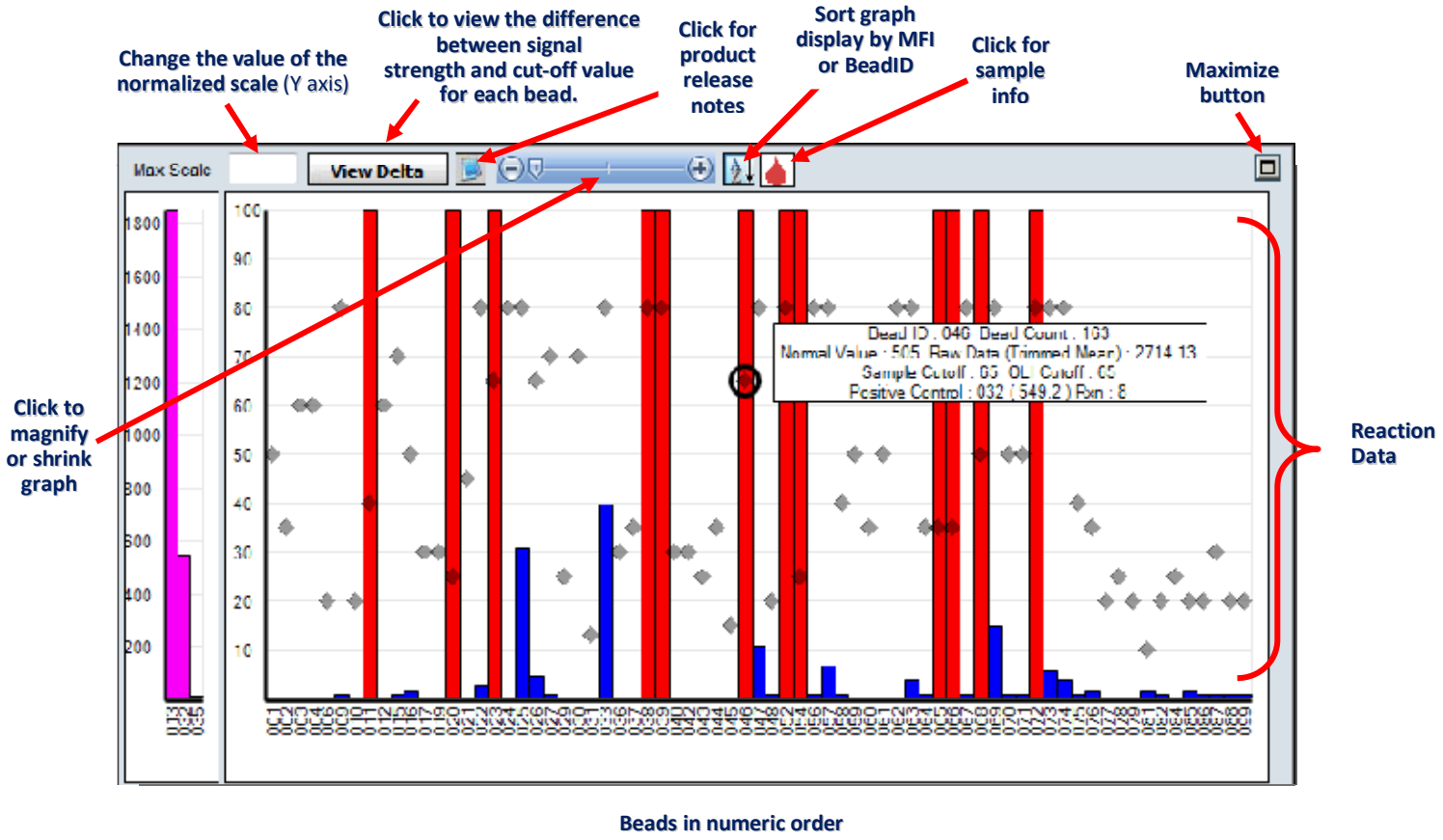


Bead Info Tab

Quadrant 3(Reaction Profile)

The Reaction Profile

Quadrant3 displays the reaction profile for the current sample against all beads in the analysis.



- **X-axis:** Beads listed in numeric order from left to right
- **Y-axis:** Normalized value (% positive)
- **Data points:** Bars represent the normalized value for all beads in the current sample.
- **Bar colors:** Positive reaction = **Red**; negative reaction = **Blue**; current bead = **Green**.
- **False Positive or False Negative:** Light Blue
- **Excluded bead:** Gray

When a bar is selected on this histogram, the bead profile histogram, (in Quadrant 2) and QC panel histogram, (in Quadrant 1) refresh to display the selected bead.

This histogram may be expanded when you click the **Maximize** button at the top, left corner. The histogram maximizes to the width of your screen, allowing for more space to view the bars in graph.

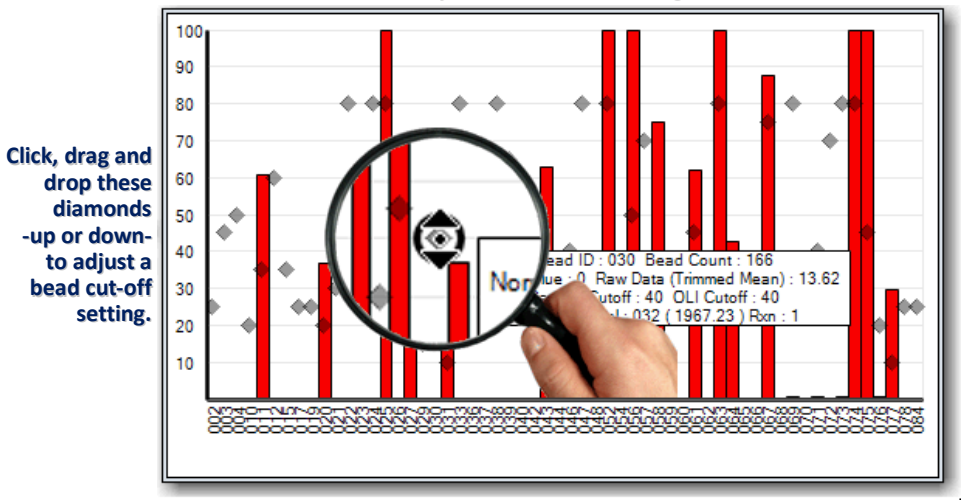
Click the button again to return the histogram to its original size within the quadrant.

The **diamonds**◆ inside the histogram indicate the current cutoff position for each bead.

Bead-level cutoff adjustments can be made in this quadrant by dragging and dropping the arrows within the bars. To adjust bead cutoff values, follow these instructions:

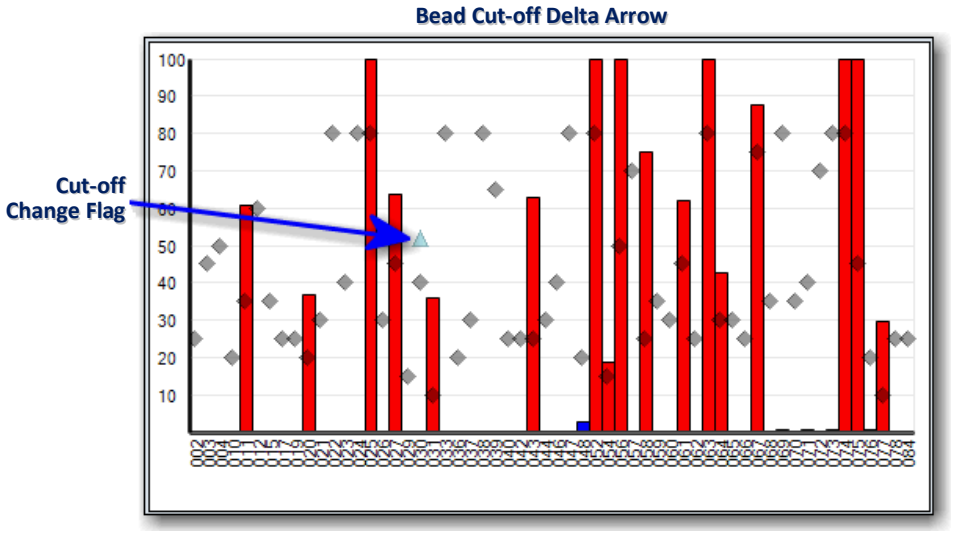
- Click and hold the bead cutoff diamond and drag it up or down to a new cutoff setting. The cutoff value is displayed next to the cursor and changes as you drag the bar up or down.

Adjust Bead Cut-off Settings



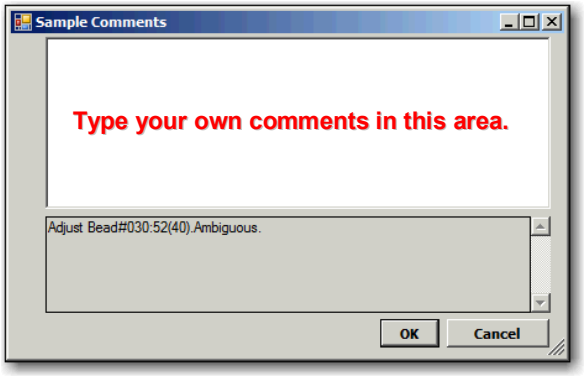
When a cutoff adjustment has been made, the diamond changes into a Delta Arrow ▲ that points in the direction the cutoff was moved. The tip of the arrow points to the location of the new bead cutoff value along the x-axis.

Bead Cut-off Delta Arrow

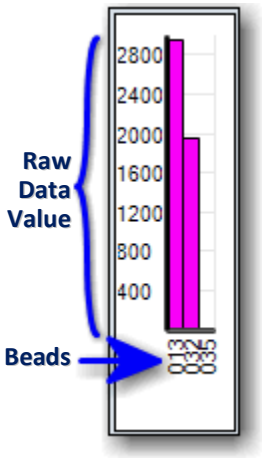


You can hover your mouse pointer over any bar and details for that bead are displayed for the sample.

You can add comments to the sample by typing in the **Comment** field at the bottom. Double-clicking in this text box opens a much larger window to type your comments in.



The Magenta and the **white**, (or non-colored bar on the right) represent the raw data values for the positive and negative control beads of a LABType assay:



Magenta Positive Control

White Negative Control

X-axis: Beads in numeric order.

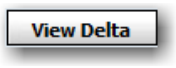
Y-axis: Raw data value, (trimmed mean).

Data points: Bars represent the raw data value of a bead vs. the sample reaction.

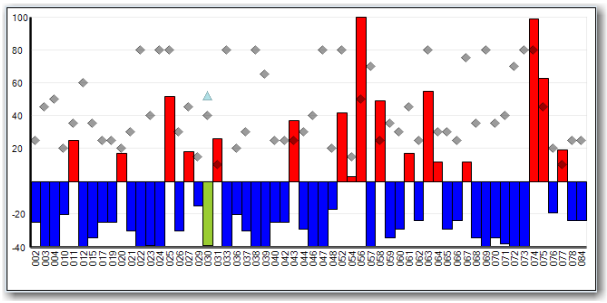
Bar colors/display:

- Positive control = **Magenta**
- Negative control = White

To expand the histogram, double-click in the area between Quadrants 1 and 3. To resize the histogram to its original size, double-click between Quadrant 1 and 3 again. Or, click the **Maximize/Minimize** button.



To view the **Delta** data, (the difference between the signal generated and the cutoff point for each bead) click the **View Delta** button.



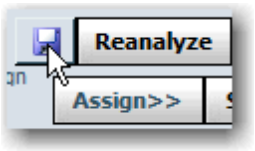
Quadrant 3: Delta View

To go back to the normalized view, click the same button which now says **View Normal** 

.

Would you prefer to make View Delta the default view so that it automatically displays each time you bring up a sample in the LABType Analysis window?

- Save the layout while this quadrant is in the View Delta mode by clicking the **Save Layout** button.



After you exit Fusion and log in again, your LABType sessions will display Quadrant 3 in View Delta mode.

Quadrant 4(Test Results)

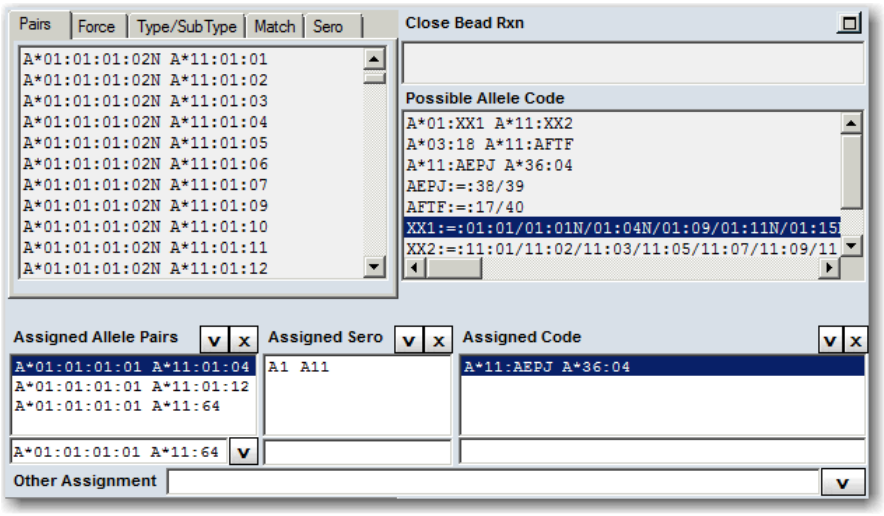
Quadrant 4 displays the typing results for the current sample. In general, the typing results include possible results and user assignments for allele pairs, coded results, serological equivalency results, and other assignments.

The left side shows various pair tab assignments suggested by the software. You must make all final assignments by bringing a suggested pair into the final assignment area or by typing in an allele pair.

There are five tabs here:

- The **Pairs** tab displays the possible allele pairs results that match the reaction pattern for the sample.
- The **Force** tab displays a list of alternate possible allele pair results for each bead if an additional false reaction is allowed.
- With the **Type/Subtype** tab, when an allele from one list is selected, the matching allele(s) are highlighted on another list to show the possible match-ups.
- The **Match** tab displays the coded format of the actual allele pairings for the sample.
- The **Sero** (serology) tab displays all suggested serology equivalent data for the sample, based on the possible allele pairs.

The right side shows possible allele code assignments for the sample, as well as close bead reactions.



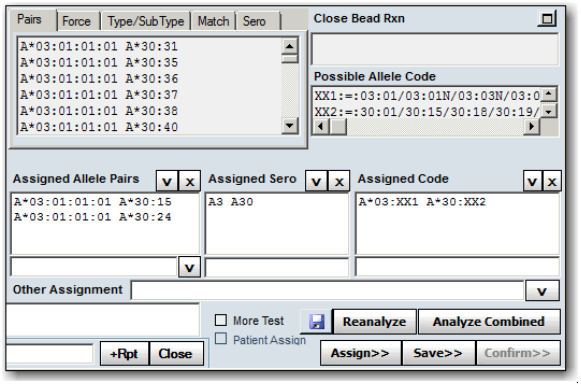
Quadrant 4 – Test Results

The Pairs Tab

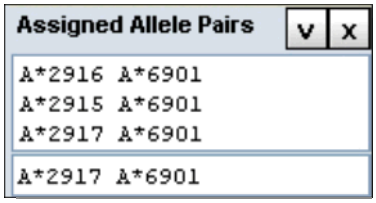
The **Pairs** Tab displays the possible allele pairs results that match the reaction pattern for the sample.

The pairs are suggested by HLA Fusion.

Pairs	Displays allele pairs.
Force	Allows one force positive or negative.
Type/Sub Type	Displays two sets of alleles. When one of the first is selected, matches from the second are highlighted.
Match	Groups and condenses pairs with the same reaction pattern.
Sero	Displays all suggested serology equivalent data for the sample.



- The list identifies the pairs and groups them by either full-match pairs, (no false reactions) or the number of false reactions.
- Results with false reactions are listed with the false reacting bead/well identified.
- The results display one allele pair per row.
- Possible homozygous NMDP-coded results are noted in the **System Comment** field.



Allele pairs are grouped by demographic frequency groups:

- **G1** (it is frequent on both alleles)
- **G2** (it is frequent on one of two alleles)
- **G3** (it is not frequent on either allele)

Each allele pair group is identified by "(G#)" at the end of each allele pair to indicate demographic frequency.

If the closest matching results include a false reaction, the false reaction bead is also listed.

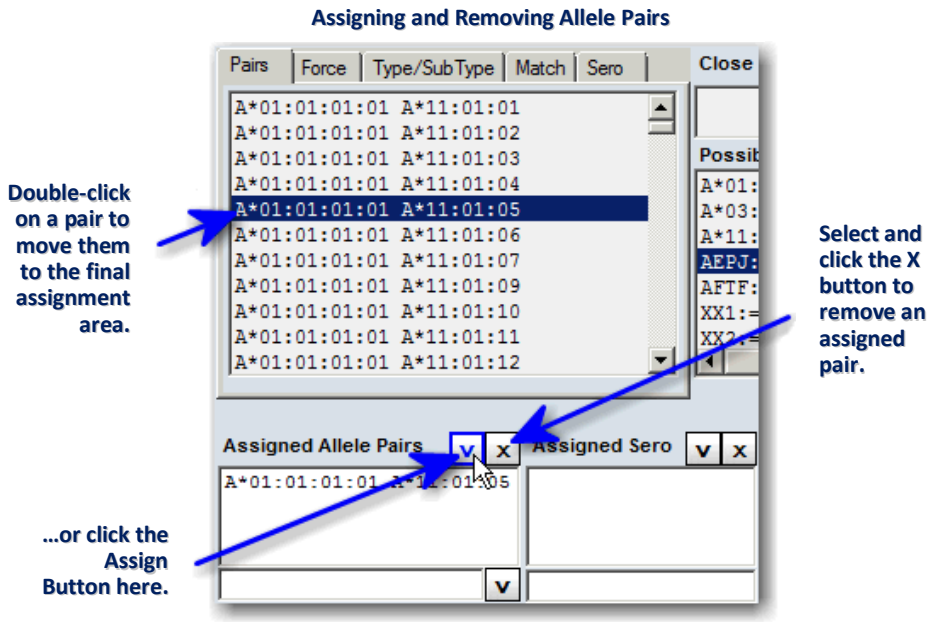
No Solution is listed if there are no results that match the sample's reactions within an allowable number of false reactions. When this occurs, increase the number of false reactions and reanalyze.

Assign an Allele Pair from the Suggested List

Double-click on an allele pair under the Pairs **tab to assign it to the final allele pairs assignment area.**

Alternatively, you can click to highlight an allele pair on the list under the **Pairs** tab and click the **down arrow V** (assign) button next to the **Assigned Allele Pairs** title to add it to the final assignment area. Multiple allele pairs can be assigned.

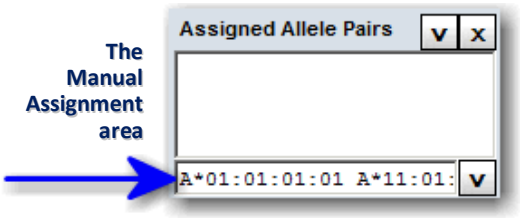
To remove an assignment, click and highlight the assignment on the **Assigned Allele Pairs** list and click the **X** (remove) button.



Manually Assign an Allele Pair

Manual assignments must be entered in the **Manual Entry Field**, in standard allele nomenclature format. Separate alleles with a space.

1. Enter an assignment into the text field below the **Assigned Allele Pairs** area.
2. Press the **Enter** key to display the typed allele on the **Assigned Allele Pairs** list above.



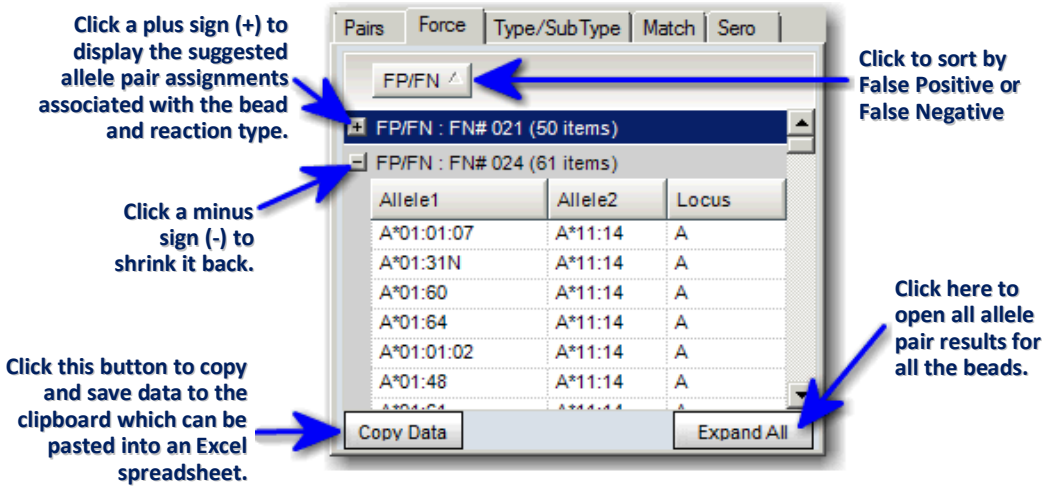
You can also make an assignment into the Manual Entry field by selecting a suggested allele pair and clicking the **Assign** button (**V**) to move the pair into the Manual Entry field, followed by pressing the **Enter** key.

Note: If you highlight more than one allele pair from the Pairs List, only the first one highlighted is assigned to the manual entry field.

Force Tab

The **Force** tab displays a list of alternate possible allele pair results for each bead if an additional false reaction is allowed. In other words, when there is a full match result, the system evaluates the sample with a single false reaction.

- This list is applicable for only one (1) forced false reaction.
- All results are grouped by order of the beads and reactions—the default is to list beads in ascending order, with false negative reactions listed first.
- Use this tool for homozygous, or rare allele assignments.
- False reactions are shown in light **blue** bars in the histogram in Quadrant **3** to make it easy to locate and look at bead data.



Results are grouped by bead and reaction type, False Negative, (FN) or False Positive, (FP).

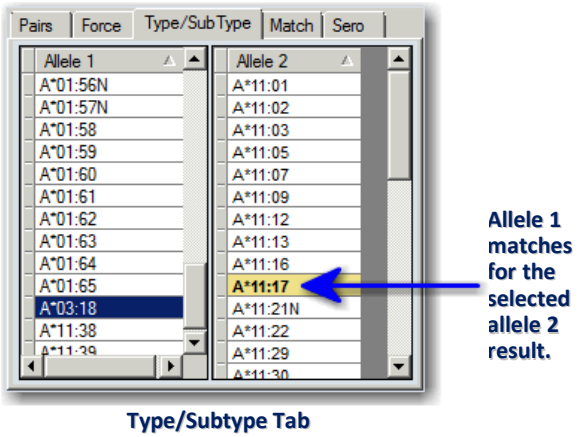
You can change the order by clicking **Allele 1, Allele 2 or the FP/FN** button until the results are displayed in the order you prefer.

- Click any **Plus Sign** (+) to display the suggested allele pair assignments associated with the bead and reaction type.

Click the **Expand All** button to open all allele pair results for all the beads simultaneously.

Click the **Collapse All** button to close all results for all beads simultaneously.

- Click **Copy Data** to send a copy of this data to the system clipboard so it can be pasted into an Excel spreadsheet.



Type/Subtype Tab

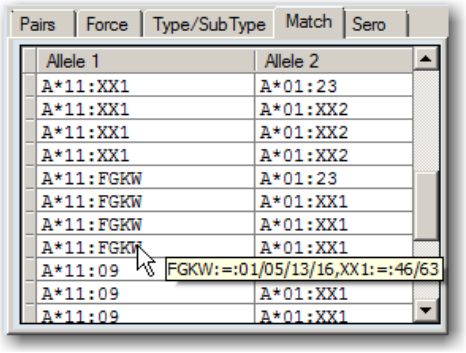
Type/Subtype Tab

When an allele from the left side of the list is selected, the matching allele(s) are highlighted on the right side to show the possible match-ups in the results.

Note: The side-by-side placement of the two lists is not intended to imply any allele pairing.

Match Tab

The **Match** Tab displays the coded format of the actual allele pairings for the sample. A *Matched Reaction Pair* is a pair of alleles, (or group of alleles) with a reaction pattern that completely matches the reaction pattern of the current sample.



Match Tab

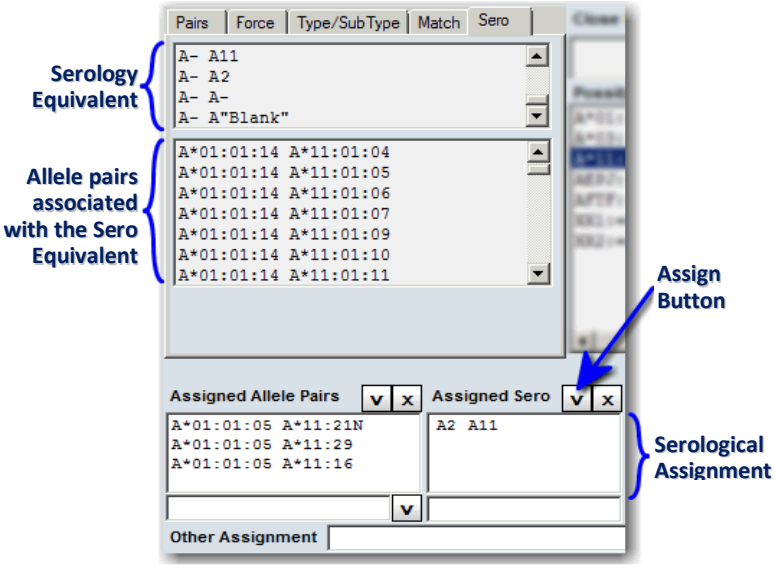
- This result differs from the **Possible Allele Code** results. The **Possible Allele Code** condenses the results into a single code where possible.
- Hovering your cursor over a coded allele format displays its code definition.

Sero Tab

The Sero, (serology) tab displays all suggested serology equivalent data for the sample, based on the possible allele pairs.

Note: Make sure you have imported the current serology equivalent file through the Utilities menu. If you have selected the Computer Assigned Serology check box for LABType product configuration, adjusting the sample cutoff values automatically results in serology assignments.

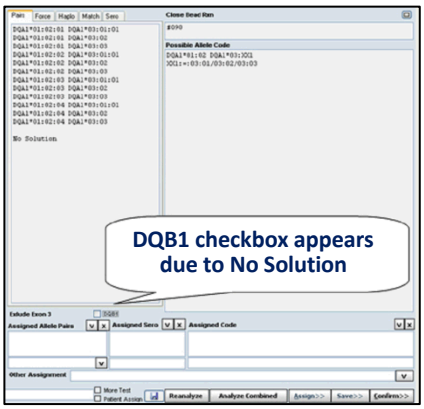
Only one serology assignment can be made at a time per locus for the sample. Therefore, a current serology assignment is replaced if you assign a different one.



Suggested Serology Equivalent Tab

1. In Quadrant 4, click on the **Sero** Tab to display the Serology Equivalents for the current sample in the top pane of the tab, above its associated allele pairs.
2. Double-click an equivalent, or highlight it and click the **V** (assign) button to copy it to the **Assigned Sero** field.
3. Click the **X** (remove) button to delete a serological assignment, or to select and assign a different equivalency to replace it.
4. For Class II manual serology assignments there is a pop-up message that allows the user to specifiy if the assignment is for DQA1 / DQB1 , DPA1/DPB1 or DRb1/DPB345.

Note: To set auto-assigned serology results, select Computer Assigned Serology on the LABType product configuration page. Users will be prompted to designate alpha and beta for DQ and DP loci while making manual assignments.



Exclude Exon 3 Probes for a Locus

If you are analyzing samples from a DPA/DPB or DQA/DQB kit containing Exon 3 probes, some of the samples may result in false reactions, or no solution. This is due to the limited sequence information available for Exon 3 probes. For such samples you can choose to analyze without the Exon 3 probes.

As the example shows, if there is a false reaction or no solution for samples with these loci, a checkbox is displayed to allow you to exclude the Exon 3. The checkbox only appears with false reactions.

If you exclude Exon 3 probes for a locus, it has the following results:

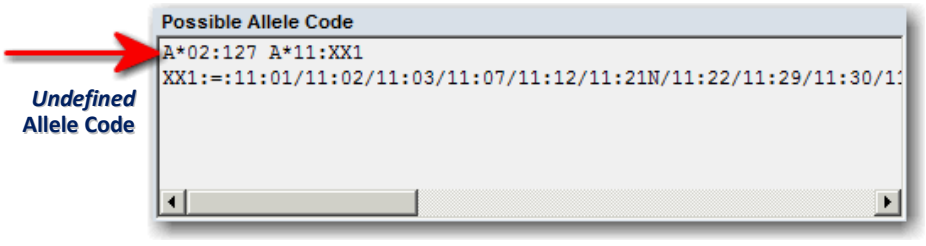
- A comment is included in the System Comment field (Exclude <locus> Exon 3 probes).
- All Exon 3 probes are displayed as **Gray** bars on the Reaction Profile, (Quadrant 3).
- The <loci> check box is displayed with a check mark.

Note: If the false or no solution is corrected by making cutoff adjustments without having to exclude the Exon 3 probes, the check box disappears. All Exon 3 manual exclusions and/or global adjustments will be kept as-is, whether the Exon 3 probes are included or excluded.

Allele Code Assignment

Allele code assignment is performed on the far right panel of Quadrant 4.

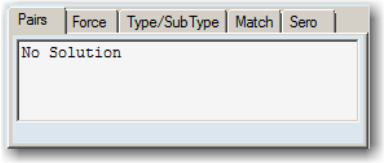
- The **Possible Allele Code** field displays possible coded results for all pairs that fully match the sample.
- The type of code used is dependent on your selection when you configured Fusion for LABType analysis, or for this sample – P & G Group, NMDP code, (default) local code, (user-defined) or no code.
- The possible coded result is listed at the top section of the field.
- The code definition is listed below it.
- If there are no codes for suggested alleles, then the suggestion is listed with XX, meaning the code is undefined.
- For multiple XX suggestions, each suggestion is distinguished from the others by numbering such as XX1, XX2, and so forth.



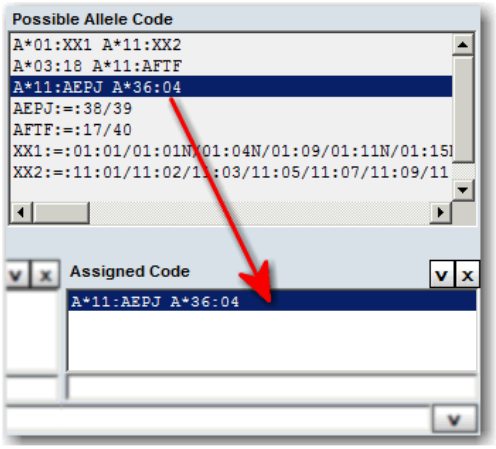
Undefined Allele Code

- The allele codes displayed in the **Possible Allele Code** field are condensed by the system based on suggestions from the list of possible allele pairs displayed under the **Pairs** tab. Note: If allele code (possible and assigned) lengths are greater than 4680 then they may appear as a blank line. We suggest that you use "+RP+" to see the complete results. This also applies to MicroSSP.

- The allele code is based on the current NMDP code or local code installed in the system. By default, the system assigns NMDP codes to the alleles. You can optionally change these codes to either No Code, Local Code or Cross Code.
- **No Solution** is listed if there are no results that match the sample's reactions within an allowable number of false reactions. If the sample shows no solution, increase the number of false reactions in the upper right quadrant for a suggested result.



Allele Code Assignment



- Double-click the possible allele code, or select the suggested code and click the **V** (assign) button.
- Click the **X** (remove) button to remove an allele code assignment.

Manual Allele Code Assignment

1. Type an assignment into the text field just below **Assigned Allele Code**. Make sure you type the assignment in correct allele code format:
   - The new nomenclature format: **X*##:##(####) X*##:##(####)**, where **X**=locus type and **#**= code number).
   - The previous nomenclature format: X*#### X*####, where X=locus type and #= code number).

Otherwise, Fusion will not accept it and prompts you to make corrections.

Note: If you click on the **Translate** button to display alleles in the new nomenclature format, you cannot enter a manual allele code unless you reanalyze the sample and the alleles are again displaying in the previous nomenclature format.

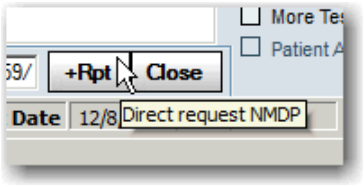
Press the **Enter** key to move the allele code you typed in to the **Assigned Allele Code** field.

Note: If you have a homozygous result, the assigned code can be edited in the Manual Allele Code field to show the homozygous coded results once.

Unknown Allele Codes

Unknown allele codes are marked with **XX** followed by a sequential number. The numbers are reset to **1** for each sample and locus. When you see unknown codes, you should first make certain you have imported the latest NMDP file. If you have the latest code file and are still seeing XX codes, you can store these unknowns for later submission to the NMDP in a "**.**txt" file named **nmdp_code_report.txt**,(by default stored in `C:\OLI Fusion\data\NMDPExport`) but the location can be changed by modifying the path in **Utilities>URLs & Paths**). Code information is appended to this text file as it is added; the newest additions are at the bottom.

1. From the **Possible Allele Code** field, click the XX code to display the NMDP Code Report buttons, (to the right of the System Comment field).

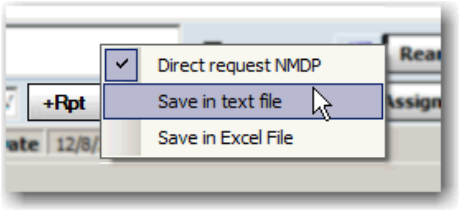


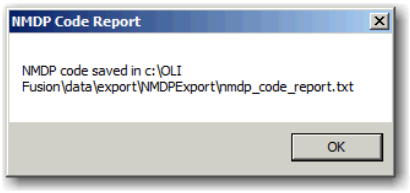
NMDP Code Report Buttons:

Click the **Assign** button (**V**)and choose one of the following:

- To send the unknown code information directly to NMDP, click the **+RPT** +Rpt button. If you're connected to the Internet, Fusion will open the *Bioinformatics.NMDP.Org* webpage.

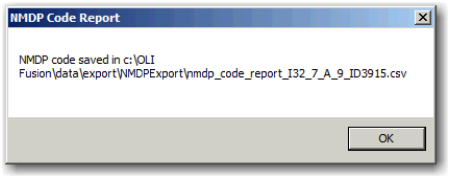
- To add the unknown code information to a text file, (by default stored in `C:\OLI Fusion\data\NMDPExport`) right-click on the **+Rpt** button and select **Save in text file**.





- After the unknown code has been saved, Fusion displays a confirmation message that the text file has been saved.

- To add unknown code information to an Excel file, (by default stored in `C:\OLI Fusion\data\export\NMDPExport`), right-click on the **+Rpt** button and select **Save in Excel File**.



After the spreadsheet file has been saved, Fusion displays a confirmation message.

When you're done, click the **Close** button, (on the right of the **+Rpt** button) to remove the buttons from the display.

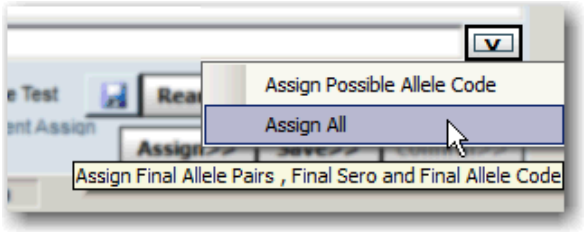
Note:	The **+Rpt** button retains the last selection you made, (direct, text or Excel) so it can be used as a shortcut. Unless you want to change your selection, the next time you report XX code simply click **+Rpt**.

Other Assignment

The **Other Assignment** field may be used to make a sample assignment that is not restricted to any format. In addition, you can highlight and add serology or allele pair or code assignments and add them to the field for modification.

You can make other code assignments in one of two ways:

- Type an allele pair or allele code into the **Other Assignment** field.
- Click the **V** (assign) button and select one of two options:



1. To assign just the possible allele code, select **Assign Possible Allele Code** to bring the highlighted Possible Allele Code into the Other Assignment field.

2. Select **Assign All** to bring the Possible Allele Code, Assigned Serology or Assigned Allele Pairs assignment(s) into the Other Assignment field.

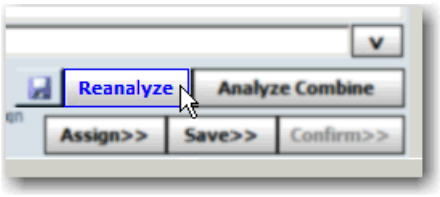
You can also choose to modify any of the copied code, if desired.

Entered alleles are assigned and included in reports that are run which include this sample, but allele assignments made this way are not listed in the final assignment field for this sample.

Reanalyze

If you have imported a new NMDP code, local code or serology equivalent file into the system, **or** you change the number of false reactions allowed for a no-solution sample, you can click the **Reanalyze** button to analyze the data using the new reference file(s) or to reflect false reaction changes.

Reanalyze Button



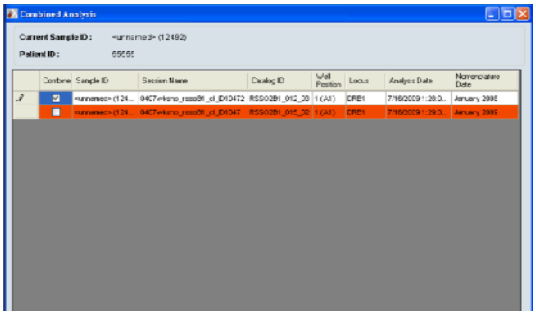
Note:	This reanalysis replaces only the NMDP, local or serological codes, or analyzes with different false reactions settings. All other setting changes generally result in an automatic reanalysis of the sample immediately following the setting change.

Analyze Combined LABType Sessions

HLA Fusion supports a combined analysis feature for both LABType and Micro SSP analysis sessions. In a combined analysis, the reactions from two tests of the same sample are combined together in a single analysis that may generate a higher resolution result. The previous test must have the same sample ID.

Note:	To combine a generic or HD LABType sample with Exon 4-7, the combination must be done from the Exon 4-7.

From the Analysis Window, click on the **Analyze Combined** Analyze Combined button. The next pop-up window displays a list of previous sessions that have used the current sample and share the same sample ID.



1. Select the desired previous session(s) by selecting the associated Combine check box.
2. Click the **Analyze** Analyze button at the bottom of the pop-up window.
    - The reaction pattern table includes bead information for all the sample tests. This table's Bead ID listings provide indication that the selected sessions have been combined and reanalyzed.
    - If you combine one sample in the previous nomenclature format with a sample in the newer nomenclature format, the possible and assigned allele pairs and code are displayed in the new format. If the sample with the previous nomenclature format contains an allele that is not included in the new nomenclature, that older allele is dropped.

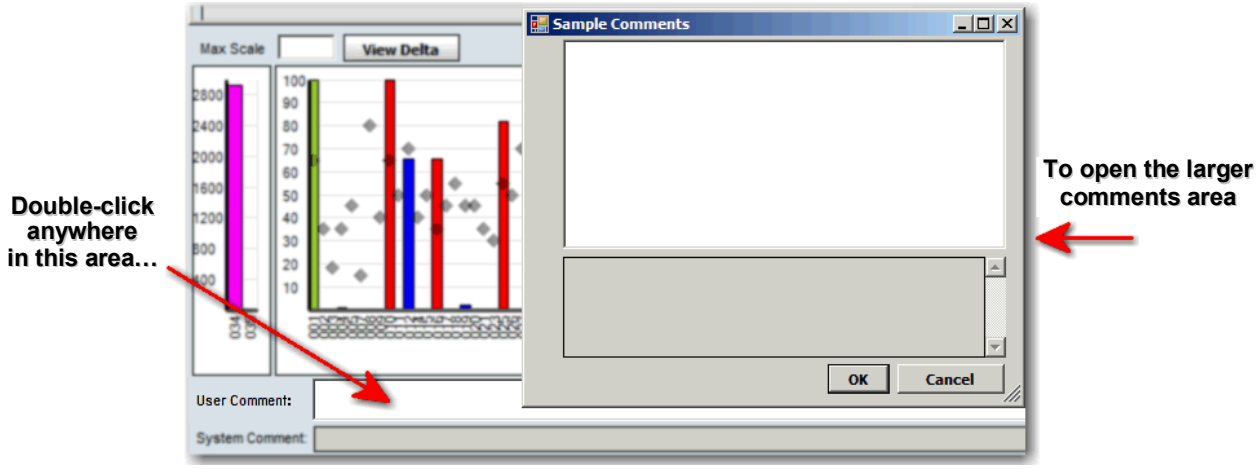
To rerun the combined analysis, click the **Reanalyze Combine** button.

- If the nomenclature dates between the current one and the one(s) being combined with it, conflict, then the session(s) you selected is highlighted red.
- If you click the **Analyze** button and there is a conflict on nomenclature dates, a warning message is displayed that gives you the option of continuing or canceling the combined analysis. The nomenclature of the sample test you selected to combine with the current one will be used if you continue.

Adding User Comments to Samples

Comments you or the system add to the **Comments Field** are displayed with the results in the current analysis session, data look up and reporting functions in HLA Fusion. They are separated into user and system comments. You can only add or edit the comments in the user comment field.

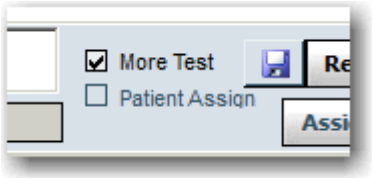
1. In the analysis window, enter your comments into the **User Comment** field below the Assignments area, (maximum of 255 characters).



Comment Field

Comments are saved only after you click the **Save** Save>> or **Confirm** Confirm>> buttons.

Flagging a Sample for Further Testing



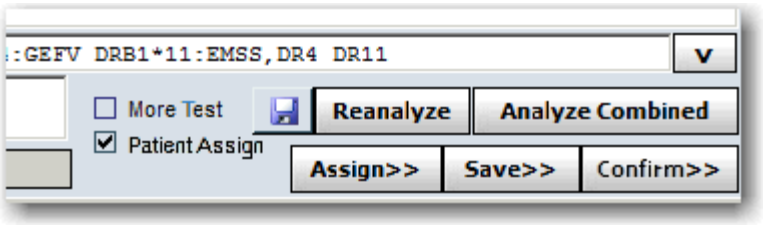
You can indicate the need for further testing of a sample by selecting the **More Test** check box. The More Test indication is displayed in results, data look-up and reports for the sample.

Assigning Serology and Allele Code Results to a Patient

Note: This feature is available only to Lab Supervisors and for saved samples.

This check box is grayed-out until the sample has been saved or assigned and can only be selected by those with Lab Supervisor privileges. If selected, serology and allele code results are then added to the patient's record.

- In the analysis window, check the **Patient Assign** check box, located below the Assignments area.
- Click **Confirm>>** to preserve the setting.



- If you previously assigned results to the patient, a message displays asking whether or not you want to overwrite the previous assignment.

The Print Screen button prints the currently displayed analysis window.

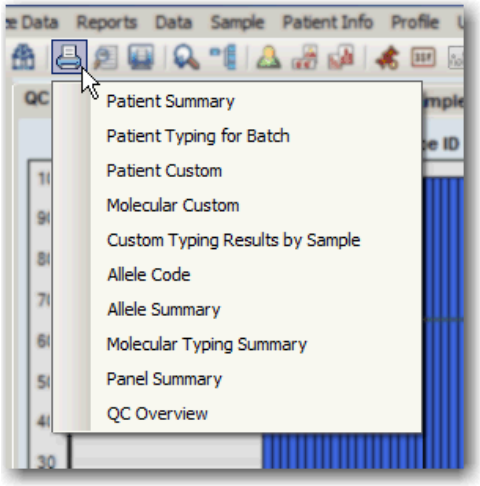
- From the analysis window, click the **Print Screen** button on the Fusion Toolbar to print the current analysis screen.

Preview or Print Reports

To view a LABType report for the current sample, use the Preview Report and/or Print Report buttons on the toolbar.

In the Analysis Window, click the **Preview Report** button or the **Print Report** button to display a list of reports you can preview or print for the current sample.

Or, hover your mouse pointer over the **Print** button to see a list of available reports.



Note: If you select Molecular Custom, you will not be able to create a new custom report at this point. The only custom reports available from the analysis window are ones you may have previously created through the **Reports** window.

Assign Coded Results

Use the **Assign** button to assign and save all unambiguous possible coded results, (those results for which there is only one coded result). For the assignment of Serological or Allele pairs, or when you want to choose in the case of ambiguous results, you must manually move them to Assigned and click the **Save** Save button.

Translate (noncurrent nomenclature format only)

The **Translate** button Translate is displayed only if the sample allele format is in the older nomenclature. Clicking the Translate button does the following:

- Translates and displays all Assigned, (except from the Other Assignment field) and possible allele code/pairs/haplo in the latest nomenclature format.
- If a matching allele in the new format cannot be found, the allele remains displayed in the old format.
- You can view and print this display, but results cannot be saved or reported in this new nomenclature format.
- To go back to the older allele format, you can navigate to another sample and then return to this sample.

Save Assignments

Note: Make sure you've made the assignments before you save.

Lab technicians and supervisors can save analysis results for further review and approval. Saved samples are available for confirmation by a Lab Supervisor *only*.

- From the analysis window, click the **Save** Save>> button located in the bottom right corner of the analysis window to save analysis results for all the specificities currently listed in the Final Assignments results box.
- The **Save>>** button does not assign results; it simply saves the sample results and comments.

Note: If comments are added, the sample must be saved in order to also save the comments.

- After saving, Fusion automatically moves to the next sample.
- For confirmation, a Supervisor needs to access the sample for which you have saved the assignments. You can return to the sample any time prior to confirmation.
- If you need to make changes, click the **Reanalyze**  button and then the **Save** button again.

Confirm Assignments

Lab Supervisors can confirm analysis results. When they do, samples are marked as ***Approved***. The **Confirm** button is colored **Purple** when you view a confirmed sample.

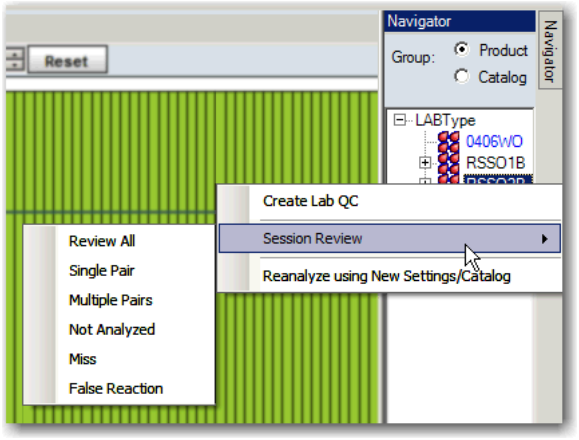
- From the analysis window, click the **Confirm**  button located at the bottom right corner of the window, to confirm all analysis results that have been saved in the Final Assignments results box.
- You automatically move to the next sample to continue confirming results.
- When you first return to a confirmed sample, you will see that the **Confirm**  button is now shaded **Purple** to let you know it has been confirmed previously.

Navigator Right-Click Menu Options for LABType

Session-Level Options

There are three menu options that are displayed if you right-click on an active session in the Navigator, (select the session first with a left-click):

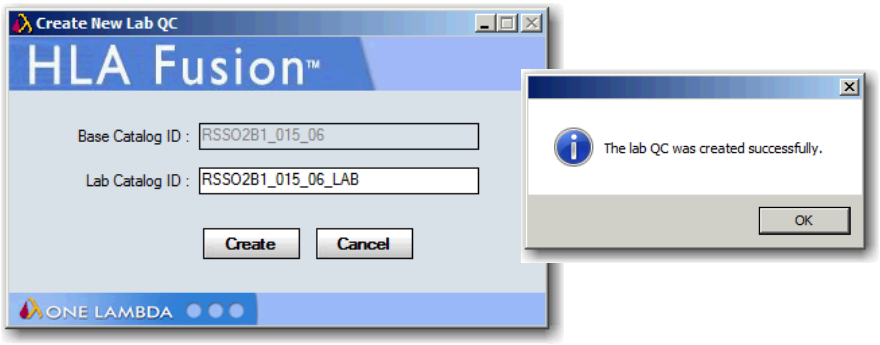
Session-Level Navigator Menu Options



Create Lab QC

Allows you to save the catalog file and the QC parameters from the selected session as a **Lab QC** panel.

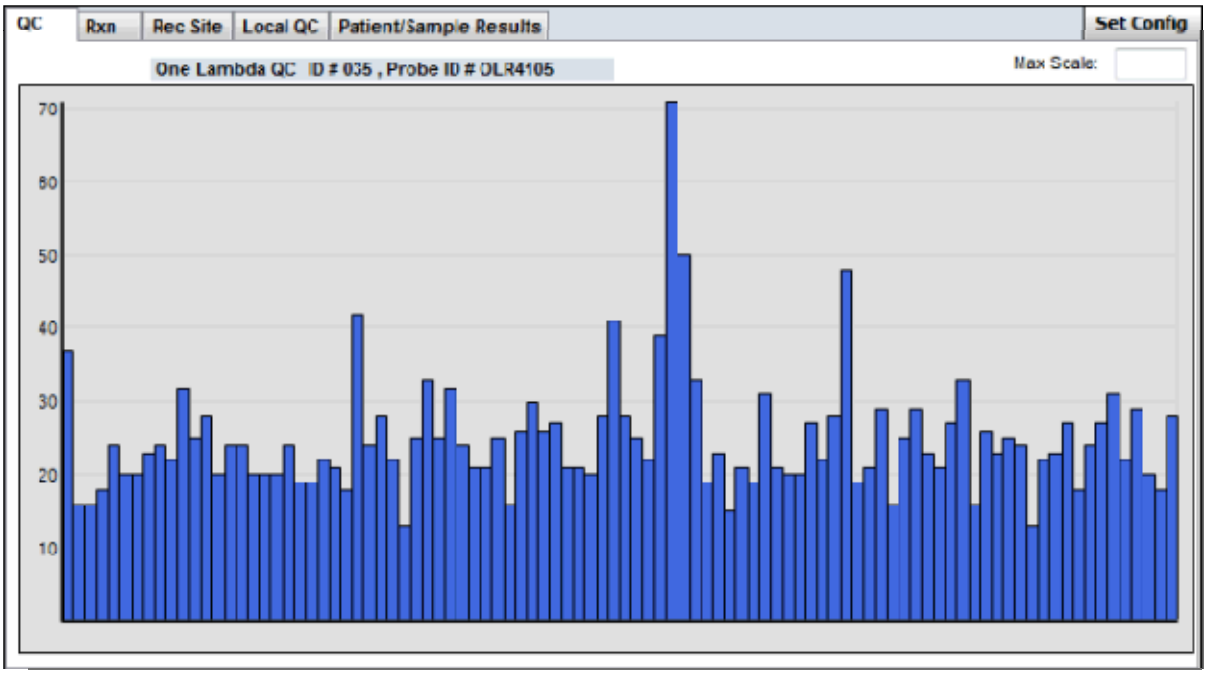
- The local QC is set up similarly to a catalog file where the user can, upon launching a *new* analysis, select the local QC from the catalog list. The local QC information is then used in the analysis session instead of the One Lambda QC.
- When selected, a dialog box displays and prompts you to name the new lab QC (default name = [**`current catalog ID]_LAB`**).



Create new QC Session Dialog Box

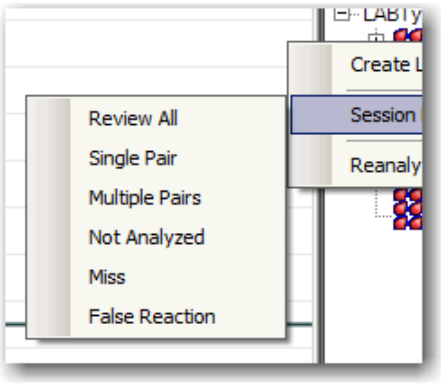
After accepting or entering the name, click the **Create**  **button**.

- The system then saves the current session as a local QC using the selected name appended with a date and time stamp (format: yyyymmddhhmmss).
- For ***new*** sessions, this local QC is available for selection from the catalog file drop-down list when you import LABType sessions.
- This QC is also listed in the **View QC** drop-down via the LABType sample configuration menu when you open a new analysis session.



Local QC after being selected from View Lab QC

Session Review



This right-click option provides various sub-menus, (filter criteria) that allow you to review the samples in a session according to the type of results obtained:

- **Review All** (default) - all samples are listed and available for analysis.
- **Single Pair** - only samples with unambiguous results are listed, (samples displayed with red square markers in the Results Summary graph on the session Summary tab).
- **Multiple Pairs** - only samples with ambiguous results are listed, (samples displayed with orange square markers in the Results Summary graph on the session Summary tab).
- **Not Analyzed –** when selected, the Navigator will display only those samples or sessions which have been imported, but not yet analyzed. These sessions will appear in **Blue**.

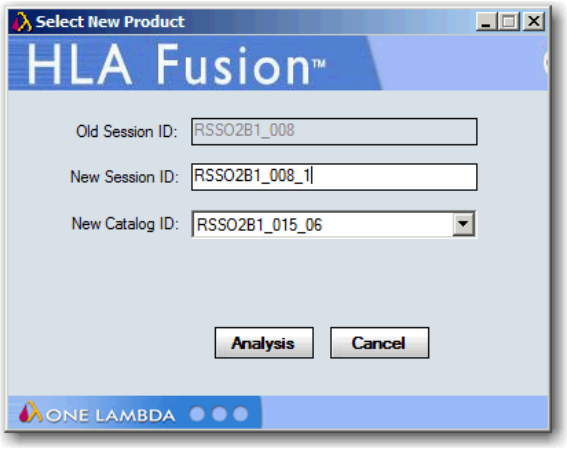
Miss - only samples with no solution are listed, (samples displayed with gray square markers in the Results Summary graph on the Session Summary tab).

- **False Reaction** - only samples with false reactions are listed, (samples displayed with pink square markers in the Results Summary graph on the Session Summary tab).

The samples in the session on which you right-clicked are filtered based on the sub-menu option you select. The filtering criteria is then loaded into the batch navigation list. Fusion then takes you to the analysis window where the samples are displayed in order of the batch navigation list.

Reanalyze with New Nomenclature

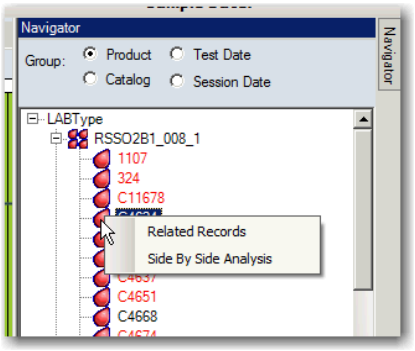
Allows the session to be reanalyzed using a new or updated catalog file.



1. Modify or rename the **Old Session ID** by giving it a **New Session ID**.
2. Click the drop-down arrow in the **New Catalog ID** field and select a new catalog file from the list.
3. Click the **Analysis** button. The session on which you right-clicked is now reanalyzed using the catalog file you selected.

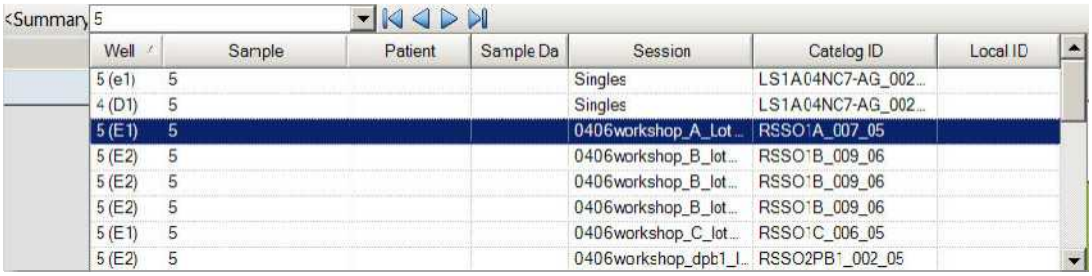
Sample-Level Options

There are two menu options that are displayed if you right-click on an active sample in the Navigator, (select the sample first with a left-click) **Related Records** and **Side-By-Side Analysis**.



Related Records

A **Related Record** is a record that is associated with the current sample by Patient ID, or Sample ID.



Sample Drop-Down List for Related Records

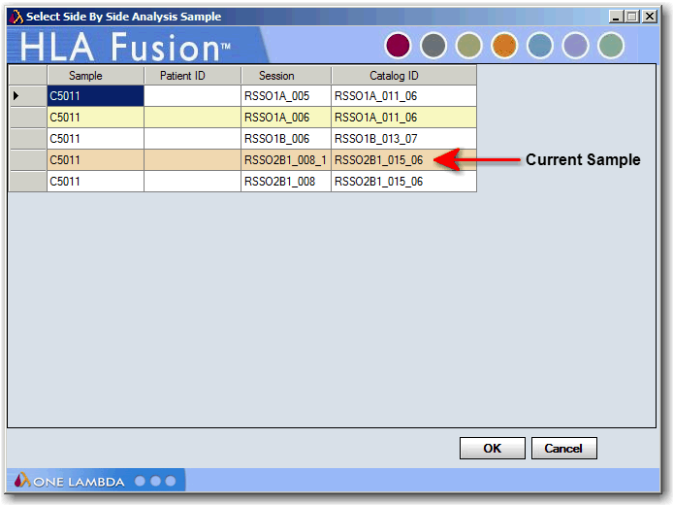
Note: This option is also available when you use the **Related Records** toolbar button.

Select this menu option to load all records related to the current sample into the Sample drop-down list.

- Use the sample navigation arrows to display the analysis of each related record one by one.
- To go back to viewing the samples in the current session, click the **<<Summary** link at the top of the window.

Side By Side Analysis

Use this option to compare the current sample analysis with one previously conducted.



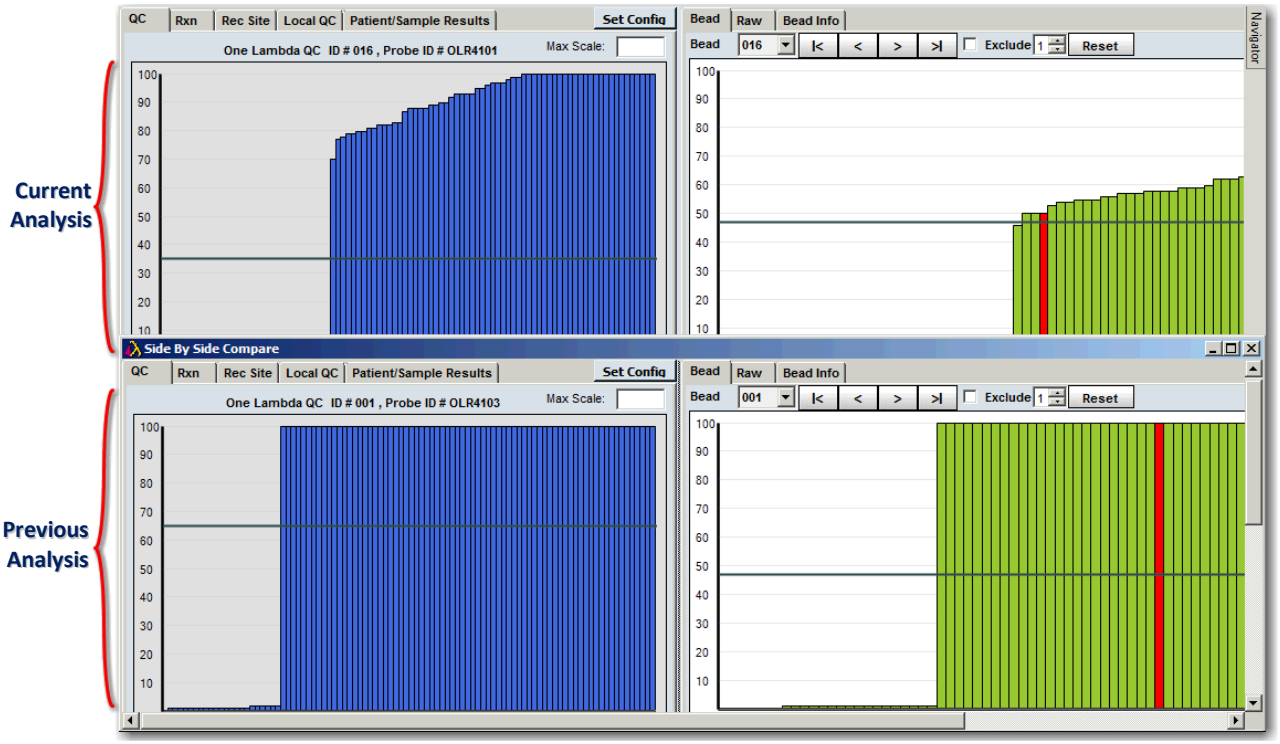
Side-by-Side Analysis menu option

Note: This option is also available by using the **Side By Side Analysis** toolbar button.

The current, on-screen sample analysis has a light **Brown** background.

Select a previous sample analysis from the displayed list to compare to the current one.

1. Click the **OK** button and the two analysis windows are then displayed in a comparison window.



Example of Side-by-Side Analysis Windows

Each window can be resized and moved by dragging and dropping.

1. Click the **Side-By-Side Analysis** toolbar button to cancel the comparison display.

Micro SSP Analysis

The Micro SSP™ HLA typing trays use the sequence-specific primer technology. These trays are available in 96-well format and a few other formats such as E-Gel 96 (V), E-Gel 96 (H), and Centipede. Analysis results are based on catalog specifications, NMDP code, and serology equivalent references that you can import through the Fusion software.

The software suggests the allele pair assignments, but the final assignment has to be made by the user. The results can be saved in the database for further review by lab technicians and for final approval by the lab supervisors.

There are a few things that should be completed or verified before you start an analysis session:

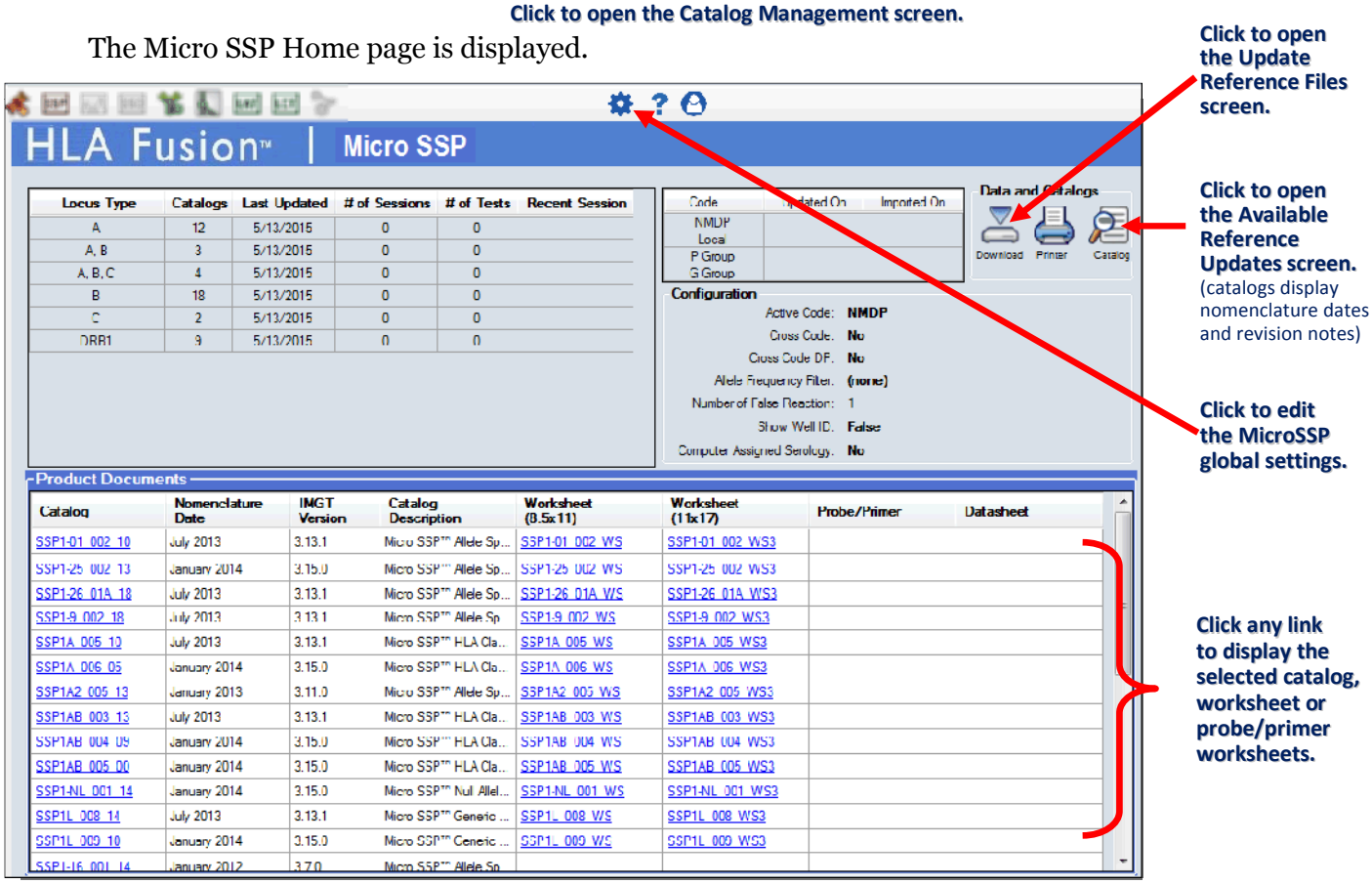
- Make sure you have the latest catalog files, as well as NMDP code, local code, (if used) or serology equivalent reference files before you analyze. You can download or update catalogs from the Micro SSP Home Page.
- View and modify global product configuration settings before starting analysis. Global settings are displayed and be can be modified on the Micro SSP Home. Global settings apply across all newly- imported sessions.
- The default setting of HLA Fusion is to automatically move to the next sample after a sample has been saved or confirmed. If you prefer to remain on a sample, make the change in the General Configurations section of the Fusion Explorer Home page.

Note: Some of the above tasks require you to have supervisor user privileges. You may have to verify with your supervisor that these tasks have been completed.

Start Micro SSP Analysis

1. Click the **Micro SSP** button on the home page panel, or the Micro SSP icon on the Fusion toolbar, or select **Analyze Data > Micro SSP**.

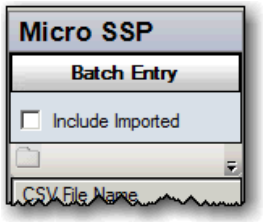
   The Micro SSP Home page is displayed.



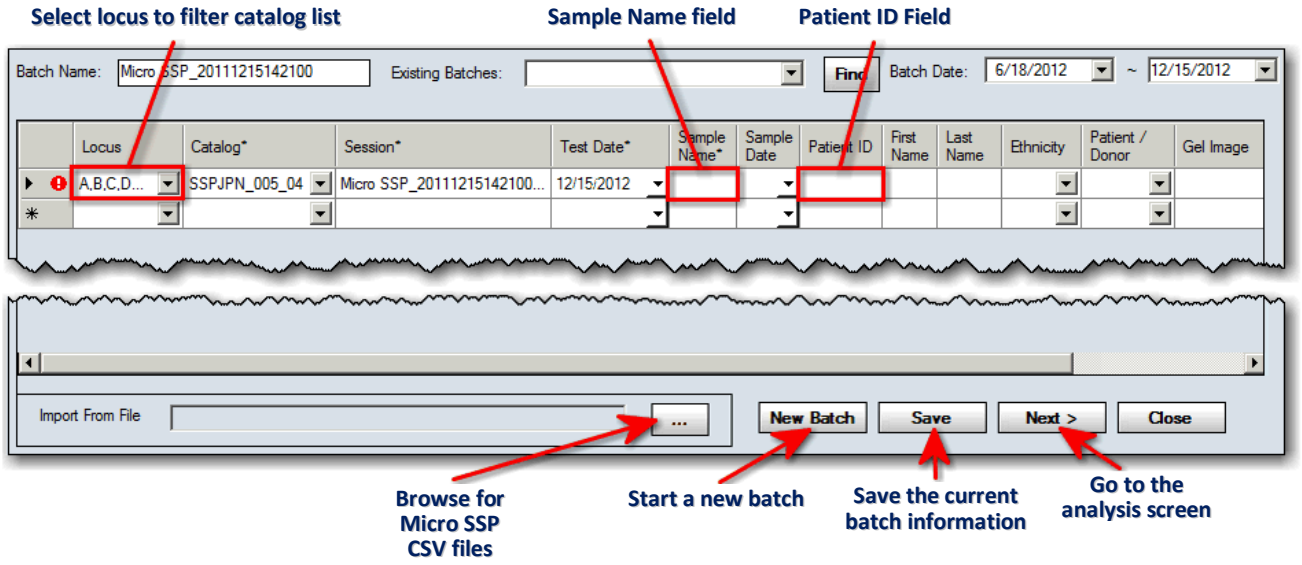
Note: Open worksheets and probe/primer sheets to verify the accuracy of revision numbers, (these documents do not contain a revision number in their filename).

1. Begin by clicking the **Batch Entry** button at the top, left side of the screen.

   Place a check mark ✔ next to **Include Imported** if you also want to bring in batches which have previously been imported.



The **Batch Entry** window is displayed.



The system assigns a Batch Name automatically. Optionally, you can change the name.

Note: A batch must be unique to the Fusion database for each product type. If it already exists, the software prompts you to rename the batch. It is highly recommended that you do not use any special characters in this field since they may serve a specific purpose as field separators.

2. Use the browse button (**...**) at the bottom of the window to search for and import one or more Micro SSP .csv files *or* follow the steps below.

3. Use the drop-down menu in the **Locus Filter** field to select a locus by which to filter the catalog listing. This will limit the catalog list in the next field to only those catalogs that include the selected locus.

4. Use the drop-down menu in the **Catalog** field to select a catalog file.

Note: If you need to import more catalogs, click the **Download** link on the Micro SSP Home Page for instructions on how to add new catalog files to the database.

The catalog drop-down list may not be immediately updated if you downloaded the catalogs during this import session. You may need to click the **Home** button and then click the **Micro SSP** button again to return to the import process.

5. Accept the session name in the **Session** field, or modify it.

6. Enter a name in the **Sample Name** field. If this is an existing sample name, other fields such as the Patient ID and Ethnicity, are populated with existing data. You can also double-click in the Sample Name field to display the Select Sample window from which you can select a sample.

7. Click the drop-down arrow in the **Sample Date** field and select a date. The analysis window for this session is displayed.

8. Enter an ID in the **Patient ID** field. If this is an existing patient/donor ID, other fields such as the First and Last Name and Ethnicity, are populated with existing data. You can also double-click in the Patient ID field to display the Select Patient window from which you can search for and select a patient ID.

   If they are not already filled-in, you can enter a name for the patient or donor in the **First Name** and **Last Name** fields.

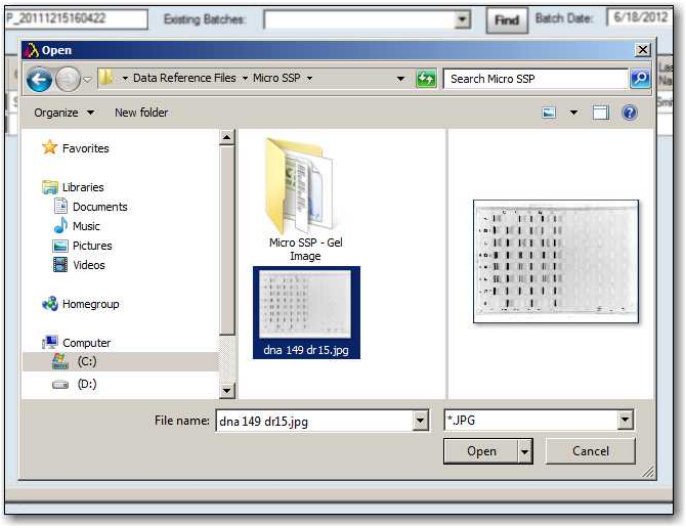
9. If it is not already filled-in, click the drop-down arrow in the **Ethnicity** field to choose the patient/donor ethnicity.

10. If not already filled-in, click the drop-down arrow in the Patient/Donor field to choose either patient, donor, or both.

11. If you want to associate a gel image with the sample, double-click in the **Gel Image** field and browse to the location of the image you want to add to the sample.

Note: Fusion supports the BMP, JPG, BMP and TIF image formats. However, certain versions of the TIF format may not be supported by the Windows version used on your computer.

Select Gel Image Browser



- Repeat the above steps until you complete the batch information, or until you want to save and complete the batch later. Each Micro SSP batch session can consist of as many samples as you wish to analyze with the same or with different catalog information.

Take one of the following actions once you are ready to stop creating the batch:

- Click the **Next>**  button to open the Micro SSP analysis window.
- Click the **Save**  button to save the current batch information and return to it later.
- Click **New Batch** to start creation of a new batch.
- Click **Close**  to exit the **Batch Entry** window.

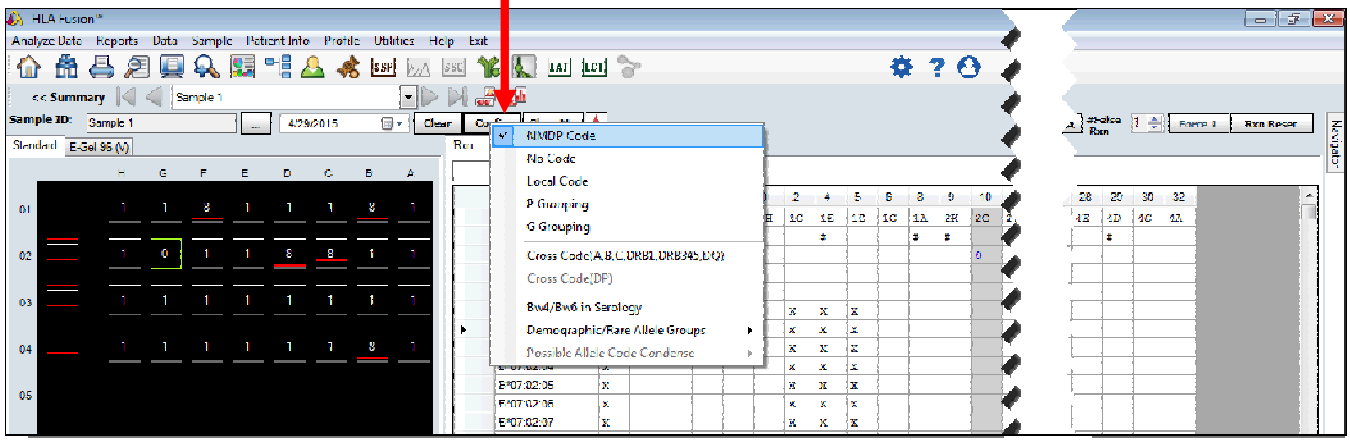
Configure Micro SSP Data Analysis

Global defaults for Micro SSP product configurations can be set from one of two places:

- The **Micro SSP Home Page**
- The **Utilities** menu on the main HLA Fusion home screen.

In addition, configurations can also be set from *within the analysis window* for the current Micro SSP sample by clicking on the **Config button** to view a pop-up list of configuration options.

Micro SSP Sample-Level Configuration Menu



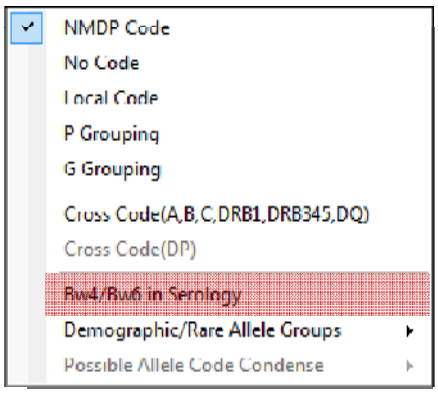
Assign Code

By default, the system assigns NMDP codes to the alleles. However, the user can optionally change these codes to one of the following options:

- **No Code** - The results, allele pairs assembled into a string with no formatted code, are simply condensed without applying a coded format.
- **P Grouping** -Codes Allele strings in P grouping as published by IMGT.
- **G Grouping -** Codes Allele strings in G grouping as published by IMGT.
- **Local Code** - assigns user-defined code definitions, (code used by your Lab) for suggested code results.

- **Cross Code** - allows allele combinations that cross serological groups (e.g.,**EAPW = DRB1*04:01/33/35/38/72/76**). By default, cross coding is turned off so that allele pairs are condensed only within the same allele groups.
- **Bw4/Bw6 in Serology**

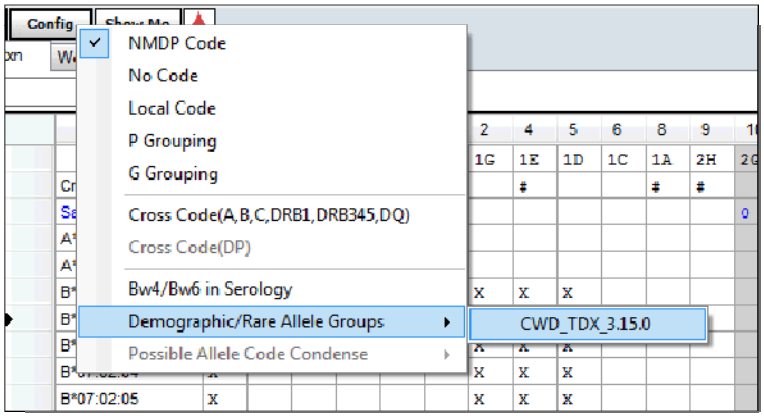
Bw4/Bw6 in Serology



Serology has identified many pairs of HLA-B alleles which appear to differ only at the Bw4/Bw6 region - the two mutually exclusive serological epitopes.

If you select this option, Bw4/Bw6 is added to the serology results.

Demographic Information



The **Demographic Information** option allows you to organize alleles based on their frequency.

Based on the demographic selection you make, HLA Fusion displays as many as three allele groups in the allele pairs list:

- **Group 1:** Frequent on both alleles
- **Group 2:** Frequent on one or the other of the alleles only
- **Group 3:** Frequent on neither allele

If the Demographic Information option is not active, it means you need to import an allele frequency input file.

Using the Micro SSP Analysis window

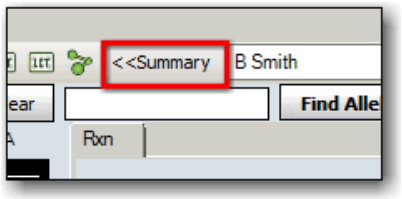
The analysis window displays detailed analysis information for each sample in the session. You can review the allele assignments suggested by the program, modify and accept the assignments.

HLA Fusion suggests possible typing results, but you must make the final assignment. Any adjustments made in the analysis window are sample-specific and affect only the current sample.

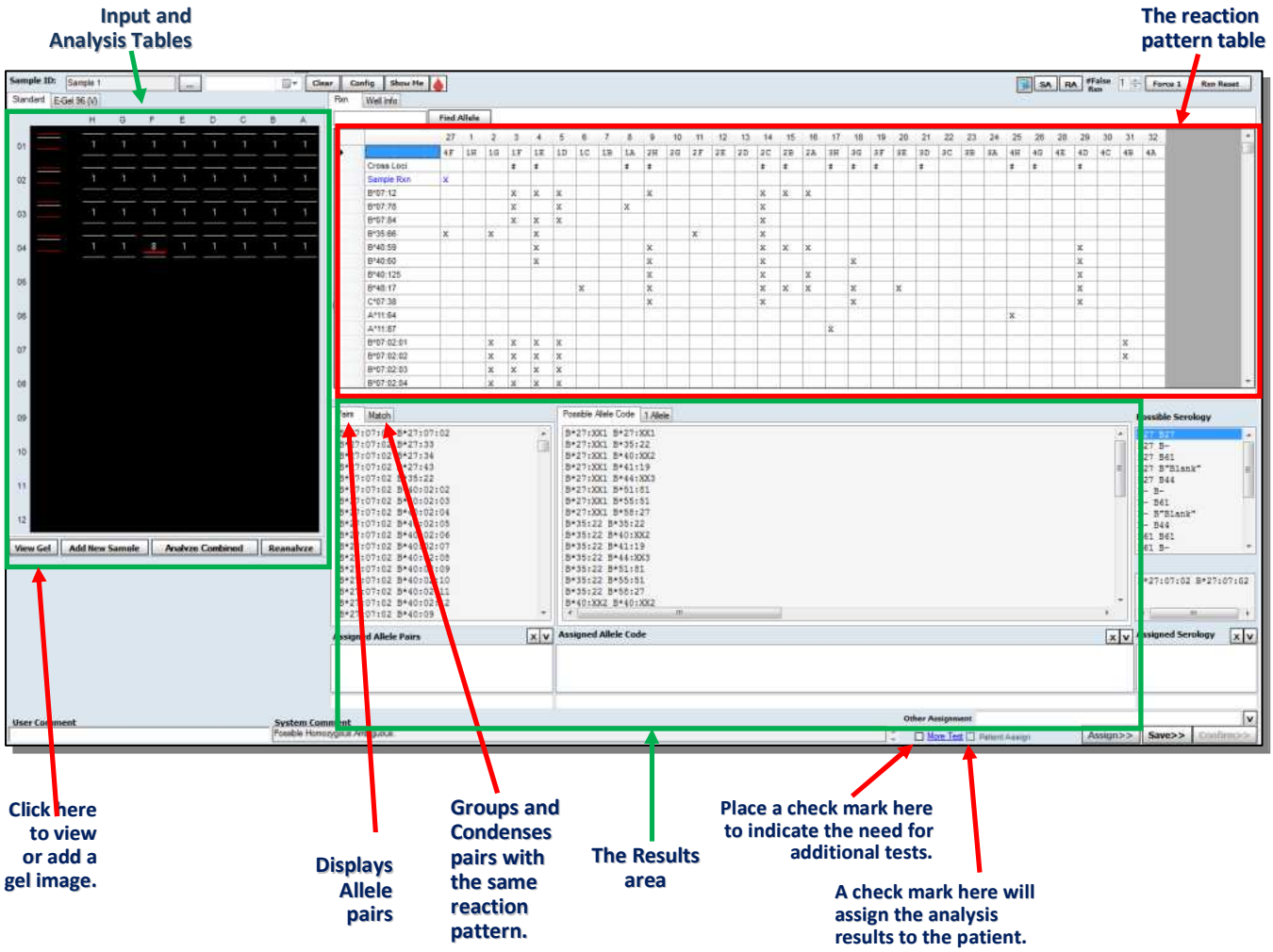
From the Analysis Window you can do the following:

- Use the test gel pane to change reactions and sample row positions.
- Change the allowable number of false reactions.
- Force one false reaction.
- View and print sample analysis results.
- Add comments and mark for more testing.

You can return to a session summary from the analysis window any time by clicking the**<<Summary** link from the HLA Fusion toolbar next to the Sample ID.

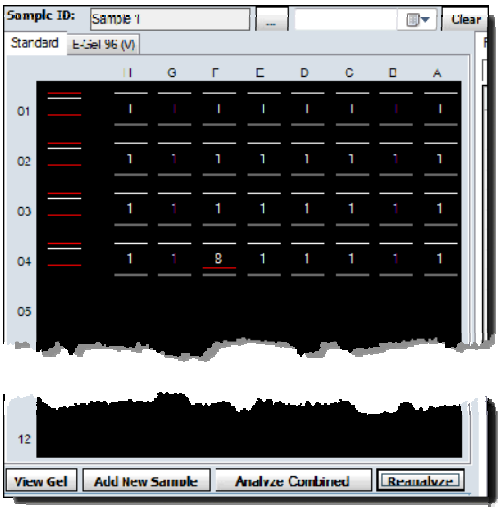


MicroSSP Analysis screen



Test Gel Pane

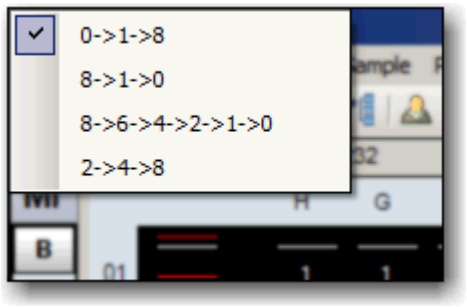
The pane on the left side of the window displays each well of the test in rows that are intended to duplicate the test gel. Each well is shown with a reaction button.



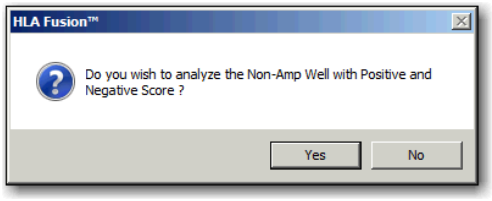
When clicked or entered from the keyboard, you can modify the reaction for the selected well between the following settings:

- **8** = positive reaction
- **1** = negative reaction
- **O**= no clear amplification, (wells with a **O** will be excluded from analysis)

Note: If you right-click in the black area of the test gel pane, you can select a different order for the reactions when you click on a well: 0->1->8, or 8->1->0,etc.

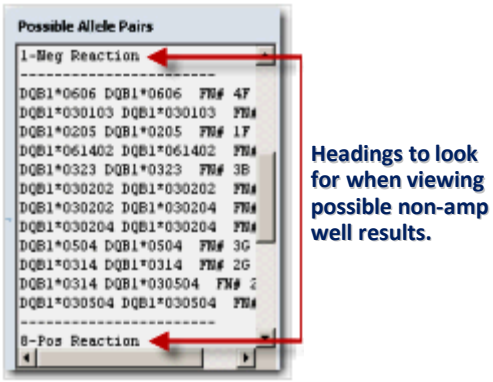


- After you analyze a tray, you can no longer add any more sample information to that tray.
- If the sample has not been analyzed, the right most button on the bottom of this pane is labeled **Analyze**. If analysis already exists for the sample, then the button is labeled **Re-Analyze**.
- This button is only enabled when a Sample ID has been entered. If a Sample ID has not been entered when this button is clicked, the Sample ID field is flagged with "**!**" as being empty, and no analysis is performed.
- If other than the first well (**1**H) reaction is set to zero (**0**), a message displays, allowing you to see system-suggested reaction information to help you decide if you want to analyze the non-amp well with a positive or a negative score. If more than one well is set to zero, the message does not display, but the suggested reaction information can still be viewed.



To see the possible reactions if the well was positive or negative, click **Yes** and scroll down the **Possible Allele Pairs** list to the headings **Neg Reaction**, **Pos Reaction**. If neither type of result can be suggested, the heading is **No Solution** and it will not be followed by results.

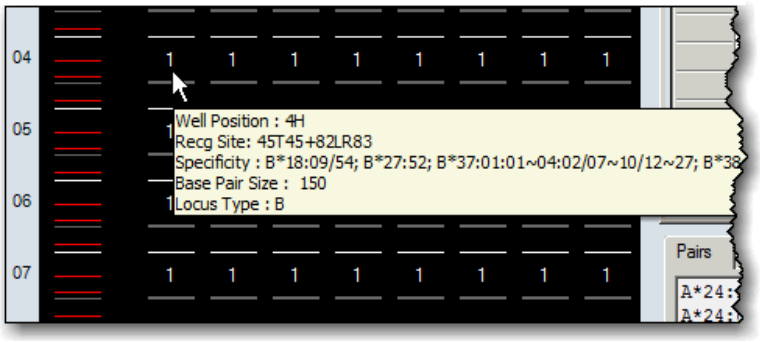
Possible Results for One Non-Amp Well



View Well Details

You can view comprehensive details about the current sample by hovering your cursor over a well in the test gel area of the analysis window.

View Well Details (with your mouse over a well)

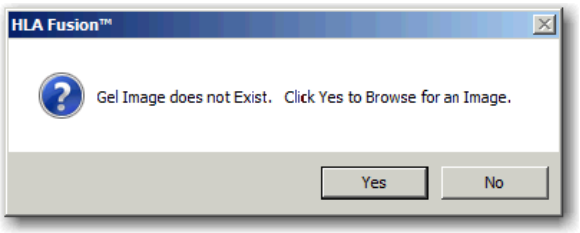


Working with Gel Images

- If you have a gel image <u>already</u> <u>linked</u> to the current sample, you can **view it**, or **unlink it**.

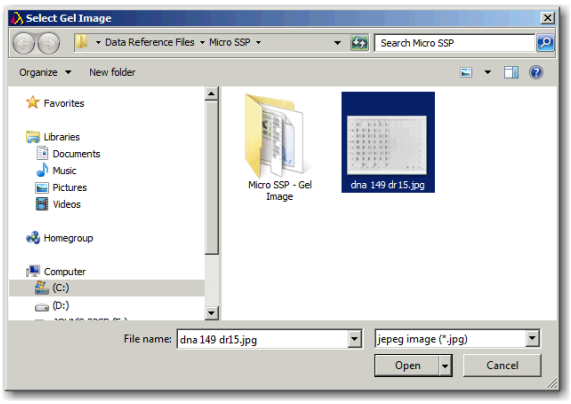
OR

- You can search for and **link** another gel image to the current sample.

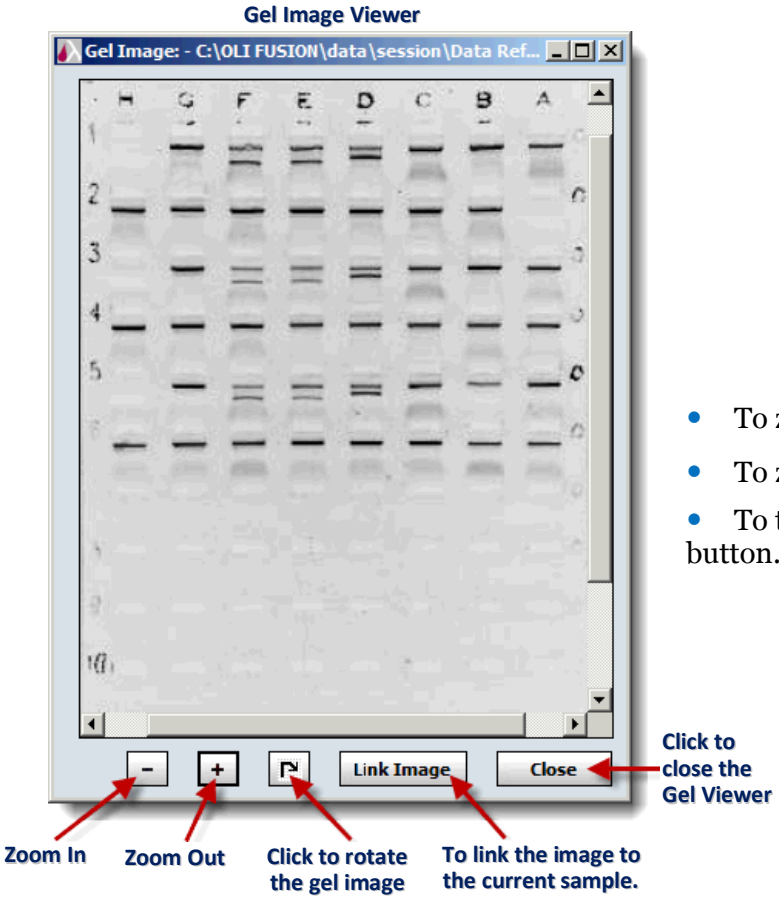


Here's how you can link a gel image to the current sample:

1. Click the **View Gel** View Gel button at the bottom, left of the gel image screen. If no image is currently linked to this sample, you'll see this message:
2. Click the **Yes** button and Fusion opens the **Select Gel Image** screen.
1. Browse to a new gel image and click the **Open** Open button.
2. Fusion opens the **Gel Image** window and displays the gel image you've selected. The window can be resized if needed.



If you want to link this image to this sample, click the **Link Image** Link Image button.



- To zoom in, click the **+** button.
- To zoom out, click the **-** button.
- To turn the image, click the **Rotate** button.

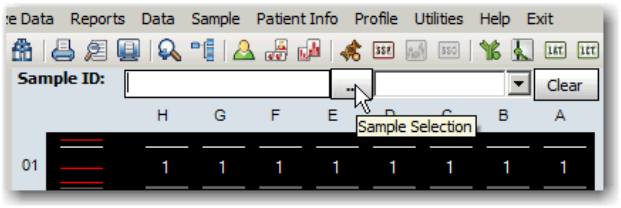
To **Unlink** an image already associated with the current sample:

1. Click the **View Gel** View Gel button.
2. When the image is displayed in the **Gel Image** viewer, click the **Unlink** UnLink button.

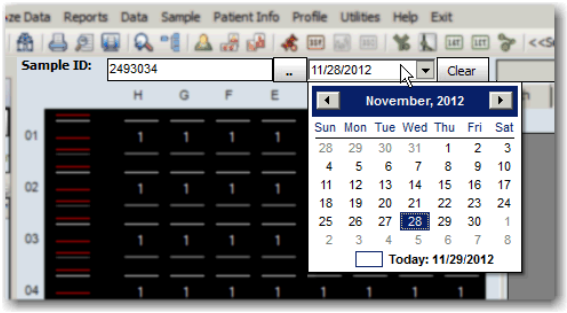
Add Samples

There are two methods that samples can be added and analyzed in a session:

1. Click the **Add New Sample** Add New Sample button.
2. Type a new Sample ID, or Sample Name, in the **Sample ID** field, (above the gel image).



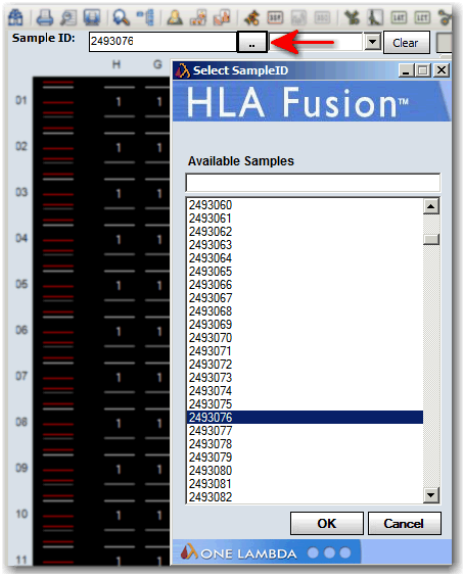
3. Select the **Sample Date** by clicking the **Down Arrow▼**in the **Date** field to the right of the Sample ID field.
4. And click the **Analyze** Analyze button.



OR

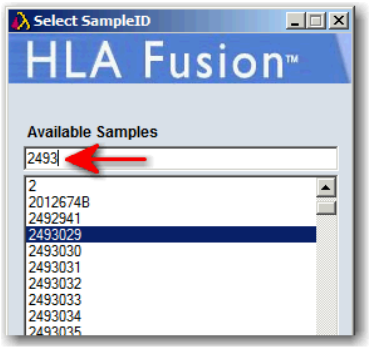
Here's an alternate method to add existing samples for analysis in Micro SSP:

1. Click the **Sample Selection** button to the right of the Sample ID field.



Select an existing sample from the list of **Available Samples**.

You can use the text box at the top as a search tool.



2. Click the **OK** button at the bottom of this window to move the sample from the list of Available Samples to the Sample ID text box above the gel image viewer. You may use the existing Sample Name, or create a new one.

3. Select/create a **Sample Date**.
4. Click the **Analyze**  button.

View Gel

Within the Serology Analysis window, you can view the gel for the current sample. This tool finds the gel file, (JPEG format) associated with the CSV data file and displays it in the Analysis window.

1. Click on the **View Gel** button. A picture of the gel for the current sample is displayed as a new window.
2. Click the **Close** button or click on **X** to close the gel.

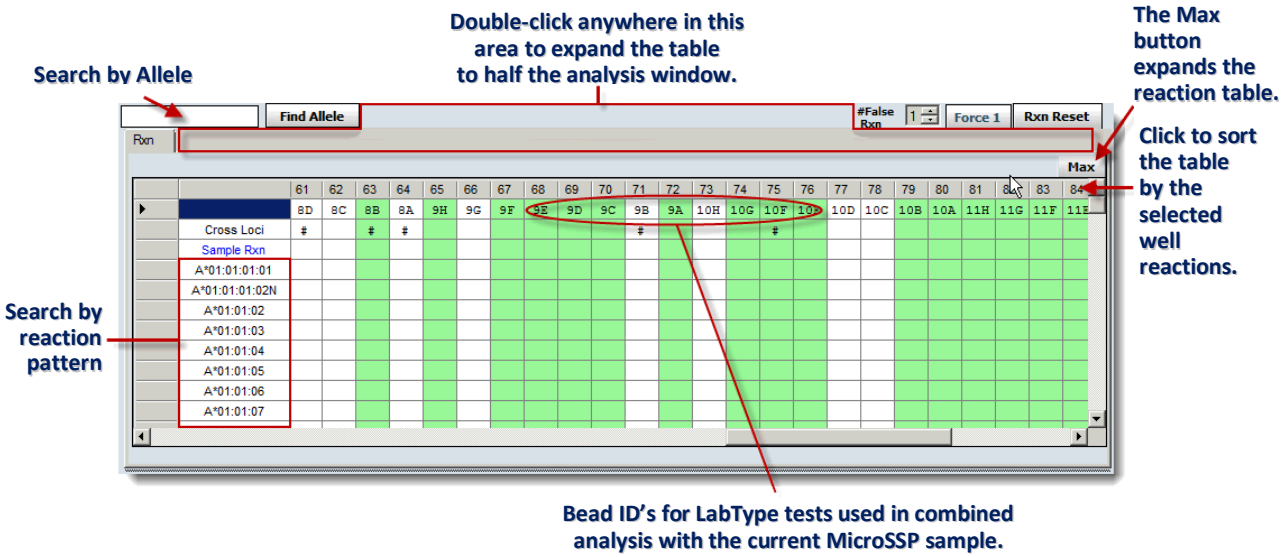
Modify the Session Start Position

For multi-test trays, you can skip tray positions to match your gel photos by clicking the **Add New Sample** button until the correct test start position is displayed.

Rxn (Reaction) Tab

The reaction pattern table displays the positive reactions for each well, or bead, if combined with LABType, (x-axis) versus every allele, (y-axis) defined in the current catalog.

- The Reaction Pattern Table is displayed in the right pane of the Micro SSP analysis window.



Default configuration:

- Wells, (Beads if it's a combined analysis with LABType) are sorted by sample reaction.
- The well ID depends on the row and location of the sample in the test gel pane.
- The current sample appears in a **Blue** font, just below the cross loci row.
- Positive alleles are listed below the sample row and are highlighted in yellow.
- Cross loci wells are identified with the pound sign (#).
- **Salmon** coloring indicates a false positive. **Green** indicates a false negative.

①	Positive reactions are displayed as an "**X**" on the table, (**blue** for the current sample and **black** for the rest). PC, NC and excluded beads are displayed as "**0**" on the table.
②	If you want to expand the table to full window size, click the Max button. To minimize it again, click the Min button.
③	Double-click in the area just above the table, between the **Find Allele** and **Max** buttons, to expand the table to half the analysis window. To size the table back to its original size, double-click in the same area again.
④	Type an allele into the field and click the **Find Allele** button to display the allele and its reaction pattern in the first row. Double click on an allele name to bring that allele to the top of the table. You can bring all of a certain allele group to the top by entering an allele group (i.e., DRB1*07).
⑤	Click on the blank row header to either the left of an allele name or the sample reaction to move all the beads with that reaction to the left. Click the **Rxn Reset** button, (*above the Max button*) to reset the table to its original configuration.
⑥	When a column header is clicked, the table is sorted by reaction criteria for that well or bead, (*if combined with LABType*). The first click sorts in ascending order from top to bottom. The second click sorts in descending order.
⑦	If you use the **Analyze Combined** button from the analysis window to analyze a LABType test and a Micro SSP test, the Bead IDs from the LABType test are displayed in the Well ID row on the Rxn table. These are recognizable by the bead ID followed by an underscore and a **0**.

Number of Allowable False Reactions

If HLA Fusion cannot determine any results that exactly match the reaction pattern entered, it analyzes the reaction assuming that there is one false reaction in the sample.

If a solution still cannot be found, the system continues to search through additional false reactions until the number of allowable false reactions has been reached, or a solution is found.

The false reaction setting allows you to set the number of allowable false reactions:

Minimum setting = **0**

Maximum setting = **4**

- In the **# False Rxn** field, click the up or down arrow to change the number of allowable false reactions.

Note: Regardless of the maximum false reactions set here, sample analysis stops at the first false reaction found.

Force One False Reaction

When a sample has a result with no false reactions, (exact match result) the **Force 1** feature forces HLA Fusion to re-analyze the reaction to allow for one possible false reaction in any well. This feature is used to search for results for which one additional reaction can change the results.

1. From the analysis window, click the **Force 1**button to force the program to analyze the sample with one false reaction.

Click the **Reanalyze** Reanalyze button to reset the analysis to the original results.

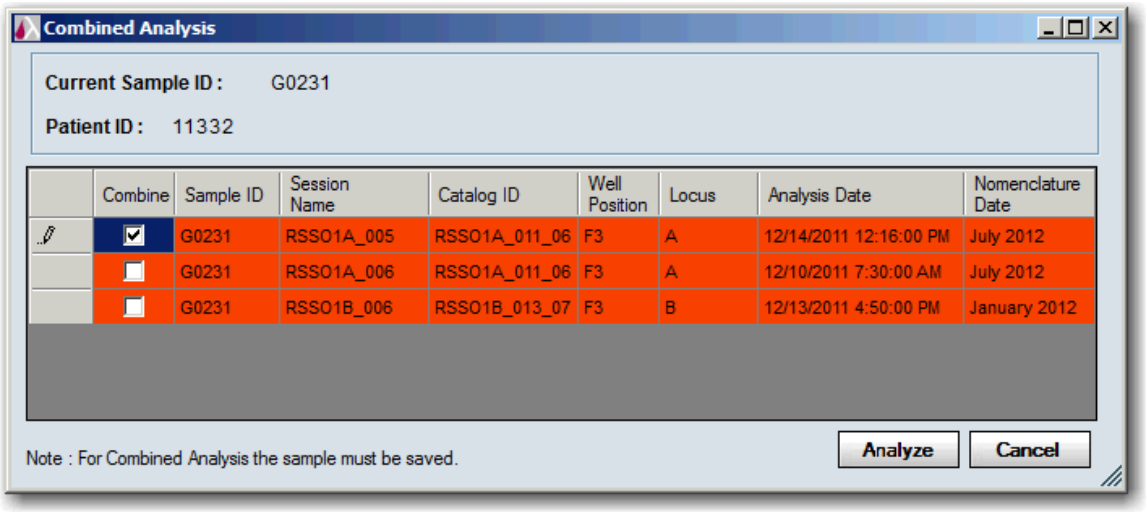
Click the **Rxn Reset** button to return the Rxn Pattern table to the default settings.

Micro SSP Combined Analysis

The HLA Fusion software supports a combined analysis feature. In a combined analysis, the reactions from two tests of the same sample are combined together in a single analysis. The previous test must either have the same Sample ID or be associated with the same Patient ID.

To combine results for a sample, you need to start or continue a Micro SSP allele-specific test and have a previously saved Micro SSP or LABType session to combine with it. After combining sessions, the possible typing assignments are displayed, and the reaction pattern table changes to reflect the reaction pattern of both tests.

1. From the analysis window, click on the **Analyze Combined** button below the reaction pattern table. The **Combined Analysis** window displays a list of previous sessions that have used the current sample and share the same Sample ID.



Select the desired previous session(s) by selecting the associated **Combine** check box on the far left.

Click the **Analyze**  button at the bottom of the pop-up window.

Note: If you combine one sample in the previous nomenclature format with a sample in the newer nomenclature format, the possible and assigned allele pairs and code will be displayed in the new format. If the sample with the previous nomenclature format contains an allele that is not included in the new nomenclature, that older allele is dropped.

To rerun the combined analysis, click the **Reanalyze Combined** button.

- If the nomenclature dates between the current one and the one(s) being combined with it conflict, then the session(s) you selected is highlighted **Red**.

- If you click the **Analyze**  button and there is a conflict on nomenclature dates, a warning message is displayed that gives you the option of continuing or canceling the combined analysis. The nomenclature of the sample test you selected to combine with the current one will be used if you continue.

Note: Notice that the **Analyze Combined** button in the analysis window changes to **Reanalyze Combined** button. This is an indication that the selected sessions have been combined. If sessions are combined, a note is added to the system comments box.

Make Typing Assignments in Micro SSP Analysis

HLA Fusion provides computer-suggested allele pairs and coded assignments. Final typing assignments can only be made by you, or your supervisor.

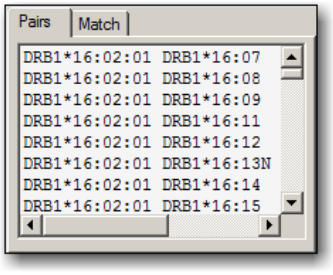
From the analysis window you can do the following:

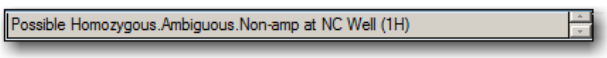
- Switch between code formats
- Apply Bw4/Bw6 to serology results
- Apply frequency filters
- Assign non-coded allele pairs
- Assign a coded allele pair
- Assign serology equivalents
- Make manual assignments
- Remove assignments
- Save and confirm assignments

Pairs Tab

The **Pairs Tab** displays the possible allele pairs results that match the reaction pattern for the sample. The pairs are suggested by the software.

- The list identifies the pairs and groups them by either full-match pairs, (no false reactions) or the number of false reactions. Results with false reactions are listed with the false reacting bead/well identified.
- The results display one allele pair per row.
- Possible homozygous pairs are flagged in the **Comment** field.



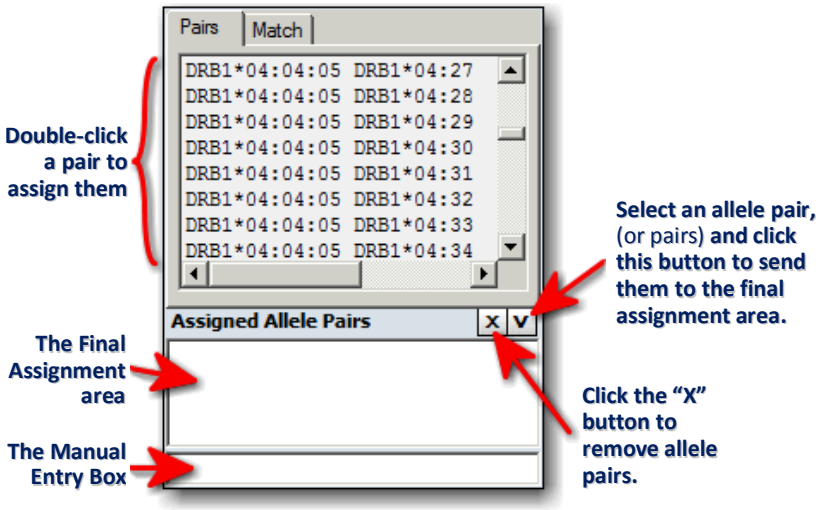


Assign an Allele Pair from the Suggested List

1. Double-click on an allele pair under the **Possible Allele Pairs** to assign it to the final pairs assignment area.

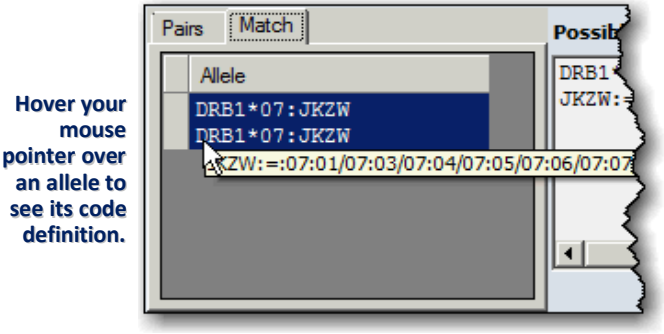
   Alternatively, you can click to highlight an allele pair on the list under the **Pairs** tab, and click the **V** (assign) button next to the **Assigned Allele Pairs** title to add it to the final assignment area.

To remove an assignment, select the assignment on the **Assigned Allele Pairs** list and click the **X** (remove) button.



Match Tab

This data grid displays the coded format of the actual allele pairings for the sample. A *Matched Reaction Pair* is a pair of alleles, (or group of alleles) with a reaction pattern that completely matches the reaction pattern of the current sample.

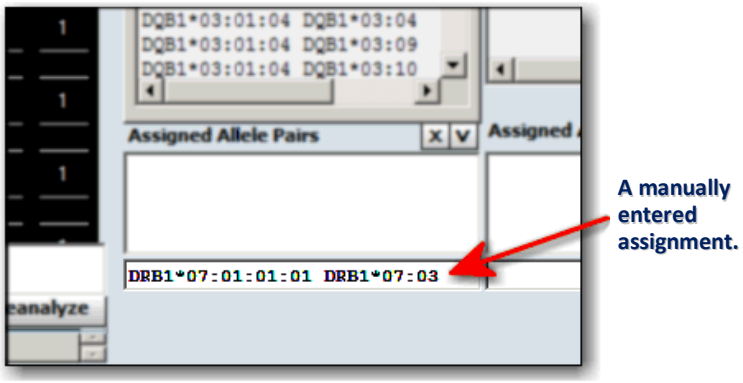


- This result differs from the **Possible Allele Code** results. The **Possible Allele Code** condenses the results into a single code, where possible.
- Hovering your cursor over a coded allele format displays its code definition.

Manual Allele Pair Assignment

1. Make sure you type the assignment in the correct allele code format:

   - New nomenclature format: X*##:##(####) X*##:##(####), where X=locus type and #= code number.
   - Previous nomenclature format: X*#### X*####, where X=locus type and #= code number.

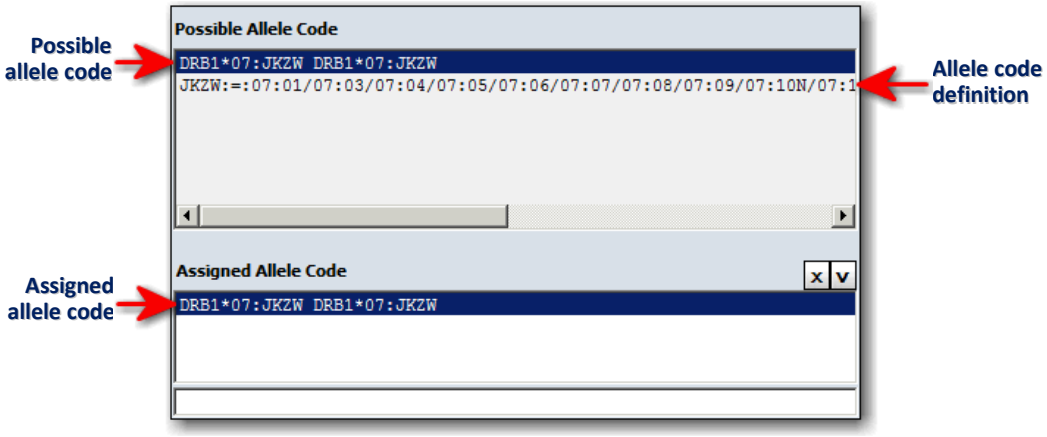


Type an assignment into the text box directly below the **Assigned Allele Pairs** list.

Press the **Enter** key on your keyboard to move the typed allele upwards into the **Assigned Allele Pairs** text box.

Possible Allele Codes

The **Possible Allele Code** field displays the possible coded results for all results that fully match the sample. The type of code used is dependent on your configuration selection: NMDP code, (default) local code, (user-defined) or no code.



- The possible coded result is listed at the top section of the field. The code definition is listed below it.
- If there are no codes for a particular suggestion, then the suggestion is listed with XX, meaning the code is undefined. For multiple XX suggestions, each suggestion is numbered as XX**1**, XX**2**, etc., to distinguish one from the other.
- The allele codes displayed in the **Possible Allele Code** field are condensed by Fusion based on suggestions from the list of possible allele pairs displayed under the **Pairs** tab.
- The allele code is based on the current NMDP code, or local code installed in the system. By default, the system assigns the NMDP codes to the alleles. You can optionally change these codes to either No Code, Local Code or Cross Code.
- **No Solution** is listed if there are no results that match the sample's reactions within the allowable number of false reactions.

Allele Code Assignment

1. Double-click the possible allele code, or select the suggested code and click the **V** (assign) button.

Select an allele code and click the **X** (remove) button to remove an allele code assignment.

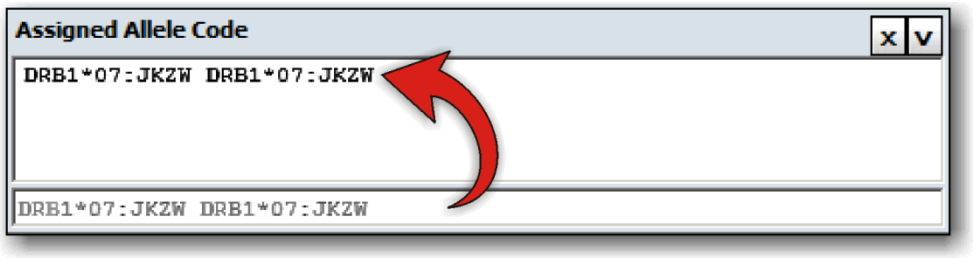
Manual Allele Code Assignment

1. Type an assignment into the text field just below **Assigned Allele Code**. Make sure you type the assignment in correct allele code format:
   - New nomenclature format: X*##:##(####) X*##:##(####), where X=locus type and #= code number.
   - Previous nomenclature format: X*#### X*####, where X=locus type and #= code number.

   Otherwise, the system does not accept it, and prompts you to make corrections.

Note:	If you click on the **Translate** button to display alleles in the new nomenclature format, you cannot enter a manual allele code unless you reanalyze the sample and alleles are again displaying in the previous nomenclature format.

Press the **Enter** key to move the allele code you typed in to the **Assigned Allele Code** field.

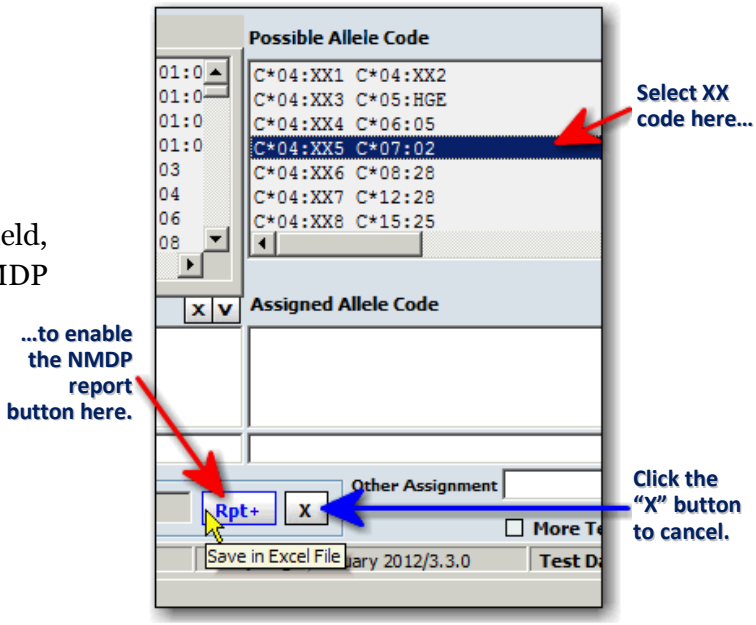


Note: If you have a homozygous result, the assigned code can be edited in the Manual Allele Code field to show the homozygous-coded results once.

Unknown Allele Codes

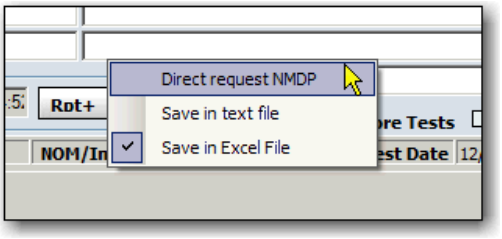
Unknown allele codes are marked with XX followed by a sequential number. The numbers are reset to 1 for each sample and locus. When you see unknown codes, you should first make certain you have imported the latest NMDP file. If you have the latest code file, and are still seeing XX codes, you can store these unknowns for later submission to the NMDP in a .txt file named **nmdp_code_report.txt**. By default the text file is stored in `C:\OLI Fusion\data\NMDPExport`, but the location can be changed by modifying the *Interface* path. Code information is appended to the end of this text file as it is added; the newest additions are at the bottom.

1. From the **Possible Allele Code** field, select the **XX** code to enable the NMDP Code Report buttons at the bottom of the screen.

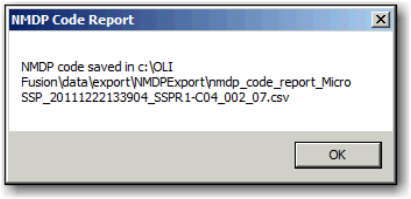


Right-click the **Report** Rpt+ button and choose one of the following:

To send the unknown code information to NMDP, select **Direct Request NMDP**.



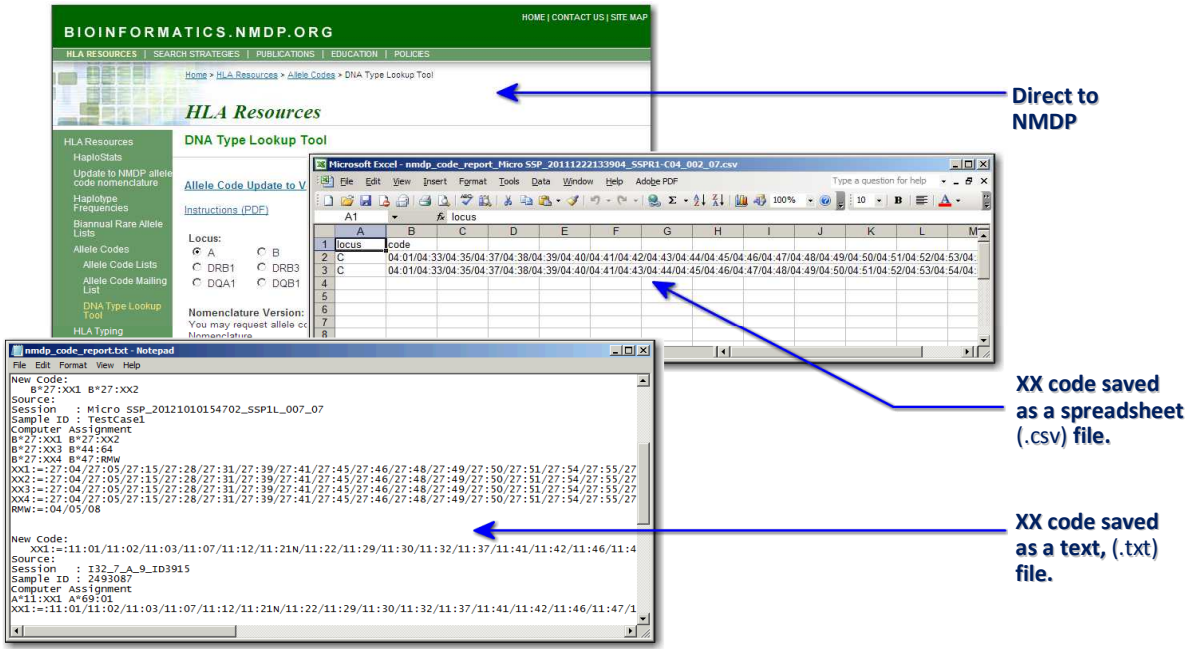
- To add the unknown code information to a text file, (by default stored in `C:\OLI Fusion\data\NMDPExport`), select **Save in text file**.
- To add the unknown code information to an Excel file, (by default stored in `C:\OLI Fusion\data\export\NMDPExport`), select **Save in Excel File**, or simply left-click the mouse button.



When you're done, click the X button to remove the buttons from display.

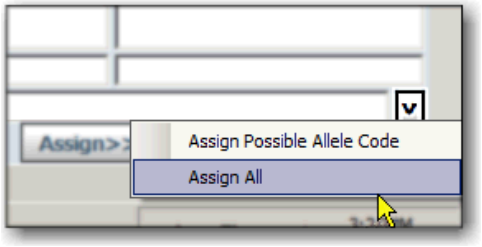
Note: The **+Rpt** button retains the last selection you made, (direct, text or Excel) so it can be used as a shortcut; unless you want to change your selection, the next time you report XX code simply click the **+Rpt** button.

The following shows examples of each result:



Other Assignment

The **Other Assignment** field can be used to make a sample assignment that is not restricted to any format. In addition, you can highlight and add serology or allele pair or code assignments and add them to the field for modification.



You can make other code assignments one of two ways:

- Type an allele pair or allele code into the **Other Assignment** field.
- Click the **V** (assign) button and select one of two options:
  1. To assign just the possible allele code, select **Assign Possible Allele Code**.
  2. Choose **Assign All** to bring the Possible Allele Code, Serology or Assigned Allele Pairs assignment(s) into the **Other Assignment** field.
- You can then choose to modify any of the copied code if desired.
- The entered allele is assigned and is included in reports that are run that include this sample.
- It is not listed in any final assignment fields for this sample.

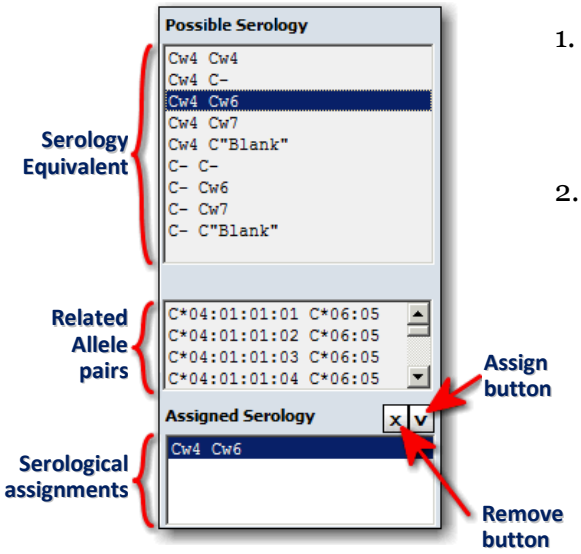
Possible Serology Field

The serology equivalent field displays all serology equivalent suggestions for the sample based on the possible allele pairs. When you select a displayed serology equivalent, the allele pairs associated with it are displayed in the field below.

Note:	Make sure you have imported the current serology equivalent file through the Utilities menu. If a zero (0) appears in the serology assignments, this means you need to import the current serology equivalent file.

- Only one serology equivalent assignment for the sample can be made at a time. Therefore, a current serology assignment is replaced if you select and assign a different one.

Note: If this is a multi-loci test, more than one locus can be assigned. However, for single locus tests, only one locus can be assigned.



1. Double-click a serology suggestion, or highlight it and click the **V** (assign) button to copy it to the **Assigned Serology** field.
2. Select the a serology equivalent and click the **X** (remove) button to remove it. Or, select and assign a different one to replace it.
3. For Class II manual serology assignments there is a pop-up message that allows the user to specifiy if the assignment is for DQA1 / DQB1 , DPA1/DPB1 or DRb1/DPB345.

Translate (noncurrent nomenclature format only)

The **Translate** button 

is displayed if your alleles format is displayed with older nomenclature. Clicking the button does the following:

- Displays all assigned, (except from the Other Assignment field) and possible allele code/pairs in the latest nomenclature format. If a matching allele in the new format cannot be found, the allele remains displayed in the old format.
- You can view and print this display, but results cannot be saved or reported in this new nomenclature format.
- To go back to the older allele format, you can navigate to another sample, and then return to this sample.

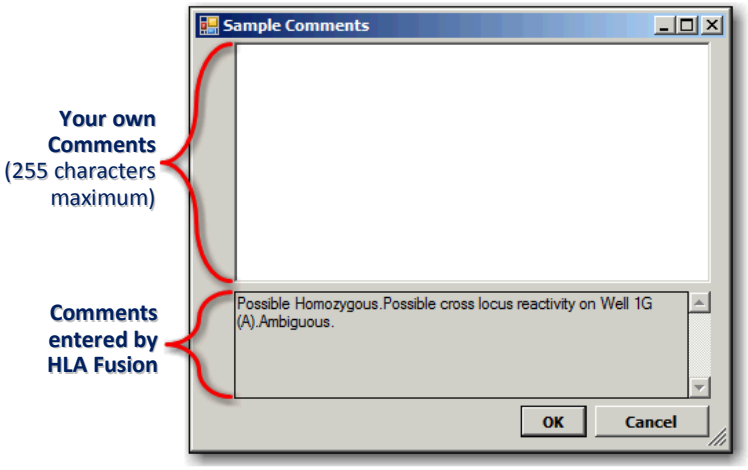
Adding Comments to Samples

Comments you, or Fusion adds to the **Comments** field are displayed with the sample results in the current analysis session, data look up and reporting functions in HLA Fusion.

1. In the analysis window, type sample comments into the **User Comment** field below the Assignments area.

Or double-click in the User Comments field to open a larger writing space.

Comments are only saved after you click the **Save** Save **button.**

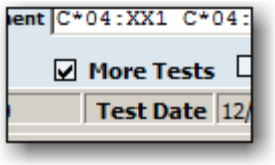


Note: The larger User Comments field expands to allow for a maximum of 255 characters.

Flagging a Sample for Further Testing

You can indicate the need for further testing of a sample by selecting the **More Tests** check box followed by clicking the **Save >>** button. The More Tests indication is displayed in results, data look up and reports for the sample.

- In the analysis window, click the **More Tests** check box, located below the Assignments area.



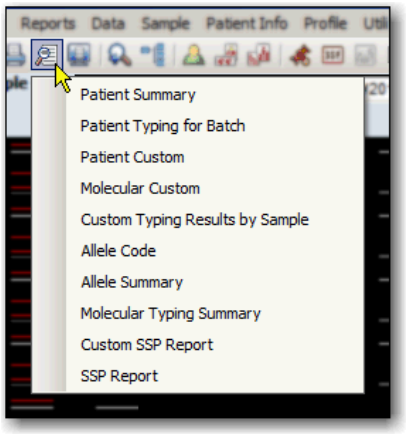
Printing the Current Analysis Window

The **Print Screen** button prints the currently displayed analysis window.

- From the analysis window, click the **Print Screen** button on the toolbar to print the current analysis screen.

Preview or Print Reports

To view a Micro SSP report for the current sample, use the **Preview Report** and/or **Print Report** button on the toolbar.



In the analysis window, click the **Preview Report** button or the **Print Report** button to display a list of reports you can preview or print for the current sample. The drop-down report menus are identical for either Preview Report or Print Report.

Note: If you select **Molecular Custom**, you will not be able to create a new custom report at this point. The only custom reports available from the analysis window are ones you previously created through the **reports** window.

Assign Coded Results

Use the **Assign** Assign>> button to assign and save all unambiguous possible coded results, (those results for which there is only one coded result).

Save Assignments

Lab Technicians and Supervisors can save analysis results for further review and approval. Saved samples are available for confirmation by a lab supervisor *only*.

- From the analysis window, click the **Save** Save>> button, located in the bottom right corner of the analysis window to save the analysis results.
- Fusion will automatically move to the next sample.
- Samples must be saved in order to associate any user-created comments in the database or reports. For confirmation, a supervisor needs to access the sample for which you saved the assignments.

Confirm Assignments

Lab Supervisors can confirm analysis results. Samples are marked as *Confirmed*.

- From the analysis window, click the **Confirm** 

button, located in the bottom right corner of the analysis window, to confirm all analysis results.

You automatically move to the next sample to continue confirming results.

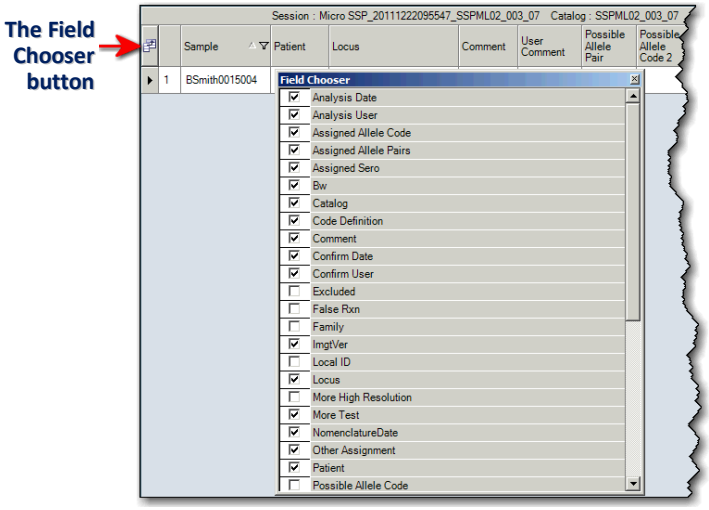
When you first return to a confirmed sample, you see that the **Confirm** 

button is now shaded **purple** to let you know it has been previously confirmed.

Micro SSP Session Summary

The summary table can be launched by clicking on a session in the **Navigation Tree** on the far right of the screen. It lists each sample in the session and any saved analysis results.

- Double-click a sample in the Summary Table to go directly to the analysis screen for this sample.



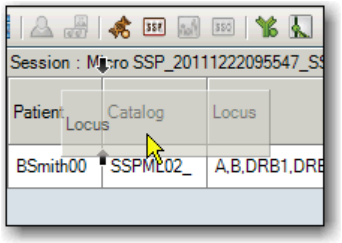
Click on the **Field Chooser** button to the left of the table headings to display the Field Chooser.

In this window, you can select or clear the check boxes next to column headings to include or exclude those columns from the **Summary Table**.

Selecting or clearing check boxes in this window instantly updates the table.

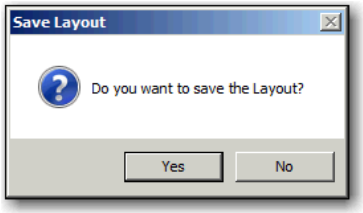
Note: If you do not see a particular field available through the field chooser, and you are sure it should be there, go to C:\HLA Fusion\temp and delete the file named **`SSP_Layout.xml`**.

- Click on any column header of the Summary Table to sort the table by that column. The small **Up** ▲ or **Down** ▼ arrow in the column header indicates the sorting order: up for Ascending and down for Descending.



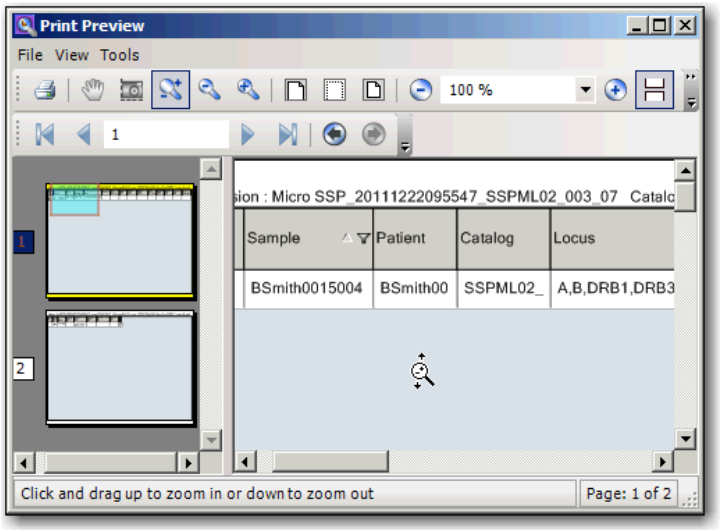
You can also click on a header and drag and drop it to change the column order.

- You can save any modifications you've made to the layout by clicking the **Yes** button in the message box when it appears.



Your changes are saved for all future Micro SSP session summaries on this same computer until further modifications are made and saved.

- Click the **Export** button, (located at the bottom of the screen) to save the Summary Table on your computer or network, (default location is **C:\OLI FUSION\data\report**). The file will be saved in the Excel spreadsheet (.XLS) format.
- Click the **Print** button to create a hard copy of the Summary Table.
- Click the **Preview** button to view and/or resize the Summary Table before printing.



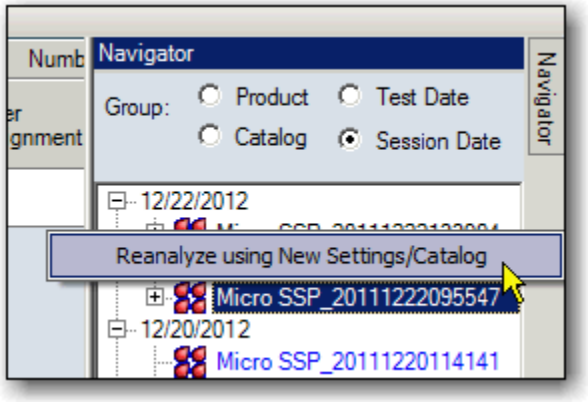
In the print preview window, the page view slider on the left displays icons for each page of the report.

- Click on a page icon to display that page in the preview window.

Navigator Right-Click Menu Options for Micro SSP

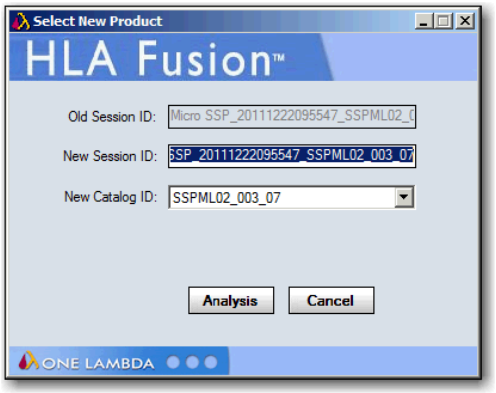
Session-Level Options

There is a menu that displays if you right-click on an active session in the Navigator, (select the session first with a left-click):



Reanalyze with New Nomenclature

Allows the session to be reanalyzed using a new or updated catalog.

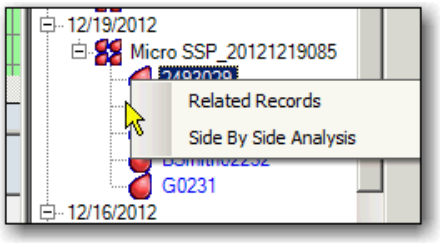


1. After right-clicking on a session, the **Select New Product** screen opens.
2. Rename the session.
3. Click the drop-down arrow ▼ in the **New Catalog ID** field and select a new catalog from the list.
4. Click the **Analysis** Analysis button.

   The session on which you right-clicked is now re-analyzed with the catalog you've selected.

Sample-Level Options

Two menu options are displayed if you right-click on an active sample in the Navigator, (select the sample first with a left-click).

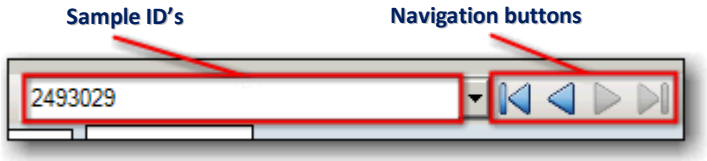


Related Records

A related record is a record that is associated with the current sample by Patient ID or Sample ID.

Note: This option is also available when you use the **Related Records** toolbar button .

- Right click a sample from the Navigator and select **Related Records** to load all records related to the current sample into the **Sample** drop-down list, (at the top, center of the screen).



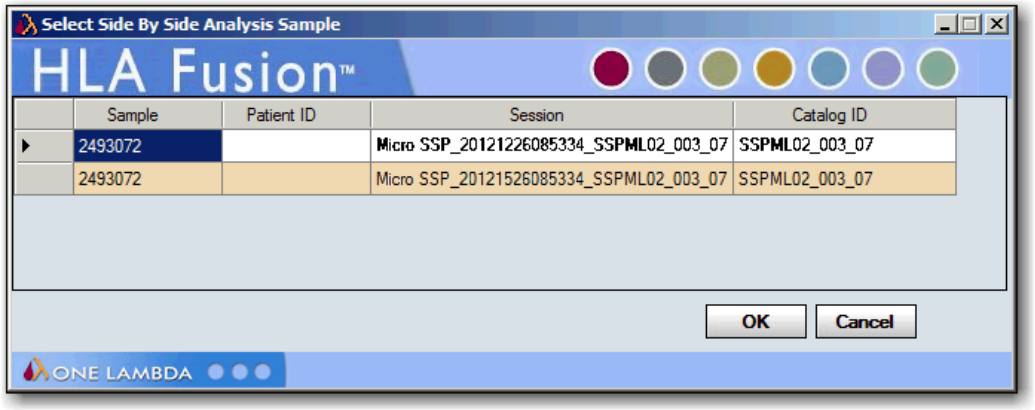
Use the sample navigation buttons to display the analysis of each related record one-by-one.

To go back to viewing the samples in the current sessions, click the **<<Summary** link at the top of the window.

Side By Side Analysis

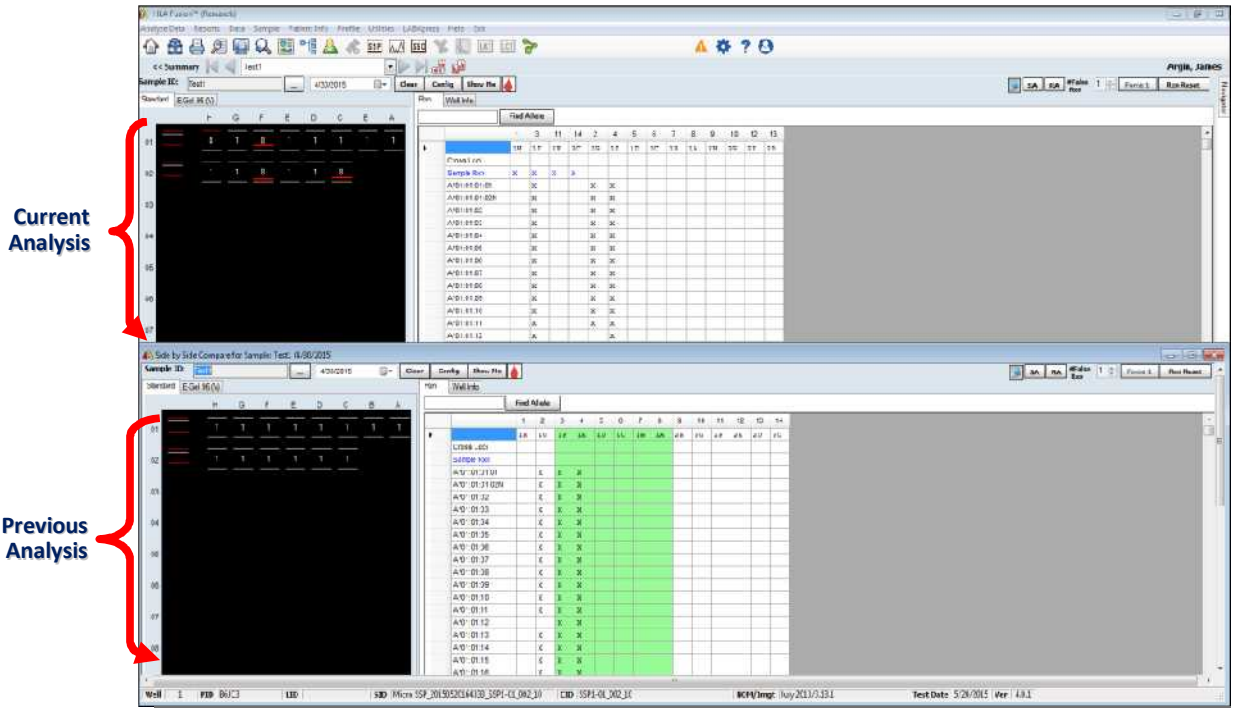
Use this option to compare the current sample analysis with one previously conducted.

Note: This option is also available when you use the **Side By Side Analysis** toolbar button .



- Right-click the sample, and select **Side By Side Analysis**.
- Select a previous sample analysis from the displayed list to compare it to the current one. The two analysis windows are then displayed in a comparison window.

Side-by-Side analysis display



- Each window can be resized and moved by dragging and dropping.
- Click the **Side-By-Side Analysis** toolbar button again to cancel the comparison display.

LABScreen Analysis

The LABScreen analysis feature of the program allows you to analyze Luminex CSV output files from LABScreen products. Analysis results are based on the catalog specifications provided with the HLA Fusion software.

A few things should be completed or verified before you start an analysis session:

- Make sure you have the latest catalog files.
- You can download or update catalogs from the LABScreen Home Page.
- Some features, such as w632 normalization, may not be available if you have not already imported the appropriate catalog(s).
- View and modify global product configuration settings before starting analysis. Global settings are displayed and be can be modified on the LABScreen Home Page, or through the Utilities menu. Global settings apply across all newly imported sessions.
- Save time importing CSV files by verifying that the default URLs and paths are pointing to the locations where these files are commonly stored on your system or network. These settings can also be modified in the General Configuration section of the default Fusion Home page.
- If you prefer HLA Fusion to stay on a sample you have just saved or confirmed, rather than automatically move to the next sample, this can be set in the General Configurations section of the Fusion Explorer Home page.

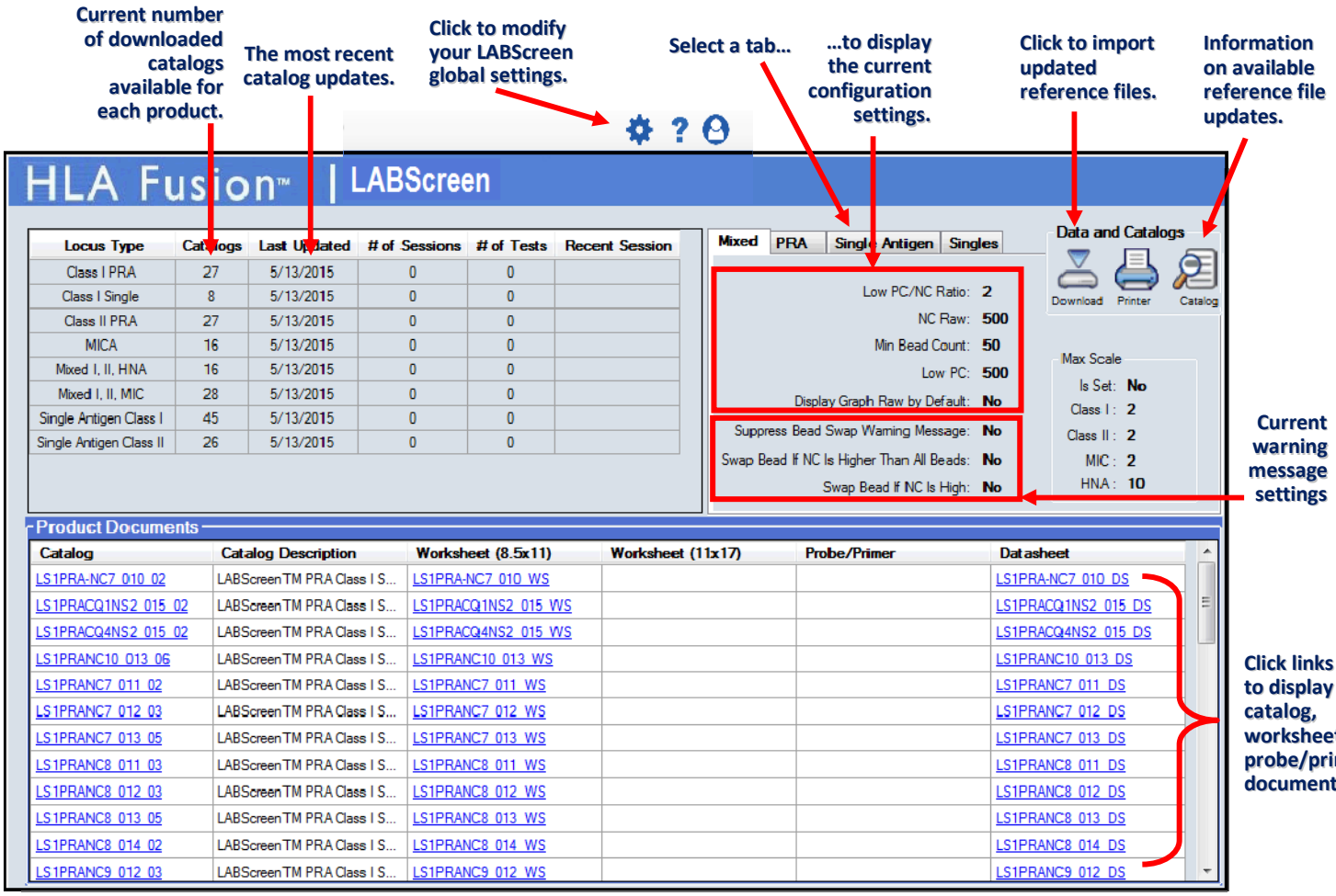
Note: Some of the above tasks require supervisor user privileges. You may have to verify with your supervisor that these tasks have been completed.

Starting LABScreen Analysis

Note: If you want to set W632 Normalization as the default for LABScreen Single Analysis, select the check box next to Use W632 Normalization as Default in the LABScreen Single Analysis product configuration page.

Acquiring LABScreen Session Data

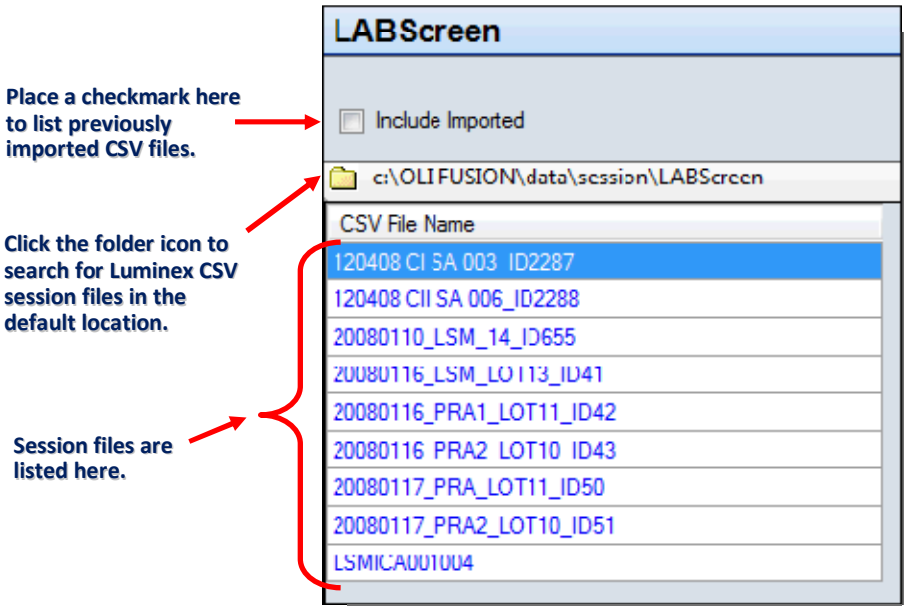
Select the **LABScreen** button from the Home Page panel  or the Fusion toolbar  .



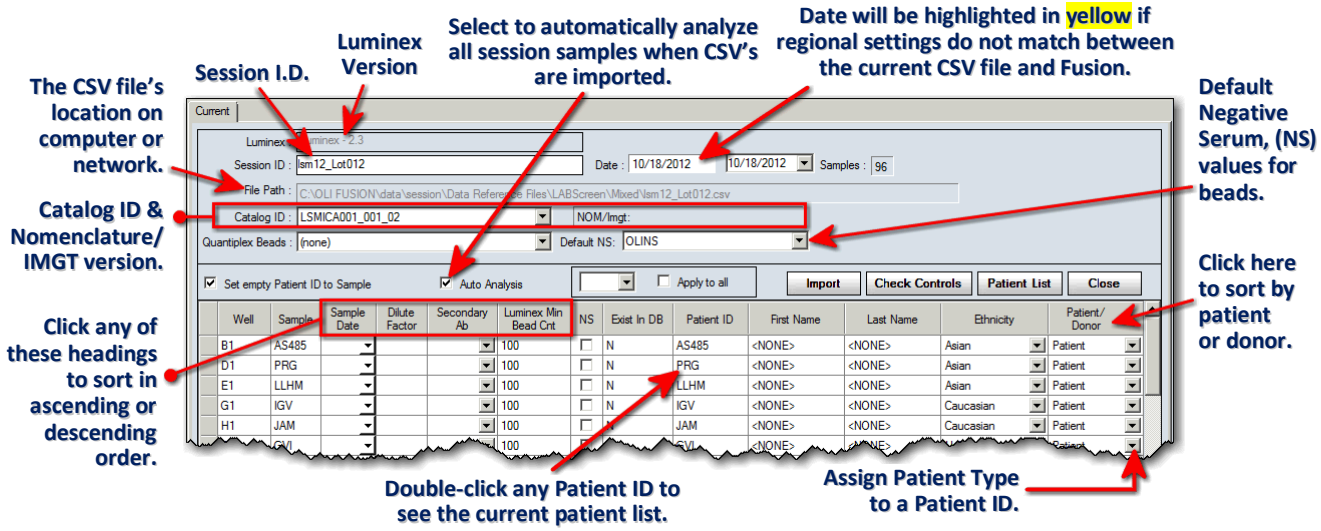
The LABScreen Home page is displayed.

Note: Open worksheets and probe/primer sheets to verify the accuracy of revision numbers, (these documents do not contain a revision number in their filename).

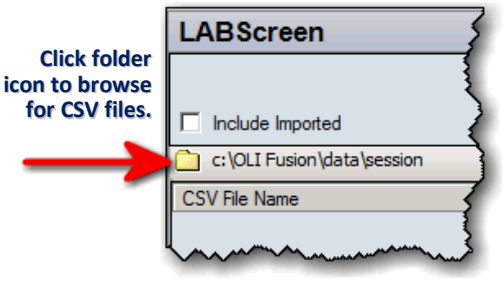
Select a session from the CSV File Name List.



The **LABScreen Session Import** window displays.

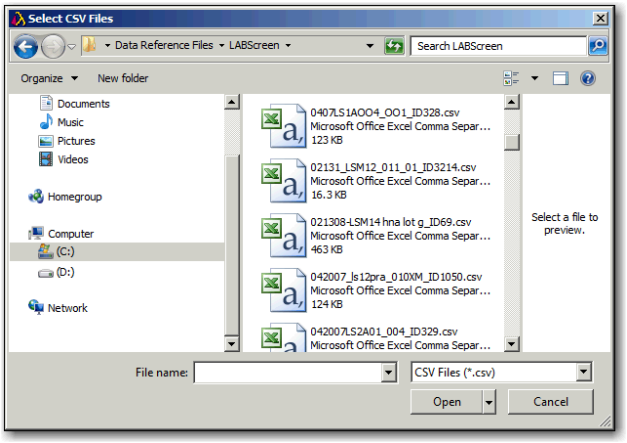


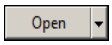
1. Click the small folder icon at the top of the LABScreen CSV File Name list.



2. Select a file from the list of previously imported CSV files, or click the **Folder** Icon to browse to the location of LABScreen CSV file(s) on your computer or network.

Browse to Find LABScreen Session Files



3. Select a CSV session file(s) and click the Open  button to display its associated samples in the Current Sample/Patient Details table.

Note: You may see CSV files for products other than LABScreen, or other miscellaneous CSV files. This means that you must first click on a sub folder for LABScreen, or that your LABScreen session files are not contained within their own folder in the directory to which HLA Fusion is pointing.

Note: HLA Fusion converts Luminex-generated CSV file data, such as date and time, to the local regional code if a regional code is specified in the CSV file. (A regional code cannot be specified for CSV files created with Luminex software versions 2.2 or earlier.) If the first date field is highlighted yellow, it indicates a regional code mismatch. In this case, it is recommended that you use the drop-down selector in the second date field to choose the appropriate date, taking into consideration regional date format differences.

If a sample is already associated with a patient, the patient ID and any existing, related patient information is displayed.

To add patient information, do one of the following:

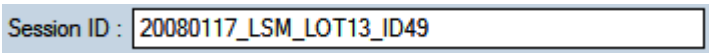
- To add data from the system, double-click in the Patient ID column of the Sample/Patient Details table or click the **Patient List** button on the toolbar. The **Import Patient** window is displayed, allowing you to import the patient information file.
- To manually add patient data, type data into the patient-related fields of the table.
- You can assign the sample ID to empty patient ID fields by selecting the check box for ***Set empty patient ID to Sample***.

To assign secondary Ab to the samples, do one of the following:

- To assign secondary Ab to individual samples, select from the **Secondary Ab** drop-down, or type one in the associated field.
- To assign a secondary Ab to all of the samples, select from the **Apply to all** drop-down or type one in the field, and then select the **Apply to all** check box.

The system assigns a session ID automatically. Optionally, you can change the ID.

LABScreen Session ID field



Note: A session ID must be unique to the Fusion database. If the session ID already exists, the software prompts you to rename the session. It is also highly recommended that you do not use any special characters in this field since they may serve a specific purpose as field separators.

4. Select a catalog file. Your catalog selection method is one of the following, depending on the CSV file and the catalog files you have imported for LABScreen.

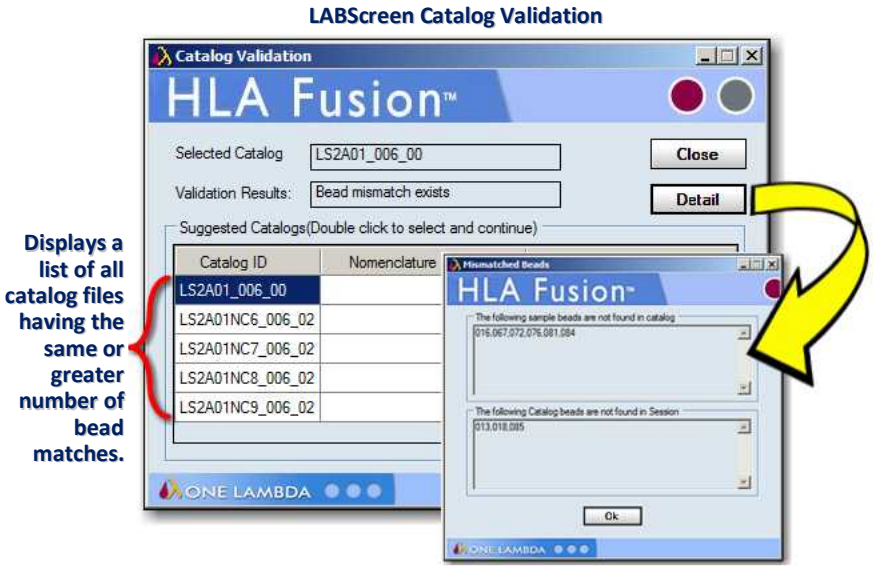
Note: If you need to import more catalogs, click the **[Download]** link on the LABScreen home page to add new catalog files to your database. The catalog drop-down list may not be immediately updated if you downloaded the catalogs during this import session. You may need to click the **Home** button and then click the **LABScreen** button again to return to the import process.

If the CSV file specifies a template name, (applies only to CSV files from Luminex 2.2 and later) and one of the available catalogs is associated with that template, then that catalog is automatically selected.

You can also select a different catalog from the one the system has selected by using the drop-down list in the **Catalog ID** field and selecting any catalog listed.

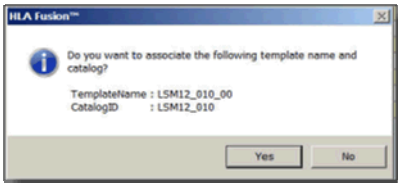
If there is no template match, the system then considers the closest bead match between the session and all available catalogs. If only one catalog is a close match, it is automatically selected and you can go to

5. When session and sample information has been verified, click the Details button. If there is more than one match, a catalog validation dialog box is displayed with the best bead matches. You can confirm the selected catalog by clicking the **Close** button. Or, you can double-click a catalog name on the list of **Suggested Catalogs**.



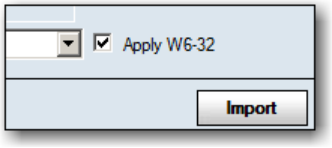
6. Following catalog validation, the system may ask you if you would like to associate that template name with the catalog.

   This means that in the future, for any CSV files referencing this template, the system automatically selects it; you can select a different catalog for the CSV file, though, before you import it.



Note: If you want to see the selected negative serum, (NS) sample overlaid with the default NS for the current sample, you must do so before you import the session.

If you pick a Class I Single Antigen CSV file and a catalog with W6-32 data in it, the Apply W6-32 check box displays. If this check box is displayed, you can choose whether or not to normalize the imported data for W6-32 by selecting the check box.



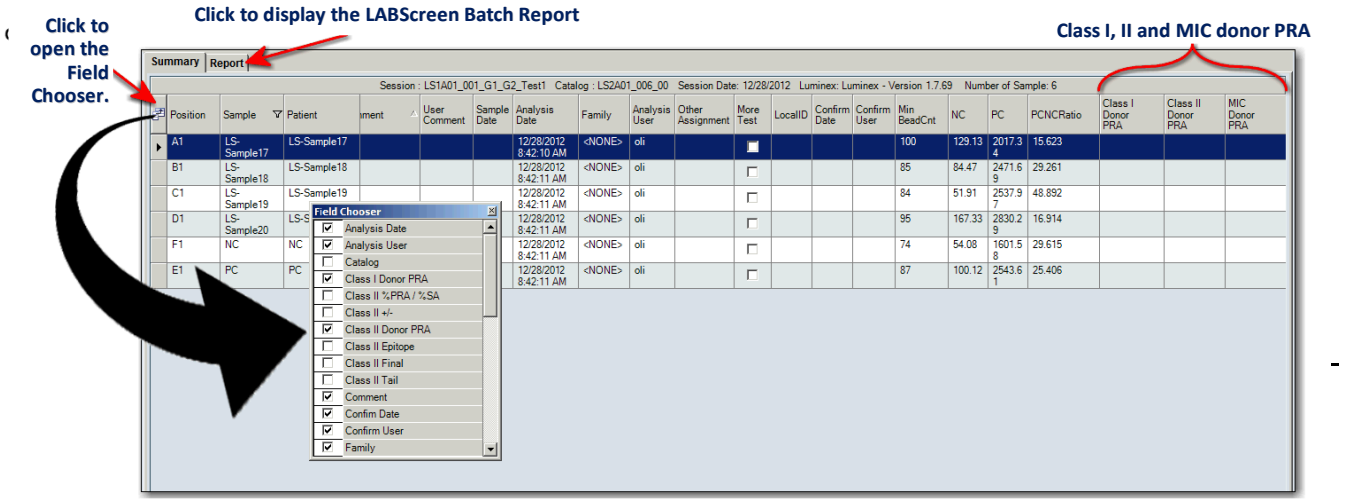
You must import a LABScreen Single Antigen catalog type and a CSV file containing W6-32 data to apply W6-32 normalization.

7. When session and sample information has been verified, click the **Import** Import button. The session is displayed in the **Navigator** tree on the right for subsequent analysis.

You can continue importing Luminex session files, or you can click a session on the Navigator to start analysis. Either way, you can navigate between sessions and samples in various ways during analysis.

LABScreen Session Summary Screen

In the **Navigator** Tree, click on a Session Name. The **Session Summary Table** is displayed.

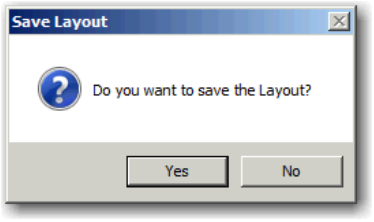


LABScreen Session Summary Screen

- Double-click a sample in the Summary Table to go directly to the analysis screen for this sample.
- Scroll left and right to see all the columns of the Summary Table.
- Click on the **Field Chooser** button to the left of the table headings. The **Field Chooser** box displays. You can select or clear the check boxes next to column headings to include or exclude those columns from the Summary Table. Selecting or clearing check boxes in this window instantly updates the table.
- Click the **Auto Accept All** Auto Accept All button to allow automatic assignment and acceptance, (both Tail and Epitope) of results upon import.

Note: If you do not see a particular field available through the field chooser, and you are sure it should be there, go to C:\HLA Fusion\temp and delete the file named: **`x_x_x`**`(antigen type)`**`_Layout.xml`**. For a list of the names used to represent the layout files for the different screening antigen products, consult the section, *Session Summary Layout File Naming*.

- The session summary table columns and order can be modified and your selections saved. When you exit the Field Chooser, a pop-up message displays, asking whether you want to save any changes you made in the field chooser. If you select **Yes**, only the selected columns display on this same computer until further modifications are made and saved.



Note: Two columns of session data will always display, even if you save the field chooser settings: **Sample ID** and **Well Pos.**

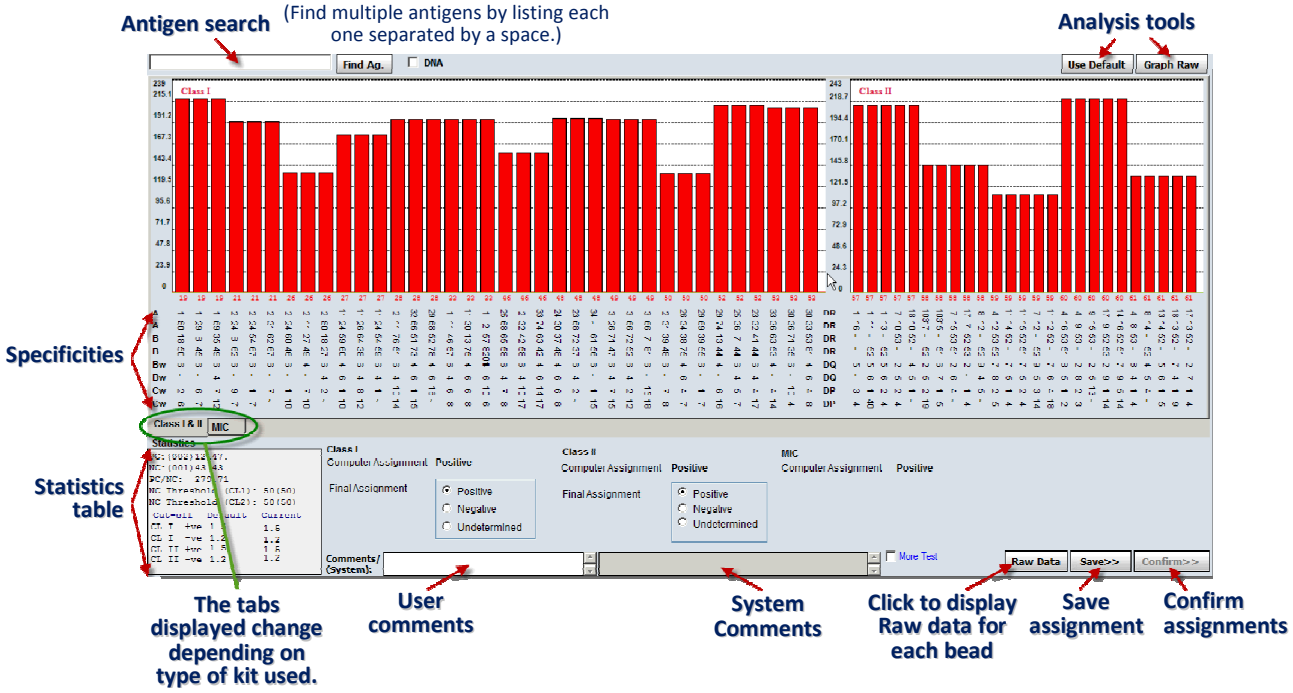
- In addition to the Field Chooser, you can click on any column header in the Summary Table to sort the table by that column. The arrows in the column header indicate the sorting order—up ▲ for ascending and down ▼ for descending. You can also click on a column header and drag and drop it to change the column order.
- Click the **Export** Export button to save the Summary Table as an Excel, (*xls) spreadsheet on your computer, or on the network, (the default location is **`C:\OLI FUSION\data\report`**).
- The **Print** Print and **Preview** Preview buttons displayed here provide functionality similar to other HLA Fusion programs.

Using the LABScreen Mixed Analysis Window

For each LABScreen Mixed sample in the current session, you can view the test data, adjust cutoffs, assign screening results and more:

- Review data and make overall assignments
- Circle antigens in the specificity table
- View molecular specificities
- View Class I, Class II and MIC screening results
- Adjust cutoffs
- Review a raw data table for all beads in the sample
- Overlay the negative serum sample on the current sample
- Add comments, mark the sample for more testing and view a sample analysis report
- Save and confirm results

The LABScreen Mixed Analysis Screen:



Note: If you prefer to make **Graph Raw** the default view when you access the LABScreen analysis window, go to the LABScreen product configuration settings and select the check box next to **Display Graph Raw by Default**.

- Both HLA Class I and Class II are displayed in a single window on the first tab of the screening results. MIC results can be accessed from a subsequent tab. Analysis results are either positive, negative, or undetermined.
- The normalized value is displayed using the ratio formula for each bead in the sample.
- Beads coated with Class I antigens are listed on the Class I histogram on the left side of the Class I/II window, and beads coated with Class II antigens are shown on the Class II histogram on the right side of the window. The X-axis labels show bead numbers, and the Y-axis labels list ranges of normalized bead values for each histogram.

Bar Colors:

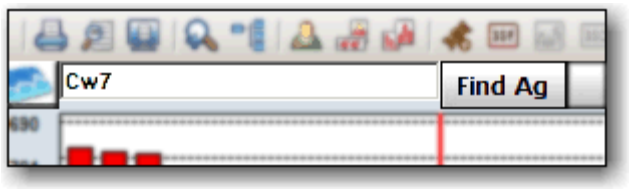
- **Positive =**
- **Negative =**
- **Undetermined =**

Find Antigen

Enter single or multiple antigens to circle the antigen(s) on the specificity, (center) area of the analysis window.

1. From the analysis window, type antigens, separated by a space, into the field next to the **Find Ag** Find Ag (Antigen) button. The antigen strings you type in must match the antigen displayed on the window.

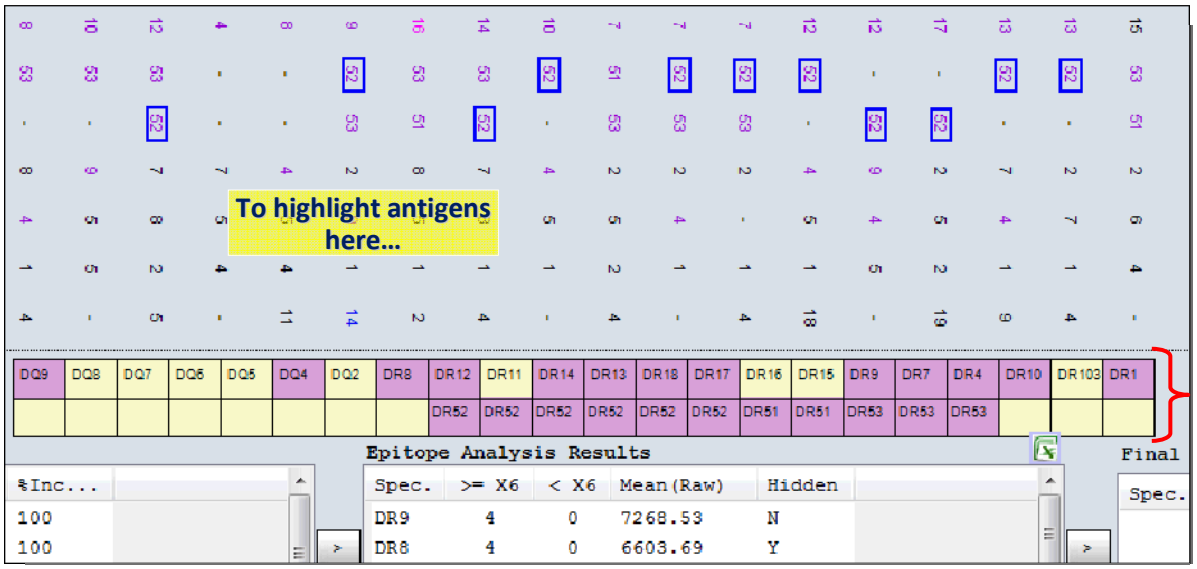
The Find Antigen Field



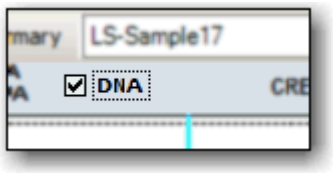
Click the **Find Ag** Find Ag button to circle the entered antigens.

Note:	If the antigen entered is a broad antigen, then its split antigens will be circled. For example, if A9 is entered, then A23 and A4 will be circled.

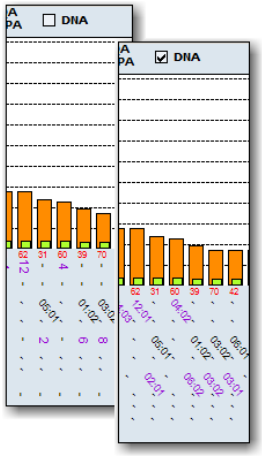
You may also click on any of the boxes in the **CREG Bar**, (as shown above) to circle the antigens in the Specificity area without having to type the antigen in the Find Antigen field.

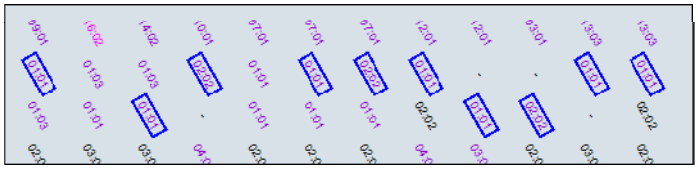


View Molecular Typing for Antigens



1. From the analysis window, select the **DNA** check box below the **Sample Name** at the top to display molecular typing for the antigens in the sample. Note: Antigens will now be highlighted by diagonal boxes in the Specificity area.





Molecular typing is displayed in **Purple** in the central, specificity area of the screen.

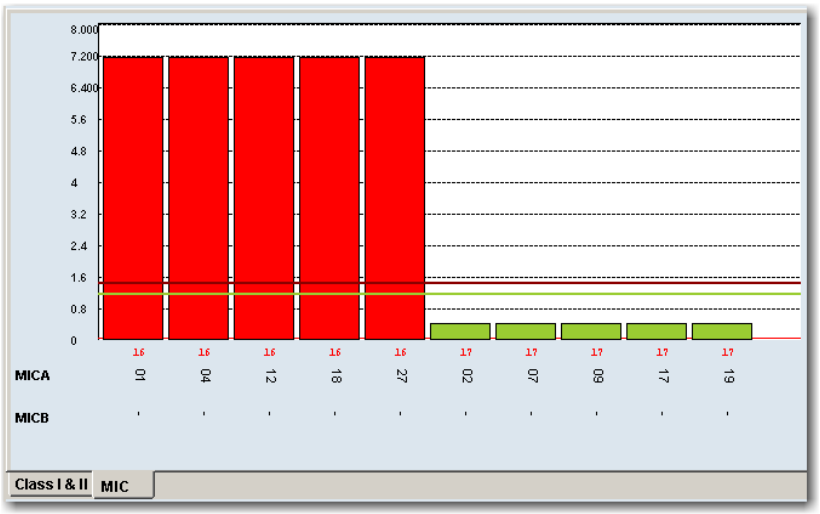
Clear the **DNA** check box to return to the display of serological specificities.

View MIC Antibody Screening Results

Select the tab labeled **MIC** to review MIC results for the sample.

1. From the analysis window, click the **MIC** tab to display MIC screening results.

MIC Antibody Analysis Screen



To return to Class I and Class II results, click the **Class I & II** tab at the bottom, left.

Adjust Cut-offs

You can change the positive or negative cut-off value for each sample by clicking and moving the cut-off lines on the histograms. However, you can change only one threshold cut-off at a time.

- From the analysis window, click on the cutoff bar, and drag and drop it up or down the bead graph to re-analyze the sample with a new cut-off value.

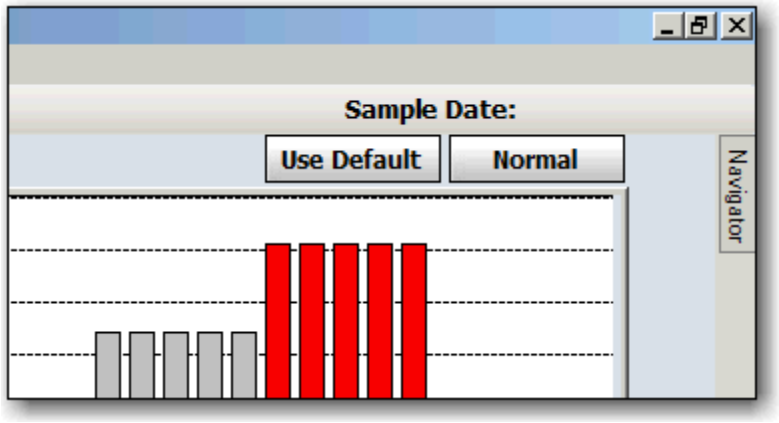
Cutoff colors:

- The **Positive** cutoff threshold is colored **Red**.
- The **Negative** cutoff threshold is colored **Green**.

Reset All Options to Default

Any changes made can be returned to default values.

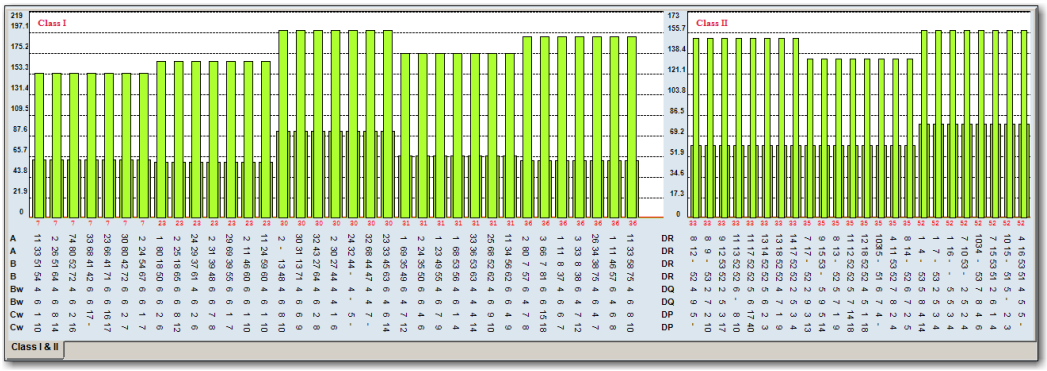
- From the analysis window, click the **Use Default** Use Default button in the upper right portion of the window to return all changed settings to default values. The sample is re-analyzed with the default values that were used when the sample was selected for analysis.



Graph Raw

The Raw Data graph shows the raw Mean Fluorescent Intensity, (MFI) value of each bead overlaid with the imported NC Serum MFI.

1. From the analysis window, click the **Graph Raw** Graph Raw button in the upper right portion of the window to display a raw data graph with background values from the selected or default NS for each bead.



2. Click the **Normal** Normal button, (top right) to return to a normalized graph.

Raw Data Table

Analysis information is displayed in tabular form. Positive wells are in **Red** text. Rows highlighted in yellow have reaction values over the threshold.

1. To display a sample's data in tabular form, click the **Raw Data** Raw Data button in the lower right portion of the LABScreen analysis window.

LABScreen Mixed Raw Data Table

Sample : LS-Sample18 Patient : LS-Sample18 Well Pos : B1
Session : LS1A01_001_G1_G2_Test1 Current Formula : BaseLine Test Date : 12/28/2012 8:42:11 AM
Catalog : LS2A01_006_00 Min. Region Threshold : X6 Formula : Baseline
NC Bead : 1 Negative Control Sample : OLINS Min Value : 2069.99

Bead ID	Sample Raw	Sample NC	LSNS Raw	LSNS NC	Baseline	NBG Ratio	Rxn	Count	S1	S2	S3	S4	S5	S6	S7	S8	Molecular Specificity
001	84.47	84.47	23.1	23.1	0	1	NC	641									
002	2471.69	84.47	11337	23.1	0	0.06	PC	617									
003	281.64	84.47	106.9	23.1	113.37	0.72	1	85	DR1								DRB1*01:01,-,-,-,-,-,-,-,-,-
004	4231.38	84.47	152.1	23.1	4017.91	7.61	6	209	DR1								DRB1*01:02,-,-,-,-,-,-,-,-,-
005	8973.91	84.47	103.8	23.1	8808.74	23.64	8	164	DR103								DRB1*01:03,-,-,-,-,-,-,-,-,-
077	502.13	84.47	256.1	23.1	184.66	0.54	2	485					DQ6				-,-,-,-,DQA1*01:02,-,DQB1*06:04,-,-,-,-,-
078	110.72	84.47	275.5	23.1	0	0.11	1	420					DQ6				-,-,-,-,DQA1*01:02,-,DQB1*06:09,-,-,-,-,-
079	142.67	84.47	408.7	23.1	0	0.1	1	310								DP2	-,-,-,-,-,-,-,-,DPA1*02:01,-,DPB1*02:02,-
080	119.87	84.47	259.9	23.1	0	0.13	1	445								DP13	-,-,-,-,-,-,-,-,DPA1*02:01,-,DPB1*13:01,-
082	137.58	84.47	231.2	23.1	0	0.16	1	274								DP15	-,-,-,-,-,-,-,-,DPA1*02:01,-,DPB1*15:01,-
083	6891.33	84.47	141.2	23.1	6688.76	13.35	8	213								DP18	-,-,-,-,-,-,-,-,DPA1*02:01,-,DPB1*18:01,-

2. Click on a column header, (i.e., Baseline) to sort the table by that criteria.

3. Click the **Close** ✖ button located at the upper right corner of the screen to close the **Raw Data Table** window and return to analysis.

Raw Data Report

For easier navigation, exporting and printing, you can create a report containing raw data information for the current sample.

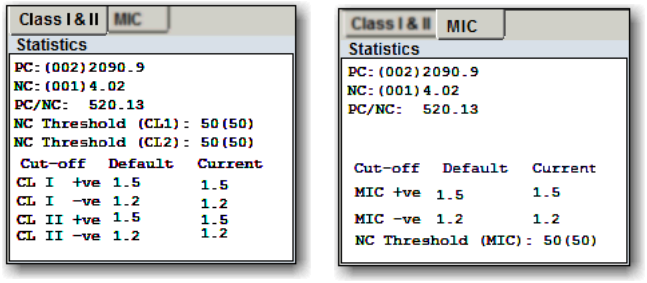
1. Once the Raw Data Table is displayed, click the **Report** Report button in the bottom right portion of the Raw Data Table window to display a report of the raw data.

You may also use the **Print Screen** Print Screen button to export data.

Statistics Table

This section of the LABScreen Mixed analysis window is in the lower left corner of the window, and displays statistics for each type of screening results. The values shown vary according to the screening results tab that is active.

LABScreen Mixed Statistics tables

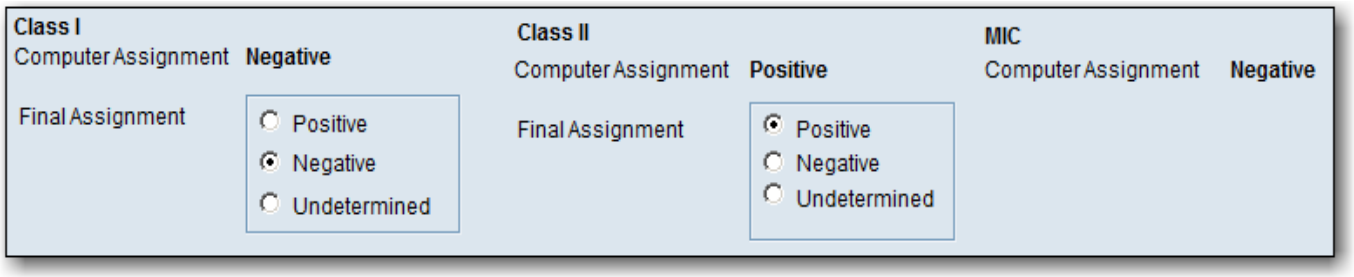


Making Assignments

The **Final Assignment** radio buttons display the Fusion-suggested assignment. To accept the assignment as displayed, save or confirm the sample.

To modify the suggested assignment, do the following:

- From the analysis window, select an assignment for each class using the Final Assignment options, (Positive, Negative or Undetermined).



Saving Assignments

Lab technicians and supervisors can save analysis results for further review and approval. Saved samples are available for confirmation *only* by a lab supervisor

- From the analysis window, click the **Save** 

button, located at the bottom right corner of the analysis window to save analysis results for all the specificities currently listed in the **Final Assignments** field.

After clicking the Save button, Fusion automatically moves you to the next sample.

For confirmation, a supervisor needs to access the sample for which you saved the assignments. You can return to the sample any time prior to confirmation if you need to make changes.

Confirming Assignments

Lab supervisors can confirm analysis results. When they do so, samples are marked as *Confirmed*.

The **Confirm** button is **Purple** when you view a confirmed sample.

- From the analysis window, click the **Confirm** 

button, located in the bottom right corner of the window, to confirm all analysis results that have been saved in the Final Assignments Results box.

After confirmation, Fusion automatically moves to the next sample to continue confirming results.

When you first return to a confirmed sample, you'll see that the **Confirm** 

button is now shaded **purple** to signify that it has been previously confirmed.

Adding Comments to Samples

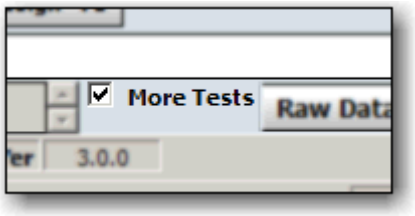
Sample comments are displayed for the sample's results in the current analysis session in all analysis, data look up, and reporting functions in HLA Fusion.

- In the analysis window, type sample comments into the **Comments (System)** field below the Assignments area.
- Or, double-click in either field to display a pop-up window that allows more text characters to be entered.

Flagging a Sample for Further Testing

You can indicate the need for further testing of a sample by selecting the **More Tests** check box and saving. The More Tests indication is displayed in results, data look up and reports for the sample.

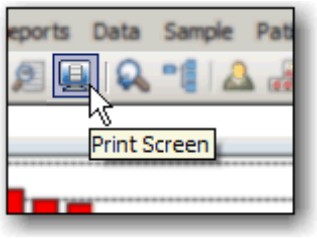
- In the analysis window, select the **More Tests** check box below the Assignments area if more tests are needed.



Printing the Current Analysis Window

The **Print Screen** button on the Fusion toolbar sends the currently displayed analysis window to the default printer.

- From the analysis window, click the **Print Screen** button on the toolbar to print the current analysis screen.
- It is printed to the default printer you have selected for this computer.

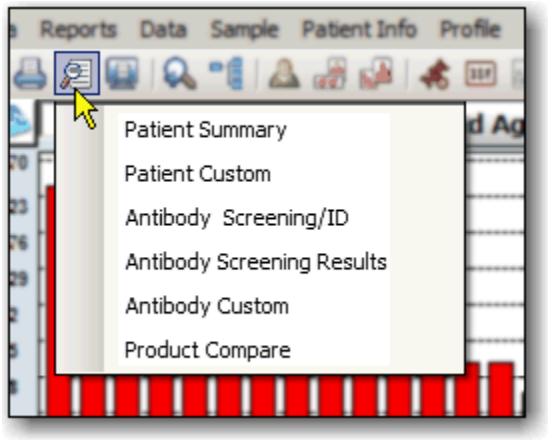


Previewing and Printing Reports

To view or print an Antibody Screening Mixed Data report for the current sample, use the Preview Report button on the toolbar.

- In the analysis window, click the **Preview Report** button or **Print Report** button to display a list of reports you can print or preview for the current sample.

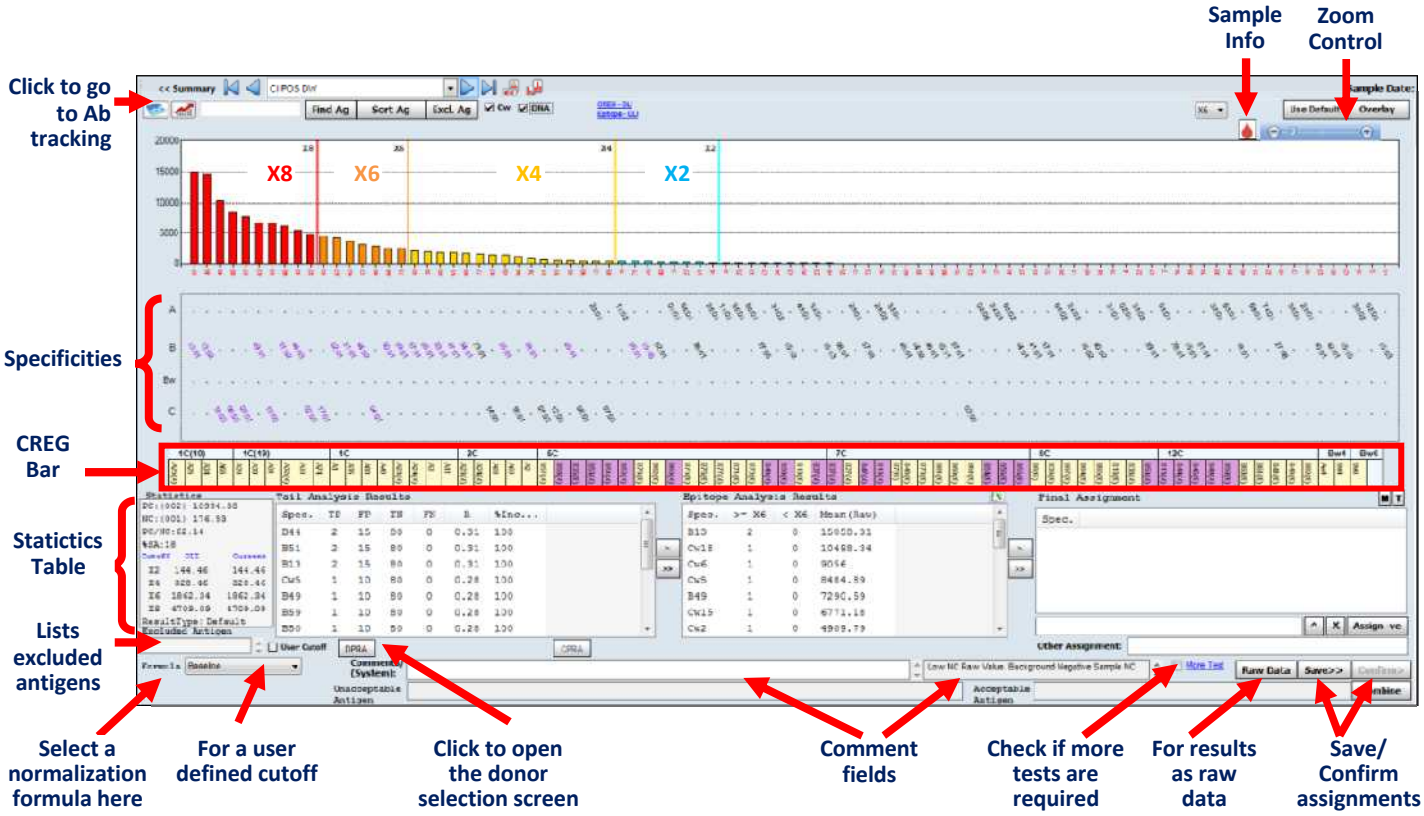
Reports available to preview or print



Using the LABScreen PRA, Single Antigen & Singles Analysis Window

There are several tasks you can perform from the LABScreen window for PRA, Single Antigen, and Singles product analysis:

- Review data and assign specificities
- Circle antigens in the specificity table
- View molecular specificities
- Adjust cutoffs for the sample
- Graph raw data
- Exclude an antigen from analysis
- Sort antigens for Single Antigen samples
- Make tail or epitope analysis assignments
- Manually enter an assignment
- Assign a sample as negative
- Add comments, mark for more testing and/or view a report for the current sample.



If you prefer Graph Raw as the default view when viewing the LABScreen analysis window, access the LABScreen product configuration settings and click the check box **Display Graph Raw by Default**.

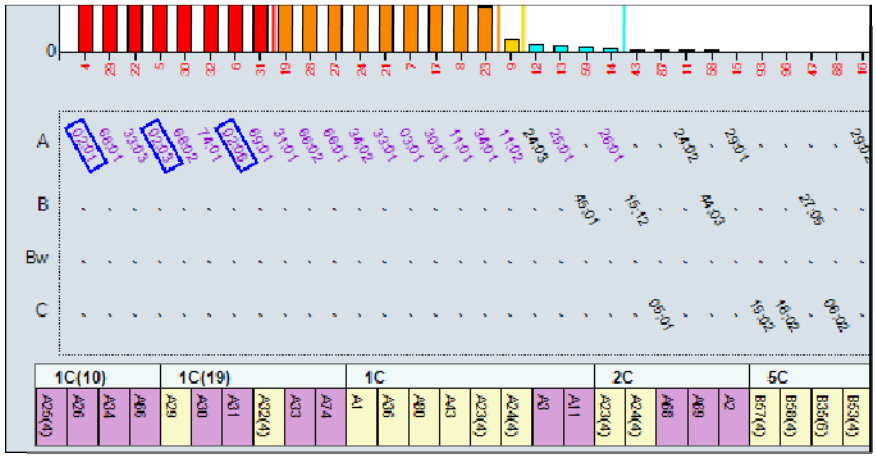
CREG Table

The **CREG Groups** are displayed at the top of the table, with the specificities for the group displayed below. Specificities are highlighted in one of the following colors.

Note: If you want to hide the display of the CREG bar, click the CREG title at the top of the window. A dialog box displays asking if you want to hide the CREG bar. Click **Yes** to hide it. To re-display it, click again on the CREG title and click the **Yes** button to show it.

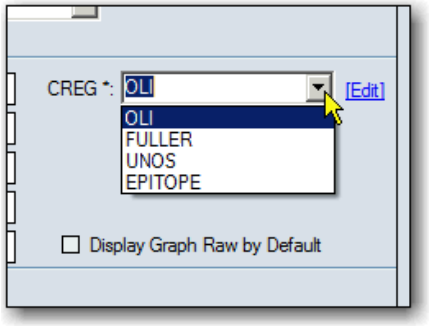
- **Purple** = positive assignments from the Epitope Analysis Results box
- **Pink** = Tail assignments that are masked by Epitope analysis
- **Blue** = Cw assignments
- **Green** = Bw4 and Bw6 assignments

- Click a CREG group, or antigens to circle the corresponding specificities.
- Right-click an antigen to move the specificity to the **Final Assignments** box.



Do the following if you want to use a different CREG table:

- Click the **LABScreen** LABScreen home page button, or select **Utilities > Antibody Product Configuration > Set Analysis Configuration**.
- From the Home page, click the **Edit** link to display the **Analysis Configuration Settings** menu.
- Select a table from the CREG drop-down list.
- Click the **Save** button **at the bottom of the menu**.



Note: For information on creating or editing a CREG list, review the section, *Managing CREG List Information*.

Find Antigen

To enter multiple antigens, use a space to separate each entry. All entered antigens are circled in the specificity field.

Clicking on the labels for Tail Analysis Results, Epitope Analysis Results, or Final Assignment fields circles all specificities listed in the selected results field.

Clicking the **Excluded Antigen** field label circles the excluded antigens.

If you use the Find Antigen feature while the window is displaying molecular specificities, you are not able to see the circled antigens until you deselect the DNA check box.

1. From the analysis window, type antigens or CREG groups (e.g., 1C or 2C) into the field next to the **Find Ag** (Antigen) button.

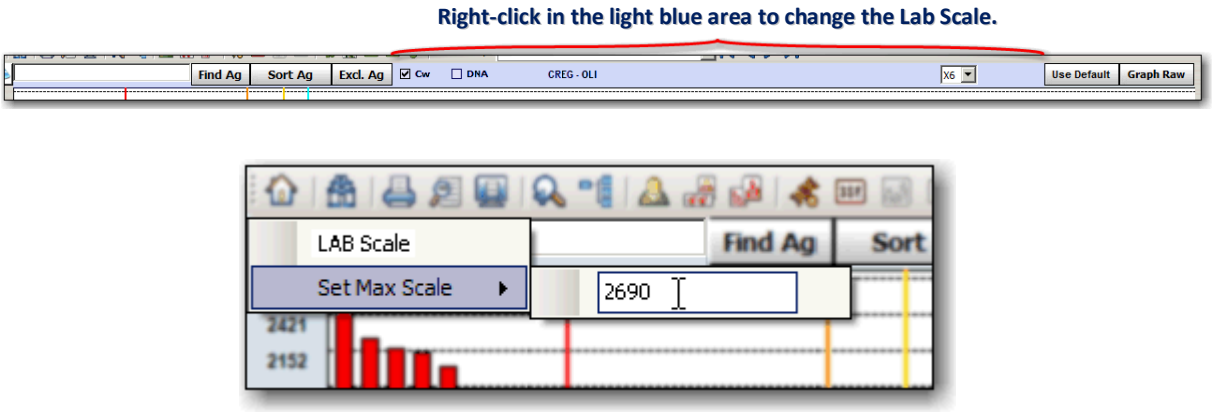
4. Click the **Find Ag** Find Ag button and Fusion will circle the entered antigens or CREG groups.

Click the **Find Ag** button *again* to remove the circles from antigens in the specificity field.

Change the Lab Scale

The maximum value for the bead graph scale, per the baseline, user or raw data formula can be modified from the analysis window. To do so, follow these steps:

- Right-click in the background area of the analysis window, just above the top value of the y-axis of the bead graph.



- Select **Set Max Scale**.
- Type a new value in the **Scale** field and press the **Enter** Enter key on your keyboard.

  To return to the LAB Scale value, follow the above steps, but select the **LAB Scale** option.

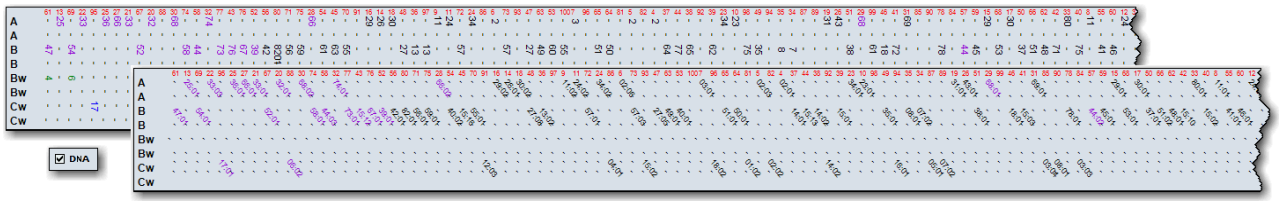
View Molecular Specificities

Molecular specificities are displayed in the specificity field of the analysis window, and can be used to make allele assignments. Screening results are displayed and saved as serological specificities.

1. From the analysis window, select the **DNA** ☑ DNA check box near the top of the Analysis Screen to display molecular specificities.

Clear the check box to return to the serological specificities.

Molecular specificities are displayed when the DNA Check box is selected.

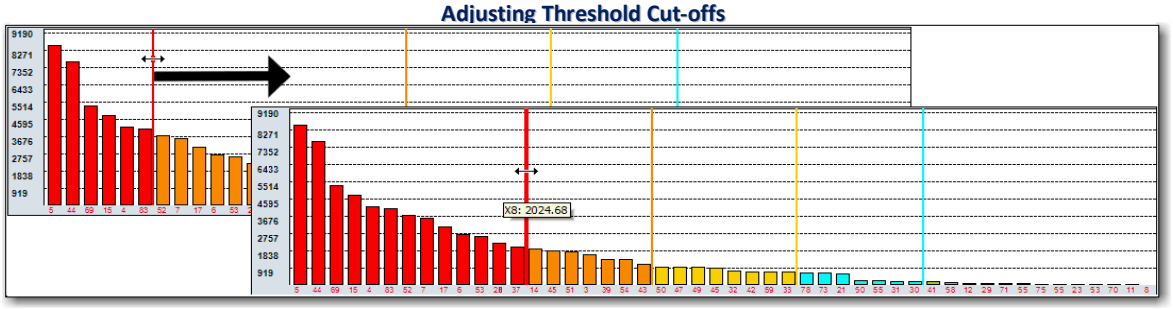


Adjust Cut-offs

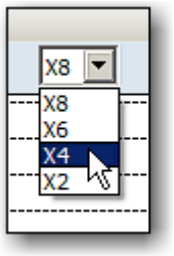
You can change a threshold cut-off value for each sample. You can only change one threshold cut-off at a time.

1. In the analysis window, click on the threshold bar you want to adjust.
2. Drag and drop the cut-off bar to adjust the cut-off and re-analyze the sample.

Adjusting Threshold Cut-offs



Select Minimum Positive Threshold



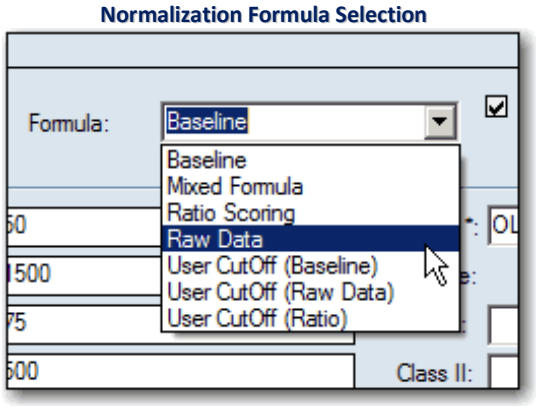
You can change the minimum positive threshold by using the pull-down menu above the bead graph.

- From the analysis window, select a new positive threshold from the **Threshold** drop-down list, (next to the analysis tools near the top of the window). The sample is re-analyzed according to the new threshold. The effects of the threshold change are displayed in the result boxes.

Change Normalization Formula

By default, LABScreen analysis uses the Baseline normalization formula. You can change the normalization formula used in analysis to any of the following: Ratio Scoring, Mixed and Raw Data. When using the Raw Data normalization formula, the sample negative control is shown as a black line on the Bead reactivity graph. Changes apply only to the current sample.

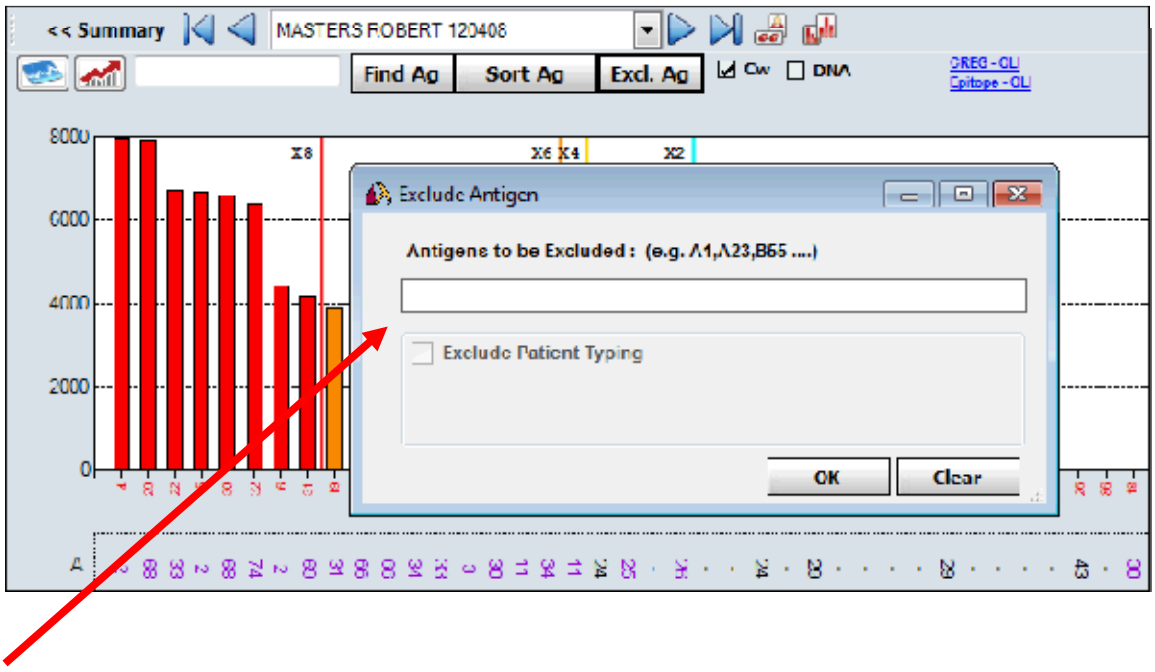
- From the analysis window, select a new normalization formula from the **Formula** drop-down list. The sample is re-analyzed.



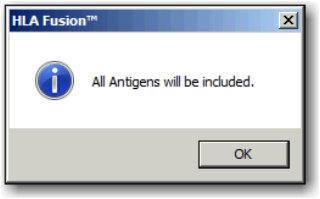
Exclude Antigen(s) from Analysis

All antigens entered are excluded from analysis. To enter multiple antigens, use a comma to separate antigen entries.

1. From the analysis window, click the **Excl. Ag**. Excl. Ag button. The Exclude Antigen pop-up box is displayed.

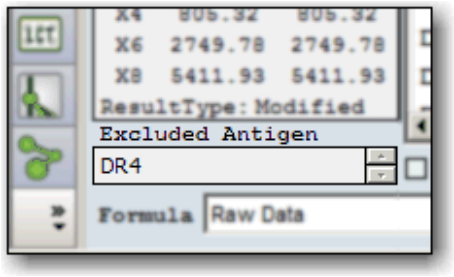


2. Type the antigens to be excluded and click the OK button. Note: the use of wildcard characters, i.e. * is not allowed here.



If you change your mind and click the Clear [Clear] button, your entries will be deleted and you'll see this message:

The sample is re-analyzed, and the excluded antigens are listed in the Excluded Antigens field under the analysis statistics box.

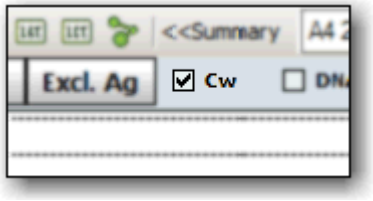


To include all these antigens again, click the **Excl. Ag** [Excl. Ag] button again, click the **Clear** button to remove antigens from the field, and then click **OK** to re-analyze with these antigens included.

Note: To also exclude all typing antigens for the associated patient, select the **Exclude Patient Typing** check box.

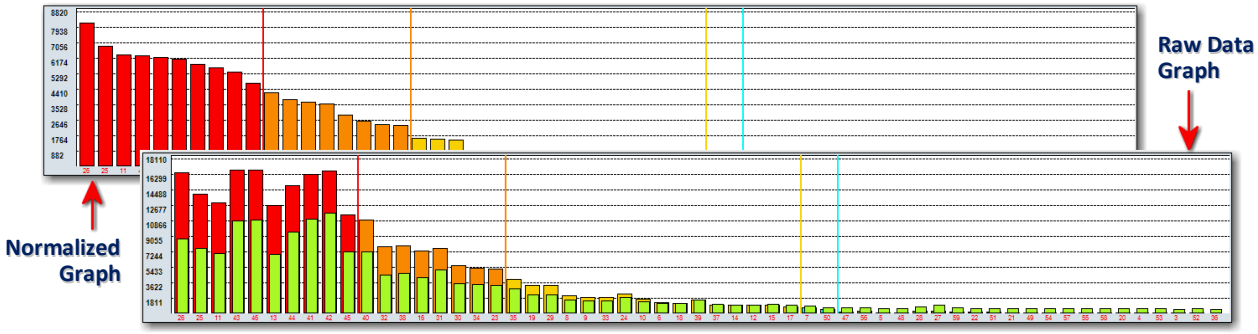
Include/Exclude Cw

You can include or exclude Cw antigen specificities from analysis.



1. Near the top of the analysis window, select the **Cw** check box to re-analyze with Cw specificities.

Clear the **Cw** check box to re-analyze without Cw specificities.



Reset All Options to Default

Any changes you make can be returned to the default values.

- From the analysis window, click the **Use Default** Use Default button in the upper right corner of the window to return all changed settings to the default values for this sample.
- The sample is re-analyzed with the default values.

Force Positive

If a sample has a low bead count, the **Force +ve** Force +ve button is displayed, allowing you to force a positive result by recalculating for allowance of low bead counts.

- For low negative control samples, click the **Force +ve** Force +ve button to analyze the sample as positive.

  The sample is re-analyzed.

Graph Raw

The **Raw Data Graph** shows the raw Mean Fluorescent Intensity, (MFI) value of each bead overlaid with the imported NC Serum MFI.

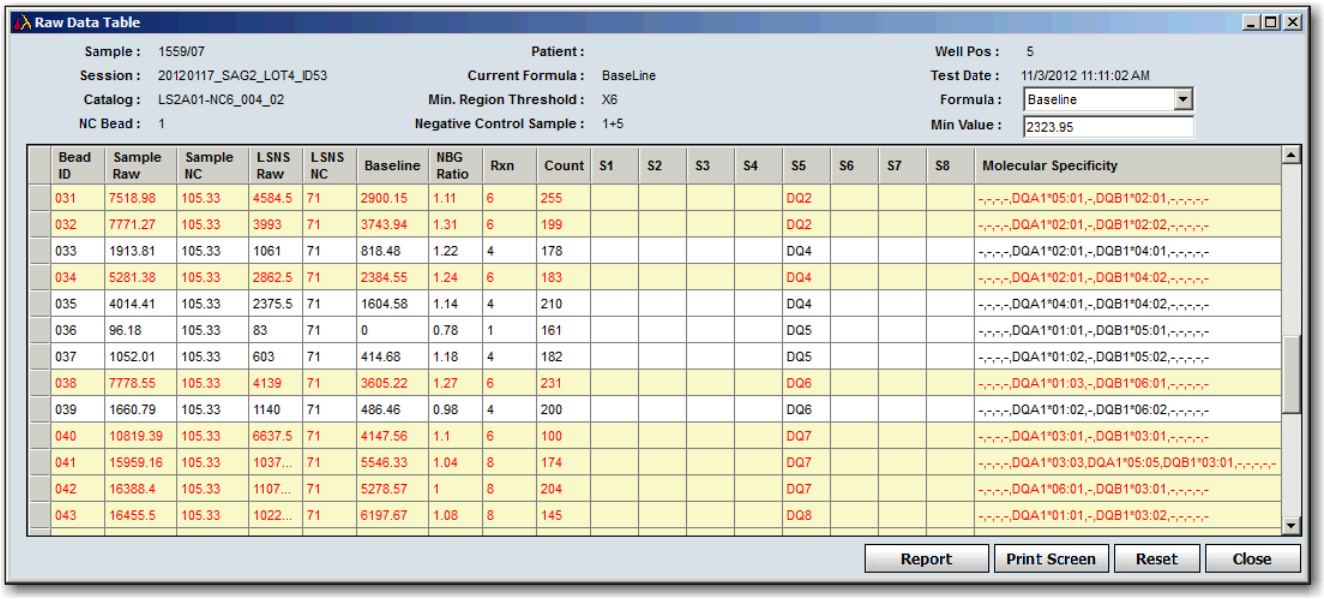
1. In the analysis window, click the **Graph Raw** Graph Raw button to display raw data graph with background values.

Click the **Normal** Normal button to return to normalized graph.

Raw Data Table

Positive beads are displayed in red text. Rows highlighted in yellow have normalized values that are above the value in the Min Value box. Changes made to the normalization formula and minimum normalized value apply only to the raw data table and not to analysis.

1. From the analysis window, click the **Raw Data** Raw Data button on the bottom right of the analysis window to display **Raw Data Table**.



Bead ID	Sample Raw	Sample NC	LSNS Raw	LSNS NC	Baseline	NBG Ratio	Rxn	Count	S1	S2	S3	S4	S5	S6	S7	S8	Molecular Specificity
031	7518.98	105.33	4584.5	71	2900.15	1.11	6	255					DQ2				-,-,-,-,DQA1*05:01,-,DQB1*02:01,-,-,-,-,-
032	7771.27	105.33	3993	71	3743.94	1.31	6	199					DQ2				-,-,-,-,DQA1*02:01,-,DQB1*02:02,-,-,-,-,-
033	1913.81	105.33	1061	71	818.48	1.22	4	178					DQ4				-,-,-,-,DQA1*02:01,-,DQB1*04:01,-,-,-,-,-
034	5281.38	105.33	2862.5	71	2384.55	1.24	6	183					DQ4				-,-,-,-,DQA1*02:01,-,DQB1*04:02,-,-,-,-,-
035	4014.41	105.33	2375.5	71	1604.58	1.14	4	210					DQ4				-,-,-,-,DQA1*04:01,-,DQB1*04:02,-,-,-,-,-
036	96.18	105.33	83	71	0	0.78	1	161					DQ5				-,-,-,-,DQA1*01:01,-,DQB1*05:01,-,-,-,-,-
037	1052.01	105.33	603	71	414.68	1.18	4	182					DQ5				-,-,-,-,DQA1*01:02,-,DQB1*05:02,-,-,-,-,-
038	7778.55	105.33	4139	71	3605.22	1.27	6	231					DQ6				-,-,-,-,DQA1*01:03,-,DQB1*06:01,-,-,-,-,-
039	1660.79	105.33	1140	71	486.46	0.98	4	200					DQ6				-,-,-,-,DQA1*01:02,-,DQB1*06:02,-,-,-,-,-
040	10819.39	105.33	6637.5	71	4147.56	1.1	6	100					DQ7				-,-,-,-,DQA1*03:01,-,DQB1*03:01,-,-,-,-,-
041	15959.16	105.33	1037...	71	5546.33	1.04	8	174					DQ7				-,-,-,-,DQA1*03:03,DQA1*05:05,DQB1*03:01,-,-,-,-,-
042	16388.4	105.33	1107...	71	5278.57	1	8	204					DQ7				-,-,-,-,DQA1*06:01,-,DQB1*03:01,-,-,-,-,-
043	16455.5	105.33	1022...	71	6197.67	1.08	8	145					DQ8				-,-,-,-,DQA1*01:01,-,DQB1*03:02,-,-,-,-,-

LABScreen PRA/SA Raw data table

Click on a header to sort the table by that category.

Note: You can select a different formula from the **Formula** drop-down list, (either baseline, ratio scoring, or raw data), but if you do this, you must also adjust the **Min Value** (lowest value of a positive for the current sample based on the selected reaction threshold) so it correlates with the new formula.

2. Click on the ☒ button located at the upper right corner of the table, or the Close Close button to exit and to return to analysis.

Raw Data Report

For easier navigation, exporting and printing, you can create a report containing the raw data information for the current sample.

1. Once the Raw Data Table is displayed, click the **Report** Report button on the bottom right portion of the Raw Data Table window to display a report of the raw data.

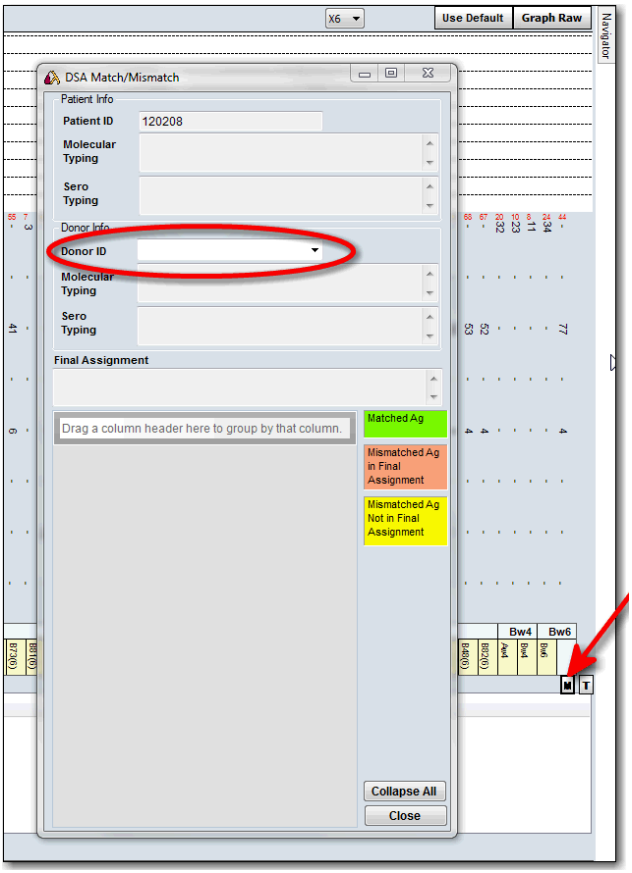
Displaying DSA (Donor Specific Antigen)**Match/Mismatch**

By clicking the M button, you can display all the DSA match/mismatch information for the patient associated with this sample and the donor(s) associated with the patient.

Note:	If you do not have a patient associated with this sample, you will receive a warning message, and will not be able to display any DSA match/mismatch information until you associate a patient to the sample and at least one donor to the patient.

To display the information, take the following steps:

1. Click the **M** button, (next to the **T** button on the right). If you have a patient associated with this sample, the DSA Match/Mismatch window opens.



If necessary, select another donor from the **Donor ID** drop-down list.

Use the ✚ or ▬ buttons to expand, or collapse the table.

The colors on the table mean the following:

- **Green**: represents a matched antigen.
- **Orange**: represents a mismatched antigen that has been confirmed in the final assignment.
- **Yellow**: represents a mismatched antigen that has not yet been confirmed in the final assignment.

Adding Comments to Samples

Comments you or the system add to the Comments field are displayed with the results in the current analysis session, data look up and reporting functions in HLA Fusion.

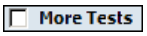
1. In the Analysis Window, type sample comments into the **Comment** field below the Assignments area.

Comments are saved when you click **Save.**

Flagging a Sample for Further Testing

You can indicate the need for further testing of a sample by selecting the **More Tests**☑check box and saving.

The More Tests indication is displayed in results, data look up and reports for the sample.

- In the analysis window, check the **More Tests** 

check box, located below the Assignments area.
- The Test Selection window is displayed.
- Select the check boxes next to the additional tests you want run.
- Enter a name for the test list you are creating.
- Click **Save** to save the test list and return to the analysis window.

Printing the Current Analysis Window

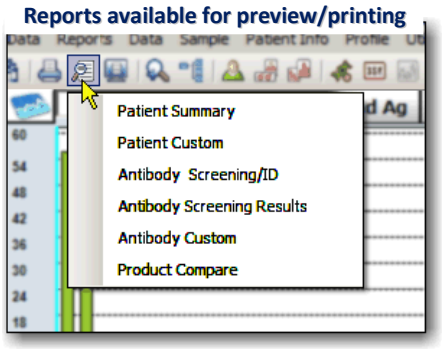
The Print Screen button prints the currently displayed analysis window.

- From the analysis window, click the **Print Screen**  button on the toolbar to print the current analysis screen.

Previewing and Printing Reports

To view or print a report for the current sample, use the Preview Report button on the toolbar.

- In the analysis window, click the **Preview Report** button  or **Print Report** button  to display a list of reports you can print or preview for the current sample.



Note:	If you select Antibody Custom, you are not be able to create a new custom report at this point. The only custom reports available from the analysis window are ones you previously created through the **Reports** window.

Making Final Assignments

Final assignments can be made from either the Tail, (not applicable to LABScreen Singles samples) or Epitope results fields.

Note:	If you want the Mean, (Normal) of positives to be used for Epitope analysis, instead of the Mean, (Raw) of positives, check the setting **Use the Mean of Normal** on the LABScreen PRA, Single Antigen and Singles product configuration screens.

From the analysis window, do one of the following to make assignments:

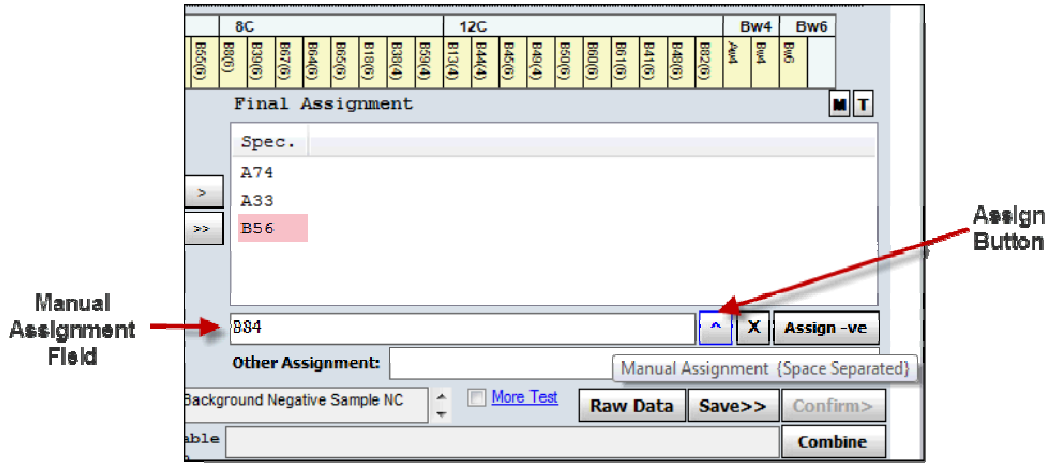
- Double-click an antigen specificity in the **Tail** or **Epitope Analysis** results box to assign the specified antigen to the **Final Assignment** list.
- Click to highlight the specificity and click the **Assign Single** > button to move it to the **Final Assignment** list.

  Click the Assign All >> button to the right of the Tail or Epitope list to move all the current results on that list to the Final Assignments area.
- Right-click on a specificity, or CREG group on the CREG Table to assign it to the **Final Assignments** area.

Manual Assignments

Manual assignments can be entered in the field below the Final Assignments results box. Enter multiple manual assignments simultaneously by leaving a space between each specificity.

1. From the analysis window, type a manual antigen specificity assignment in the field under the **Final Assignment** box.



2. Click the Assign button (**⮝**), just above the Manual Assignment field, or press the **Enter** key to add the assignment to the **Final Assignment** results box.

Assigning Negative Sample Values

You can assign a negative value to a sample even if analysis shows some positive results.

- From the analysis window, click the **Assign –ve** Assign -ve button, (located just above the Manual Assignment field) to force the sample to have a negative value.

Removing Assignments

Specificities can be removed from the Final Assignments results box. You can remove more than one specificity by holding down the Ctrl key and clicking each specificity you want to remove.

- From the analysis window, click to highlight specificities on the Final Assignment list, (hold down the **Ctrl** Ctrl key to select more than one) and click the **Remove** Remove button, (located below the Final Assignments results box).

Saving Assignments

Lab Technicians and Supervisors can save analysis results for further review and approval. Saved samples are available for confirmation *only* by a lab supervisor.

- From the analysis window, click the **Save** Save>> button, located at the bottom right corner of the analysis window, to save the analysis results for all the specificities currently listed in the **Final Assignments** field.

Fusion automatically moves to the next sample.

For Confirmation, a supervisor needs to access the sample for which you saved the assignments. You can return to the sample at any time prior to confirmation if you need to make changes. Click the **Reanalyze** button and then the **Save** button again.

Confirming Assignments

Lab supervisors can confirm analysis results. When they do so, samples are marked as *Confirmed*. The **Confirm** button is **Purple**-colored when you view a confirmed sample.

- From the analysis window, click the **Confirm** Confirm > button, located in the bottom right corner of the window, to confirm all analysis results that have been saved in the Final Assignments results box.

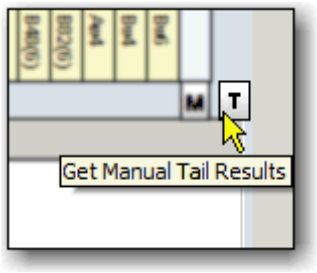
  Fusion automatically moves to the next sample to continue confirming results.

When you first return to a confirmed sample, you'll see that the **Confirm** Confirm > button is now shaded **Purple** to let you know it has been confirmed previously.

Getting Tail Analysis Values (*Except* Singles)

Tail analysis values can be displayed in the analysis with the final assignments, but are not stored for look up or reporting.

- From the analysis window, click the **T** button, located to the upper right of the Final Analysis results box, to display tail analysis values in Final Assignments results box.

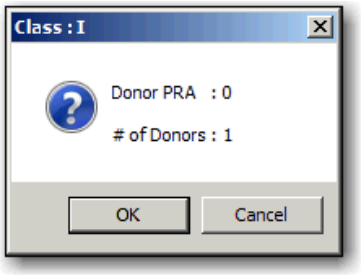


Donor PRA (*Except Singles*)

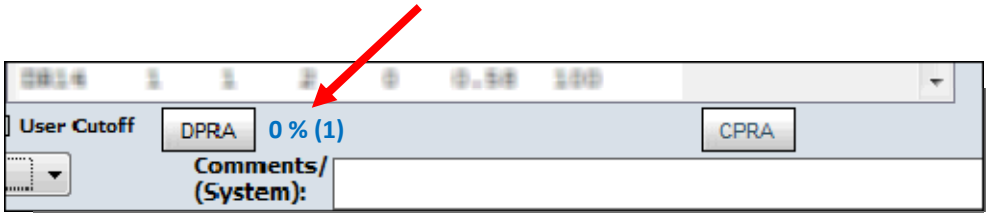
You can display the percentage of PRA from available donors in the system or from selected donor groups who match the computer-assigned antibodies for the current sample.

Note: To select a donor, or donor groups, click the **Donor PRA** button. You can also auto-select groups by selecting **Utilities > General Settings**. To create a donor group, select **Patient Info > Manage Patient**, select **Donor** in the Patient/Donor field, and fill in the donor group field.

1. For Single Antigen or PRA analysis, click the **Donor PRA (DPRA)** DPRA button. A pop-up box displays the percentage of matching donor PRA and the total number of donors that were considered in the calculation.

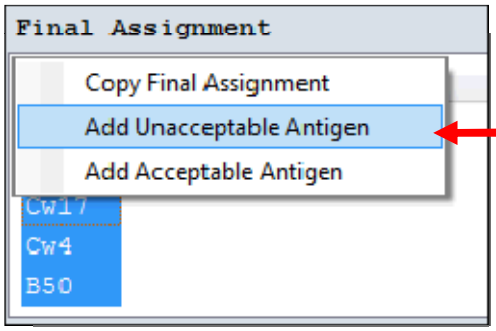


Click **OK** to close the box. The percentage and number of donors remains displayed next to the **Donor PRA** button.



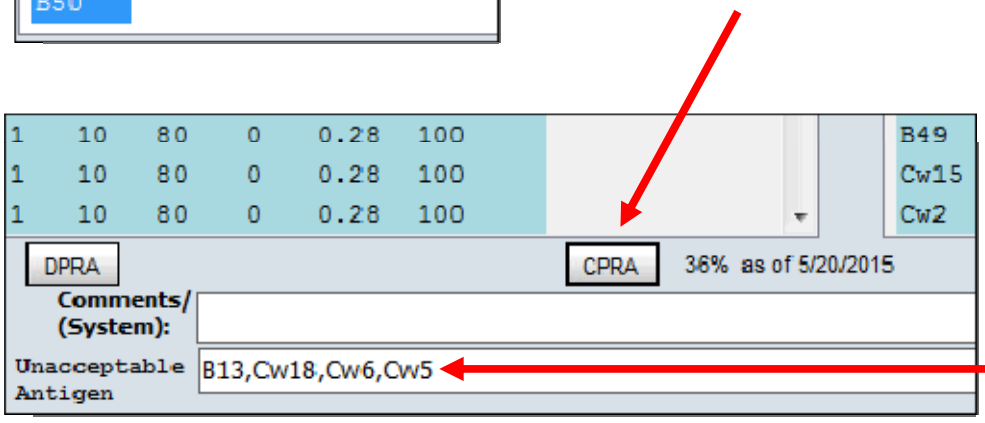
Calculated PRA

You can perform **Calculated PRA (CPRA)** analysis by clicking on the CPRA CPRA button, found to the right of the DPRA button on the lower left panel. Clicking the **CPRA button** will calculate PRA (UNOS calculator) using unacceptable antigens assigned to the patient record.



From within the **Final Assignment** box, select several antigens by highlighting them, then right-click and **choose "Add Unacceptable Antigen."**

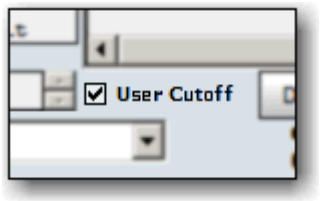
Now, click the **CPRA** button.



The percentage score will appear next to the CPRA button. The list of selected antigens appears below to the left under the System Comments area.

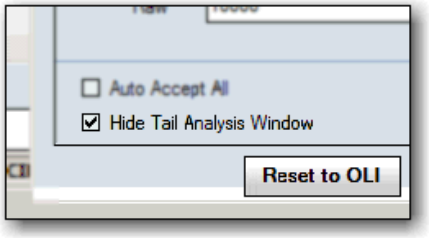
Choosing Minimum Positive Threshold Cutoffs (*Except* Singles)

You can set the minimum positive threshold cutoffs to use with any LABScreen PRA or Single Antigen sample. To set the cutoffs for X8 - X2, review the section *Changing Antibody Screening Analysis Configuration*. You can then switch between the OLI provided cutoffs and the ones defined through Fusion by doing the following:



- To choose user-defined cutoffs, select the check box next to User Cutoff
- To go back to using the OLI cutoffs, clear the User Cutoff check box.

Hiding Tail Analysis Values (Single Antigen)



You can choose to hide the display of Tail analysis values from Single Antigen sample analysis, but these values remain stored for look up or reporting.

1. Select the **Utilities > Antibody Product Configuration > Set Analysis Configuration** menu option.
2. Select **LABScreen Single Antigen** from the Product Type drop-down menu at the top of the display.
3. Select the **Hide Tail Analysis Window** check box, located at the bottom of the Single Antigen product configuration dialog box.
4. Click the Save button at the bottom of the menu**.**

LABScreen Single Antigen samples imported after this configuration change do not display the tail analysis assignment area on the sample analysis window.

Navigating Between Class I and Class II (PRA Class I and II Combined)

For Combined Class I and II LABScreen PRA sessions, each class is analyzed separately and needs to be saved separately for the combined results to appear in the database.

Make sure that you have already created a combined Class I and Class II LABScreen PRA catalog before you import the combined sessions.

- From the analysis window, click the ***Run Class I*** and ***Run Class II*** buttons Run Class II, located in the upper left part of the analysis window, to switch between Class I and Class II results for the current sample.

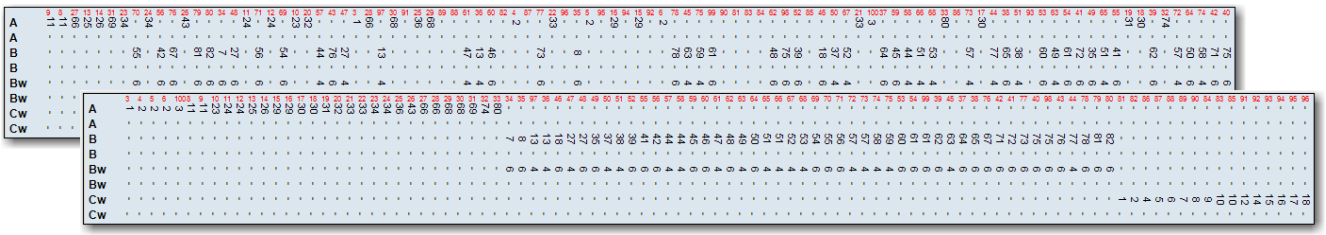
Sort Antigen (Single Antigen)

Single Antigen trays can be sorted in order of specificity, instead of reaction value.

1. For Single Antigen analysis, click the **Sort Ag**. Sort Ag Button.

The graph is sorted by bead number.

2. Click the **Refresh** Refresh button to return to the default graph.



LABScreen Mixed Batch Analysis allows you to quickly analyze a session and save it for later review and final assignments. You cannot view samples graphically during batch analysis, and no final screening assignments are made.

- Batch analyze a session
- View the Batch Analysis report
- Save analysis results

Overview

After batch analysis is performed, the LABScreen Batch Analysis Report is displayed. Results can be saved, but they need to be confirmed individually.

Save Batch Analysis

Lab technicians and supervisors can save batch analysis results for further review and approval. Samples are marked as *Ready*.

1. Click **Save>>** at the bottom of the report menu to save all samples to the database.

1. Click **Exit** to close and return to the Main Menu.

Review/Analyze Samples

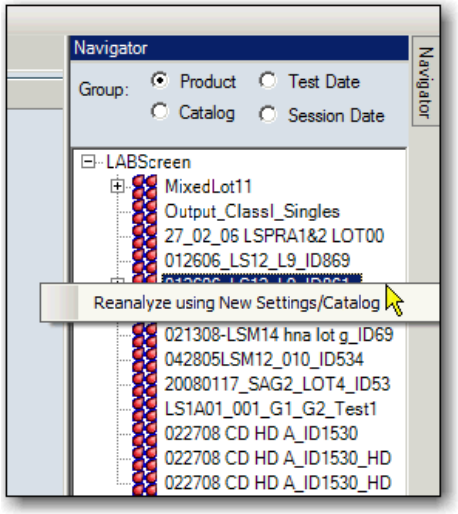
To let you view batch results in more detail after saving, the Analyze button displays the session in the Analysis window. Each sample needs to be saved individually if you did not save the batch analysis session before reviewing the batch results.

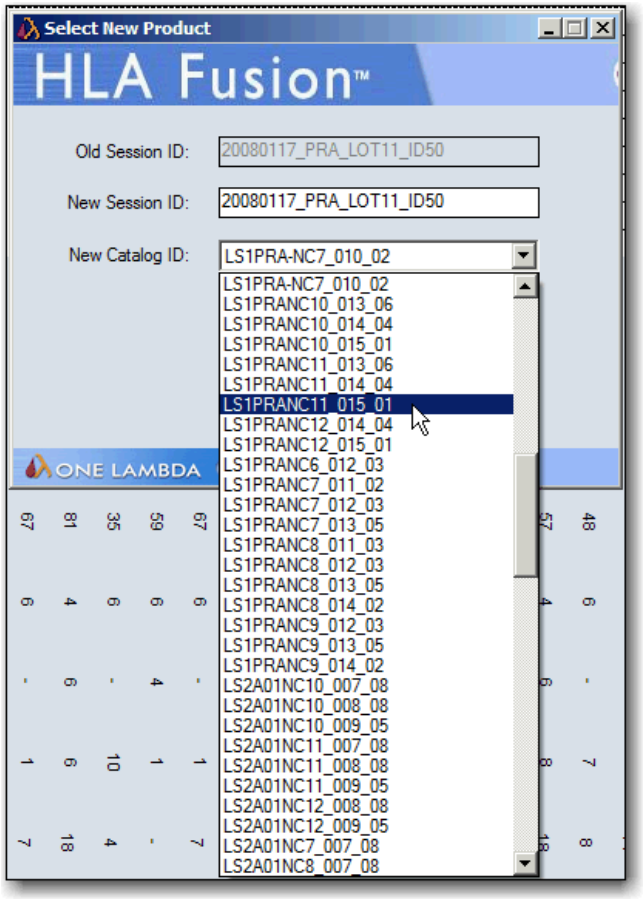
Navigator Right-Click Menu Options for LABScreen

Note: These options apply to all LABScreen sessions and samples.

There are analysis options available through the Navigator - depending on whether you are in the LABScreen session summary view, or on an analysis screen for a sample.

By right-clicking on the Current Session in the Navigator window, you'll see menu options that allow you to affect your LABScreen analysis sessions before, during or analysis.





Reanalyze with New Settings/Catalog

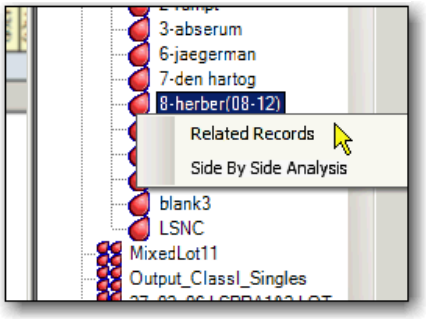
Allows the session to be reanalyzed using new settings or an updated catalog. Here's how:

1. Click the drop-down arrow in the **New Catalog ID** field and select a new catalog from the list.
2. Rename the session, (Sessions must have unique names).
3. Click the **Analysis** Analysis button. The session on which you right-clicked is reanalyzed with the catalog you've selected.

Sample-Level Options

There are two menu options that are displayed if you right-click on an Active Sample in the Navigator, (select sample first with a left-click):

Sample-level Navigator Options



Related Records

A related record is a record that is associated with the current sample by Patient ID or Sample ID.

Note: This option is also available by using the **Related Records** toolbar button.

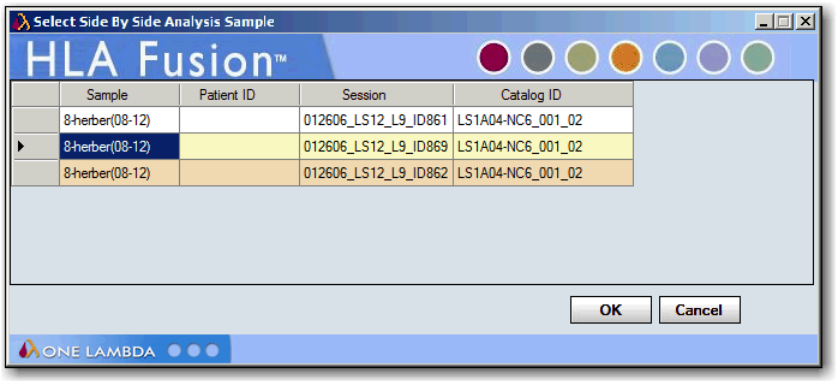
- Right-click a sample in the Navigator, and select **Related Records** to load all records related to the current sample into the Sample drop-down list at the top of the screen. Use the sample navigation arrows to display the analysis of each related record one by one.
- To go back to viewing the samples in the current sessions, click the **<<Summary** link at the top of the window.

Side-By-Side Analysis

Use this option to compare the current sample analysis with one previously conducted.

Note: This option is also available by using the **Side-By-Side Analysis** toolbar button.

Side-by-side Analysis Selection List



- Right click on a sample from the Navigator, and select **Side By Side Analysis**. Select a previous sample analysis from the displayed list to compare to the current one. (The current sample is displayed with a light **brown** background.)
- The two analysis windows are then displayed together in a comparison window.
- Each pane of the window can be resized and moved independently by dragging and dropping. Click the **Side-by-side Analysis** toolbar  button to cancel the comparison display.

LAT Analysis

The LAT™ analysis feature of the program analyzes CSV output files, manually-entered reaction patterns, or ELISA results as a new session and can continue the analysis of a previously unfinished session. Analysis results are based on catalog specifications provided with the software.

There are a few things that should be completed or verified before you start an analysis session:

- Make sure you have the latest catalog files before you analyze. You can download or update catalogs from the LAT Home Page by clicking on [Download].
- View and modify global product configuration settings before starting analysis. Global settings are displayed and be can be modified on the LAT Home Page by clicking on, [Edit] or through the Utilities Menu . Global settings apply across all newly imported sessions.
- Save time importing CSV files by verifying that the default URL's and paths are pointing to the locations where these files are commonly stored on your system or network. These settings can be modified in the **Utilities > General Settings** section of the default Fusion Home page.

Note:	Some of the above tasks require you to have Supervisor Privileges. You may have to verify with your supervisor that these tasks have been completed.

Starting LAT Analysis

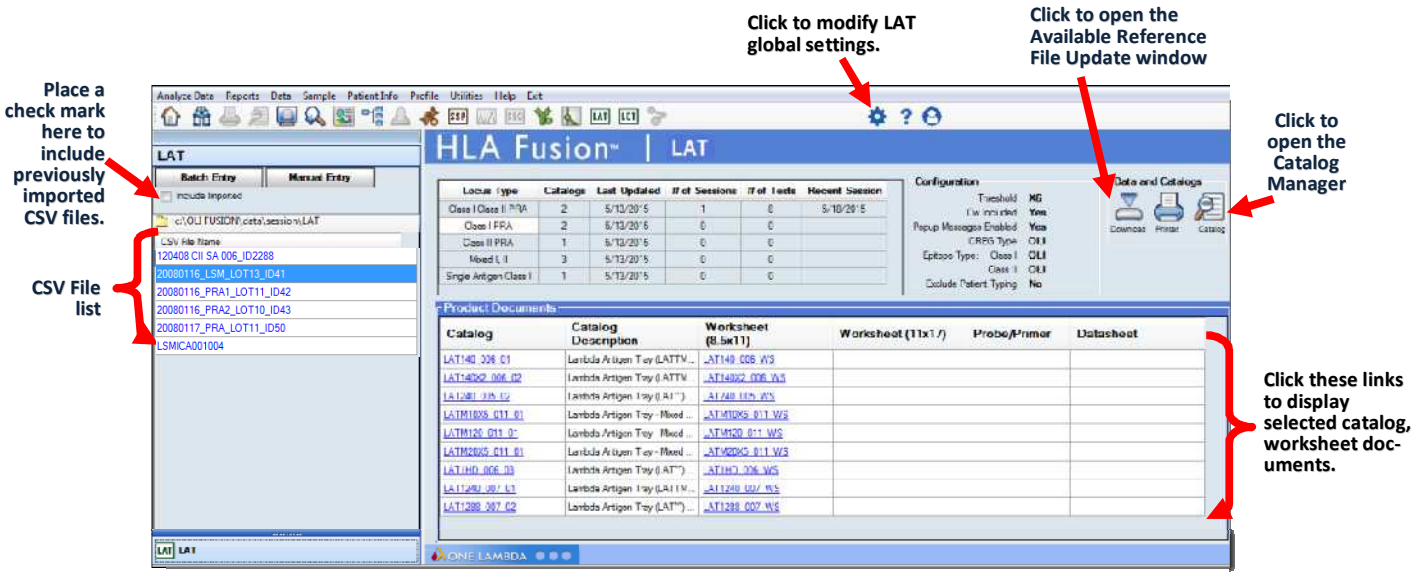
Acquiring LAT Session Data

There are four basic methods to import session data for LAT Analysis in HLA Fusion:

1. **Manual Entry▶** the data from only one session is manually entered from the keyboard.
2. **Batch Entry▶** the data from several sessions are manually entered in a series.
3. **CSV file▶** a properly-formatted CSV file is directly imported into Fusion for LAT Analysis.
4. **ELISA▶**read analysis data directly from the Biotek ELX 800 ELISA reader.

Click the **LAT** LAT button from the Home Page panel, or the **LAT** icon on the Fusion Toolbar to open the LAT program.

The LAT Home page is displayed.

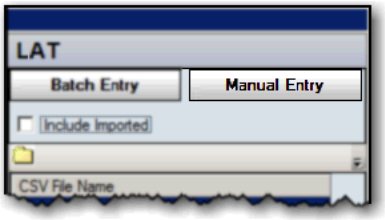


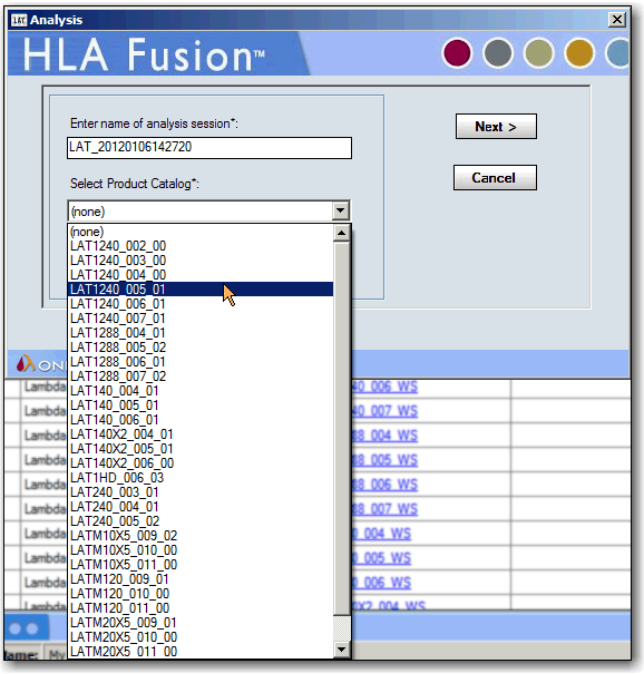
Note: Open worksheets to verify the accuracy of revision numbers, (*these documents do not contain a revision number in their filename*).

Single Session Manual Entry

To manually enter a single session for LAT Analysis, do the following:

1. Click the **Manual Entry** button at the top of the LAT Home panel.

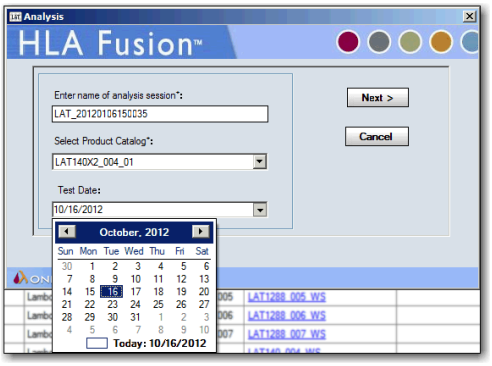




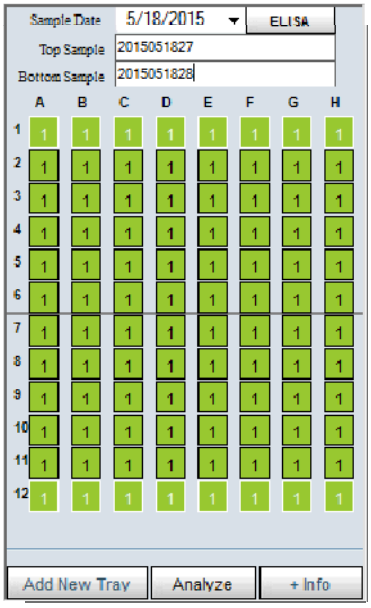
2. In the top text field of the next window, enter a unique name for the new manually-entered LAT Analysis session.

3. Click the **Down▼Arrow** of the **Select Product Catalog** field and select the appropriate LAT Product Catalog.

4. Next, type in the correct **Test Date**, or click the **Down▼Arrow** to reveal the pop-up calendar and select the test date.



5. Click the **Next** Next > button.



The Data Input Menu displays.

This allows you to input reaction values for a new sample.

You can enter the samples and reactions into a session—a 10 test tray, or a 20 test tray. Data may be entered manually by clicking on each well, or by obtaining raw data values from an ELISA reader.

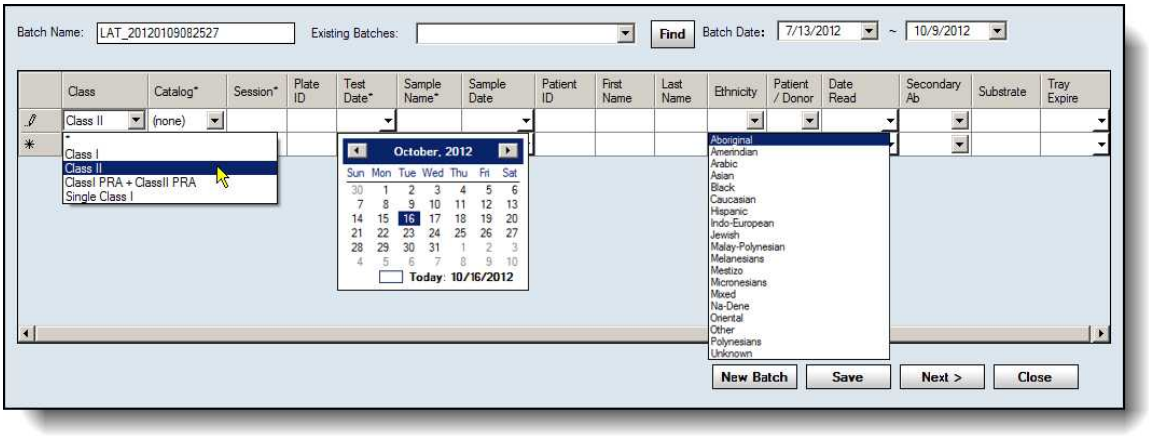
6. Enter a **Sample Name**(s). A unique Sample Name is required for analysis. The Sample Date may be changed here if necessary.

Manual Batch Entry

To manually enter a more than one session for analysis, do the following:

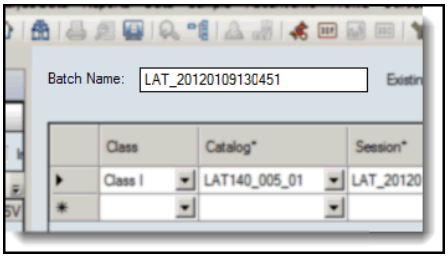
1. Click the **Batch Entry** button.

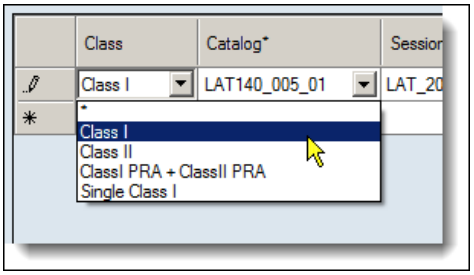
A blank **Session Summary** Screen opens.



Unlike Manual Entry which is limited to just one session, Batch Entry allows you to enter a group of sessions with the Session Summary screen. This allows you enter data in a tabular format with each row representing one session.

2. Enter a unique name for this batch, or accept the default batch name which Fusion suggests.



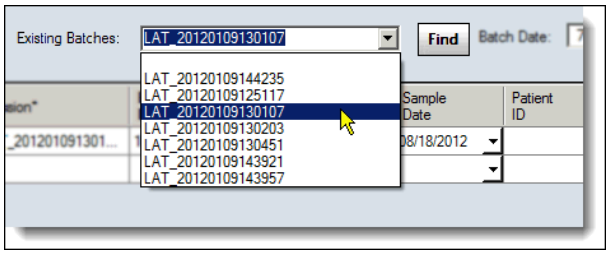


3. Manually select and/or enter session data beginning with the HLA class, (I, II, Class I PRA + Class II PRA and Single Class I) at the left side of the Session Summary Screen and continue to the right until all the available data for a session has been entered.

The fields with an asterisk (✱) are required. This includes the fields that are completed by using drop-downs, (**Catalog Name** and **Test Date**) and the **Session ID**.

Continue entering session data as needed. Note that once you've entered data for a session and have started entering data for the next session, you cannot return to the previous line of session data. However, after a batch has been saved it can be reopened and edited.

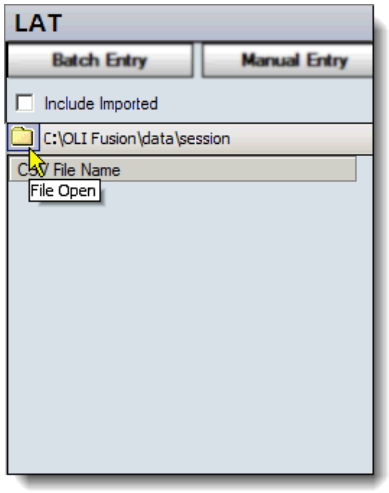
4. When all data for a batch of sessions has been entered, click the **Save** Save button at the bottom of the screen. The batch has been saved and is included in the list of **Existing Batches** in the drop-down list at the top of the screen.



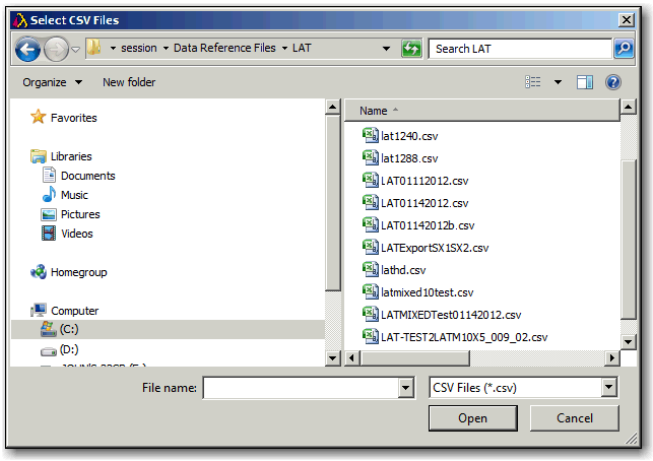
5. After you're finished entering session data for this batch, click the **Next** Next > button.

Similar to Manual Input of Session data as discussed previously, the Data Input Menu and the main LAT Analysis window appears.

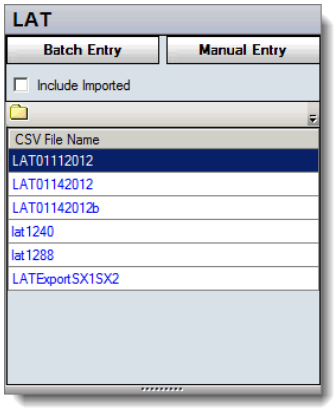
Importing CSV files in LAT



1. Click the **Folder** Icon to open the **Select CSV Files** list.



2. Select one or more sessions from the **Select CSV Files** list.
3. Click the **Open** Open button.

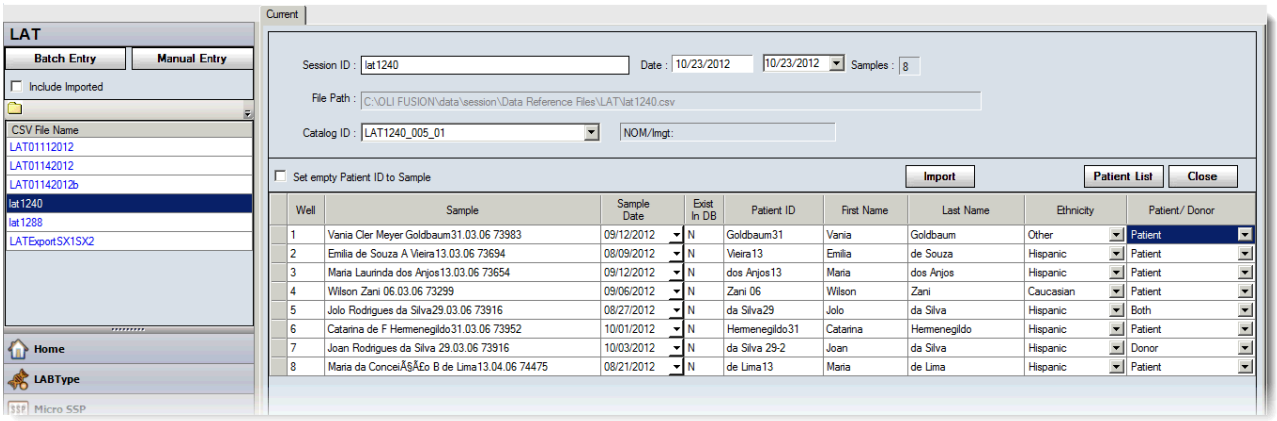


The CSV Files are now displayed in the CSV File Name List.

Note: You may see CSV files for products other than LAT, or other miscellaneous CSV files. This means that you must first click on a sub folder for LAT, or that your LAT session files are not contained within their own folder in the directory to which HLA Fusion is pointing.

4. Click on a CSV file to display its associated samples in the **Current Sample/Patient Details** table.

Current Sample/Patient Details Table

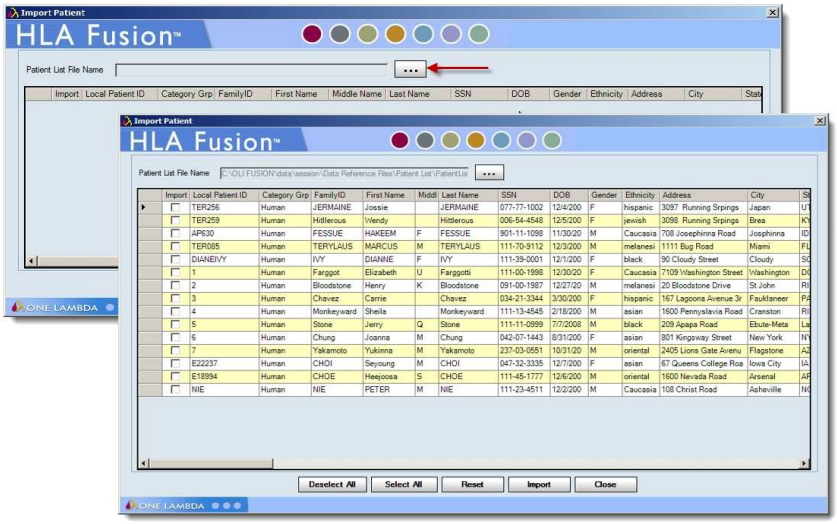


If a sample is already associated with a patient, the Patient ID and any existing, related patient information is displayed.

To add patient information, do one of the following:

1. To add data from the system, click the **Patient List** Patient List button.

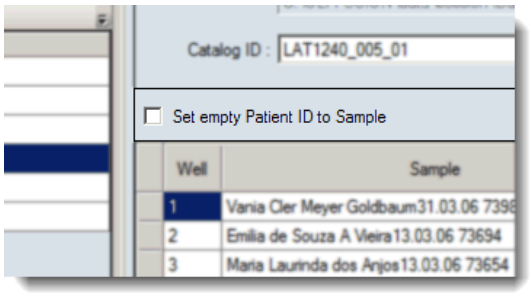
The **Import Patient** window is displayed, allowing you to import the patient information file.



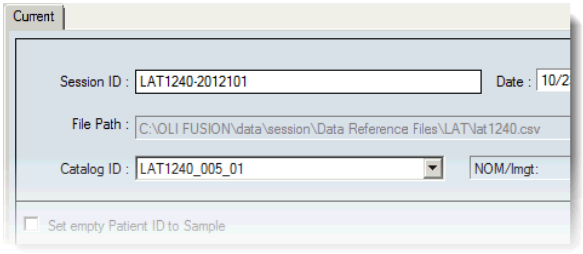
Click the Browse Button to locate Patient Information

To manually add Patient Data, simply type data into the patient-related fields of the table.

- You can have Fusion assign the Sample ID to empty Patient ID fields by checking the box for assigning the Sample ID to empty Patient IDs.



2. The system assigns a Session ID by default. Optionally, you can type in a different Session ID.

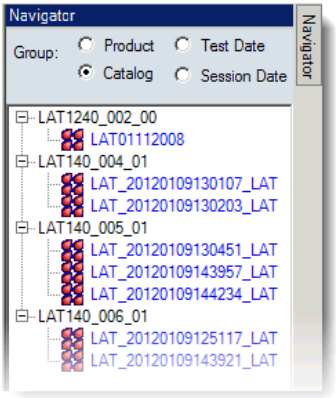


Note: A session ID must be unique to the Fusion database. If the session ID already exists, the software prompts you to rename the session. It is highly recommended that you not use any special characters in this field since they may serve a specific purpose as field separators.

3. Accept the displayed Catalog file, or select a Catalog file from the drop-down list in the **Catalog ID** field.

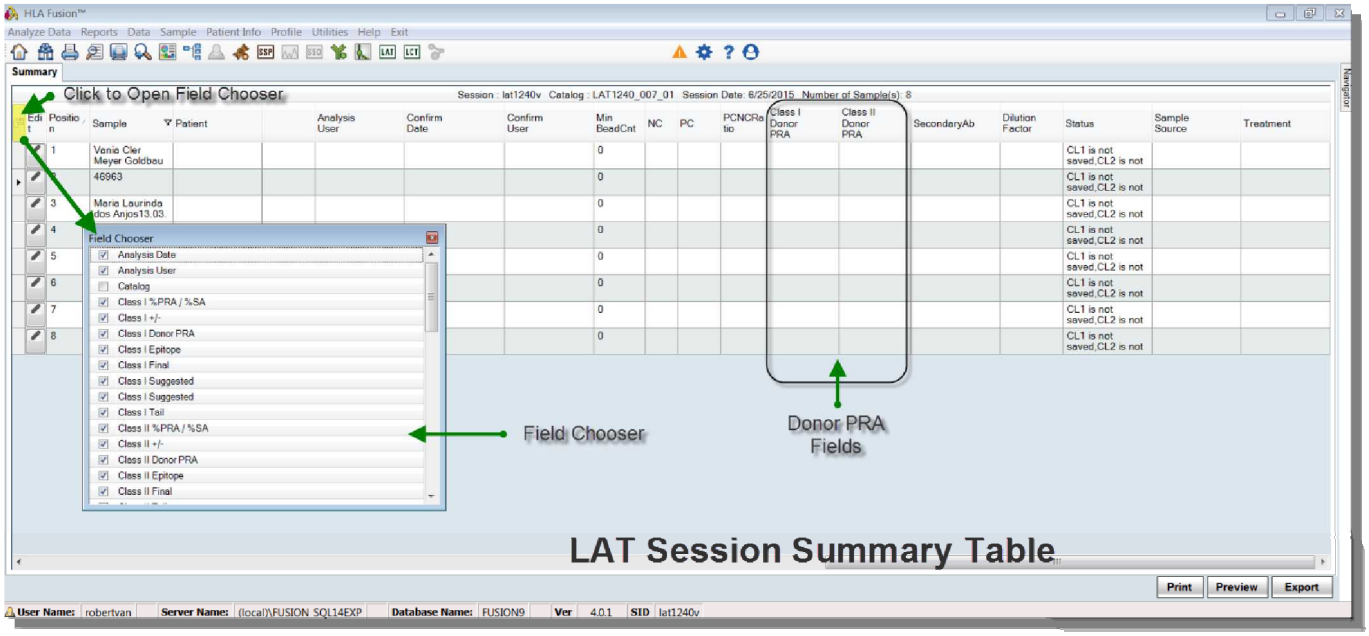
Note: If you need to import more catalogs, click the **Download** [Download] link on the LAT Home page. The catalog drop-down list may not be immediately updated if you downloaded the catalogs during the current import session. You may need to click the **Home** button and then click the **LAT** LAT button again to return to the import process.

4. When session and sample information have been verified, click the **Import** Import button. The session is now displayed in the Fusion **Navigator** tree on the right side of the analysis screen for subsequent analysis.



You can select a session from the Fusion **Navigator** to view its summary; then select a sample from the session summary to view its analysis. Or, you can continue importing samples from the Import Sample list.

5. In the **Navigator**, click on a Session Name. The **Session Summary Table** is displayed:



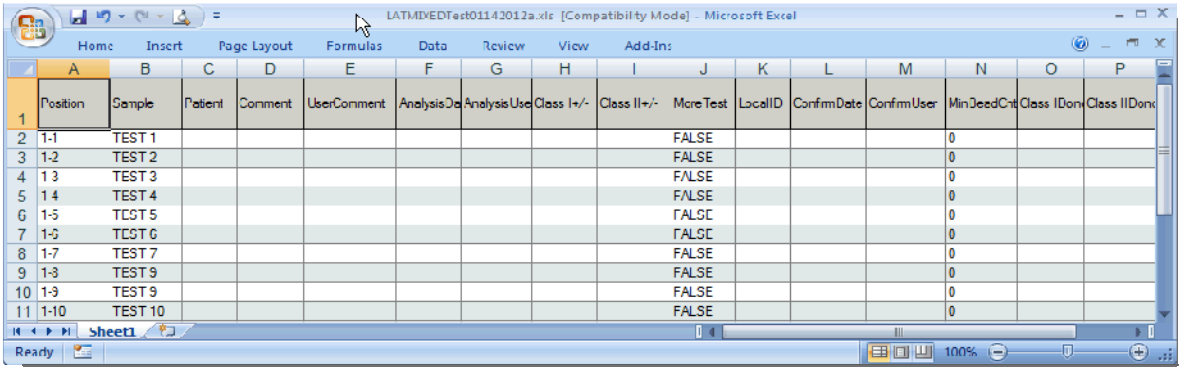
- Double-click a sample in the Summary Table to go directly to the analysis screen for this sample.
- Scroll left or right to display all of the Summary Table fields.
- Click on the **Field Chooser** button to the left of the table headings. In this window, you can select or clear the check boxes next to column headings to include or exclude those columns from the Summary Table. Selecting or clearing check boxes in this window instantly updates the table.

Note: If you do not see a particular field available through the field chooser, and you are sure it should be there, go to C:\HLA Fusion\temp and delete the file named **`x_x_x`** (*antigen type*) **`_Layout.xml`**.

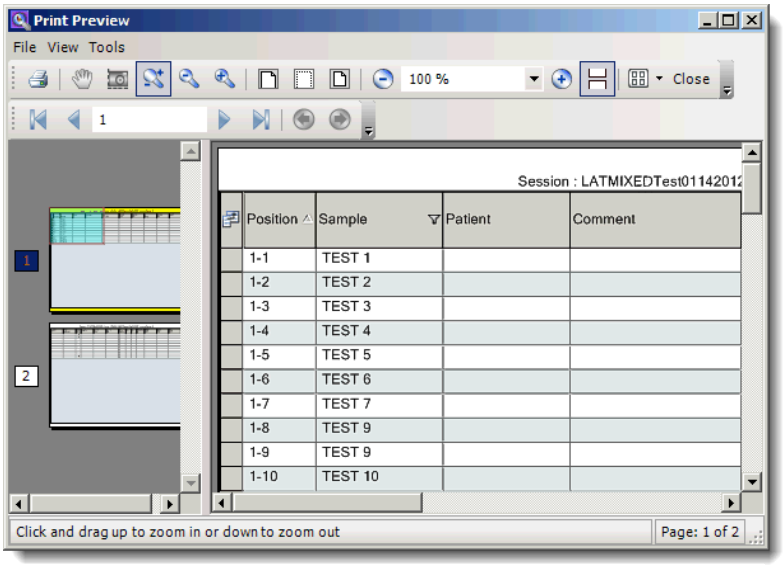
- Click on any column header of the Summary Table to sort the table by that column. The arrow in the column header indicates the sorting order - up for ascending and down for descending. Columns can also be dragged-and-dropped to change their order.
- The session summary table columns and order can be modified. When you close the **Field Chooser**, a pop-up message displays to let you choose whether or not to save any changes you made. If you click **Yes**, your changes are saved for all future LAT session summaries on this same computer until further modifications are saved.

- Click the **Export** button to save the Summary Table on your computer or the network, (default locations `C:\OLI FUSION\data\report`). The file is saved in Excel (*.xls) format.

Summary Table exported as an Excel spreadsheet



- Click **Print** to print out a report of the Summary Table.
- Click **Preview** to view a report of the Summary Table.



Print/Preview Summary Table

- In the print preview window, the page view slider on the left allows you to select different pages of the report.

- The session summary table columns and order can be modified. You can save any modifications you make to the layout by clicking the **Save Layout** button. Your changes are saved for all future LAT session summaries on the same computer until further modifications are made and saved.

If you want to exclude a sample from an analysis session, select the **Exclude** check box next for that sample. The sample is still displayed on the Reports sample list; to prevent it from being included in report data, do not select that sample during report creation.

Using the LAT Mixed Analysis Window

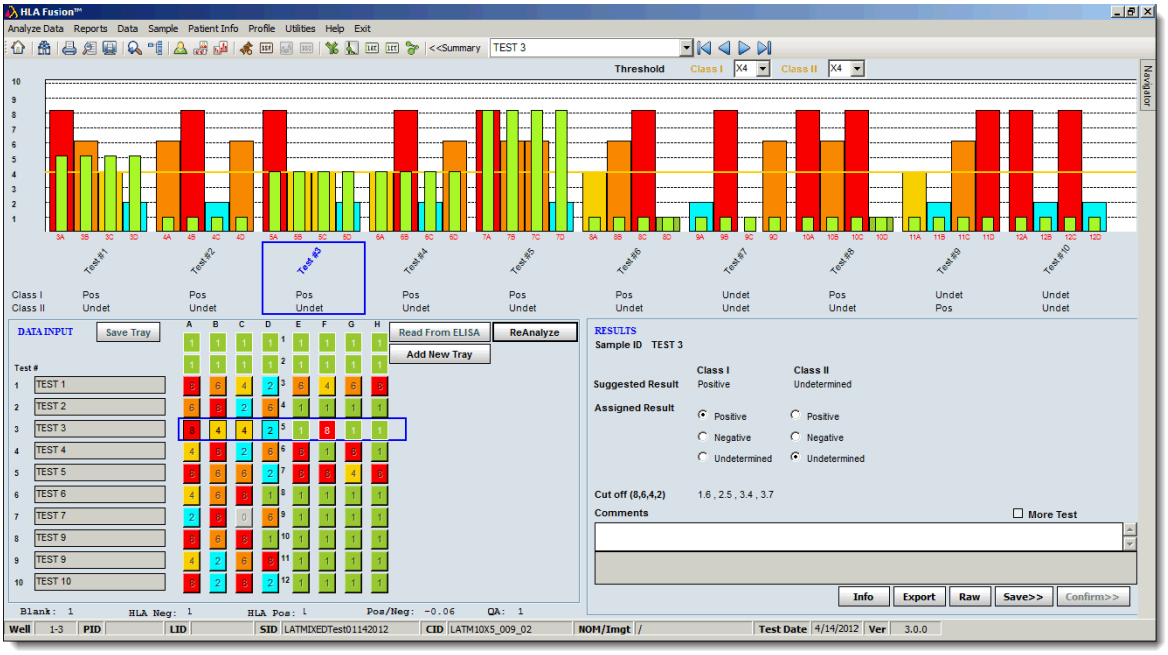
For each sample in the current session, you can view the test data and assign screening results. HLA Fusion analyzes a sample when you move to view that sample. To analyze an entire session, you must view all samples in the session and assign the results.

From the analysis window you can:

- View and print sample analysis results
- Circle antigens in the specificity table
- Sort by well position
- Add comments and mark the sample for more testing
- View a Quick Report for the current sample
- Export reaction data to a CSV file

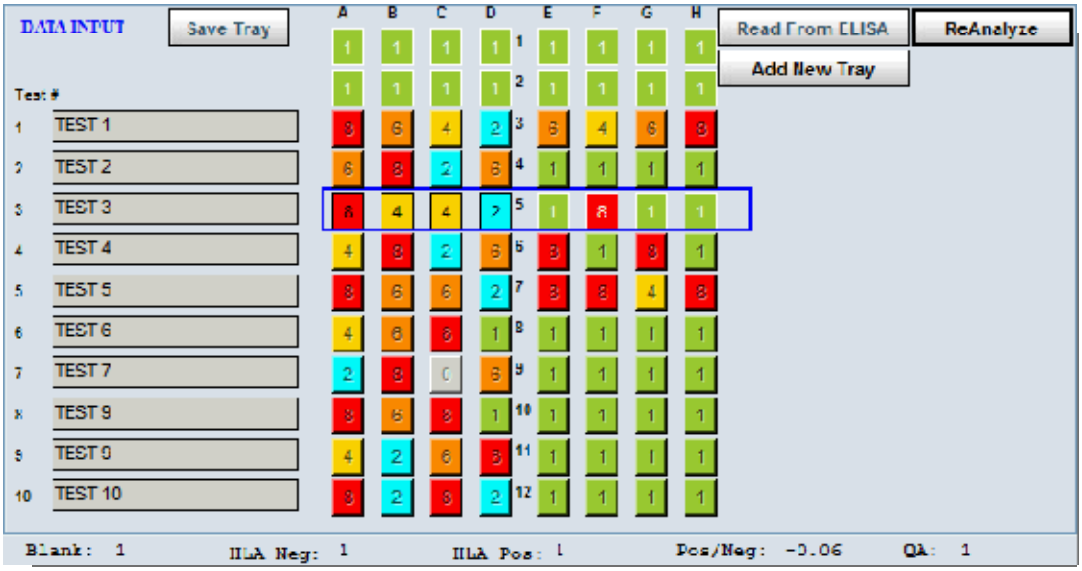
Note: You can return to a session summary from the analysis window any time by clicking the **<<Summary** link from the HLA Fusion toolbar next to the sample/session ID.

LAT Mixed Analysis Screen



Entering Data and Reaction Pattern

The data input menu displays the current reaction for an existing sample or allows you to input reaction values for a new sample. This area allows you to enter the samples and reactions into a session—10 test tray, or 20 test tray. Data may be entered manually or by obtaining raw data values from ELISA reader.



Data input and reaction pattern (10 test tray)

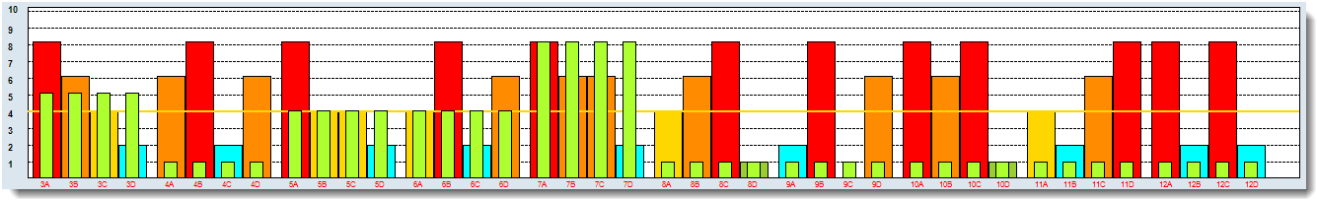
- The format of the data input section mimics an LAT mixed analysis worksheet. The reaction input panel has a tray layout. The row of wells for the current test is highlighted by a blue rectangle.
- Each well is a button that cycles through reaction values (1, 8, 6, 4, 2, 0). Buttons are color-coded to match the reactions.
- You can enter reactions by clicking a button and typing a reaction value, or by clicking the button until it displays the desired reaction. When the button changes, the focus shifts to the next button.
- Button navigation occurs from left to right (1A –1F, 2A – 2F…etc.).
- Where the product has a blank well, the corresponding reaction button is disabled.
- Sample list/entry for the tray is listed along the side of the panel. You must enter a sample ID before the reaction can be saved to the database. The session does not require that all wells of the tray be used.
- Once you analyze a tray, you can no longer add any more sample information to that tray.

Using the ELISA Reader

To read analysis data directly from the Biotek ELX 800 ELISA reader, the computer on which you are running HLA Fusion must be connected to the ELISA reader. Connect and calibrate the ELISA reader according to product specifications. HLA Fusion can analyze only 96-well Terasaki trays. ELISA reads the trays, and transfers the raw data to HLA Fusion.

- From the analysis window, click **Read From** to import data from the ELISA reader.

Note: The **Read From** button is displayed only when your computer is connected to the ELISA reader, and you have not yet entered any manual reactions for the current test.



Histogram for LAT Mixed analysis

LAT Mixed Histogram

This histogram displays the reaction value for each well position of the current tray in a session. It also displays the average negative control wells for the test group as a narrow light green bar superimposed on each reaction well bar.

Wells are sorted by test groups; Class I, Class II and control wells are sorted together.

- **X-axis** shows the well position.
- **Y-axis** lists ranges of reaction values (e.g., 1 to 10).

Bars are color-coded based on their reaction value:

- 8 = **Red**
- 6 = **Orange**
- 4 = **Gold**
- 2 = **Blue**
- 1 = **Green**

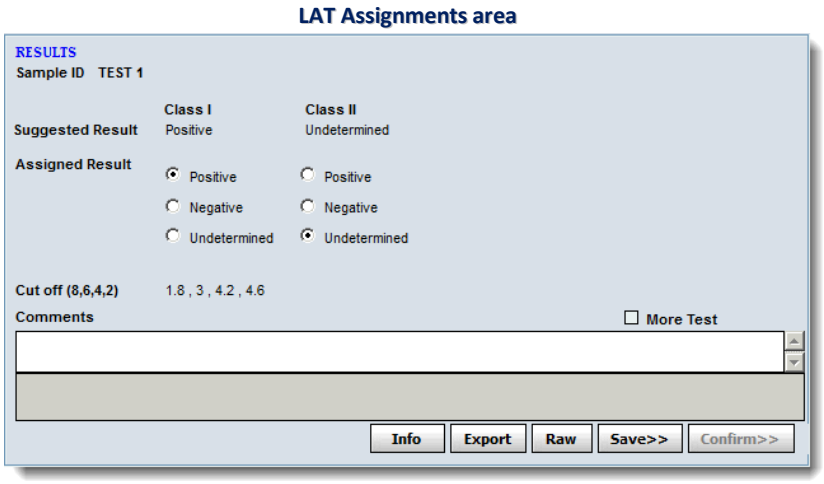
Horizontal lines represent the positive threshold you set for Class I and Class II. The line(s) assumes the same color as the RXN color code.

Making Assignments

The **Final Assignment** option buttons display the software-suggested assignment, (Positive, Negative or Undetermined). To accept the assignment, save or confirm the sample, (see the following sections).

To modify the suggested assignment, do the following:

1. From the analysis window, select an assignment for each Class using the **Final Assignment** option buttons— Positive, Negative or Undetermined.



Save Assignments

Lab Technicians and Supervisors can save analysis results for further review and approval. Saved samples are available for confirmation *only* by a Lab Supervisor.

- From the analysis window, click the **Save** Save button, located in the bottom right corner of the analysis window, to save analysis results for all the specificities currently listed in the Final Assignments results box.

Fusion automatically moves to the next sample.

For confirmation, a Supervisor needs to access the sample for which you saved the assignments. You can return to the sample any time prior to confirmation. If you need to make changes, click the **Reanalyze** Reanalyze button and then the **Save** Save button again.

Confirm Assignments

Only Lab Supervisors can confirm analysis results. When they do so, samples are marked as *Confirmed*. The **Confirm** button is **Purple** when you view a confirmed sample.

- From the analysis window, click the **Confirm** button Confirm>, located in the bottom right corner of the window, to confirm all analysis results.

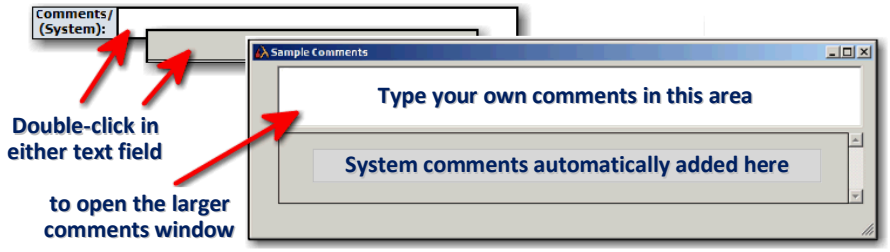
  You automatically move to the next sample to continue confirming results.

  When you first return to a confirmed sample, you see that the **Confirm** Confirm > button is now shaded **purple** to let you know it has been confirmed before.

Adding Comments to Samples

Comments you or Fusion add to the **Comments** fields are displayed with the results in the current analysis session, data look up and reporting functions in HLA Fusion.

- In the analysis window, enter sample comments into the **Comment** field below the Assignments area.



Comments are saved only after you click the **Save** or **Confirm buttons.**

Flagging a Sample for Further Testing

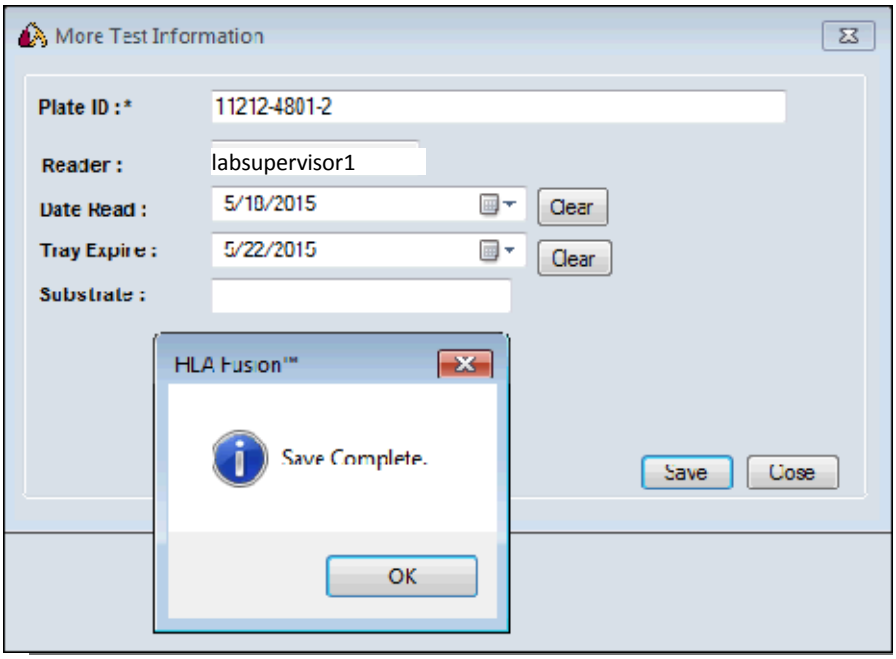
You can indicate the need for further testing of a sample by selecting the **More Tests** check box and then saving.

The **More Tests** indication is displayed in results, data look up and reports for the sample.

1. In the analysis window, check the **More Tests** More Tests check box, located below the Assignments area at the bottom, right.
2. Click **Save** Save or **Confirm** Confirm> to preserve the setting.

Adding Tray Information

You can add information about the current tray, such as expiration date, by clicking the **Info** Info button. The following dialog box is displayed when you click this button, allowing you to add information about this sample tray.



Exporting Session Data

You can click the **Export** button Export (located at the bottom, right above the **Save>>** button) to export session data into a file similar to the Luminex output CSV format.

If you have a separate workstation for ELISA and analysis, the exported file can be imported for analysis and used on another computer.

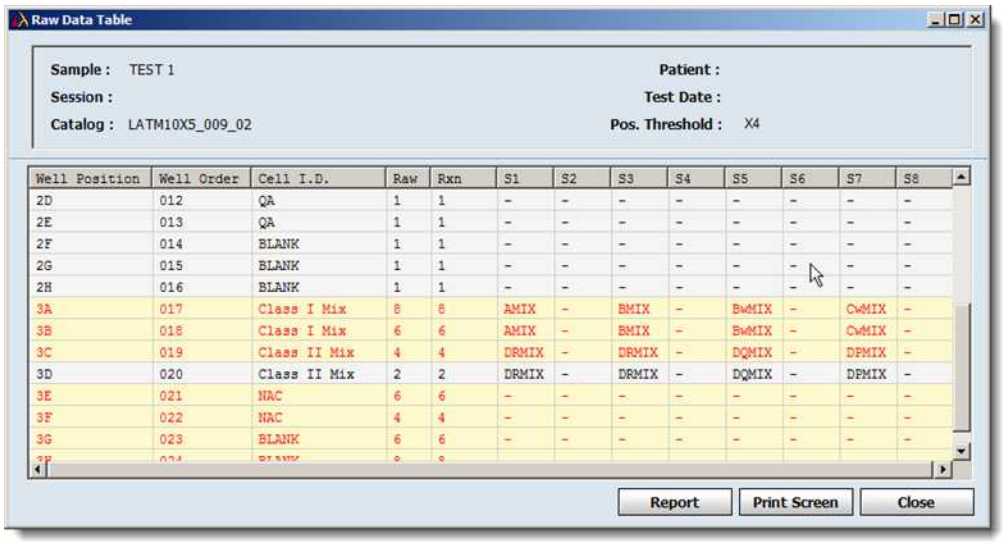
Raw Data Table

Positive beads are displayed in **Red** text. Rows highlighted in Yellow have normalized values over the minimum value.

Changes made to the normalization formula and the minimum normalized value apply only to the raw data table and not to analysis.

1. From the analysis window, click the **Raw** Raw button at the bottom right of the analysis window to display raw data table.

Raw Data table



Well Position	Well Order	Cell I.D.	Raw	Rxn	S1	S2	S3	S4	S5	S6	S7	S8
2D	012	QA	1	1	-	-	-	-	-	-	-	-
2E	013	QA	1	1	-	-	-	-	-	-	-	-
2F	014	BLANK	1	1	-	-	-	-	-	-	-	-
2G	015	BLANK	1	1	-	-	-	-	-	-	-	-
2H	016	BLANK	1	1	-	-	-	-	-	-	-	-
3A	017	Class I Mix	8	8	AMIX	-	BMIX	-	BwMIX	-	CwMIX	-
3B	018	Class I Mix	6	6	AMIX	-	BMIX	-	BwMIX	-	CwMIX	-
3C	019	Class II Mix	4	4	DRMIX	-	DRMIX	-	DQMIX	-	DPMIX	-
3D	020	Class II Mix	2	2	DRMIX	-	DRMIX	-	DQMIX	-	DPMIX	-
3E	021	NAC	6	6	-	-	-	-	-	-	-	-
3F	022	NAC	4	4	-	-	-	-	-	-	-	-
3G	023	BLANK	6	6	-	-	-	-	-	-	-	-

Click a column header to sort the table by that category.

Click the **Exit** ☒ button at the upper right corner of the table to close the window and to return to analysis.

Raw Data Quick Report

For easier navigation, exporting and printing, you can create a report containing raw data information for the current sample.

Once the Raw Data Table is displayed, click the **Report** [Report] button at the bottom right portion of the **Raw Data** table window to display a report of the raw data.

Click the **Exit** ☒ button at the upper right corner of the table to close the window and to return to analysis.

Click the **Print Screen** [Print Screen] button to display a preview of the currently visible portion of the Raw Data Table.

Click the **Printer** 🖶 button at the top left of the window to send the image directly to the printer.

Click either the **Exit** ☒ or **Close** [Close] buttons to close the window and to return to analysis.

Printing the Current Analysis Window

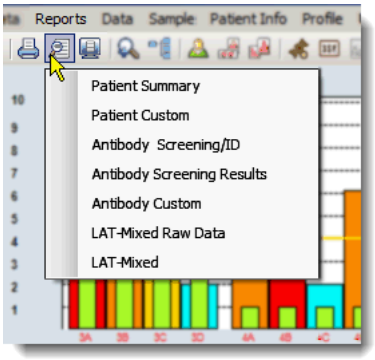
The **Print Screen** button sends the currently displayed analysis window to the default printer for your computer.

- From the analysis window, click the **Print Screen** button on the Fusion toolbar to print the currently visible portion of the analysis screen.

Previewing and Printing Reports

To view or print an Antibody Screening Mixed Data report for the current sample, use the **Preview Report** button on the toolbar.

- In the analysis window, click the **Preview Report** button or the **Print Report** button to display a list of reports you can print or preview for the current sample.



Note: If you select **Antibody Custom**, you cannot create a new custom report at this point. The only custom reports available from the analysis window are ones you previously created through the **Reports** window.

Using the LAT PRA/Single Antigen Analysis Window

This window provides detailed analysis information for each sample in the session. It allows you to review the specificity assignments suggested by the program and to modify and accept the assignments. HLA Fusion suggests possible screening results, but the final assignment must be made by the user.

From the analysis window menu you can do the following:

- Select minimum positive threshold
- Exclude selected, or Cw specificities

Note: You can return to a session summary from the analysis window any time by clicking the **<<Summary** link from the HLA Fusion toolbar next to the sample/session ID.

LAT PRA/Single Antigen Analysis

Entering the Reaction Pattern

Click each well to change its reaction value, or type a reaction value when the well is highlighted. Wells with white borders are control wells; wells with black borders are reaction wells.

1. From the analysis window, type a sample name into the **Top/Bottom Sample** fields and press the **Enter** key, (for two test trays, enter both top and bottom sample names).
2. Enter reaction patterns by clicking on wells to change the reaction value. Or, select a well and type the reaction value.

3. Click the **Reanalyze** Reanalyze button.

There is no requirement that all wells of a tray be used.

The tray input is a group of buttons representing each well. The buttons cycle through reaction values when clicked (1, 8, 6, 4, 2, 0). By default, 1 is displayed. The colors of the buttons reflect the values entered: 1=**Green**, 2=**light blue**, 4=**magenta**; 6=**red**; 8=**dark blue**.

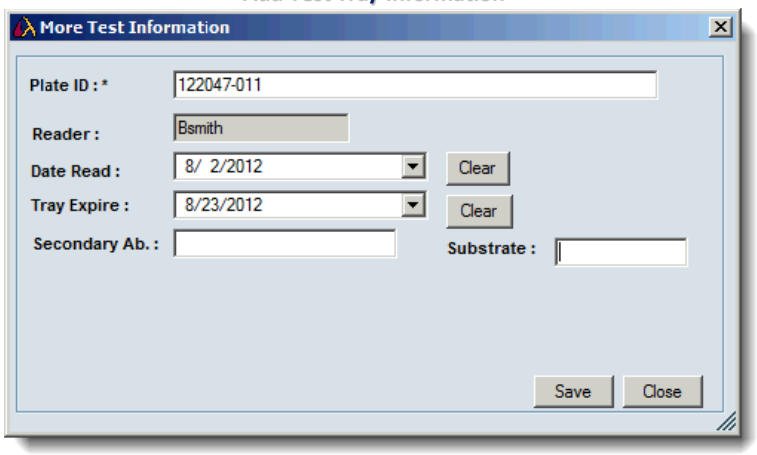
You can enter reactions by clicking a button and typing a reaction value, or by clicking the button until it displays the desired reaction. When the button reaction value changes, the focus shifts to the next button.

Button navigation is from left to right (1A –1F,2A – 2F, etc.).

The image of the tray, (button order, well position, etc.) emulates the actual LAT tray that is run. So for a 2 test tray, the top of the tray is shown first for the first sample and the bottom half of the tray is shown second, for the second sample. When you add a new tray, the top half is displayed first, then the bottom half, if applicable.

You can add information about the tray, such as expiration date, by clicking the **+ Info** + Info button. The **More Test Information** dialog box is displayed when you click this button, allowing you to add information about this tray:

Add Test Tray Information



Using the ELISA Reader

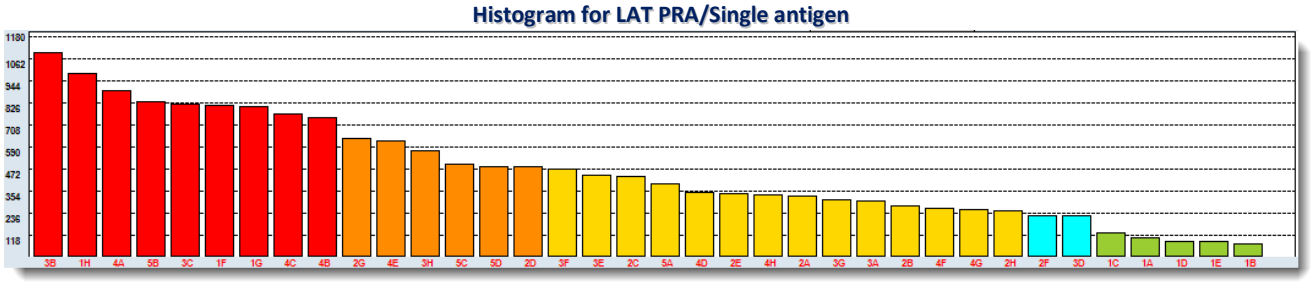
To import analysis data directly from the Biotek ELX 800 NB ELISA reader, the computer on which you are running HLA Fusion must be connected to the ELISA reader. Connect and calibrate the ELISA reader according to product specifications. HLA Fusion can analyze only 96-well Terasaki trays. ELISA reads the trays, and transfers the raw data to HLA Fusion.

- From the analysis window, click the **Read From ELISA** button to import data from the ELISA reader.

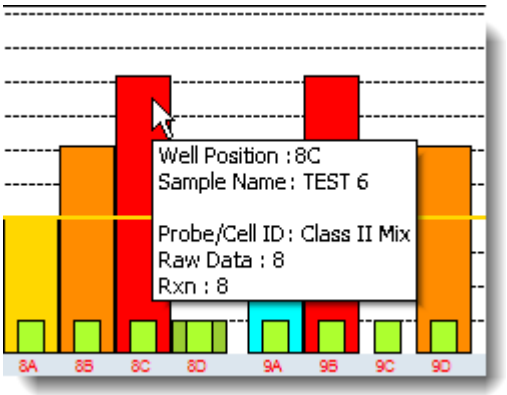
Note: The **Read From** button is displayed only when your computer is connected to the ELISA reader, and you have not yet entered any manual reactions for the current test.

LAT PRA/Single Antigen Histogram

Displays the reaction of the sample.



- Y-axis = reactivity; X-axis = well position and sample order.
- By default, the histogram is sorted from highest reaction to lowest. You can also click the **Sort by Well Position** button to sort it that way.
- **Bars** are colored according to reaction: **1**=**Green**, **2**= **light blue**, 4=**yellow**; 6=**brown**; 8=**red**.
- When you hover your cursor over a bar, a pop-up window displays Bead ID, Tray Position, Rxn, Raw Data, Threshold, Well Specificity.



CREG Table

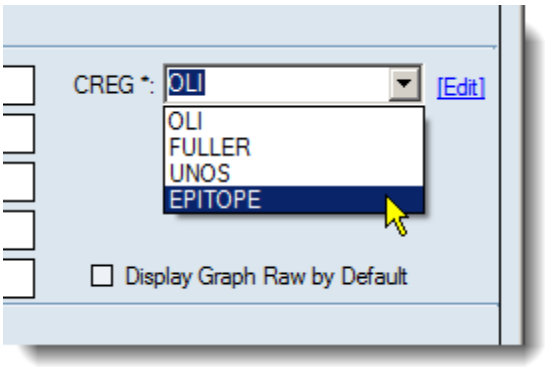
The CREG groups are displayed at the top of the table, with the specificities for the group displayed below. Specificities are highlighted in one of the following colors.

Note:	If you want to hide the display of the CREG bar, click the CREG title at the top of the window. A dialog box displays asking if you want to hide the CREG bar. Click **Yes** to hide it. To re-display it, click again on the CREG title and click the **Yes** button to show it.

- **Purple** = positive assignments from the Epitope Analysis Results box
- **Pink** = Tail assignments that are masked by Epitope analysis
- **Blue** = Cw assignments
- **Green** = Bw4 and Bw6 assignments
- Click a CREG group or antigens to circle the corresponding specificities.
- Right-click an antigen to move the specificity to the **Final Assignments** box.

Do the following if you want to use a different CREG table:

1. Click the **LAT Home Page** LAT button, or select **Utilities > Antibody Product Configuration > Set Analysis Configuration**.
2. On the LAT Home page, click the **[Edit]** link to display the **Analysis Configuration Settings** dialog box, (this dialog box is displayed already if you are accessing it through the Utilities menu).



3. Select a different table from the CREG drop-down list.
4. Click the **Save** Save button at the bottom of this screen.

Find Antigen

All entered antigens are circled in the specificity field. To enter multiple antigens, use a space to separate antigen entries. Clicking on the labels for Tail Analysis Results, Epitope Analysis Results, or Final Assignment creates circles around the specificities listed in the results area. Clicking on the "Exclude Antigen" label circles the excluded antigens.

Note: If you use the Find Antigen feature while the window is displaying molecular specificities, you cannot see the circled antigens until you deselect the DNA check box.

1. From the analysis window, type individual antigens or CREG groups, (e.g., 1C or 2C) into the field next to the **Find Ag**, (Antigen) button.
2. Click the **Find Ag** button to circle the entered antigens or CREG groups.
3. Click the **Find Ag** button again to remove the circles from antigens in the specificity field.

View Molecular Specificities

Molecular specificities are displayed only in the specificity field of the analysis window. The CREG Table and screening results are displayed and saved as serological specificities.

1. In the Analysis Window, select the **DNA** check box to display molecular specificities.
2. Clear the check box to return the display to serological specificities.

Select Minimum Positive Threshold

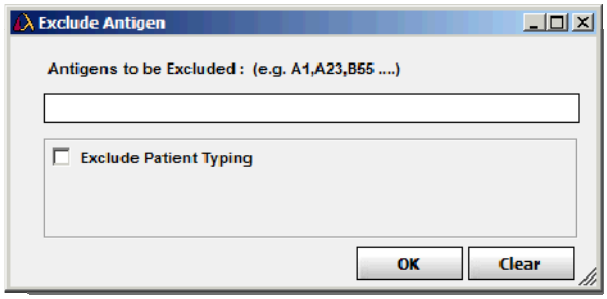
You can change the minimum positive threshold using the pull-down menu.

- From the analysis window, select a new positive threshold from the **Threshold** drop-down list next to the analysis tools near the top of the window. The sample is re-analyzed according to the new threshold. The effects of the threshold change are displayed in the result boxes.

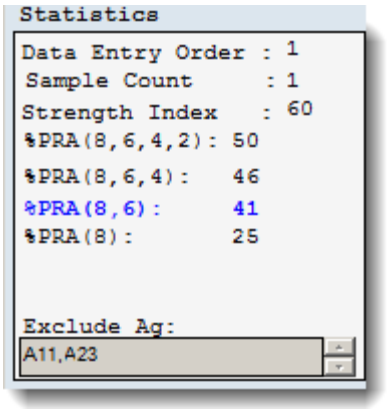
Exclude Antigen from Analysis

To enter multiple antigens, use a comma to separate the antigen entries. All antigens entered are excluded from analysis.

1. From the analysis window, click the **Excl. Ag**. button. The Exclude Antigen pop-up box is displayed.



2. Type in antigens to be excluded, separated by commas and click **OK**.



The sample is re-analyzed and the excluded antigens are listed in the Excluded Antigens field in the Analysis Statistics box.

3. To include all these antigens again, click the **Excl. Ag** button again; click **Clear** to remove antigens from the field; and then click **OK** to re-analyze with these antigens included.

Include/Exclude Cw

You can choose to include or exclude Cw antigen specificities from analysis.

- Near the top of the analysis window, select the **Cw** check box to re-analyze with Cw specificities.

  Clear the **Cw** check box to re-analyze without Cw specificities.

Navigating Between Class I & Class II

(PRA Class I & II Combined)

For Combined Class I and II PRA sessions, each HLA class is analyzed separately and needs to be saved separately for combined results to appear in the database.

Make sure that you have already created a combined Class I and Class II LAT PRA catalog file before you import the combined sessions).

- In the Analysis Window, click either the ***Run Class I*** or ***Run Class II*** buttons, located in the upper middle part of the analysis window to switch between Class I and Class II results for the current sample.

  (After you click on the Run Class I button and the analysis is completed, the button changes to Run Class II, and vice versa.)

Raw Data Table

Positive beads are displayed in **Red** text. Rows highlighted in yellow have normalized values over the minimum value. Changes made to the normalization formula and minimum normalized value, apply only to the raw data table and not to analysis.

1. From the analysis window, click the **Raw** button on the bottom right of the analysis window to display the raw data table.

Take one or more of the following actions:

- Click on a header at the top of any row to sort the table by that category.
- Click the **Report** button to create a Raw Data Table report.
- Click the **Print Screen** button to print what you see on the screen.
- Click the **Close** button to close the window and to return to analysis.

Raw Data Report

You can create a report containing raw data information for the current sample.

- Once the Raw Data Table is displayed, click the **Report** button at the bottom right portion of the Raw Data Table window to display a report of the raw data.

Exporting Session Data

You can click the **Export** button to export sample data into a comma-separated output file. This file can be imported for analysis. This feature is can be used if you have a separate workstation for ELISA and analysis.

Donor PRA

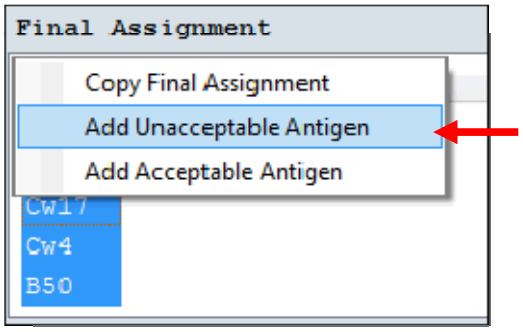
You can display the percentage of PRA from available donors in the system or from selected donor groups who match the computer-assigned antibodies for the current sample.

Note:	To select a donor group(s), select **Utilities > General Settings**. To create a donor group, select **Patient Info > Manage Patient**, select **Donor** in the Patient/Donor field, and fill in the donor group field.

1. For Single Antigen or PRA analysis, click the **DPRA** button. A pop-up box displays the percentage of matching donor PRA and the total number of donors that were considered in the calculation.
2. Click **OK** to close the box. The percentage and number of donors remains displayed next to the **Donor PRA** button.

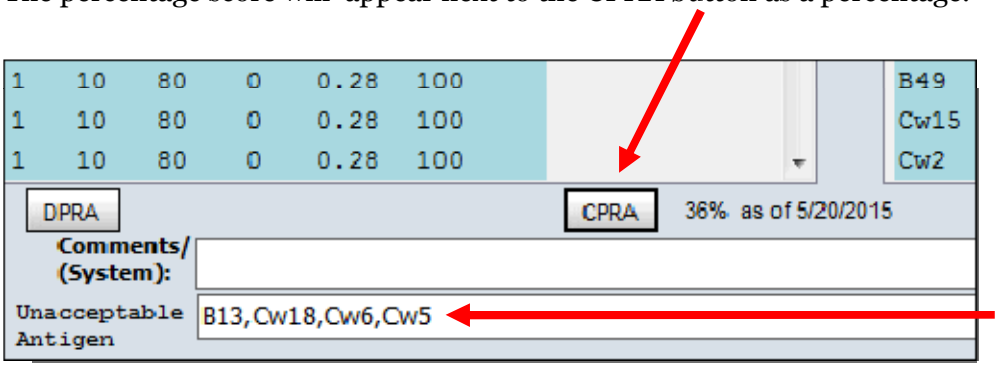
Calculated PRA

You can perform **Calculated PRA (CPRA)** analysis by clicking on the CPRA button, found to the right of the DPRA button on the lower left panel. Clicking the **CPRA button** will calculate PRA (UNOS calculator) using unacceptable antigens assigned to the patient record.



1. From within the **Final Assignment** box, select several antigens by highlighting them, then right-click and **choose "Add Unacceptable Antigen."**
2. Now, click the **CPRA** button.

The percentage score will appear next to the CPRA button as a percentage.



The list of selected antigens appears below to the left under the System Comments area.

Adding Comments to Samples

Comments that you or Fusion add to the **Comments Field** are displayed with the results in the current analysis session, data look up and reporting functions in HLA Fusion.

- In the analysis window, type sample comments into the **Comment** field below the Assignments area.

You may click and drag the bottom right corner to resize the Comments box. Comments are only saved after you click the **Save** button after completion of the analysis.

Flagging a Sample for Further Testing

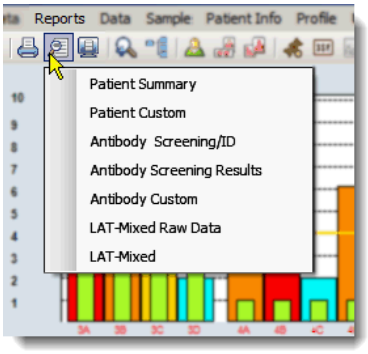
Marking a sample for more testing displays the **More Tests** check box for the sample's results in the current analysis session in all analysis, data look up and reporting functions in HLA Fusion.

- In the analysis window, check the **More Tests** check box, located below the Epitope Analysis Results section.

Previewing and Printing Reports

To view or print an LAT PRA/SA report for the current sample, click the Preview Report button on the Fusion toolbar.

- In the analysis window, click the **Preview Report** button or **Print Report** button to display a list of reports you can print or preview for the current sample.



Note: If you select Molecular Custom, you cannot create a new custom report at this point. The only custom reports available from the analysis window are those previously created through the **Reports** window.

Making Final Assignments

Final assignments can be made from either the Tail or Epitope results lists. Once a specificity has been moved to the Final Assignments area, it no longer displays in its initial results box.

From the analysis window, do one of the following to make assignments:

- Double-click an antigen specificity in the **Tail** or **Epitope Analysis** results box to list the specified antigen in the **Final Assignment** field.
- Click to highlight the specificity and click the **Assign Single** button to move it to the **Final Assignment** list.
- Click the **Assign All** button to the right of the Tail or Epitope list to move all the current results on that list to the **Final Assignments** area.
- Right-click on a specificity, or CREG group on the CREG Table to assign it to the **Final Assignments** area.

Manual Assignments

Manual assignments can be entered in the field below the Final Assignments results box. Enter multiple manual assignments by leaving a space between each specificity.

1. From the Analysis Window, type a manual antigen specificity assignment in the field under the Final Assignment box.
2. Click the Assign button ^, just above the Manual Assignment field to add the assignment to the **Final Assignment** results box.

Assigning Negative Sample Values

You can assign a negative value to a sample even if analysis shows some positive results.

- From the analysis window, click the **Assign -ve** Assign -ve button, (located just above the Manual Assignment field) to assign all samples on the Final Assignment results box a negative value.

Removing Assignments

Specificities can be removed from the **Final Assignments** results field. You can remove more than one specificity by holding down the **Ctrl** key and clicking each specificity you want to remove.

- From the analysis window, click to highlight specificities on the Final Assignment list, (hold down the CTRL key to select more than one) and click the **Remove** X button, located below the **Final Assignments** results field.

Save Assignments

Lab Technicians and Supervisors can save analysis results for further review and approval. Saved samples are available for confirmation *only* by a lab supervisor.

- From the analysis window, click the **Save** >>button, (located in the bottom right corner of the analysis window) to save analysis results for all the specificities currently listed in the Final Assignments results box.

  You automatically move to the next sample.

For confirmation, a Supervisor needs to access the sample for which you saved the assignments. You can return to the sample any time prior to confirmation. If you need to make changes, click the **Reanalyze** button and then the **Save** button again.

Confirm Assignments

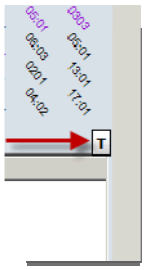
Only Lab Supervisors can confirm analysis results. When they do so, samples are marked as *Confirmed*. The **Confirm** button is purple when you view a confirmed sample.

- From the analysis window, click the **Confirm** button, located in the bottom right corner of the window, to confirm all analysis results.

  You automatically move to the next sample to continue confirming results.

When you first return to a confirmed sample, you see that the **Confirm** button is now shaded **purple** to let you know it has been confirmed before.

Getting Tail Analysis Values



Tail analysis values can be displayed in the **Final Assignments** results field, but are not stored for look up or reporting.

- From the analysis window, click the **T** button, located to the upper right of the Final Analysis results box, to display tail analysis values in Final Assignments results field.
- LAT Single Antigen samples imported after this configuration change do not display the tail analysis assignment area on the sample analysis window.

Navigating Between Class I & Class II

(PRA Class I and II Combined)

For Combined Class I and II LABScreen PRA sessions, each HLA class is analyzed separately and needs to be saved separately for combined results to appear in the database.

Make sure that you have already created a combined Class I and Class II LABScreen PRA catalog file before you import the combined sessions.

- From the analysis window, click ***Run Class I*** and ***Run Class II*** buttons, located in the upper left part of the analysis window, to switch between Class I and Class II results for the current sample.

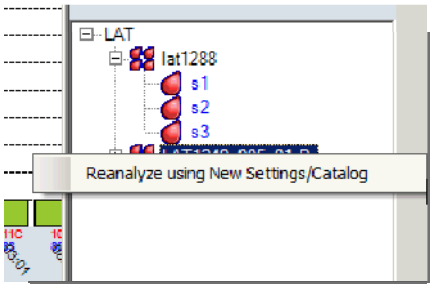
Navigator Right-Click Menu Options for LAT

Note: These options apply to all LAT sessions and samples.

There are analysis options available through the Navigator—depending on whether you are in the LAT session summary view, or on an analysis screen for a sample.

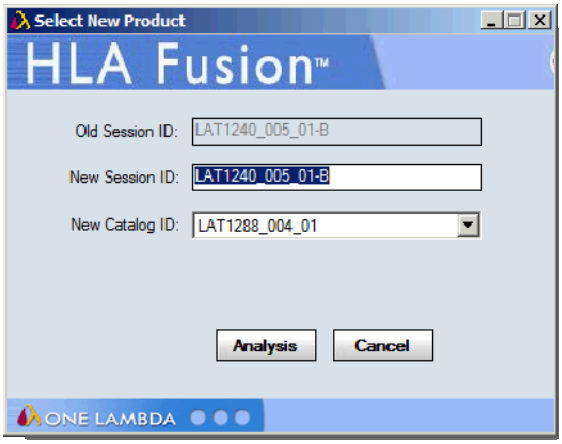
By right-clicking on either a session or a sample in the Navigator window, you access menu options that allow you to affect your LAT analysis sessions before or during analysis.

Navigator Session-level menu options



Reanalyze with New Catalog

Allows a session to be reanalyzed using a new or updated catalog.



1. Right-click on the session in the Fusion Navigator and select **Reanalyze using New Settings/Catalog**.
2. Rename the session giving it a new **Session ID**.
3. Click the drop-down arrow in the **New Catalog ID** field and select a new catalog from the list.
4. Click the **Analysis** button.

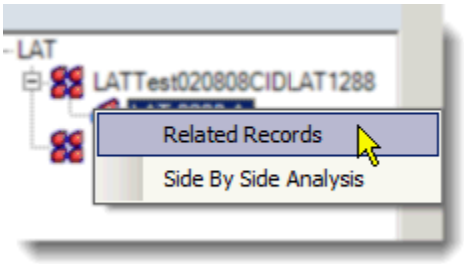
The session on which you right-clicked is reanalyzed using a new Session ID with the catalog you just selected.

Sample-Level Options

The **Related Records** and **Side By Side Analysis** options are displayed if you right-click on an active sample in the Navigator, (first select the sample with a left-click):

Related Records

A related record is a record that is associated with the current sample by patient or sample ID.



Note: This option **is also available by using the Related Records toolbar button.**

- Select this menu option to load all records related to the current sample into the Sample drop-down list. Use the sample navigation arrows to display the analysis of each related record one by one.
- To go back to viewing the samples in the current sessions, click the **<<Summary** link at the top of the window.

Side By Side Analysis

Use this option to compare the current sample analysis with a sample analysis previously conducted.

Note: This option is also available by using the **Side By Side Analysis** toolbar button.

- Select a sample to compare to the current one.

  The two analysis windows are then displayed together in a comparison window.
- Each window can be resized and moved by dragging and dropping.

Click the **Side-By-Side Analysis** toolbar button again to cancel the comparison display.

FlowPRA Analysis

The **FlowPRA** analysis feature of the HLA Fusion program analyzes manually-entered reaction values as a new session. Analysis results are based on catalog specifications provided with HLA Fusion software.

There are a few things that should be completed or verified before you start a ***FlowPRA*** analysis session:

- Make sure you have the latest catalog files and serology equivalent reference files before you analyze. You can download or update catalogs from the FlowPRA Home Page.
- View and modify global- as well as product-specific configuration settings before starting analysis. Global settings apply across all newly imported sessions.
- Save time importing catalogs and files by verifying that the default URLs and paths are pointing to the locations where these files are commonly stored on your system or network. These settings can also be modified in the General Configuration section of the HLA Fusion default Home page.

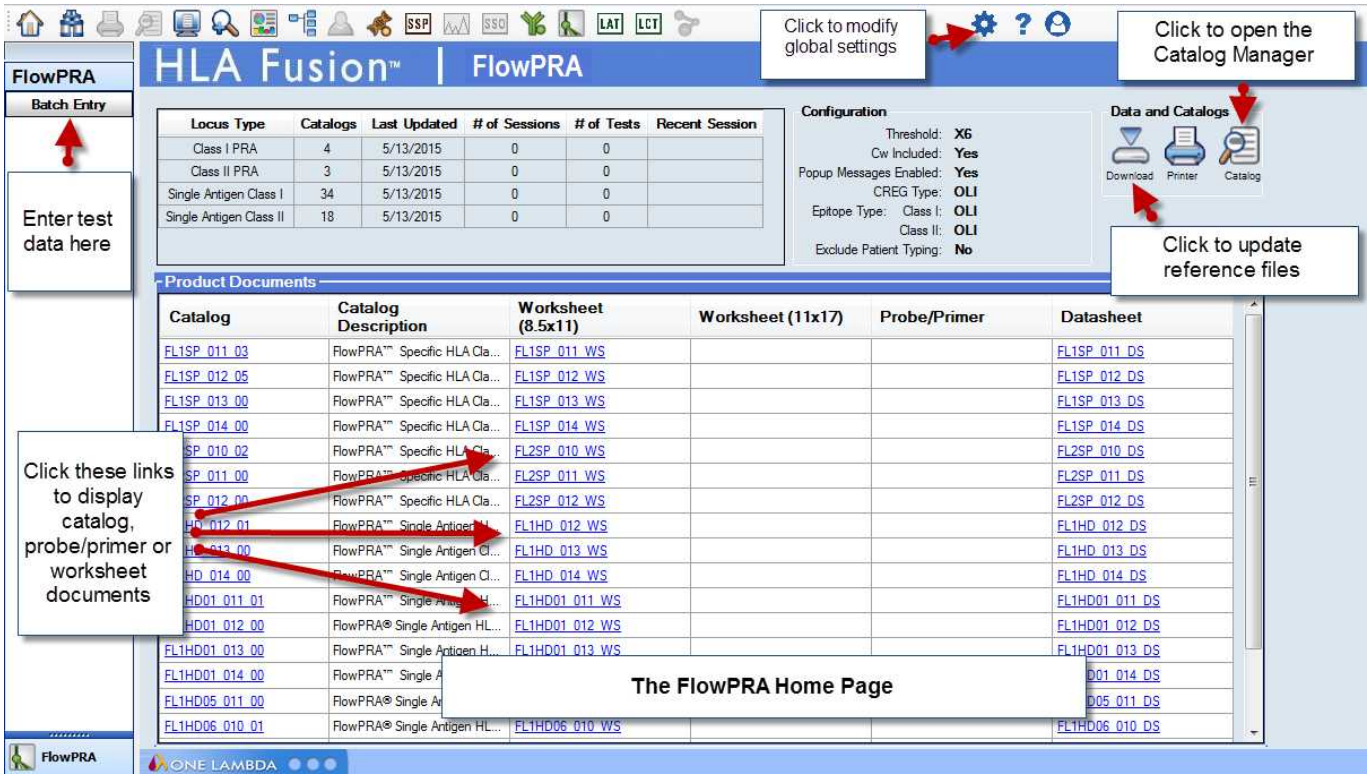
Note: Some of the above tasks require you to have Supervisor User privileges. You may have to verify with your supervisor that these tasks have been completed.

Starting FlowPRA Analysis

Acquiring FlowPRA Data

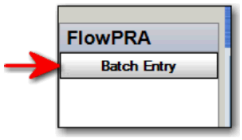
1. Select the **FlowPRA** button from the home page panel or the Fusion toolbar.

The **FlowPRA Home page** is displayed.

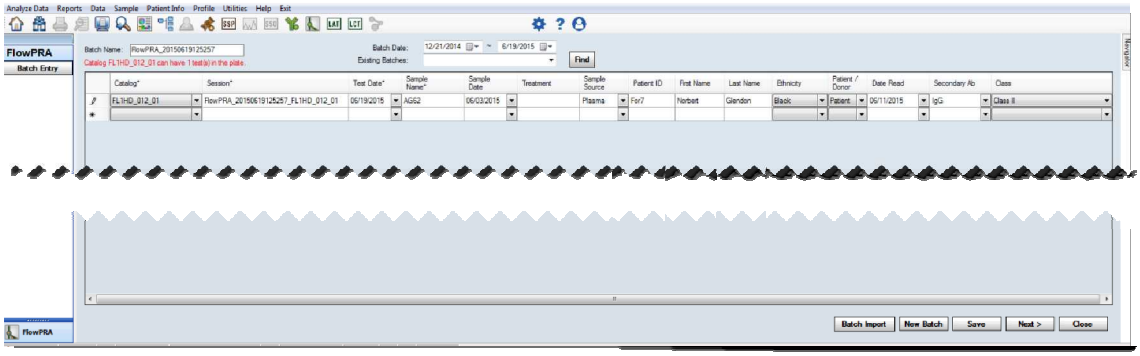


Note: Open worksheets and probe/primer sheets to verify the accuracy of revision numbers (these documents do not contain a revision number in their filename).

2. Click **the Batch Entry Button**.



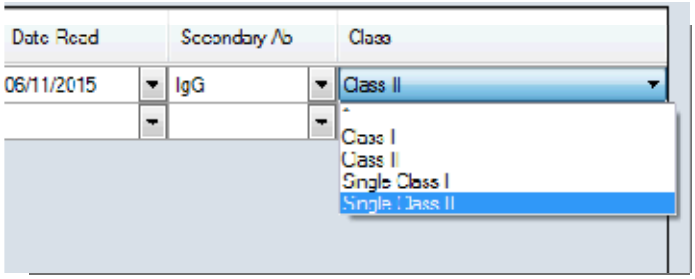
The FlowPRA Batch Entry Screen is displayed:



Notice that Fusion has automatically assigned a session name. Optionally, you can rename the session.

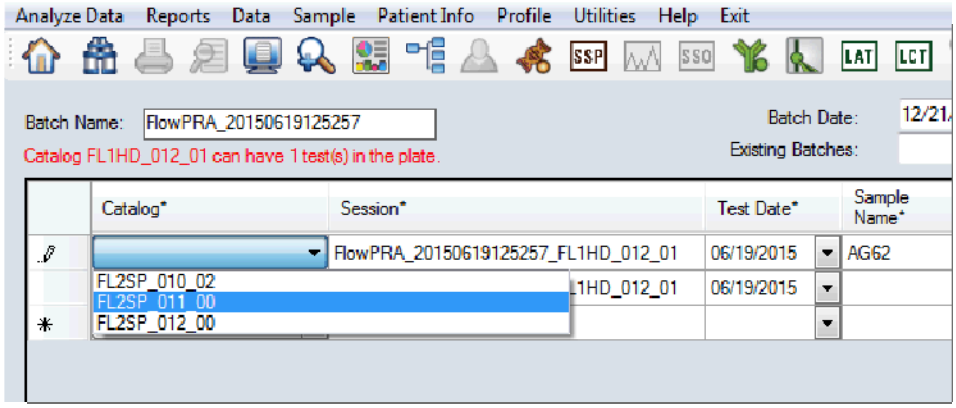
Note: A session ID or batch name must be unique to the Fusion database. If the session ID already exists, the software prompts you to rename the session. It is also highly recommended that you do not use any special characters in this field since they may serve a specific purpose as field separators.

3. Click the drop-down arrow in the Class column (on the extreme right hand side) to select the HLA class: Class I, Class II, Single Class I or Single Class II.



Note: If you need to import more catalogs, click the **Download** link on the FlowPRA home page. The catalog drop-down list may not be immediately updated if you downloaded the catalogs during this import session. You may need to click the **Home** button and then click the **FlowPRA** button again to return to the import process.

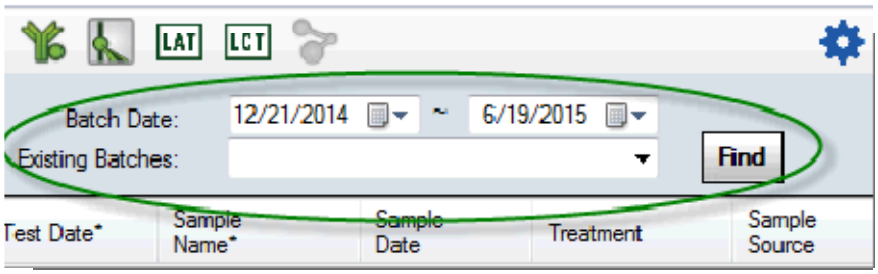
4. Use the drop-down menu in the Product **Catalog** field (on the immediate left) to select an appropriate catalog file to use for analysis:



- Accept the current date or select a different test date and click **Next>**. The analysis window for this session is displayed.

Note: In the Catalog drop-down field, Fusion only lists those product catalogs which belong to the HLA Class you selected in the Class drop-down field.

- Each FlowPRA session consists of as many samples as you wish to analyze with the same catalog information. You may also begin FlowPRA analysis on previously existing, or previously entered batches by clicking the drop-down arrow on the right side of the **Existing Batches field** near the top center of the screen (shown below).
- If the existing batch is not displayed, adjust the date range of the **Batch Date** and click the **Find** button to locate the missing batch(s):



Note: If you need to import more catalogs, click the [Download] link on the MicroSSP Home Page. The catalog drop-down list may not be immediately updated if you downloaded the catalogs during the current import session. You may need to click the Home button and then click the MicroSSP button again to return to the import process.

Note: Data entry is required for any fields with an asterisk(*).

5. Click anywhere in the **Session** field to accept the name which Fusion provides in the Session* field, or modify it.

6. Click the down arrow to open a calendar and select a **Test Date***.

7. Enter a name in the **Sample Name*** field.

FlowPRA Analysis Screens

Analyzing FlowPRA samples is similar to the LCT product. Please follow the steps outlined in the LCT sections.

LCT Analysis

The LCT analysis feature of the program analyzes manually-entered reaction values as a new session. Analysis results are based on catalog specifications provided with the HLA Fusion software.

There are a few things that should be completed or verified before you start an analysis session:

- Make sure you have the latest catalog files, as well as NMDP code, local code (if used), or serology equivalent reference files before you analyze. You can download or update catalogs from the LCT Home Page.
- View and modify global product configuration settings before starting analysis. Global settings are displayed and be can be modified on the LCT Home Page. Global settings apply across all newly imported sessions.
- Save time importing catalogs and files by verifying that the default URLs and paths are pointing to the locations where these files are commonly stored on your system or network. These settings can also be modified in the General Configuration section of the Fusion default Home page.

Note: Some of the above tasks require you to have Supervisor User privileges. You may have to verify with your supervisor that these tasks have been completed.

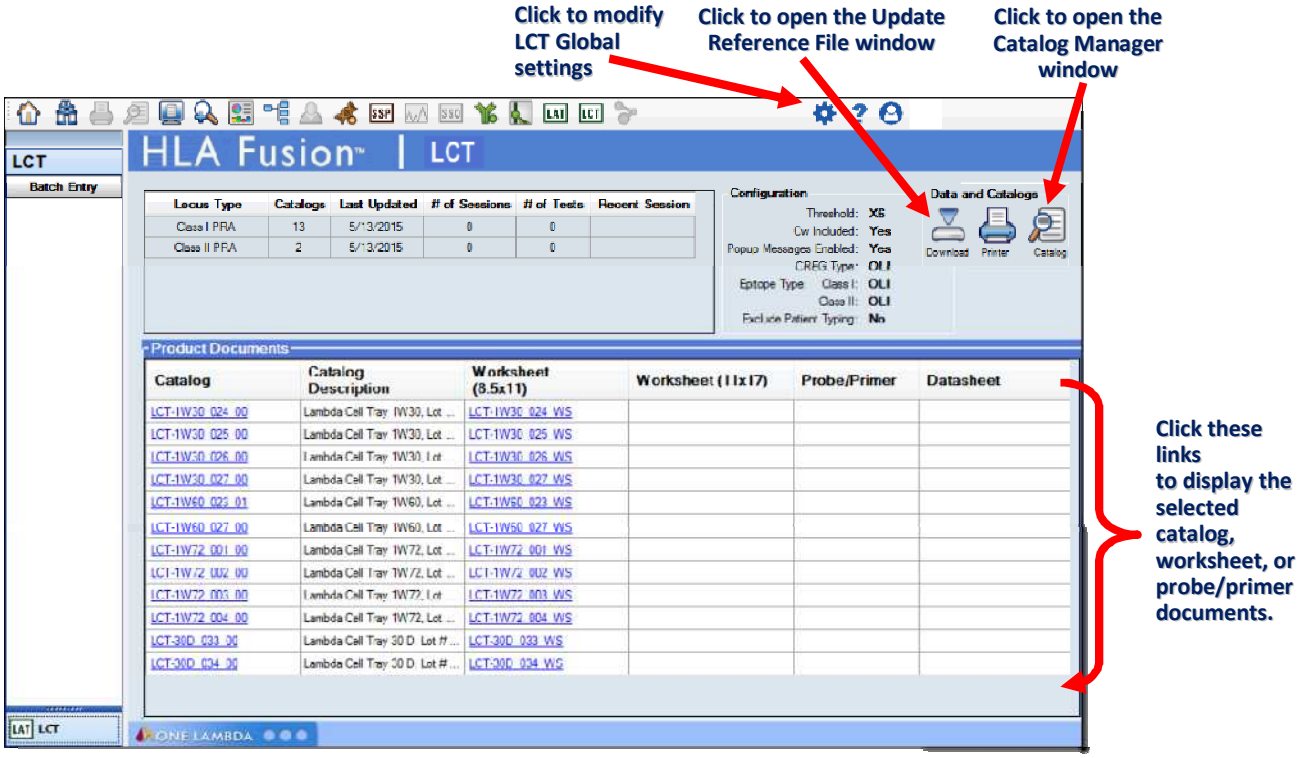
Starting LCT Analysis

Acquiring LCT Data

1. Select **LCT** button from the home page panel LCT or the Fusion toolbar LCT.

The LCT Home page is displayed.

Note: If you are not using the default Fusion user interface, the data and links shown on the right side of the window are not displayed.

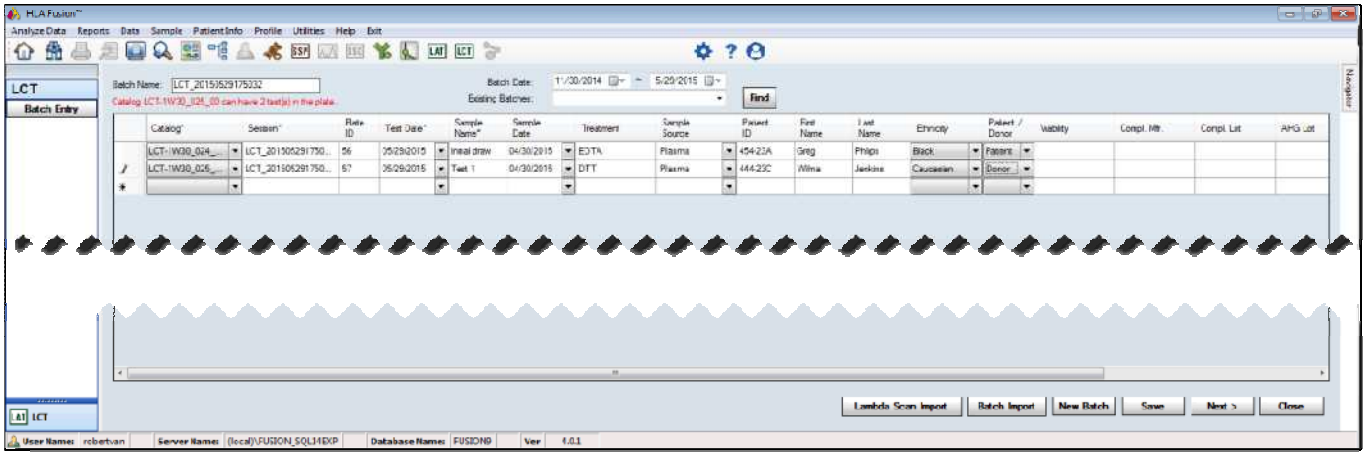


The LCT Home Page

Note: Open worksheets and probe/primer sheets to verify the accuracy of revision numbers (these documents do not contain a revision number in their filename).

3. Click **the Batch Entry Button**.

The LCT Batch Entry Screen is displayed.



Notice that Fusion has automatically assigned a session name. Optionally, you can rename the session.

Note: A session ID must be unique to the Fusion database. If the session ID already exists, the software prompts you to rename the session. It is also highly recommended that you do not use any special characters in this field since they may serve a specific purpose as field separators.

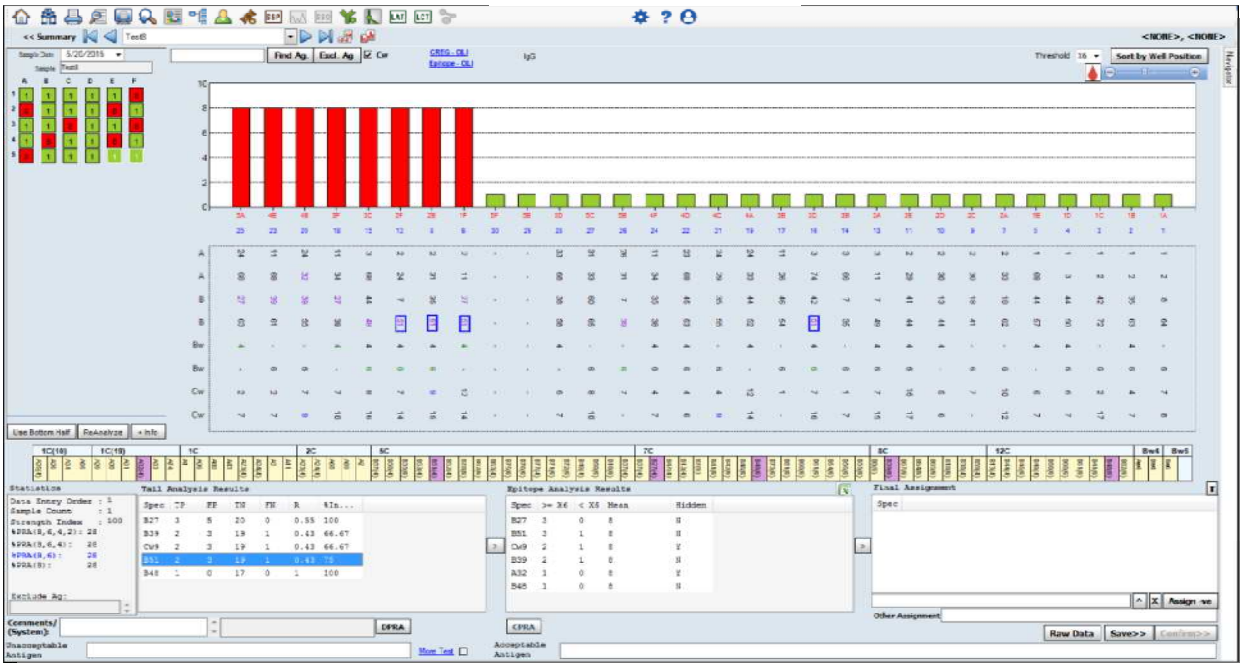
5. Use the drop-down menu in the **Catalog** field to select a catalog file.

Note: If you need to import more catalogs, click the **Download** link on the LCT home page.

The catalog drop-down list may not be immediately updated if you downloaded the catalogs during this import session. You may need to click the **Home** button and then click the **LCT** button again to return to the import process.

4. Accept the current date or select a different test date and click **Next>**. The analysis window for this session is displayed.

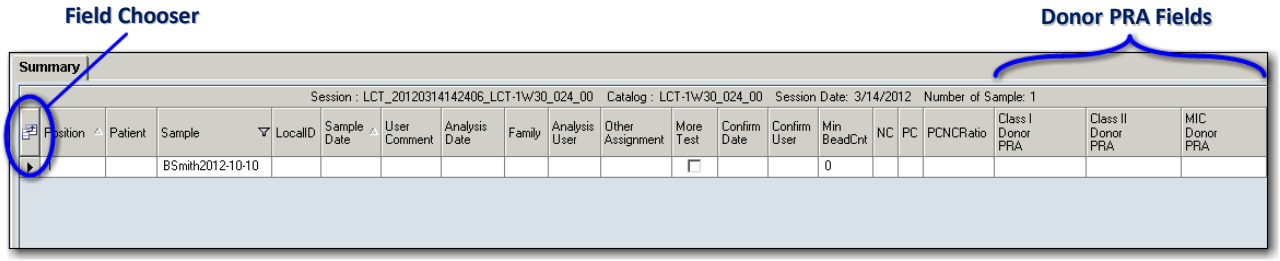
LCT Analysis Window



Each LCT session consists of as many samples as you wish to analyze with the same catalog information.

LCT Session Summary Screen

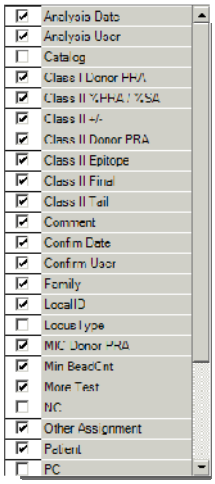
The Summary Table can be launched by clicking a session in the Navigation tree. It lists each sample in the session. This option allows you to quickly analyze a session, and save it for later review and final assignments.



LCT Session Summary Table

- Double-click a sample in the Summary Table or a data point to go directly to the analysis screen for this sample.
- Scroll left or right to view all of the Summary Table fields.
- Click the **Field Chooser** button to the left of the column heading row. The **Field Chooser** window is displayed. In this window, you can select or clear the check boxes next to column headings to include or exclude those columns from the Summary Table. Selecting or clearing check boxes in this window instantly updates the table.

Note: If you do not see a particular field available through the field chooser, and you are sure it should be there, go to C:\HLA Fusion\temp and delete the file named **`x_x_x(antigen type)_Layout.xml`**.

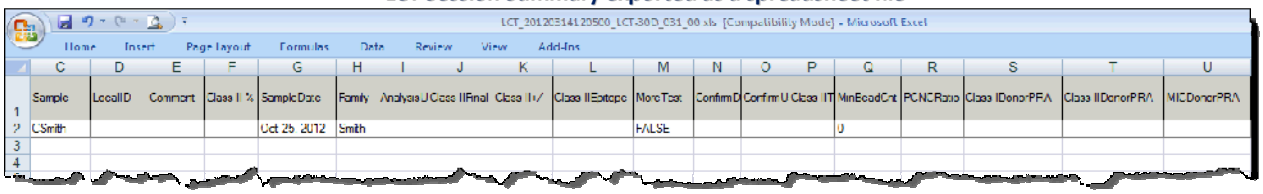


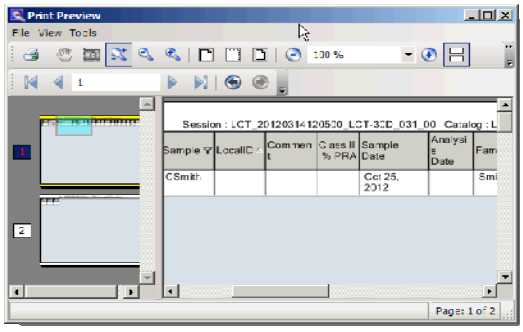
LCT Session Summary Field Chooser

- Click on any column header of the Summary Table to sort the table by that column. The arrow in the column header indicates the sorting order—up for ascending and down for descending. Columns can also be dragged-and-dropped to change their order.
- The session summary table columns and order can be modified. When you close the **Field Chooser**, a pop-up message displays to let you choose whether or not to save any changes you made. If you click **Yes**, your changes are saved for all future LCT session summaries on this same computer until further modifications are saved.
- Click the **Export** button to save the Summary Table on your computer or the network (default location is C:\OLI FUSION\data\report). The file is saved in Excel (*.XLS) format.

- Click **Print** to print out a report of the Summary Table.
- Click **Preview** to view a report of the Summary Table.

LCT Session Summary exported as a spreadsheet file





LCT Session Summary Print Preview

- In the print preview window, the page view slider on the left allows you to select different pages of the report.

- The Summary Table columns and order can be modified. You can save any modifications you make to the layout by clicking the **Save Layout** button 

. Your changes are saved for all future LCT session summary tables on this same computer until further changes are saved.

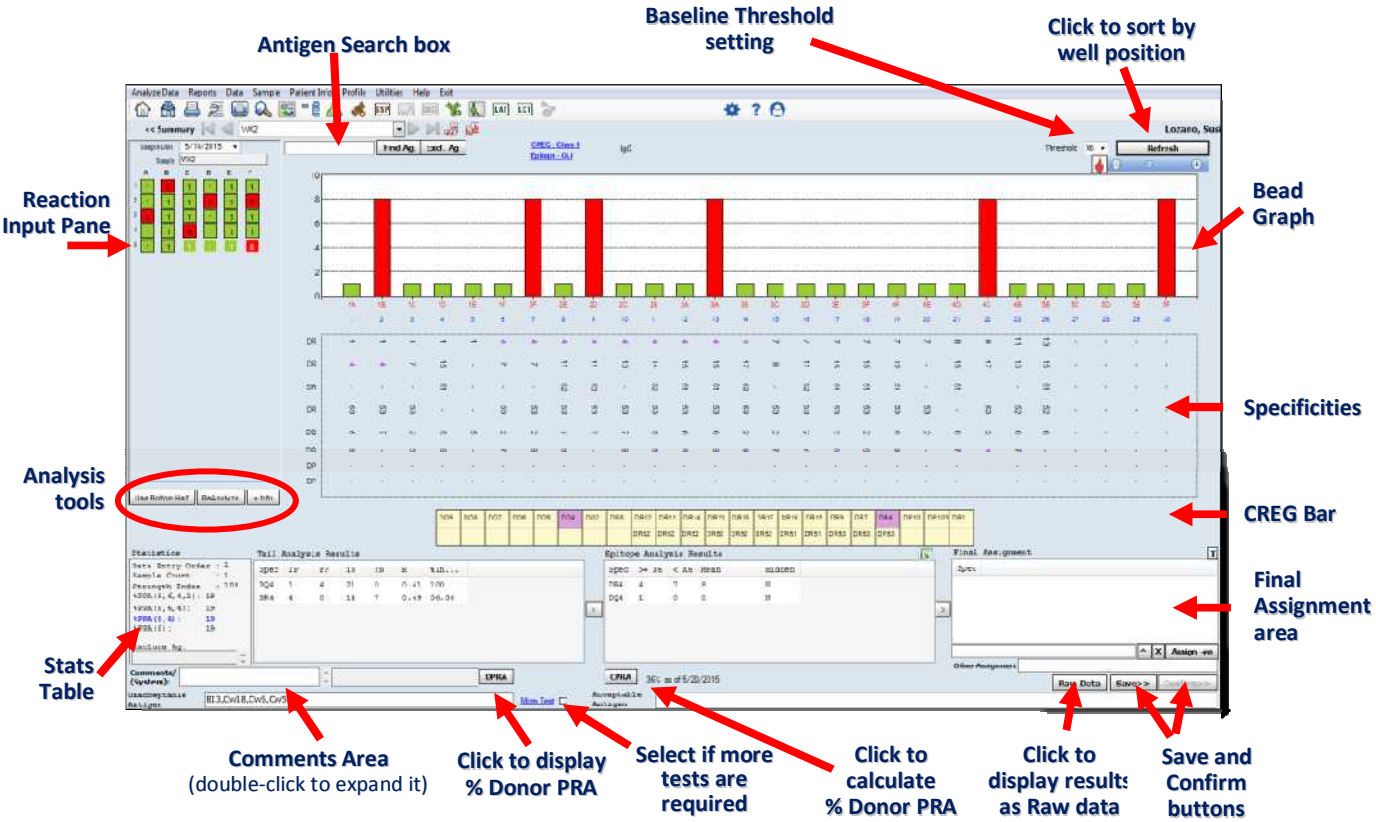
- If you want to exclude a sample from an analysis session, select the **Exclude** check box next for that sample. The sample is still displayed on the Reports sample list, so to prevent it from being included in report data, do not select that sample during report creation.

Note: Certain columns of data are considered key, and cannot be excluded for longer than the current display of the Summary Table. If you exclude one of these fields, its column is not displayed until you navigate elsewhere in the application. If you return to this Summary Table from a sample analysis window or the Navigator, that column is re-displayed. The data columns considered key is product-specific.

Using the LCT Analysis window

For each LCT sample in the current session, you can view the test data, adjust the cut-off, and assign screening results. There are several tasks you can perform from the LCT analysis window:

- Review data and assign specificities
- Circle antigens in the specificity table
- View molecular specificities
- View screening results
- Add comments and mark the sample for more testing
- View a report for the current sample



LCT Analysis Window

Reaction Input and Analysis Pane

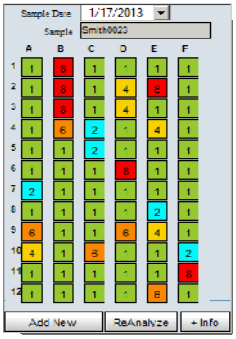
The pane in the upper left of the window displays each bead grouping of the test on a separate tab. Each bead is listed with specificity and reaction button.

To switch between panes, click on the tab of the selected bead group.

When clicked, the reaction for the selected bead switches between the following numbers and colors:

- 1 (**green**)
- 8 (**red**)
- 6 (**orange**)
- 4 (**gold**)
- 2 (**light blue**)
- 0 (**gray**)

Reaction Input & Analysis pane

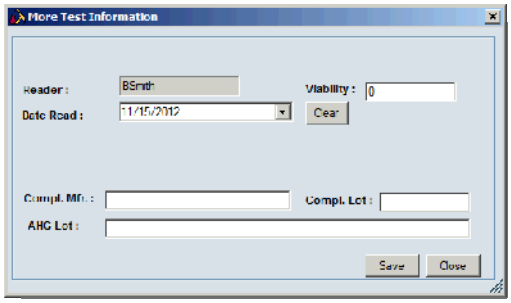


- If you change a reaction button, the focus shifts to the next button. You can also manually type in reactions instead of clicking buttons.
- This panel launches the analysis of the current sample using the latest changes in reaction.
- If the sample has not been analyzed yet, the button is labeled **Analyze**. If analysis already exists for the sample, then the button is labeled **ReAnalyze**. This button is only enabled when a Sample ID has been entered. If a sample ID has not been entered when this button is clicked, the sample ID field is flagged with **!**, and no analysis is performed.

Adding Tray Information

You can add information about the current tray, such as expiration date, by clicking the **+Info** button [+ Info]. The following dialog box is displayed when you click this button, allowing you to add information about this sample tray.

Add Tray Information screen



Find Antigen

To enter multiple antigens, use a space to separate antigen entries. All entered antigens are circled in the specificity field. Clicking on the labels for Tail Analysis Results, Epitope Analysis Results, or Final Assignment creates circles around the specificities listed in the results area. Clicking on the "Exclude Antigen" label circles the excluded antigens.

Note:	If you use the Find Antigen feature while the window is displaying molecular specificities, you cannot see the circled antigens until you deselect the DNA check box.

1. From the analysis window, type antigens or CREG groups (e.g., 1C or 2C) into the field next to the **Find Ag** (Antigen) button. 

2. Click the **Find Ag** button 

to circle the entered antigens or CREG groups.

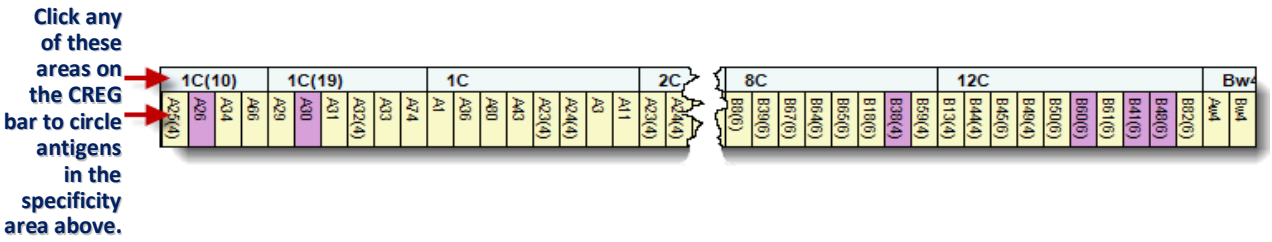
Click the **Find Ag** button again to remove the circles form antigens in the specificity field.

CREG Table

The CREG groups are displayed at the top of the table, with the specificities for the group displayed below. Specificities are highlighted in one of the following colors.

Note:	If you want to hide the display of the CREG bar, click the CREG title at the top of the window. A dialog box displays asking if you want to hide the CREG bar. Click **Yes** to hide it. To re-display it, click again on the CREG title and click the **Yes** button to show it.

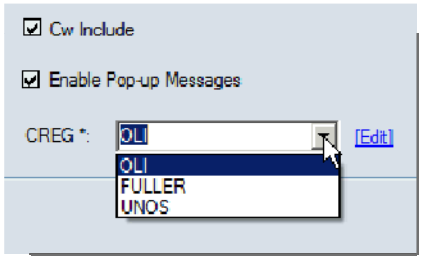
- **Purple** = positive assignments from the Epitope Analysis Results box
- **Pink** = Tail assignments that are masked by Epitope analysis
- **Blue** = Cw assignments
- **Green** = Bw4 and Bw6 assignments



1. Click a CREG group or antigens to circle the corresponding specificities.
2. Right-click an antigen to move the specificity to the **Final Assignments** box.

Do the following if you want to use a different CREG table:

1. Click the **LCT** LCT home page button, or select **Utilities > Antibody Product Configuration > Set Analysis Configuration**.
2. From the Home page, click the **Edit** link to display the **Analysis Configuration Settings** dialog box. (This dialog box is displayed already if you are accessing it through the Utilities menu.)
3. Select a table from the CREG drop-down list.
4. Click **Save**.

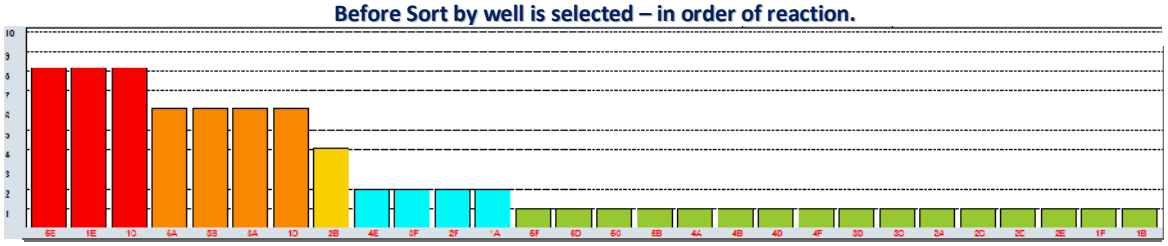


Sort by Well Position

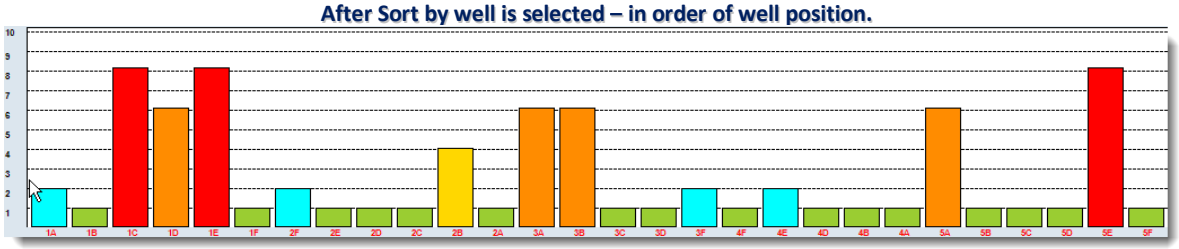
This button appears when the histogram is currently sorted by reaction. When clicked, it sorts the histogram in order of well position, and the button is labeled **Refresh**.

1. From the analysis window, click the **Sort by Well Position** button Sort by Well Position.
2. To return to sorting by reaction, click the Refresh button Refresh.

Before Sort by well is selected – in order of reaction.



After Sort by well is selected – in order of well position.

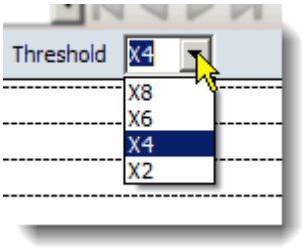


Select Minimum Positive Threshold

You can change the minimum positive threshold using the pull-down menu.

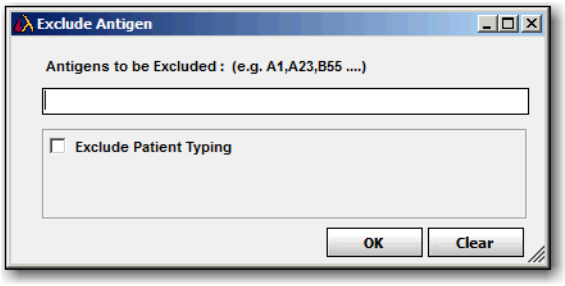
- From the analysis window, select a new positive threshold from the **Threshold** drop-down list, next to the analysis tools near the top of the window. The sample is re-analyzed according to the new threshold. The effects of the threshold change is seen in the result boxes.

Setting the Minimum Positive Threshold



Exclude Antigen from Analysis

All antigens entered are excluded from analysis. To enter multiple antigens, use a comma to separate antigen entries.



Exclude Antigen setting

1. From the analysis window, click the **Excl. Ag.** button 

. The Exclude Antigen popup box is displayed.

Type in antigens to exclude and click **OK**. Valid characters for the Exclude Antigen text box are alphabetic and numeric characters, spaces, commas, backspace characters and the carriage return.

Note: To also exclude all typing antigens for the associated patient, select the **Exclude Patient Typing** check box.

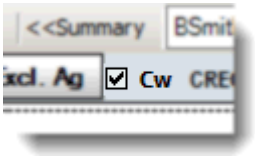
The sample is re-analyzed, and the excluded antigens are listed in the Excluded Antigens field under the analysis statistics box.

To include these antigens again, click the **Excl. Ag** button again, click **Clear** to remove antigens from the field, and then click **OK** to re-analyze with these antigens included.

Include/Exclude Cw

You can choose to include or exclude Cw antigen specificities from analysis.

1. Near the top of the analysis window, select the **Cw** check box ☑ Cw to re-analyze with Cw specificities.
2. Clear the **Cw** check box ☐ Cw to re-analyze without Cw specificities.



Raw Data Table

Positive beads are displayed in red text. Rows highlighted in yellow have normalized values over the minimum value entered in the Min Value box. Changes made to the normalization formula and minimum normalized value apply only to the raw data table and not to analysis.

1. From the analysis window, click the **Raw Data** button in the bottom right of the analysis window to display raw data table.
2. Click on a header to sort the table by that category.
3. Click ☒ in the upper right corner of the table to close the window and to return to analysis.

Raw Data Table

Raw Data Table

Sample : BSmith-01553 **Patient :** SB-2101
Session : LCT_20120330085145_LCT-60ABC_031_00 **Test Date :**
Catalog : LCT-60ABC_031_00 **Pos. Threshold :** X2

Well Position	Well Order	Cell I.D.	Raw	Rxn	S1	S2	S3	S4	S5	S6	S7	S8
1A	001	25739	6	6	A1	A2	B35	B63	Bw4	Bw6	Cw4	Cw7
1B	002	25778	1	1	A1	A23	B49	B57	Bw4		Cw7	
1C	003	25804	1	1	A1	A26	B38	B73	Bw4	Bw6	Cw12	Cw15
1D	004	25817	1	1	A1	A29	B8	B45		Bw6	Cw6	Cw7
1E	005	25826	1	1	A1	A32	B42	B44	Bw4	Bw6	Cw5	Cw17
1F	006	25796	1	1	A1	A33	B8	B62		Bw6	Cw7	Cw10
2F	007	25769	1	1	A1	A66	B50	B58	Bw4	Bw6	Cw4	Cw7
2E	008	25707	1	1	A1	A68	B7	B27	Bw4	Bw6	Cw2	
2D	009	25828	8	8	A1	A68	B18	B57	Bw4	Bw6	Cw6	Cw7
2C	010	25782	8	8	A2	A11	B13	B46	Bw4	Bw6	Cw1	Cw6
2B	011	25789	1	1	A2	A11	B13	B55	Bw4	Bw6	Cw1	Cw7
2A	012	25801	1	1	A2	A11	B56	B60		Bw6	Cw7	Cw10
3A	013	25834	6	6	A2	A11	B58	B60	Bw4	Bw6	Cw10	
3B	014	25745	1	1	A2	A23	B53	B81	Bw4	Bw6	Cw4	Cw6

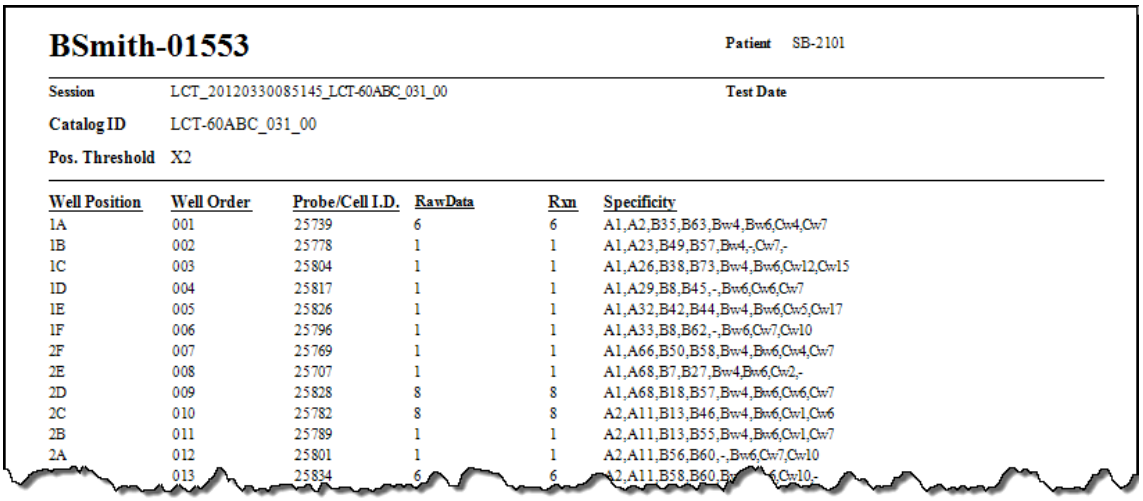
Report Print Screen Close

Raw Data Report

For easier navigation, exporting and printing, you can create a report containing raw data information for the current sample.

1. Once the Raw Data Table is displayed, click the **Report** button in the bottom right portion of the Raw Data Table window to display a report of the raw data.

LCT Raw Data Report



BSmith-01553 **Patient** SB-2101

Session LCT_20120330085145_LCT-60ABC_031_00 **Test Date**

Catalog ID LCT-60ABC_031_00

Pos. Threshold X2

Well Position	Well Order	Probe/Cell I.D.	RawData	Rxn	Specificity
1A	001	25739	6	6	A1,A2,B35,B63,Bw4,Bw6,Cw4,Cw7
1B	002	25778	1	1	A1,A23,B49,B57,Bw4,-,Cw7,-
1C	003	25804	1	1	A1,A26,B38,B73,Bw4,Bw6,Cw12,Cw15
1D	004	25817	1	1	A1,A29,B8,B45,-,Bw6,Cw6,Cw7
1E	005	25826	1	1	A1,A32,B42,B44,Bw4,Bw6,Cw5,Cw17
1F	006	25796	1	1	A1,A33,B8,B62,-,Bw6,Cw7,Cw10
2F	007	25769	1	1	A1,A66,B50,B58,Bw4,Bw6,Cw4,Cw7
2E	008	25707	1	1	A1,A68,B7,B27,Bw4,Bw6,Cw2,-
2D	009	25828	8	8	A1,A68,B18,B57,Bw4,Bw6,Cw6,Cw7
2C	010	25782	8	8	A2,A11,B13,B46,Bw4,Bw6,Cw1,Cw6
2B	011	25789	1	1	A2,A11,B13,B55,Bw4,Bw6,Cw1,Cw7
2A	012	25801	1	1	A2,A11,B56,B60,-,Bw6,Cw7,Cw10
	013	25834	6	6	A2,A11,B58,B60,Bw[illegible]6,Cw10,-

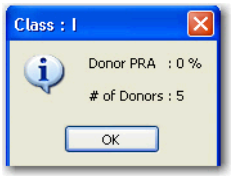
Donor PRA

You can display the percentage of PRA from available donors in the system or from selected donor groups who match the computer-assigned antibodies for the current sample.

Note: To select a donor group(s), select **Utilities > General Settings**. To create a donor group, select **Patient Info > Manage Patient**, select **Donor** in the Patient/Donor field, and fill in the donor group field.

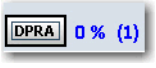
1. For Single Antigen or PRA analysis, click the **DPRA** DPRA button .

DPRA pop-up message



A pop-up box displays the percentage of matching donor PRA and the total number of donors that were considered in the calculation.

2. Click **OK** to close the box.



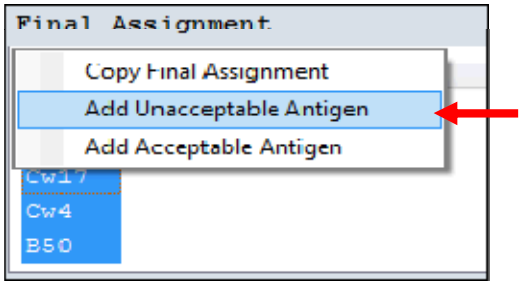
The percentage and number of donors remains displayed next to the **Donor PRA** button.

Calculated PRA

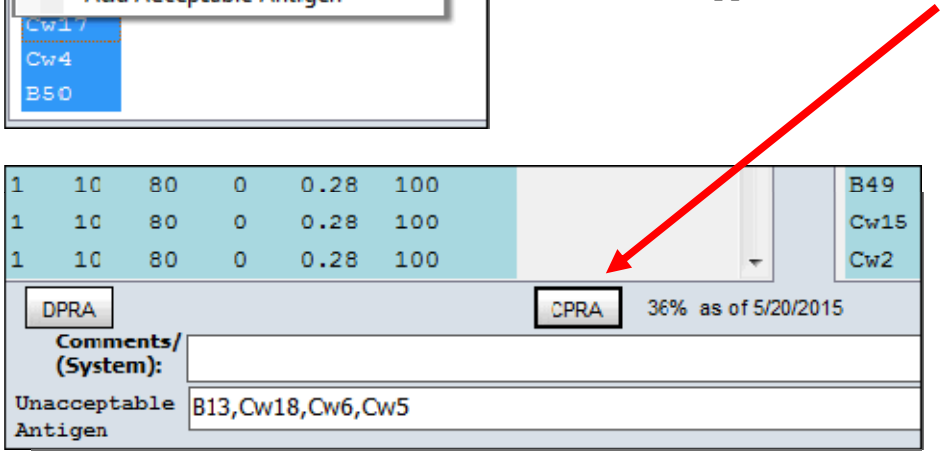
You can perform **Calculated PRA (CPRA)** analysis by clicking on the CPRA button, found to the right of the DPRA button on the lower left panel. Clicking the **CPRA button** will calculate PRA (UNOS calculator) using unacceptable antigens assigned to the patient record.

To perform **Calculated PRA (CPRA)** analysis using the unacceptable antigens for the patient,

1. From within the **Final Assignment** box, select several antigens by highlighting them, then right-click and choose **"Add Unacceptable Antigen."**



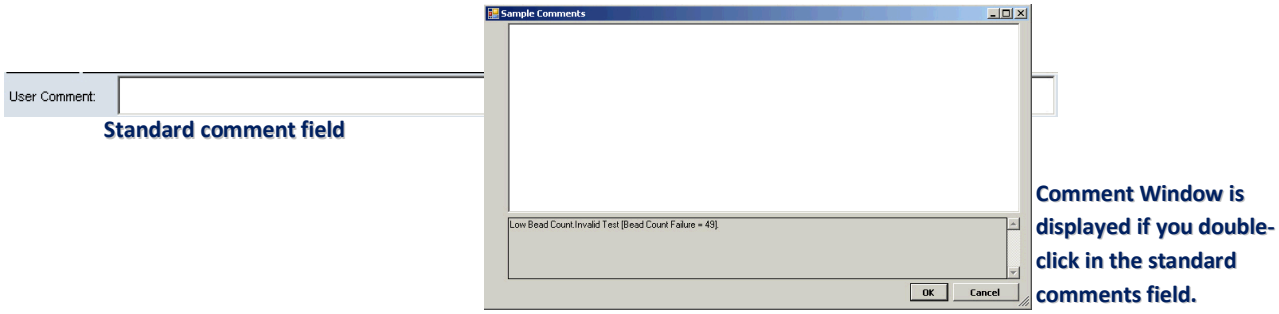
2. Click the **CPRA** button. The percentage score will appear next to the **CPRA** button.



Adding Comments to Samples

Sample comments are displayed for the sample's results in the current analysis session in all analysis, data look up and reporting functions in HLA Fusion.

1. In the analysis window, type sample comments into the **Comments** field below the Assignments area.

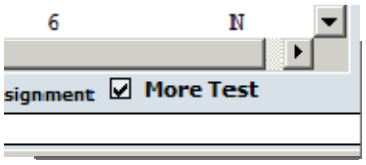


Comments are only saved when you click **Save.**

Flagging a Sample for Further Testing

Marking a sample for more testing displays the **More Tests** check box for the sample's results in the current analysis session in all analysis, data look up and reporting functions in HLA Fusion.

- In the analysis window, check the **More Tests** check box located below the Assignments area.

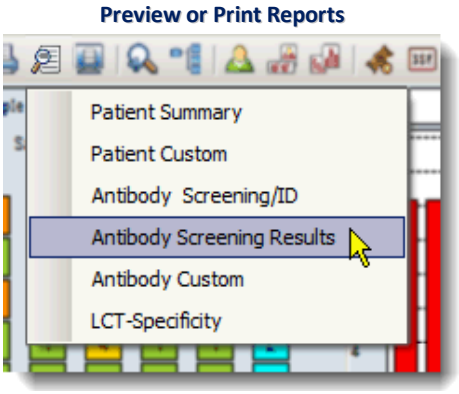


Printing the Current Analysis Window

The **Print Screen** button prints the currently displayed analysis window.

- From the analysis window, click the **Print Screen** button on the toolbar to print the current analysis screen.

Previewing and Printing Reports



To view or print an Antibody Screening Mixed Data report for the current sample, use the Preview Report button on the toolbar.

- In the analysis window, click the **Preview Report** button or **Print Report** button to display a list of reports you can print or preview for the current sample.

Making Final Assignments

Final assignments can be made from either the Tail or Epitope results lists. Once a specificity has been moved to the Final Assignments area, it is no longer displayed in its initial results box. You can select more than one specificity in a given results field by holding down the Ctrl key and clicking multiple specificities.

From the analysis window, do one of the following to make assignments:

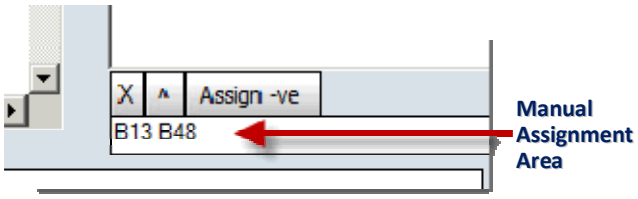
- Double-click an antigen specificity in the **Tail** or **Epitope Analysis** results box to assign the specified antigen to the **Final Assignment** field.
- Click to highlight the specificity and click the **Assign Single** button to move it to the **Final Assignment** field.
- Click the **Assign All** button to the right of the Tail or Epitope list to move all the current results on that list to the **Final Assignments** field.
- Right-click on a specificity, or CREG group on the CREG Table to assign it to the **Final Assignments** area.

Manual Assignments

Manual assignments can be entered in the field below the **Final Assignments** results field. Enter multiple manual assignments by leaving a space between each specificity.

1. From the analysis window, type a manual antigen specificity assignment in the field under the Final Assignment box.

Click the **Assign** button ^, just above the **Manual Assignment** field, to add the assignment to the **Final Assignment** results field.



Assigning Negative Sample Values

You can assign a negative value to a sample even if analysis shows some positive results.

- From the analysis window, click the **Assign -ve** button Assign -ve, located just above the Manual Assignment field, to assign all samples on the Final Assignment results box a negative value.

Removing Assignments

Specificities can be removed from the **Final Assignments** results field. You can remove more than one specificity by holding down the Ctrl Ctrl key and clicking each specificity you want to remove.

- From the analysis window, click to highlight specificities on the Final Assignment list (hold down the CTRL key to select more than one), and click the **Remove** X button, located below the Final Assignments results box.

Saving Assignments

Lab technicians and supervisors can save analysis results for further review and approval. Saved samples are available for confirmation *only* by a lab supervisor

- From the analysis window, click the **Save** button Save>>, located in the bottom right corner of the analysis window to save analysis results for all the specificities currently listed in the **Final Assignments** field.

  Fusion automatically moves you to the next sample.

For confirmation, a supervisor needs to access the sample for which you saved the assignments. You can return to the sample any time prior to confirmation if you need to make changes. Click the **Reanalyze** Reanalyze button and then the **Save** Save>> button again.

Confirming Assignments

Lab supervisors can confirm analysis results. When they do so, samples are marked as *Confirmed*. The **Confirm** button is purple when you view a confirmed sample.

- From the analysis window, click the **Confirm** button Confirm>>, located in the bottom right corner of the window, to confirm all analysis results that have been saved in the Final Assignments results box.

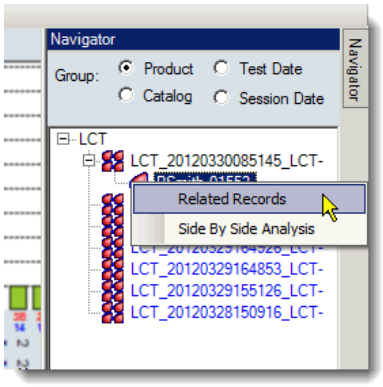
  You automatically move to the next sample to continue confirming results.

  When you first return to a confirmed sample, you see that the **Confirm** button is now shaded purple Confirm>> to let you know it has been confirmed before.

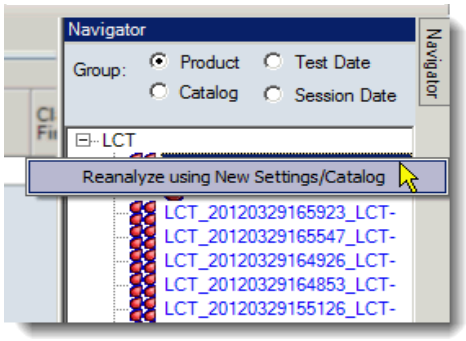
Navigator Right-Click Menu Options for LCT Sessions

Analysis options are available through the Navigator—whether you are in the LCT session summary view or on an analysis screen for a sample. By right-clicking on either a session or a sample in the Navigator window when either a session summary or analysis window is displayed, you access menu options that allow you to affect your LCT analysis sessions before or during analysis.

Right-click (Sample-level) **options**



Right-click (Session-level) **options**



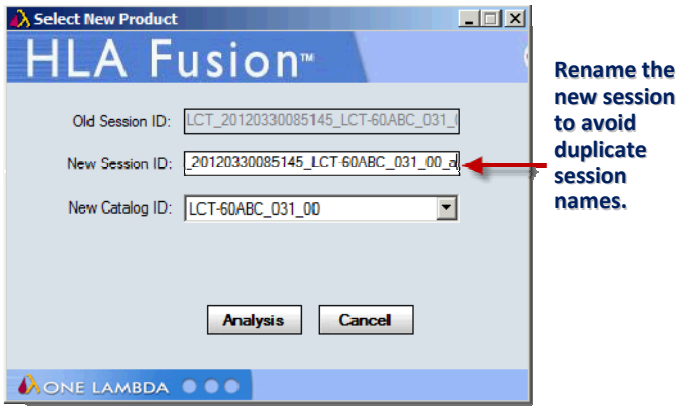
Reanalyze with New Catalog

Allows the session to by re-analyzed using a new or updated catalog file.

1. Rename the session.
2. Click the drop-down arrow in the **New Catalog ID** field, and select a new catalog from the list.
3. Click the **Analysis** button.

The session on which you right-clicked is reanalyzed with the catalog file you just selected.

Reanalyze with a new catalog



Sample-Level Options

The **Related Records** and **Side By Side Analysis** menu options are available if you right-click on an active sample in the Navigator (first activate the sample with a left click):

Related Records

A related record is a record that is associated with the current sample by patient or sample ID.

Note: This option is also available by using the **Related Records** toolbar button .

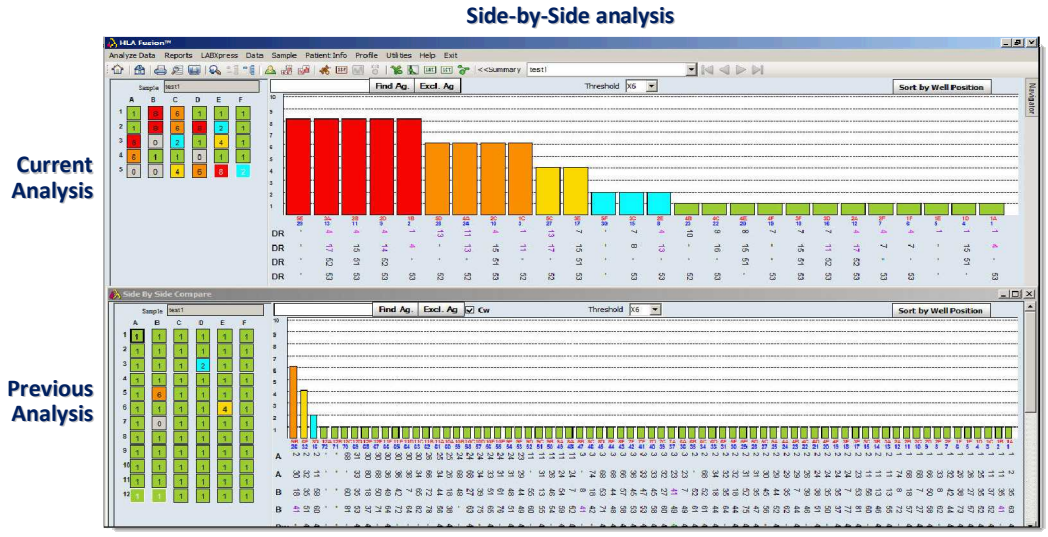
- Select this menu option to load all records related to the current sample into the Sample drop-down list. Use the sample navigation arrows to display the analysis of each related record one by one.
- To go back to viewing the samples in the current sessions, click the **<<Summary** link at the top of the window.

Side By Side Analysis

Use this option compare the current sample analysis with one previously conducted.

Note: This option is also available by using the **Side By Side Analysis** toolbar button .

Side-by-Side analysis



1. Right-click a sample from the Navigator. A list of available samples is displayed.
2. Select a previous sample analysis from the displayed list to compare to the current one. The two analysis windows are then displayed in a comparison window. Each window can be resized and moved by dragging and dropping. Click the **Side By Side Analysis** toolbar button to cancel the comparison display.

Reports

HLA Fusion™ provides different report formats in which to output your analysis data and results. From the Reports menu you can do the following:

- Create, print and export reports for analysis data for all supported products.
- Create custom reports for which you determine content type.
- Create reports for electronic submission, such as NMDP HML reports.
- Store as many as 18 reports in a My Favorites list for convenient access.
- Modify the appearance of any report, such as fonts, formatting, and background colors, (supervisors only).

In addition, the following are a few considerations before you create reports in HLA Fusion:

- The report date is in a different font than the other report contents. This is by design to allow the Crystal Reports date field to be displayed in PDF format in various language and regional settings.
- Please verify the reports and the data during the installation and validation process.
- All report files are made available to you so that you can arrange and size the fields to meet your needs.

Note: To view reports, your computer must have some form of printer driver installed. If you do not have a printer driver installed, you can download a free copy of PDF Distiller from Adobe.com, or Microsoft Office Document Image Writer from Microsoft.com. In addition, you can print and export these reports from the analysis or batch summary window.

Sample IDs, Patient IDs, Well IDs, Alleles, Serology, and so forth are sorted alphanumerically in reports, just as they are on other HLA Fusion forms and lists.

Using the Reports Window

The following sections describe how to create, save and print a report containing your analysis data. Here are the main steps you must take to create a report from this window:

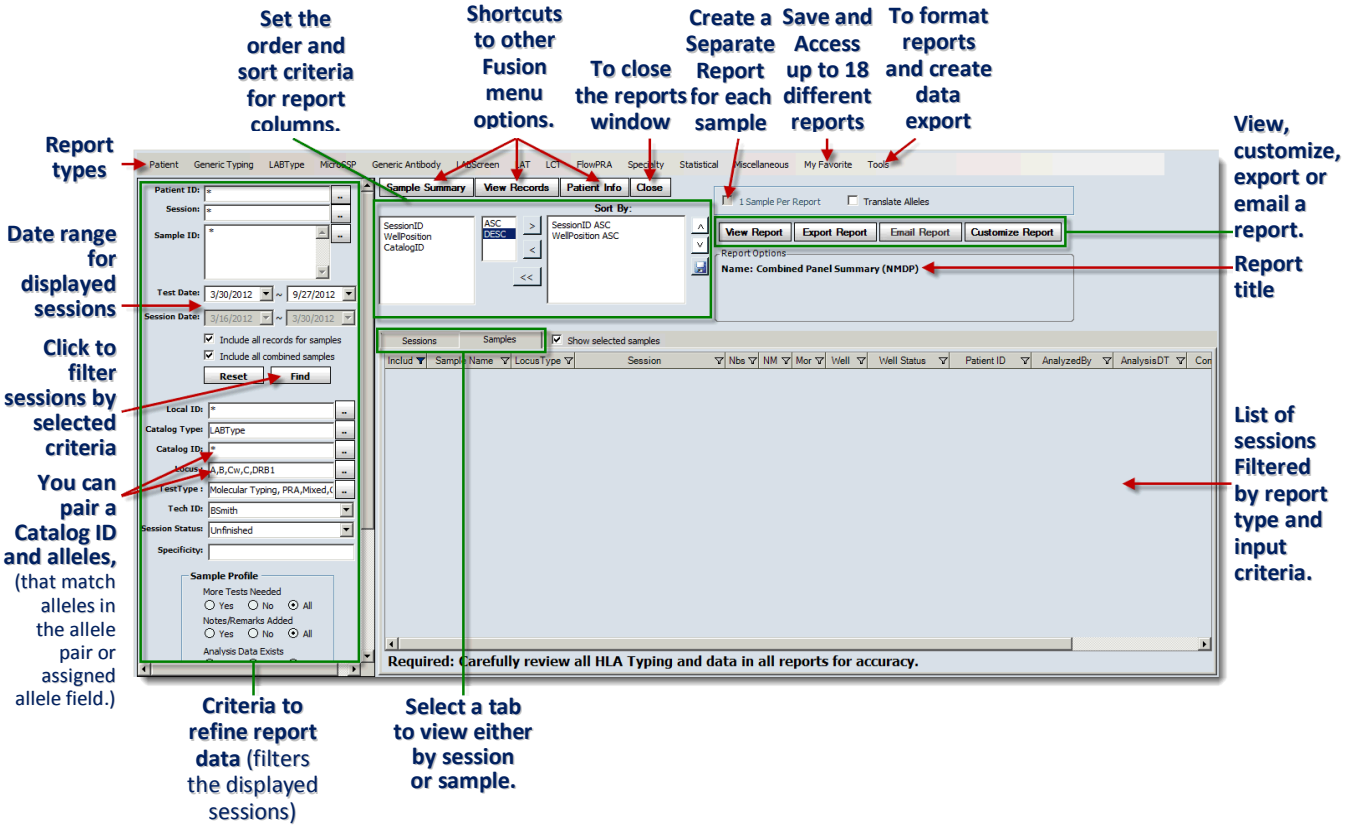
1. Select a report type.
1. As needed, select criteria to refine report input, such as date range.
2. Select the sessions or samples to include in the report.
3. Select the **View Report** or the **Export Report** button

Accessing the Reports Window

Access the Reports window in one of two ways:

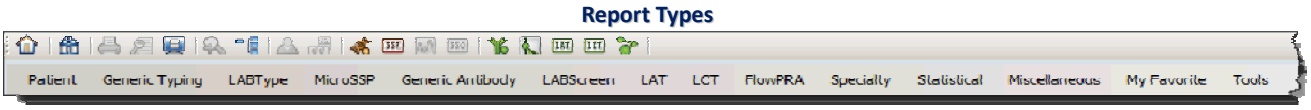
- On the home page, click **Reports** Reports button on the Fusion Explorer.
- Or click , Reports on the Fusion menu bar.

The **Reports** window is displayed, with a list of any sessions that fall within the date range (based on the session date range set in the Find dialog box). If no session are displayed, try modifying the date range.



Select Report Type

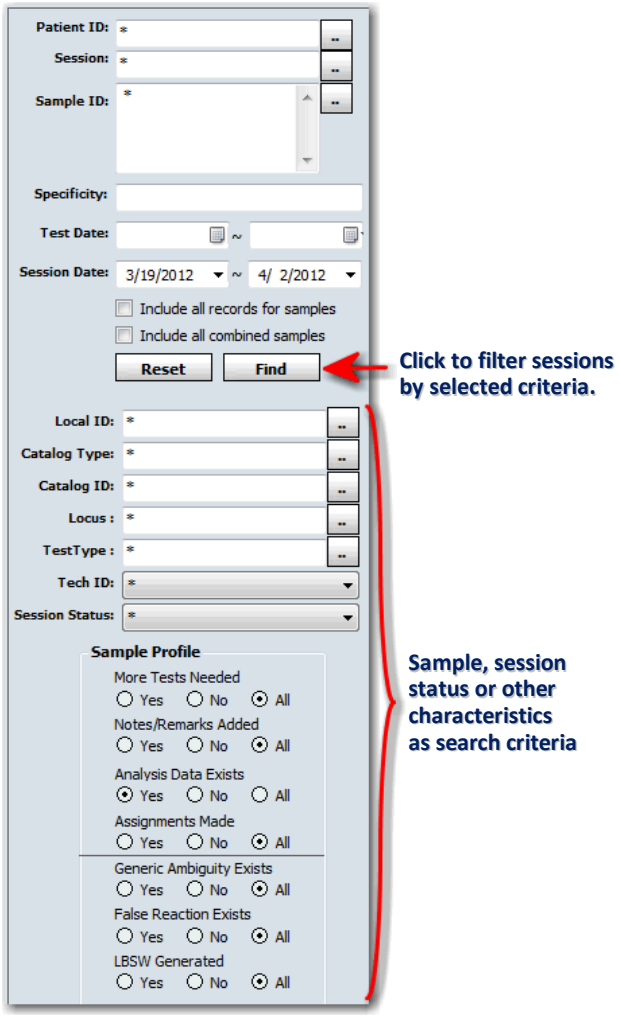
- Select a report from the report type menu options displayed at the top of the **Reports** window. The list of sessions in the right pane of the Reports window is filtered to display only the ones related to the selected report type.



Refine Report Input

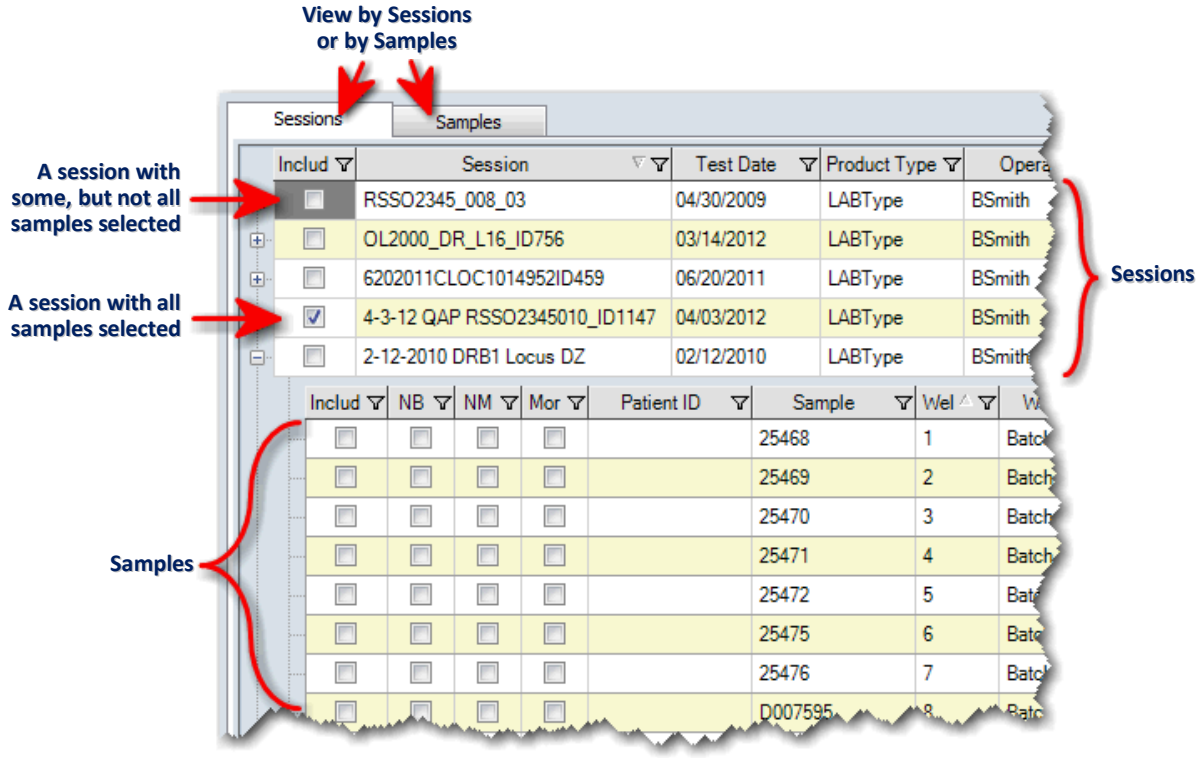
If needed, use the left panel of the **Reports** window, to further filter the sessions you want to include in your report. There are a number of criteria you can set:

1. Enter a Patient ID, Session or Sample ID fields, or browse for the information with the **Browse** ... button.
2. Adjust the date range. Use the drop-down calendars in the **Session Date** fields to select a different start and end date.
3. Enter or browse for specific sample or session characteristics or status (see below).
4. Once you set criteria and click the **Find** button on the left panel of the **Reports** window, the session list in the right panel of the window filters accordingly.



Session/Sample Selection

- In the Samples/Sessions list, click the + sign next to any session to expand the display to show its samples.

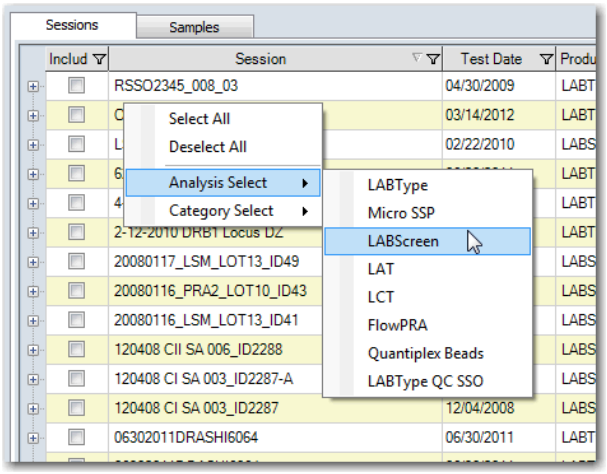


1. Select the check boxes next to each sample you want to include in a report. Select the check box next to a session ID to include all of its samples. (Deselect the check box of any sample or session you do not want to include in the report.)

2. If at least one sample has been selected for a session, the **Include** cell for that session is highlighted with grey. If all samples for a session are selected, there is a check box in the Include In cell.

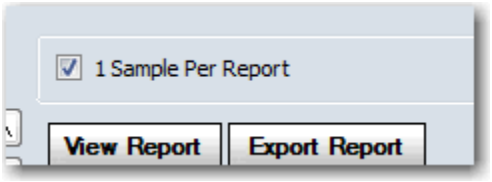
3. (Optional) To view all the samples available, or to view only the samples you have selected so far, click the **Samples** tab and select or deselect the check box for **Show selected samples**.

4. Alternatively, you can right-click on a session or sample and apply one of the following:



- **Select All:** select all sessions and samples for inclusion in the report.
- **Deselect All:** deselect all sessions and samples from inclusion in the report.
- **Analysis Select:** specify the analysis product report type (LABType, Micro SSP, LABScreen, etc.)
- **Category Select:** choose the report category—molecular or antibody.

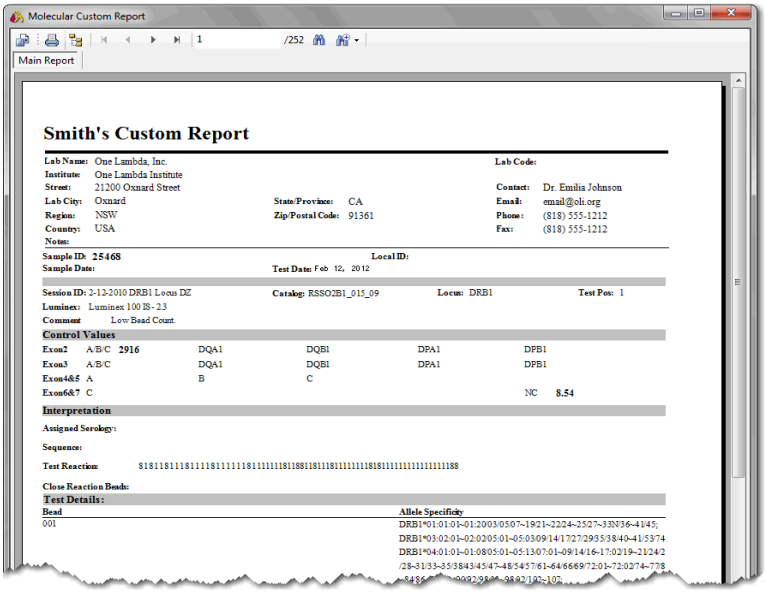
Note: To create a separate report for each selected sample, select the check box next to **1 Sample per Report**.



View, Print or Export Reports

- Once you have the report type and all the samples selected, click **View Report**. The report is displayed in a separate window, the **Report Viewer**.

Example of a report viewed in the Report Viewer



The Report Viewer contains various toolbar buttons to allow you to export, print and navigate through your report.

The functionality of these buttons is described in the following table:

Report Viewer Toolbar

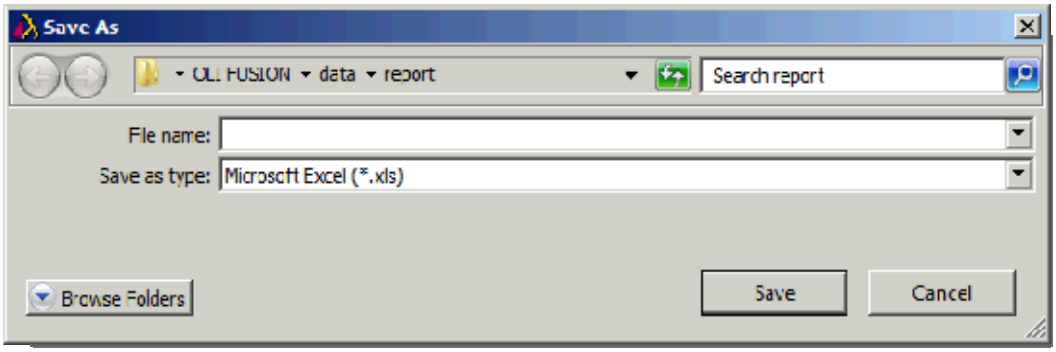
Toolbar Button	What it Does
	**Export Report:** Exports reports in one of several available formats including, Crystal Reports, PDF and Microsoft Word.
	**Print Report:** Sends the current report directly to the printer.
	**Toggle Group Tree:** Opens a *tree panel* on the left side of the Report Viewer window which lists all the samples included in the current report.
	**Report Page Navigator:** If the report has multiple pages, these buttons allow you to move to the first page, the next page, the previous page or the last page.
	**Find Text:** Clicking this button opens a text box which allows you to search and find text throughout the report.
	**Zoom:** Click the down arrow on this button to choose a zoom setting, view an entire report page, or view by the report page's width.

To close the **Report Viewer** window, click the **Close** button  in upper right corner of the viewer.

Export Report

1. Click the **Export Report** button  when you want to export a report in one of several standard formats. The **Select Output Directory and Save Type** dialog box is displayed.

Exported report destination/file save as type screen



1. Enter a name for the current exported report, or browse for a report file to export.
2. Select a format from the **Save as type** drop-down list (Excel, Acrobat, Word, or Rich Text format).
3. Click **OK**. By default, the file is saved in `C:\OLI Fusion\data\report`).

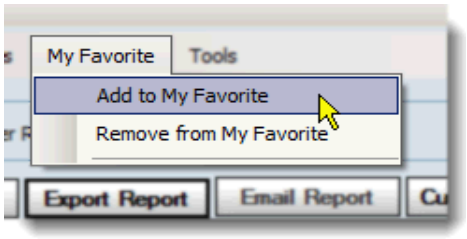
Accessing Reports from the My Favorite Menu

The **My Favorite** menu is a convenient way for you to access and generate the reports you use most. You can make as many as 18 report types available from the **My Favorite** drop-down, including custom reports. Adding to or deleting from the list is easy.

Adding Reports to My Favorite

1. Make sure you have selected the report you want to add to **My Favorite** (verify that its name is displayed in the **Report Options** section of the Reports window).

Add a new report to the My Favorites menu.

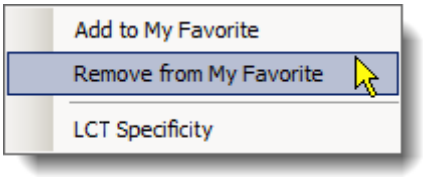


2. Select **My Favorite > Add to My Favorite**.

The current report name is added to your **My Favorite** menu. When you want to generate this report, just click on its name from the bottom portion of the **My Favorite** menu.

Removing Reports from My Favorite

1. Select **My Favorite,** and select the report you want to remove from the list of reports at the bottom of the menu. The **My Favorite** menu closes.
2. Select **My Favorite > Remove from My Favorite**.



The report you selected in step 1 is no longer displayed at the bottom of the **My Favorite** menu.

Reports Tools

Customizing Report Appearance

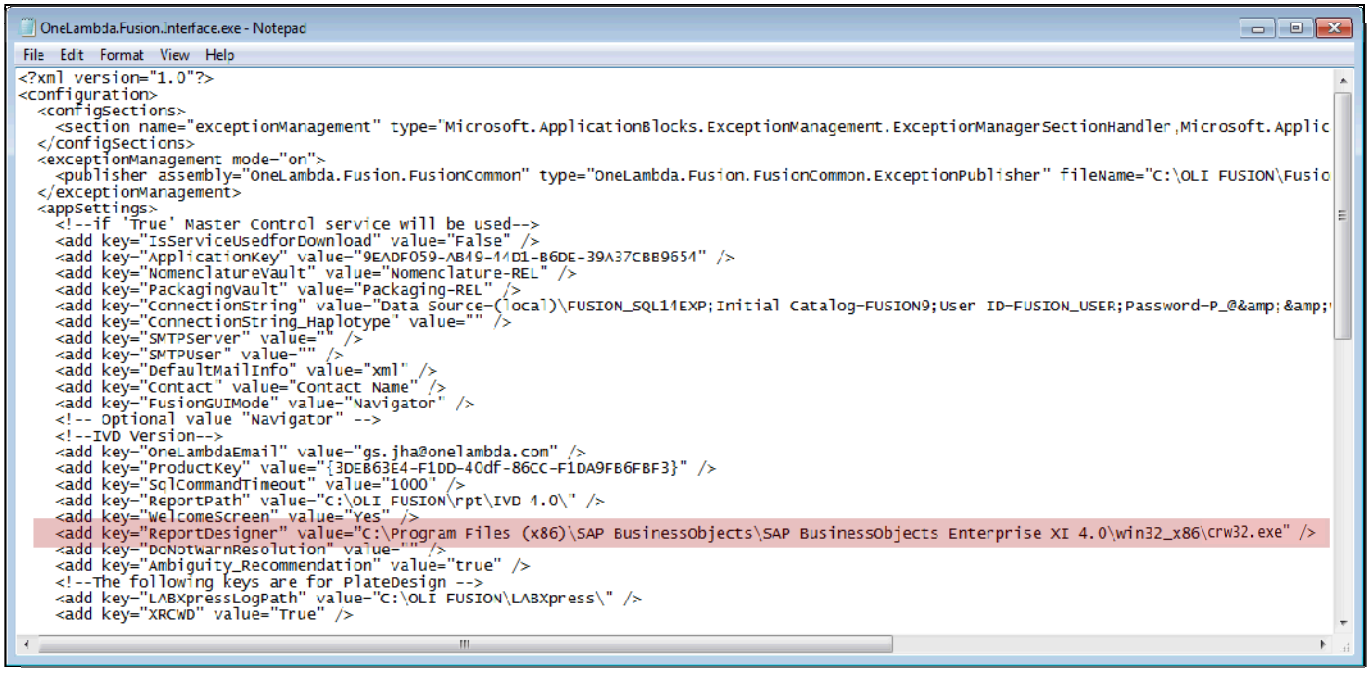
Note: You must be a supervisor-level user in HLA Fusion and have Crystal Report Designer software installed on your computer to use this feature.

This feature allows you to format the appearance of HLA Fusion reports to meet your specific needs. For example, you can change fonts, size and color as well as the location of text and data fields on the report.

- HLA Fusion automatically launches the report designer if it is installed in the default directory (`C:\Program Files (x86)\SAP BusinessObjects\SAP BusinessObjects Enterprise XI 4.0\win32_x86\crw32.exe`).
- Use Notepad to open the *OneLambda.Fusion.Interface.exe* configuration file, located **in `C:\Program Files (x86)\One Lambda\HLA Fusion 4.0`.** Make sure that the Crystal Reports Designer path name is entered on the following line of this file (see figure below):

  `<add key="ReportDesigner" value="C:\Program Files (x86)\SAP BusinessObjects\SAP BusinessObjects Enterprise XI 4.0\win32_x86\crw32.exe" />`

Editing OneLambda.Fusion.Interface.exe



- Please note that all the report files used in HLA Fusion are installed in the directory C:\OLI Fusion\rpt\IVD 4.0, and they all have the extension of .rpt. These files can be moved anywhere for central access, but to do so, you must update the location (path) in the *OneLambda.Fusion.Interface.exe* file.
- When you open a report to customize it, a backup copy is automatically created with the timestamp as the suffix of the report name. This allows you to retrieve the original report format, if needed.

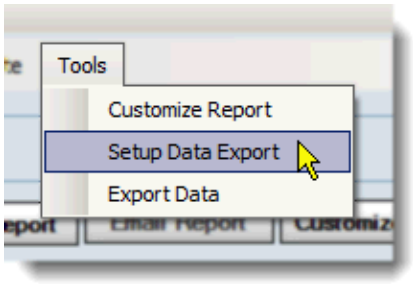
1. Select **Reports > Tools > Customize Report**.

Use the Crystal Report Designer tools to modify the appearance of your report.

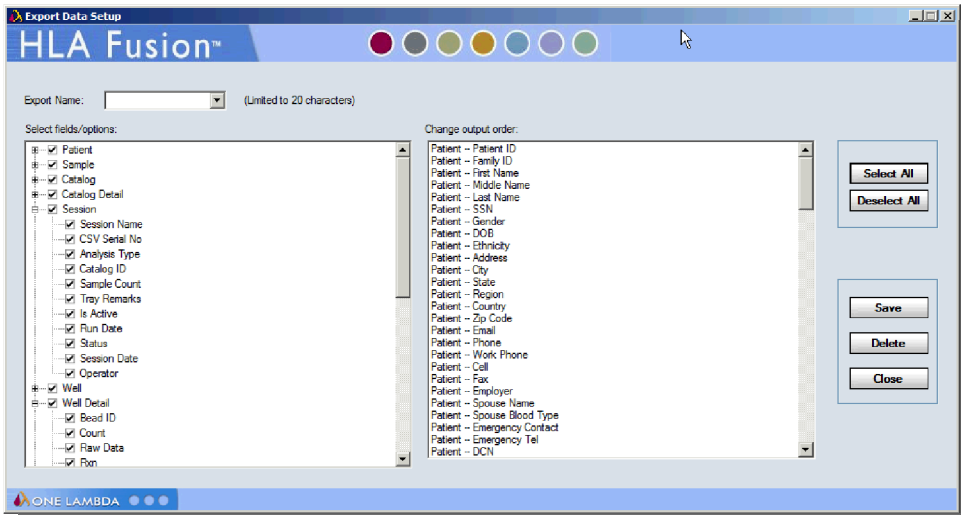
Once you have made changes to the report format, save it. Make sure you do not change the name of the report file. Next time you run this report in HLA Fusion, the report will have the appearance you last saved in Crystal Report Designer.

Creating Custom Data Export Templates

1. Select **Tools > Setup Export** to customize report data export by setting up templates that determine the type of report data (session, sample, patient, results, etc.) is exported when you select that template.



The **Export Data Setup** dialog box is displayed, allowing you to select the name of the export template, the fields to be included, and the field order you want for the template. Select check boxes on the left to select category and fields. On the right side of the dialog box, drag and drop the fields, or hold CTRL and press the Up/Down arrow keys to change the order.

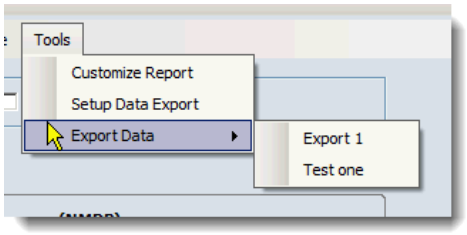


Export Data Setup screen

2. When you are done, click the **Save** button.

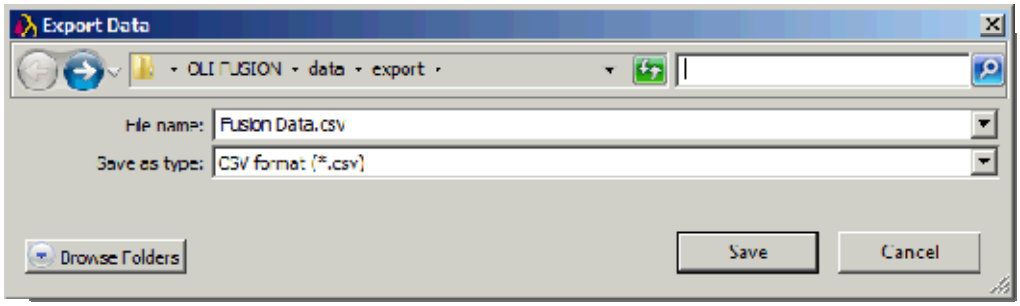
The new template is added to available export templates from the **Tools > Export Data** menu.

Export Data – Select template



3. When you are ready to export data, first select all the sessions you want to include from the available list. Then, select **Tools > Export Data**, and select one of the templates. The **Export Data** dialog box is displayed.

Export Data – file save location



4. Select the format for the exported data—XML, CSV or Text. The exported data file is saved by default in `C:\OLI Fusion\data\export`.

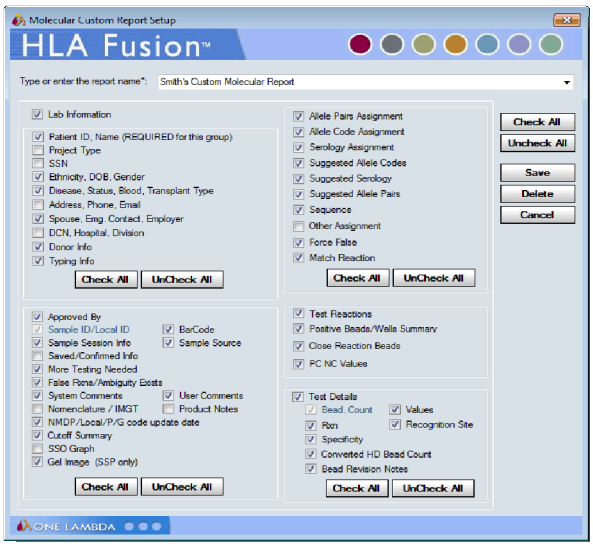
Creating Custom Reports

Certain report types allow you to customize the types of fields to include.

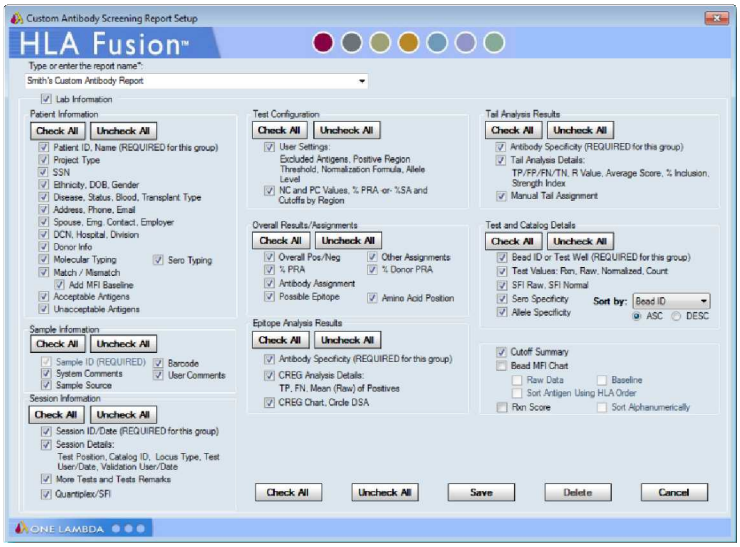
Note: For Molecular Custom or Antibody Custom reports, you must make sure the *Free 3 of 9 Extended* font is installed on your computer—otherwise, the barcode is not recognized. If needed, you can download this font for free at http://www.free-barcode-font.com/.

1. To create a custom report, select a report type containing the word "Custom" in its name, (e.g., *Molecular Custom*, under the **Generic Typing** report type menu).

2. Click the **Setup** button in the Report Option section of the window.



Molecular Custom report setup screen



Antibody Custom report setup screen

The **Custom Report Setup** window is displayed, allowing you to customize report content by selecting from various categories and fields.

Custom Molecular and Antibody Report Setup

1. Enter a name or select one from the drop-down list.
2. Select the check box next to each field you want to include in this report.

Note: To include all related fields, you can click the **Check All** button to select all the fields in the category.

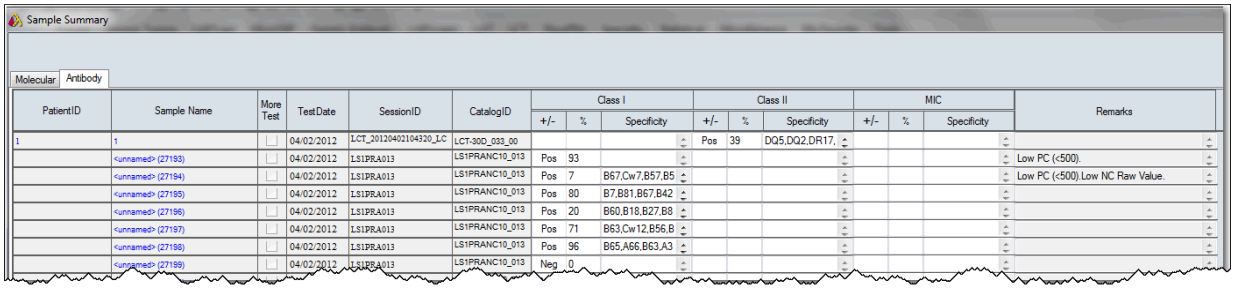
3. Click the **Save** Save button to save the custom report setup you have just selected.

Sample Summary

The Sample Summary feature lists multiple samples and their typing results.

- Select samples using the **Reports** window.
- Click the **Sample Summary** button. The **Sample Summary** window is displayed; it contains two tabs— **Molecular** and **Antibody**.

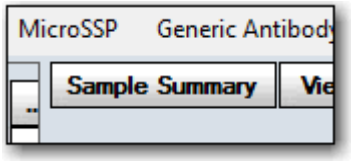
Sample Summary window



Molecular Typing Sample Summary

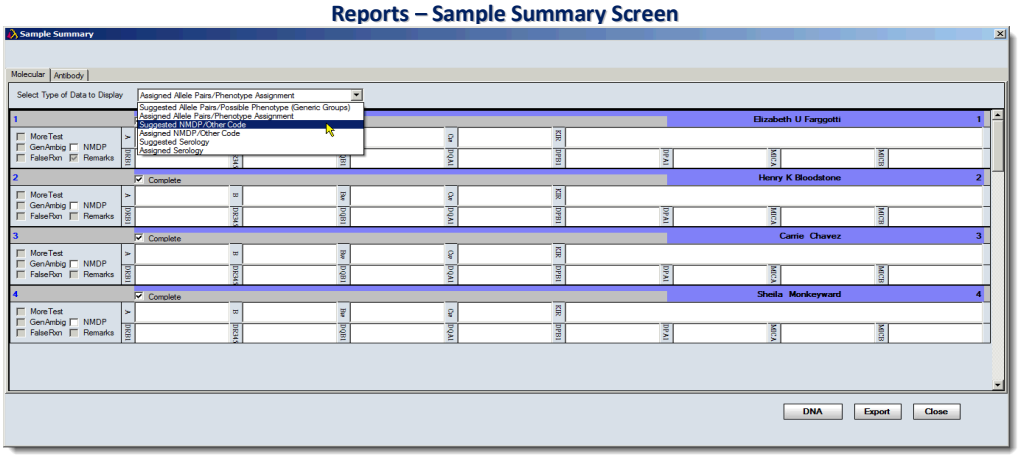
Selected antigen typing records are displayed on the Molecular tab of the Sample Summary screen. You can view typing information in a condensed format, as well as display more details for any sample.

1. Select samples using the **Reports** window.
2. Click the **Sample Summary** button. The default tab is **Molecular**.



3. Select an option from the **Select Type of Data to Display** drop-down list.

Reports – Sample Summary Screen



The window displayed depends on the option selected.

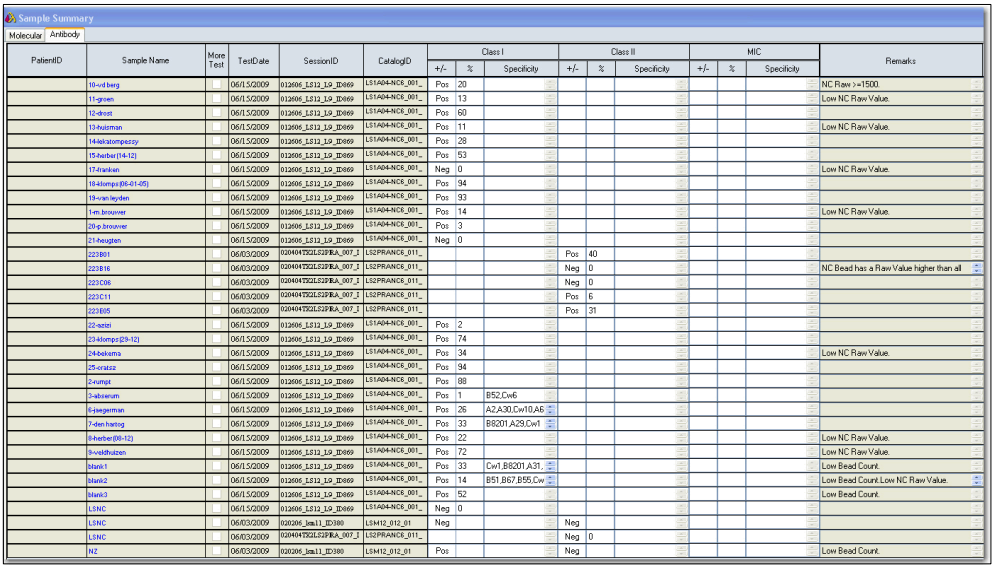
- Click the **Export** Export button to export the displayed data as an Excel file.
- Click the **DNA** DNA button to export molecular specificities as an Excel file.

4. Click the **Close** button ☒ in the upper right corner of the window to close and return to the **Reports** window.

Antibody Screening Sample Summary

Any selected antibody screening records are displayed on the Antibody tab of the Sample Summary screen. You can view screening information in a condensed format, as well as display more details for any sample.

1. Select samples using the **Reports** window.
2. Click the **Sample Summary** Sample Summary button.
3. Click the **Antibody** tab.



Reports – Sample Summary Screen

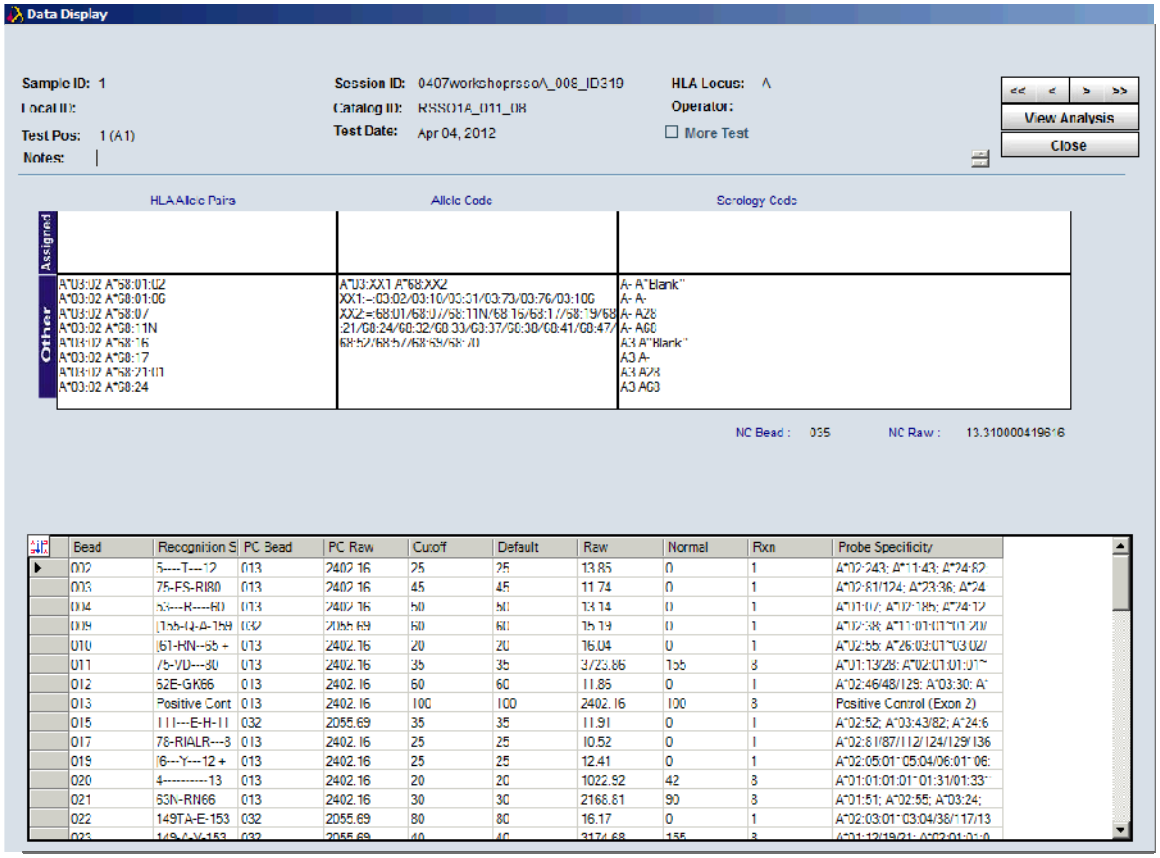
- Click the **Export** Export button to export the displayed data as an Excel file.
- Click the **DNA** button to export molecular specificities as an Excel file.

4. Click the **Close** button ☒ in the upper-right of the window to close and return to the **Reports** window.

View Records

The View Records feature presents typing results and analysis details for each sample selected. Sample information is shown for one sample at a time. From the View Records menu, you can view screening and typing records individually.

1. Select data records using the **Reports** window.



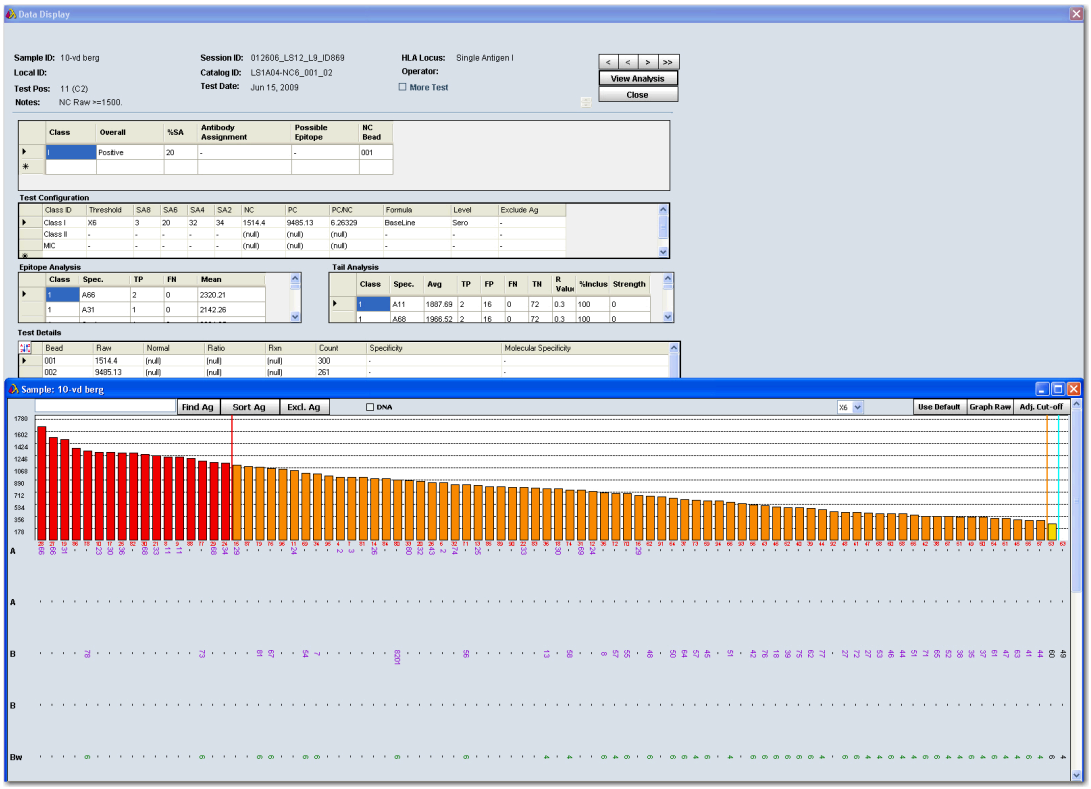
Reports – View Records Screen

2. Click the **View Records**  button.

3. Use the arrow buttons  to navigate through samples.

4. Click the **View Analysis** button  to open the analysis window for the current sample. The analysis window can be resized.

Reports – View Records Screen



5. Click the **Close** Close button to close the window and return to the **Reports** window.

Patient Info

You can view patient records associated with selected samples by clicking on the Patient Info tab. Patient information can also be viewed by patient ID using the Patient look up function of the Patient Management menu. From the **Patient Info** menu, you can view Patient/Donor records.

To view patient information, you must select a sample(s). You can view, but not edit the displayed information.

1. Select sessions or samples from the **Reports** window that have an associated Patient/Donor ID.
2. Click the **Patient Info** button Patient Info.

The Patient/Donor information screen is displayed.

Patient Information Screen

3. Click the **Test Info** tab to see that information for the current patient/donor. If more than one information card is displayed, use the arrow buttons to navigate through the patient records.

4. Click the **Close** button in the upper right corner to close and return to the **Reports** window.

Audit Trail Report

You can view and print a report of user activity for the current database. This data is only available if you have done the following:

- Set up and connected to an audit trail database (see the *HLA Fusion Database Utility User Manual*).
- Enabled Audit Logging from the HLA Fusion default home page.

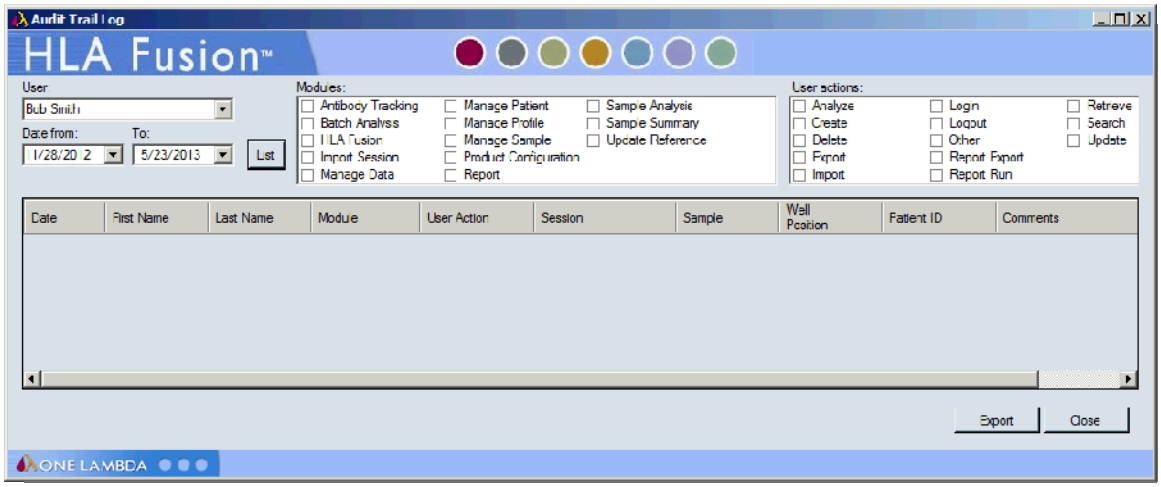
Once you have completed the above, and wish to view audit log data, take the following steps:

Access the Reports window in one of two ways:

- From the home page, click **Create Reports.**
- From the Fusion main menu options, select **Reports.**

Select **Miscellaneous > Audit Trail Log**. The Audit Trail Log dialog box displays.

Audit Trail Log Screen



- Use the drop-down arrow to select the User for whom you want to see database actions.
- Select the date range and options you want the report to include.

Click **List** List to see the report. If you want to export the audit trail report to Excel, click **Export** Export.

Report Types

There are several report types available. Although most report types are listed in this section, please note that because new reports are sometimes added between updates to this user manual, you may see more reports listed in the software.

Patient - (all patients in the Fusion database)

- *Patient Summary* - (summary of typing and antibody testing results associated with a patient)
- *Patient Typing for Batch* - (typing summary report over different loci for a set of samples, based on a selected session)
- *Patient Custom* - (you select the type of patient data to include for the selected samples)

Generic Typing - (typing data from analyzed LABType and MicroSSP samples)

- *Molecular Custom* - (you select the type of molecular data to include for a set of samples)
- *Custom Typing Results by Sample* - (you select the type of molecular data to include for selected samples)
- *Consensys Custom Report*
- *Allele Summary* - (typing report of possible allele pairs and assigned allele code results for a set of samples)
- *Allele Code* - (typing report of possible allele codes and assigned allele code results for a set of samples)
- *Molecular Typing Summary* - (typing report of the possible allele code, assigned allele code, assigned allele pairs, assigned serology, and other assignments for a set of samples)
- *Combined Sample – Generic Typing*

LABType - (data from analyzed LABType samples)

- *Panel Summary* - (report of the final NMDP coded assignment and the positive probes for a set of sample in a session)
- *QC Overview* - (summary of samples with low bead count, low positive control, pre-analysis global cutoff changes, as well as sample specific changes for a session of samples)
- *Combined Panel Summary (NMDP)* - (spreadsheet of final NMDP code assignments for single or multiple sessions)
- *Combined Sample* - LABType

MicroSSP - (data from analyzed Micro SSP samples)

- *SSP Report* - (detailed typing report for Micro SSP™ tests that may be customized)
- *Custom SSP Report*

Generic Antibody - (antibody data from analyzed LABScreen, FlowPRA, LAT or LCT samples)

- *Antibody Custom* - (User may customize a report for antibody data for a set of samples)
- *Antibody Screening/ID* - (antibody data report that is fixed in format)
- *Antibody Screening Results* - (summary table for a selected set of samples which includes the overall final results made, %PRA, other assignments, and comments)

LABScreen - (data from analyzed LABScreen samples)

- *LSM Detail* (detailed test information for antibody mixed analysis records)
- *LSM Summary* (overall test results for antibody mixed analysis records)
- *LSM Overview* (overall tests results for antibody mixed analysis records including total number of positive, negative and undetermined results. User may select the highest or lowest bead ratio found for each sample)
- *Product Comparison*

LAT - (data from analyzed LAT samples)

- *LAT Custom*
- *LAT-Mixed Raw Data* (results of multiple samples on an LAT-Mixed analysis tray, including a tray layout of the original raw data input and test results)
- *LAT-Mixed* (results of a single sample on an LAT-Mixed analysis tray, including a tray layout of the original raw data input and test results)
- *LAT-Specificity Raw Data* (Raw data results for LAT specificity or HD trays, including a tray layout of the original raw data input and test results)
- *LAT Specificity* (complete specificity report for LAT specificity and HD trays, including overall, tail, epitope, manual tail assignments, and test details)

LCT - (data from analyzed LCT samples)

- *LCT Custom*
- *LCT Specificity* (test details of a single sample on an LCT analysis tray)

FlowPRA - (data from analyzed FlowPRA samples)

- *Flow PRA Custom*
- *Flow PRA Specificity (test details of a single sample on a FlowPRA® analysis tray)*

Specialty - (reports created for specialized purpose)

- *Export Date*
- *User Reports (the following is a partial list of such reports)*
- *Antibody Reaction* - (summary table of computer specificity assignments based on reaction scores)
- *SCORE* - (export report used by SCORE software)
- *LABType* - (export report covering LABType results)
- *LABScreen* - (export report covering LABScreen results)
    - *Reaction Assignment Report* - (export report including sample ID and reaction string)
    - *NMDP Code Report*

The following specialty reports are customized for specific users:

- *LBSW*
- *HML Vo.2*
- *HML Vo.3*
- *LC*
- *NBS*
- *Thai Export*
- *UMC-Utrecht Report*
- *BML*
- *ABMDR*
- *CMDP*

Statistical - (statistical or aggregate data for trending, measurement, monitoring, etc.)

- *Allele Group Frequency* (displays the frequency of allele groups based on the first two digits of an allele assignment for selected sessions or the database)

- *Allele Group Frequency Extended* - (displays the frequency of allele groups based on NMDP code results or allelic level assignment for selected sessions or the database)
- *Cutoff Adjustment Summary* (summary of all cutoff changes made for selected sessions or based on a specific catalog file)

Miscellaneous - (reports that do not fall into one of the above categories)

- *Database Information* (describes the usage of the current database)
- *Batch Data File Summary* (a log of the status of all the sessions run in the system)
- *Serological Equivalent* (list of alleles and their serological equivalent definitions)
- *NMDP Code* (list of NMDP codes and their allele definition)
- *Typing Query* (database search report that lists the samples found for a selected allele)
- *Audit Trail Log* (a log with all specified activity for a selected users in the current Fusion database)

My Favorite - (any of the above reports saved in a favorites list)

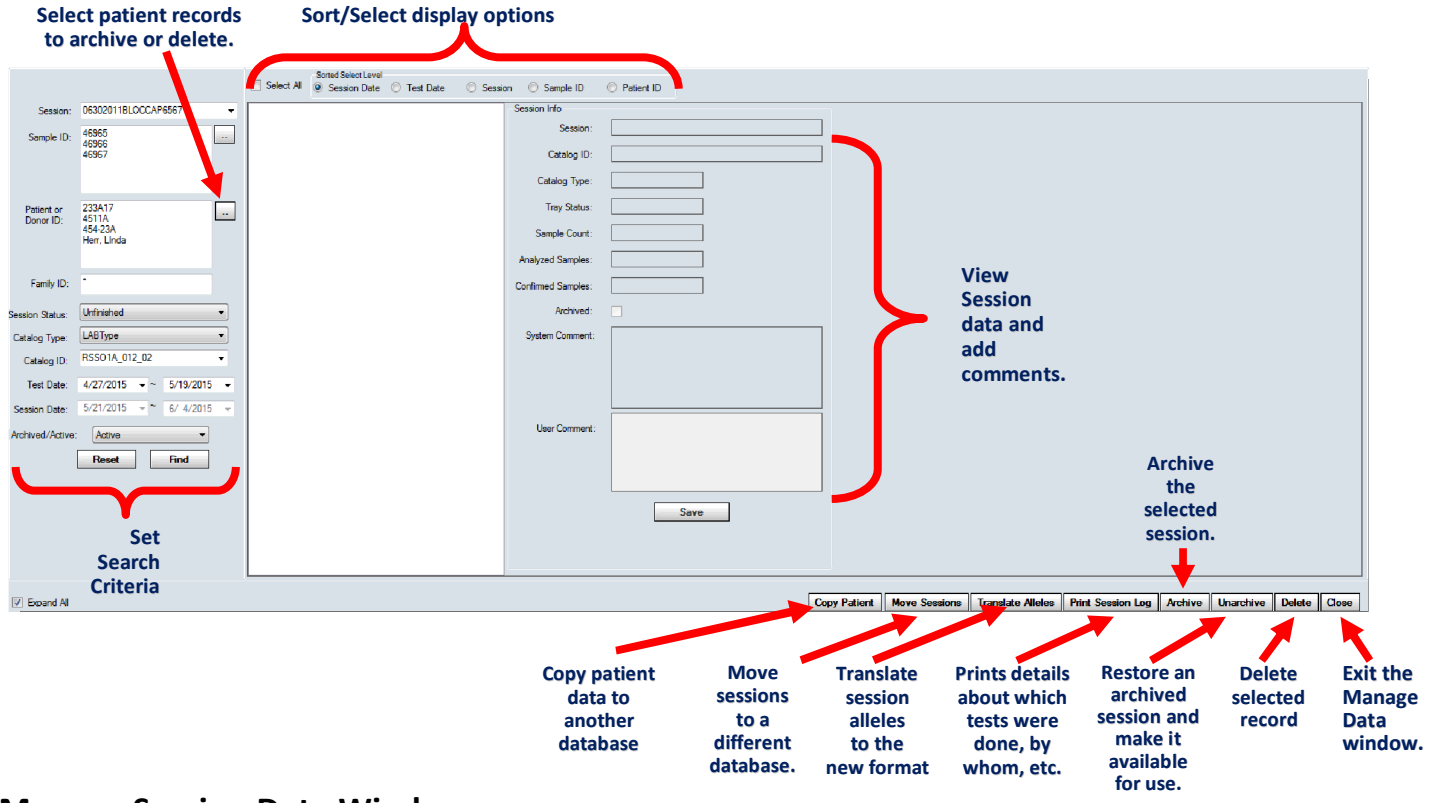
- Reports listed depend on what you have stored under this menu.

Data Management

When you select the Data menu item, a window is displayed that allows you to manage session files, as well as create log files of session data. From this menu, you can delete, archive, activate, and move sessions to a different database. You can also map the alleles in a session to the new nomenclature format.

Session Management

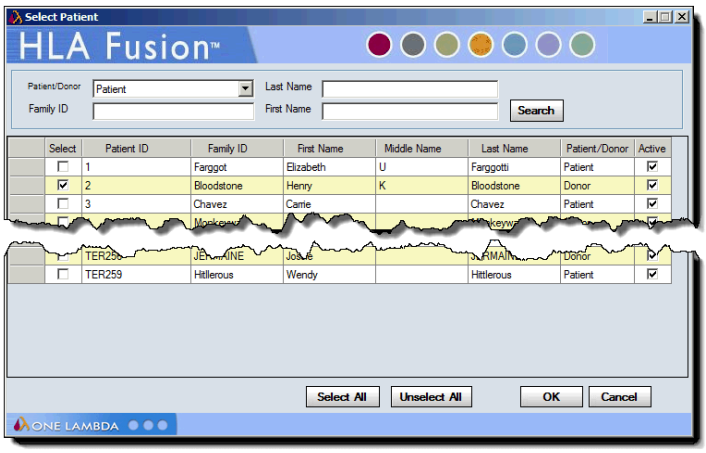
To manage your data at the session level, use the **Data** option from the HLA Fusion main menu. When you select the **Data** main menu, the Manage Data window is displayed.



Manage Session Data Window

- When you click **Translate Alleles** Translate Alleles, all final allele pairs and code for the selected sessions are converted to the new nomenclature format and stored in the database.

- When you click **Move Sessions** Move Sessions, you can select another Fusion database to which the selected sessions are moved.



HLA Fusion allows you the capability to create log files of your selected analysis sessions, which you can then print or archive.

1. Provide all necessary session input information by using the drop-down menus and search buttons on the left side of the Data window.

Once a session is selected, its information is displayed on the right side of the window, the **Session Info** pane, where you can add information.

2. Once you have all information you want to include in the log, click **Save**.

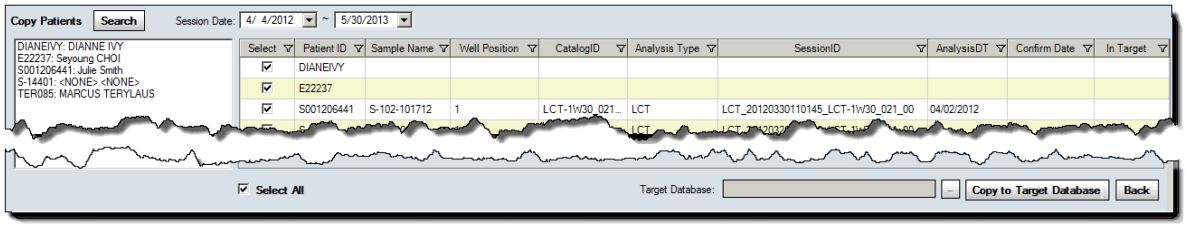
Once you have displayed the session log you want, use the **Print Session Log, Archive**, **Active** and **Delete** buttons at the bottom of the window to manage the log.

Note: Samples can also be deleted individually, without the need to delete an entire session. The only exception are LABType or Micro SSP samples that have been combined.

HLA Fusion allows you to move patient records.

1. Select **Patient ID** as the Sorted Select Level. The Select Patient window is displayed.
2. Select one or more patients.

   The following window displays:



3. Select browse (**...**) in the **Target Database** field to select the database to which you want to move the selected patient records.
4. Once you have selected the target database, click **Send to Target Database**.

Sample Management

In HLA Fusion, sample lists are an easy way to input a large list of sample IDs and other sample information into the database for use in analysis sessions. Sample lists may be in .xls, CSV or .txt file format. From the Sample List Import menu, you can import sample lists or edit sample lists prior to importation.

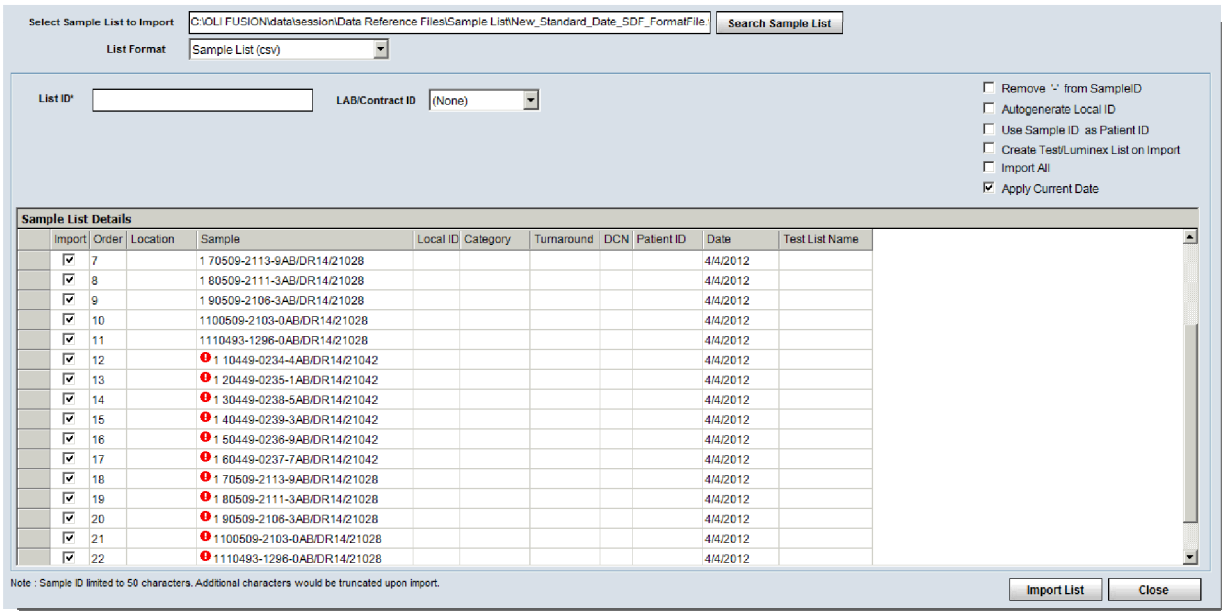
Note: Please verify all data you import as HLA Fusion performs minimal data validation upon import.

Importing Sample Lists

Sample lists are an easy way to input an extended list of sample ID's and other sample information into the database for use in analysis sessions.

1. From the Main Menu, select **Sample > Import Sample List**.

Import Sample List Screen



The Import Sample List window displays.

2. Click the **Search Sample List** button; browse for the sample list to be imported; and click **Open**.

3. Type a name in the **List ID** field, and, if necessary, select a Lab code or **Contact ID** from the drop-down list.
4. Confirm sample information, and edit if needed.
5. Click to clear the check boxes of any samples you do not want to import.
6. Click **Import List** to import the selected sample lists.
7. Click **Close** to return to the Main Menu.

Information Formats for Sample Lists

The information inside a sample list you import in to HLA Fusion must be in one of the following formats.

New packing list format

This file gives the fields (in this order):

```
ShipmentLoc(1 – 13),SampleIDName(0198-0398-0),SampleType(AB, DR or AB/DR),
TurnaroundTime(14, 21 or 14AB/21DR),DCN (3 digit).
```

Example line:

```
1 - 13,0198-0398-0,AB/DR,14AB/21DR,074
```

Pack list: Old Standard 'X' samples

This file gives the fields (in this order):

```
ShipmentLoc,SampleIDName,SampleType (1, 2, 3..., and an 'X' for AB/DR samples),DCN
```

Example line:

```
1 - 12,0287-7867-8,X,074
```

Old packing list format, '11' for AB/DR samples

This file lists (in this order):

```
ShipmentLoc, SampleIDName, SampleType (1, 2, 3..., and an '11' for AB/DR samples),
DCN
```

Example line:

```
1 - 15,0287-0779-2,11,074
```

Comma-Delimited Format

Each field is separated by commas. The use of quotes around a field is optional, and is required only if the contents of the field use a comma, which could confuse field separation. This file lists (in this order):

```
ShipmentLoc, SampleIDName, SampleType (AB, DR or AB/DR), TurnaroundTime (14, 21 or
14AB/21DR), DCN
```

Example line:

```
"1","12","0287-7867-8","AB/DR","14AB/21DR","074"
```

Tab-Delimited Format

Each field is separated by a tab. This file lists (in this order):

```
ShipmentLoc, SampleIDName, SampleType (AB, DR or AB/DR), TurnaroundTime (14, 21 or
14AB/21DR), DCN
```

Example line:

```
1     12    0287-7867-8     AB/DR   14AB/21DR       074
```

SDF Format

Each field is separated by commas. This file lists (in this order):

BoxSlot, DonarID, SampleType (AB, DR or AB/DR), TurnaroundTime (14, 21 or 14AB/21DR), DonarCenter

Example line:

```
     1120287-7867-8AB,DR14,21074
```

Local/Sample/Patient ID Only

This file is a Microsoft Excel file. This file lists (in this order):

```
Row 1:  Column Title "Local" and "Sample" and "Patient"
Column A:  LocalID
Column B:  SampleIDName (required)
Column C:  PatientIDName
Column D:  Date
```

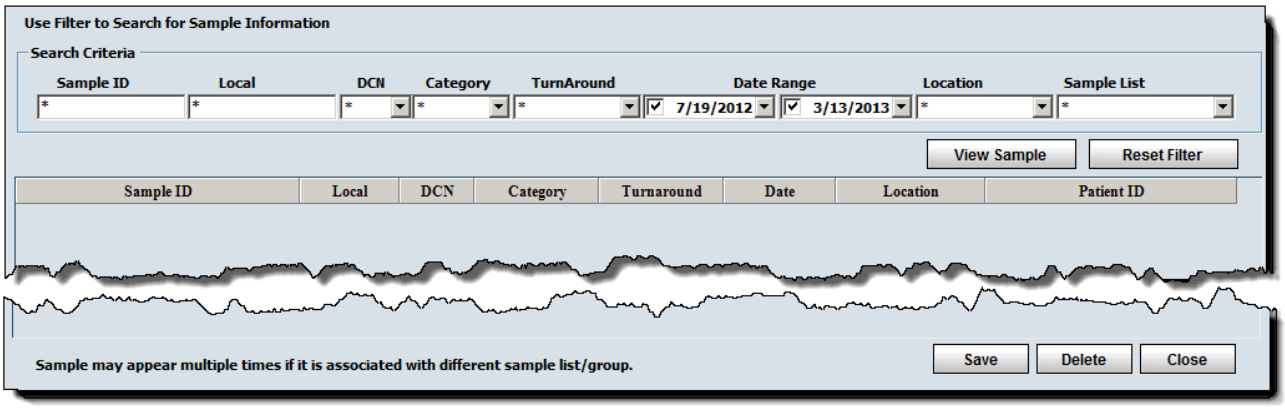
Example:

	A	B	C	D
1	LocalID	Sample	PatientID	Date
2	1	20449-0235-1AB	DR14	8/10/1957
3	1	30449-0238-5AB	DR14	2/10/1942
4	1	40449-0239-3AB	DR14	5/12/1958
5	1	50449-0236-9AB	DR14	12/1/1960

Viewing and Editing Sample Information

Sample information can be edited, but associated patient IDs cannot—only new patient IDs can be added.

1. From the Main Menu, select **Sample > Manage Sample Info**.



Manage Sample screen

2. Use the filters to find samples, and click **View Sample**.

Note: Wildcards can be used in the Sample ID field to widen the results.

3. Edit sample information.

Note: You can rename a sample by modifying the name in the Sample ID field. Sample IDs are listed alphanumerically, with all IDs beginning with numbers listed first.

4. Click **Save** to save. Or, click **Delete** to delete the sample.
5. Click **Close** to return to the Main Menu.

Note: You are not allowed to delete a sample that is part of a session that has already been analyzed.

Test Lists

A Test List is a list of Sample IDs that can be used repeatedly to automatically write the sample IDs into a session analysis that can be read by Luminex®. It is a useful tool when you have a group of samples to be run on multiple tests.

From the Test List menu you can:

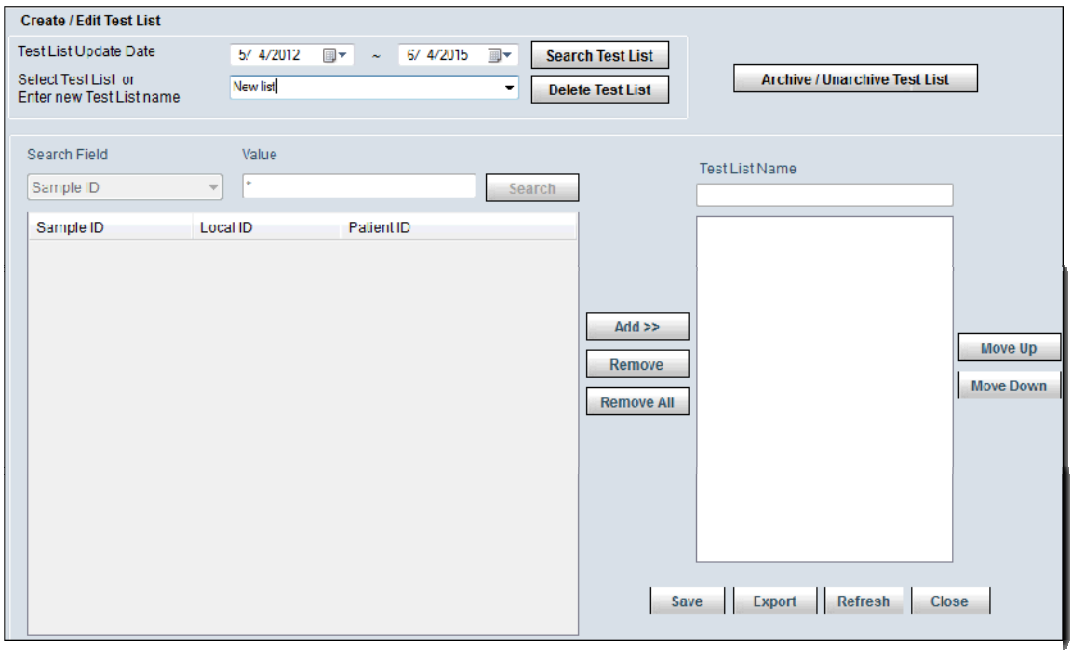
- Create new Test Lists
- View and edit existing Test Lists
- Delete Test Lists
- Export Test Lists to a .txt file

Creating New Test Lists

Test Lists must be created in the order in which the samples are to be analyzed.

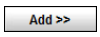
1. From the Main Menu, select **Samples > Manage Test List**.

Manage Test List Screen



2. Type in a name for the new test list, and click **Continue>>**.

3. Search for samples to add to the test list using the search fields, and click **Apply** to view search results.

4. Highlight samples, and click **Add>>**  to add them to the test list.
5. Click **Save**  to save the new test list.
6. Click **Close**  to return to the Main Menu.

Viewing and Editing Existing Test Lists

Test Lists can be viewed or edited at any time.

1. From the Main Menu, select **Manage Samples > Manage Test List**.
2. Use the drop-down list to select a test list, and click **Continue>>**.
3. Click **Delete List** to permanently delete the selected test list.
4. Click **Close** to return to the Main Menu.

Deleting Existing Test Lists

Deleting a test list removes the list from the database, but the sample IDs are not removed or changed in the database.

1. From the Main Menu, select **Manage Samples > Manage Test List**.
2. Use the pull-down menu to select a test list, and click **Continue**>>.
3. Add, remove or move samples as desired.
4. Click **Save** to save the new test list.
5. Click **Close** to return to the Main Menu.

Exporting Test Lists

Test lists can be exported for use outside of HLA Fusion only as a .txt files.

1. From the Main Menu, select **Manage Samples > Manage Test List**.
2. Use the pull-down menu to select a test list, and click **Continue**>>.
3. Click **Export** to export test list details to a .txt file.
4. If prompted to save the test list before export, click Yes to save and continue.
5. Select a location to save the test list and enter a file name for it.

6. Click **Save**.
7. When prompted to create a Luminex Patient List input, click **No**.
8. Click **Close** to close and return to the Main Menu.

Luminex Lists

HLA Fusion can create a Luminex List from a new or existing test list. You can use this list to quickly add information, such as sample ID, before you create a Luminex CSV output file. From the **Create/Edit Test List** window you can create a Luminex list.

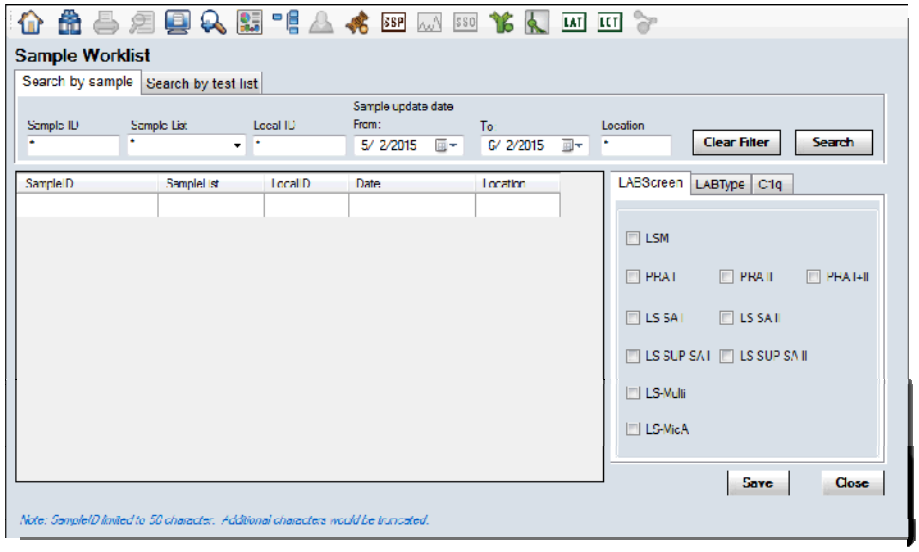
Creating Luminex Lists

Luminex List files can be edited after they are exported, but changes are not reflected in the test list from which they were created.

1. From the Main Menu, select **Samples > Manage Test List**.
2. Use the pull-down menu to select a test list, and click **Continue>>**.
3. Click **Export** to export.
4. Select a location to save the test list to and enter a file name, then click **Save**.
5. When prompted to create Luminex List input, click **Yes**.
6. Click **OK** on the confirmation message to return to the **Test List** window.
7. Click **Close** to return to the Main Menu.

Create Sample Worklists

Sample Work list functionality in HLA Fusion software gives you the flexibility to assign various tests to selected samples. This information is used in designing plates for Luminex processing.



1. Select **Sample > Create Sample Work list** from the HLA Fusion main menu.

   Do one of the following to search for samples:

   a. Click the Search by sample tab, use the search criteria to specify the samples that you would like to assign tests to, and click Search.

   b. Click the Search by the test list tab and use the search criteria to specify the test lists that you would like to assign tests to, and click Search.

2. Select one sample, or select multiple samples (by holding and dragging the mouse). The selected samples are highlighted.

3. Now assign one or more tests by selecting the check boxes for the tests you want to run on the samples (listed under LABScreen/LABType/C1q Tests).

4. Once you are done assigning tests to all the selected samples, click Save to save the work list.

5. Click **close** at any time to exit the sample worklist window.

Create Plate Design

Plate Designer functionality in HLA Fusion software gives you the flexibility to organize and plan your samples in a plate format that is ready for processing through the Luminex system. You must first create a sample work list.

1. Select **Sample > Create Plate Design** from the main HLA Fusion menu.

2. Enter a name for a new plate, or select an existing plate name from the **Plate Name** drop-down list to edit a plate.

3. Select **LABScreen**, **LABType or C1q** from the **Assay type** drop-down list.
4. Do one of the following to search for samples:

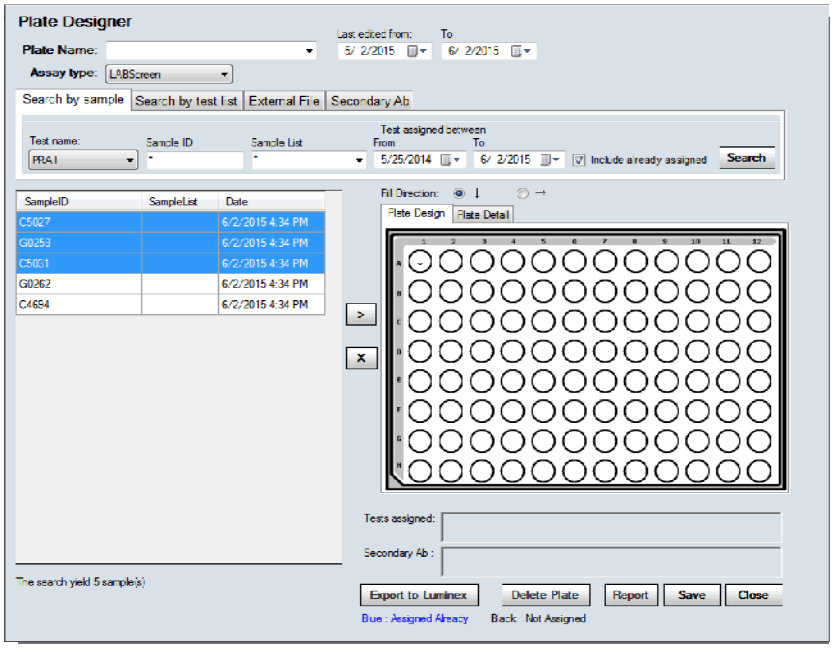
   - Click the **Search by sample tab** and use the search criteria to specify the samples that you would like to assign to the plate wells, and click **Search** Search.
   - Click the **Search by test list tab** and use the search criteria to specify the test lists that you would like to assign to the plate wells, and click **Search** Search.

- Click the **External File** tab and use the file import window to load external files containing samples in predefined file formats. Assign or reassign these tests to the samples in the plate.

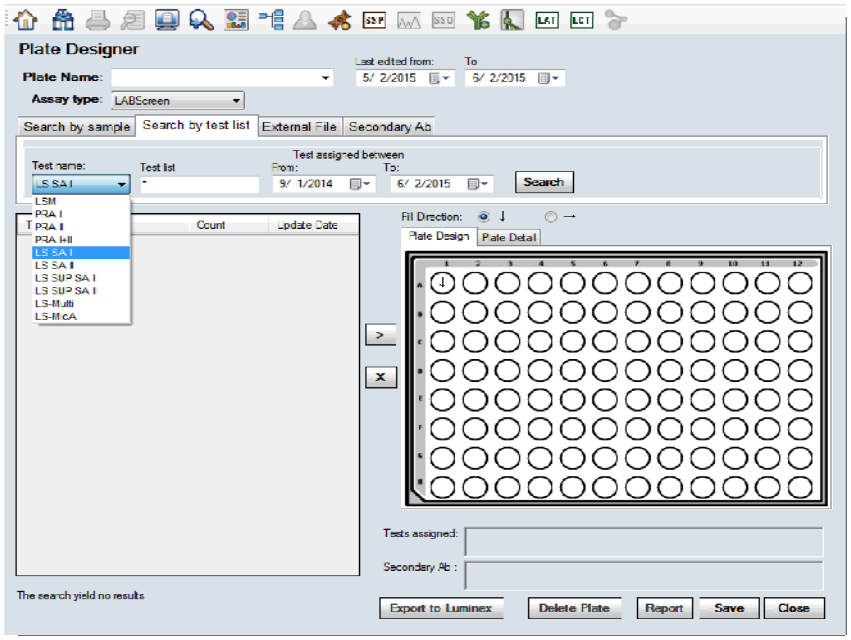
The Luminex patient list and sample lists in .CSV format (Swisslab file format) are examples of predefined external file formats.

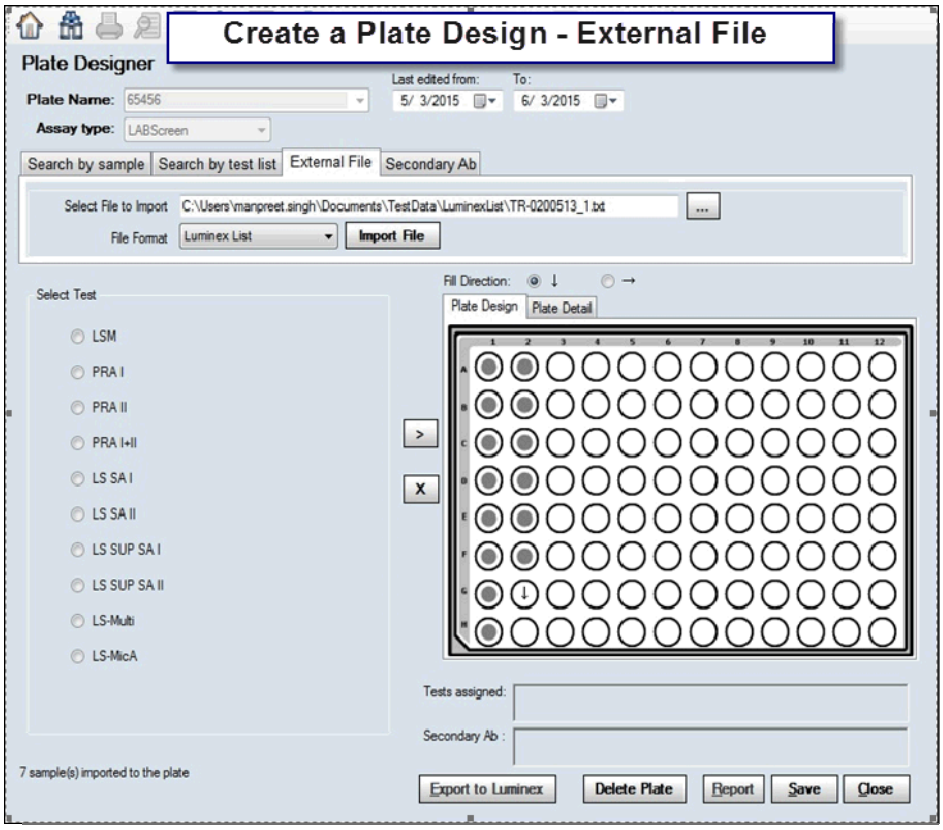
Please see the example figures below:

Create a plate design – Search by Sample



Create a plate design – Search by Test List

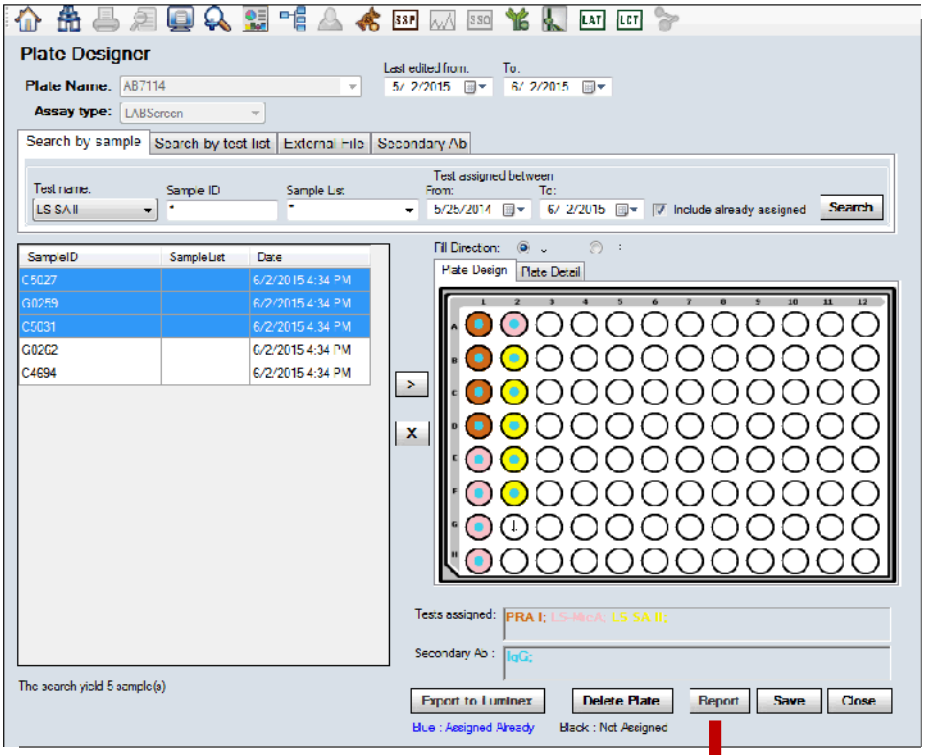



Create a Plate Design - External File
Plate Designer
Last edited from:
To :
Plate Name:
65456
5/ 3/2015
6/ 3/2015
Assay type:
LABScreen
Search by sample
Search by test list
External File
Secondary Ab
Select File to Import
C:\Users\manpreet.singh\Documents\TestData\LuminexList\TR-0200513_1.txt
File Format
Luminex List
Import File
Fill Direction:
Select Test
Plate Design
Plate Detail
LSM
PRA I
PRA II
PRA I+II
LS SA I
LS SA II
LS SUP SA I
LS SUP SA II
LS-Multi
LS-MicA
Tests assigned:
Secondary Ab :
7 sample(s) imported to the plate
Export to Luminex
Delete Plate
Report
Save
Close

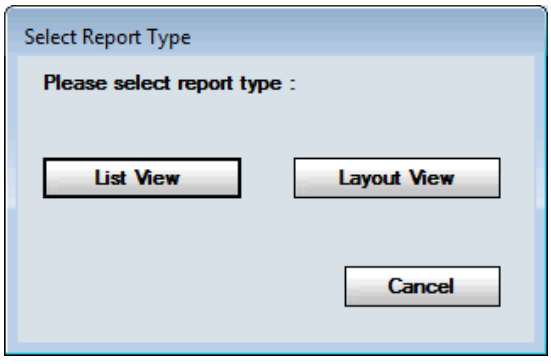
5. Choose the **fill direction** for the plate design. You can select vertical or horizontal direction.

6. Select one sample or several (by holding and dragging the mouse), and use the right arrow button > to assign these selected samples to a well in the plate. In the case of LABScreen assay the Secondary antibody IgG shall be assigned to each well of the plate design by default. Repeat this procedure until you have completed your plate design. To remove a sample from the plate, select the well or hold ctrl and click to select multiple wells that contain samples, then click **X**.

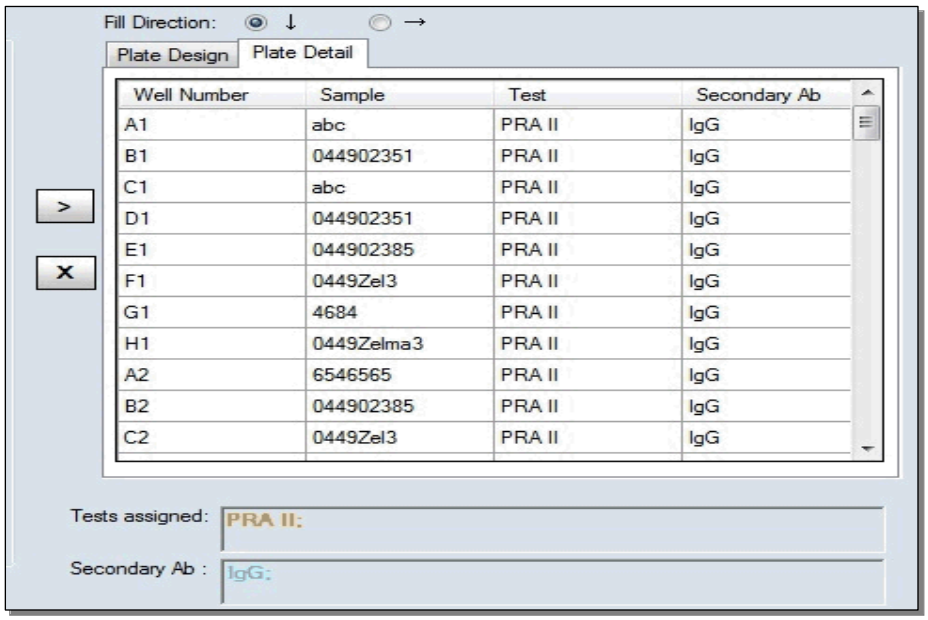
Assigning Samples to wells in a new Plate



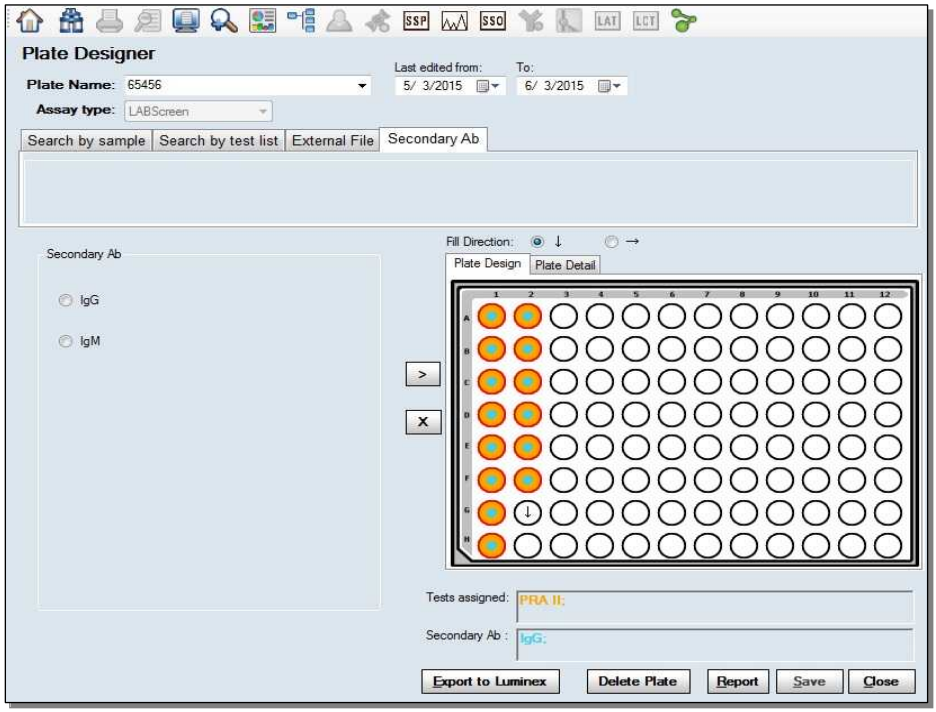
7. Click **Report** button if you want to view and print a report of your plate design information including Well Position, Sample name, Patient ID and Test name. You can choose from two types of report formats: List View, Layout View.



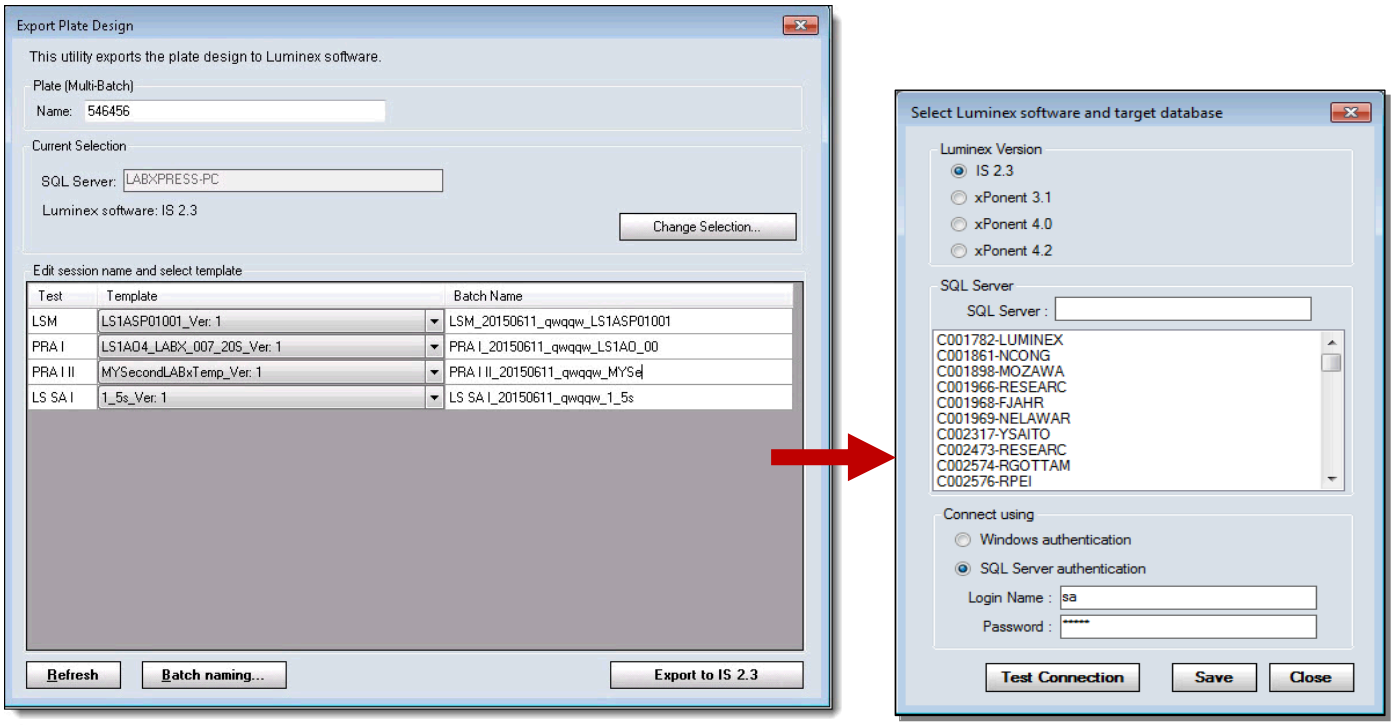
8. Click on the **Plate detail** tab to view the plate design detail. You can also view the test assignment information and secondary antibody information.



9. Click on the secondary antibody tab (rightmost tab within Plate Designer) to change the secondary antibody only in the case of the LABScreen assay type selection:



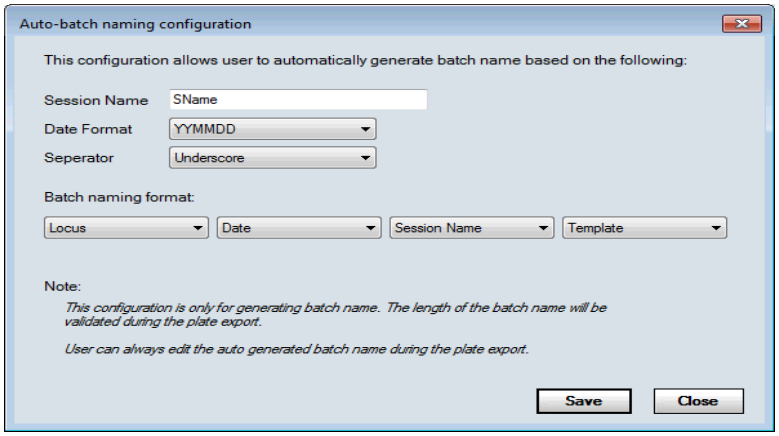
10. Click **Save** to save your plate design.



11. Click **Export to … (version of Luminex)** to export a plate design so that it can be opened and used from the selected Luminex software.

    a. Click the **Change Selection** button (above) to **select the Luminex software** and target database. Select the available luminex version where you want to export the plate design. Select the database and save the changes by clicking on **Save**.

    b. Click the **Batch naming…** button (left corner above) to configure automatic batch-naming. A new data entry screen will appear (shown below). Enter the session name and choose the date format, seperator, and batch naming format. Click on **Save** then close:



You can see the batch name information in the batch name column. Click on **Refresh** to update the template list from the luminex database. You may select the template from the **Template** column, and edit a batch name in the **Batch name** column.

12. From the **Plate Designer** screen, click on **Delete Plate** to delete the plate design.

13. From the **Plate Designer** screen, Click on **Close** to close the plate designer without saving the plate.

Patient Information

HLA Fusion™ can store patient information and associate sample IDs with patients and donors. You can store all typing and screening information in one location for each patient.

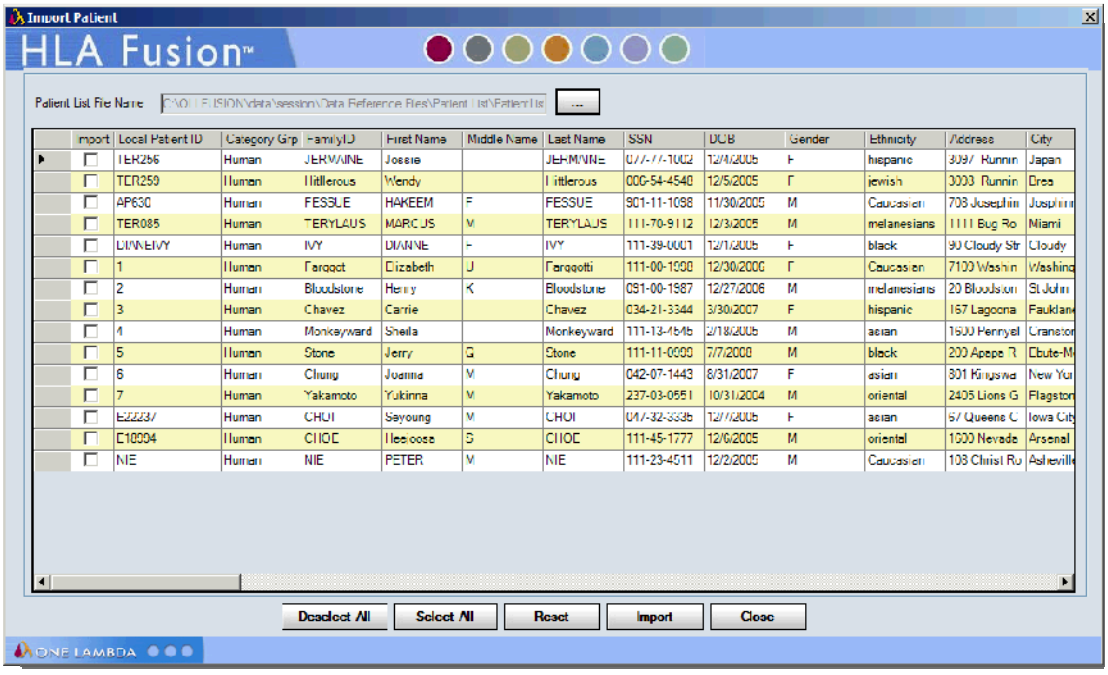
Note: Please verify all data you import. HLA Fusion performs minimal data validation during import operations.

Importing Patient/Donor Lists

After creating a Patient/Donor List, you can import the information into HLA Fusion.

1. From the Main Menu, select **Patient Info > Import Patient List**.

The Patient Import window displays:



Import Patient Window

2. Select the check box in the **Import** column for each patient you want to import.
3. Click the **Import** button to import checked patients.

4. Click **Close** to return to the main menu.

Note: The HLA Fusion system checks the patient/donor lists you attempt to import to verify that all characters contained in the data are supported by Fusion. If your list contains unsupported characters, a warning message is displayed and the list is not imported.

Newly imported patient records display alleles in the new nomenclature format. Existing patient records display alleles with the existing allele format.

Managing Patient/Donor Records

The Patient/Donor Management menu allows you to manage one record at a time.

From the Patient/Donor Management menu you can:

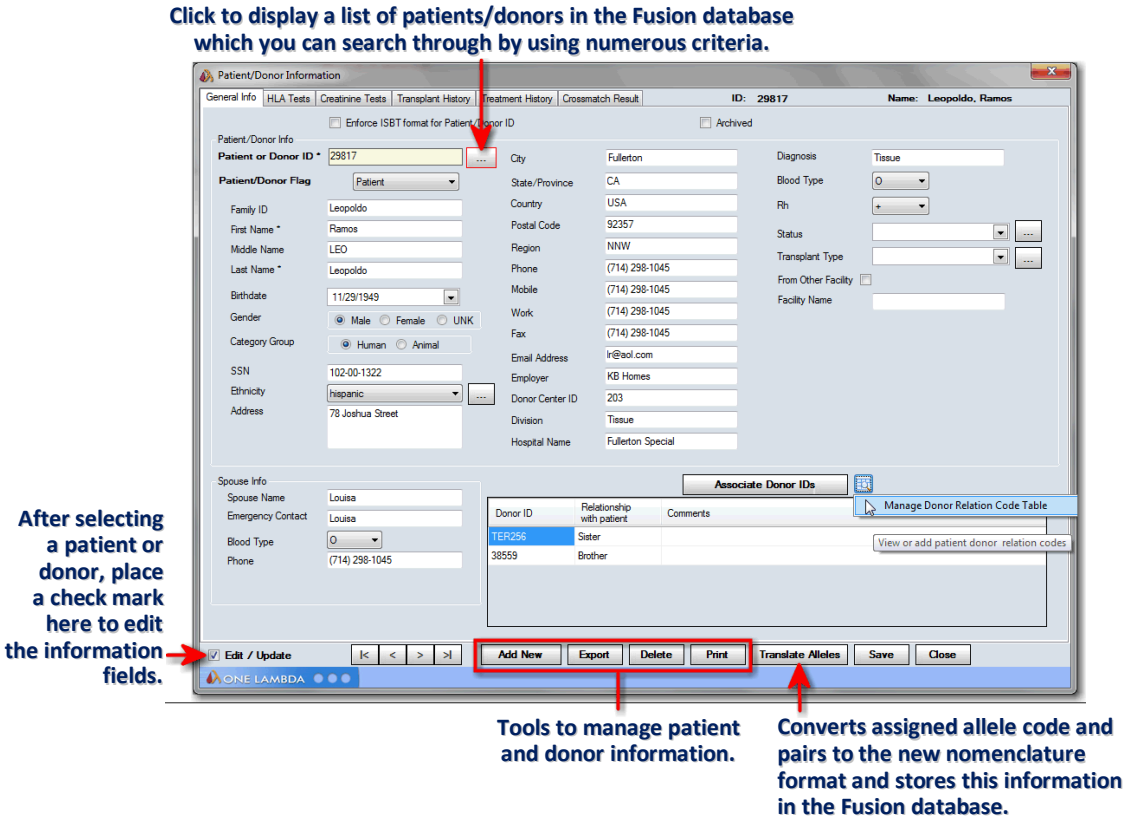
- Add new patient/donor records
- Search existing patient/donor records
- Edit patient/donor records
- Associate patient/donor IDs with sample IDs
- Associate patient and donor records
- Assign a donor to the Donor PRA
- Print, export and archive patient records

Adding New Patient/Donor Records

You can add patient information using the Patient/Donor Information menu. This is the best option for adding a small number of patient records.

Steps to Add New Patient/Donor Records:

1. From the Main Menu, select **Patient Info > Manage Patient**.



2. Enter an ID in the **Patient/Donor** field. The ID can be alphanumeric (contain letters and/or number),or click **Search** and select a patient/donor from the list.

3. Enter patient/donor information. Fields with an asterisk (*) are required.

4. Click Add New to save the data and add the patient/donor information to the Fusion database.

5. Click Close to close and return to the main menu.

Lookup Patient/Donor Records

This option allows you to browse through records or search for specific ones.

1. From the Main Menu, select **Patient Info > Manage Patient**.

2. Enter a patient/donor ID and click **Retrieve** to display patient information. Or, click **Search** to browse patient records and lookup by name, patient ID, whether it is active or archived, etc.

3. Highlight a patient record and click **OK** to display.

Editing Patient/Donor Records

Note: You must be a Supervisor in order to edit a patient/donor record.

All patient/donor information, (except patient/donor ID) can be edited.

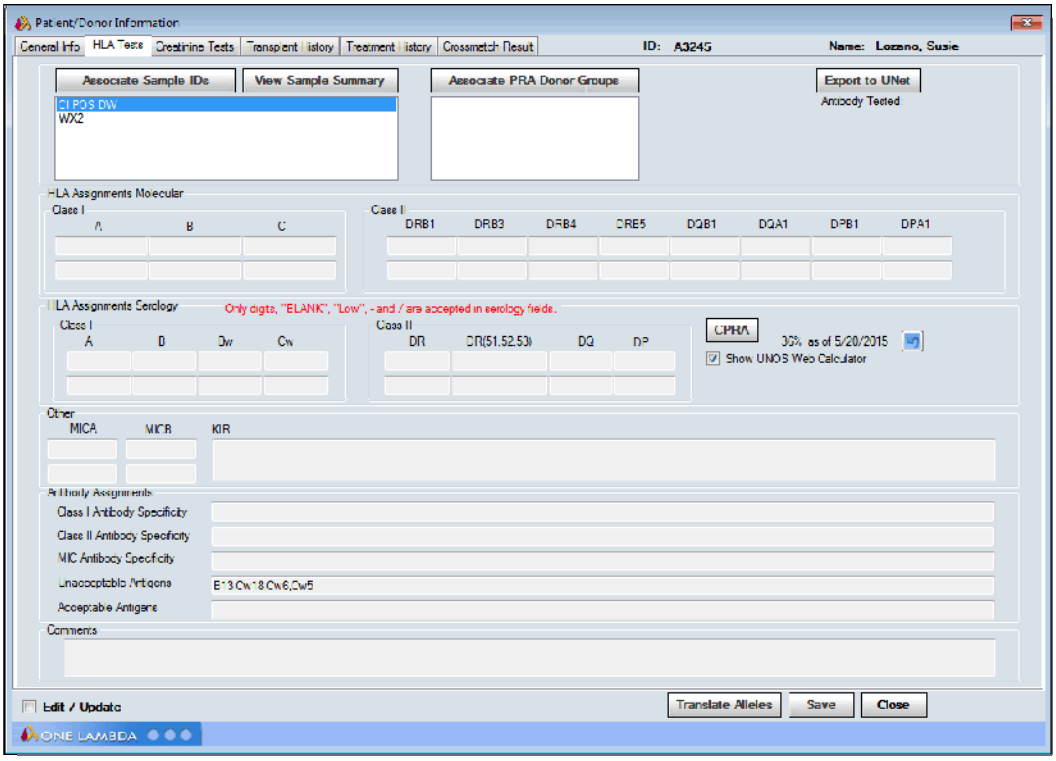
1. From the Main Menu, select **Patient Info > Manage Patient**.
2. Select a patient/donor record.
3. Select the check box next to Edit Mode. There is the same, Edit Mode check box on both tabbed forms.
4. Edit patient/donor information on one or both tabbed forms. Fields marked with an asterisk (*) are required.
5. Click **Save** to save your changes.
6. Click **Close** to return to the Main Menu.

Associating a Patient/Donor ID with Sample IDs

A Sample ID cannot be associated with more than one patient or donor record, but a patient or donor record can have more than one sample ID associated with it.

From the Main Menu, select **Patient Info > Manage Patient**.

1. Select the HLA Tests Tab.



Patient/Donor Information Screen – HLA Tests Tab

2. Click the **Associate Sample IDs** button.
3. In the ***Patient/Donor Sample Association*** window, highlight a sample ID and click> to add it to the **Patient/Donor Sample List**. (Click < to remove a highlighted sample ID from the list.)
4. Click **Save** to save the data.
5. Click **OK** to return to the patient record.
6. Click **Close** to return to the main menu.

Translating Associated Patient/Donor Results to New Allele Code

Patient or Donor results can be translated to update the allele code names to the new NMDP allele code format.

The new format will affect allele code and allele pairs assigned to the selected patient/donor, and will be stored in the Fusion database in the new format.

1. From the Main Menu, select **Patient Info > Manage Patient**.
2. Select a patient/donor record.
3. Click **Translate Alleles**.
4. Click **Save** to save data.
5. Click **Close** to return to the Main Menu.

Associating Patient and Donor Records

A Patient ID can be associated with more than one donor record, and a donor ID can have more than one patient record associated with it.

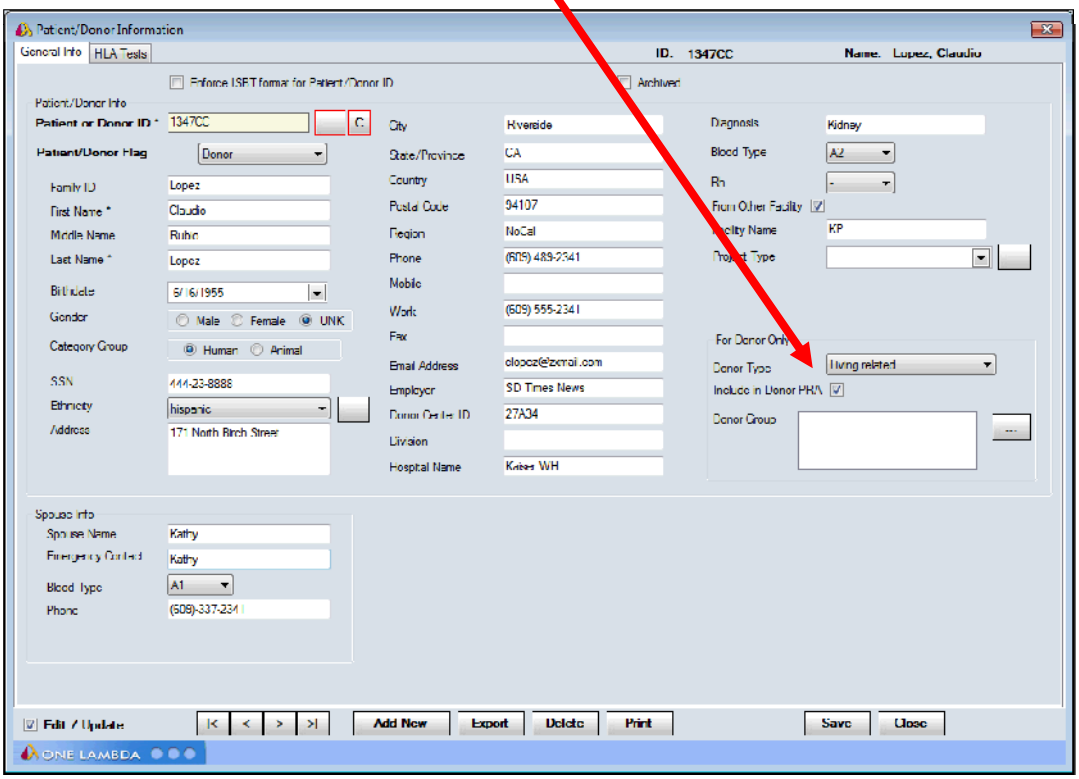
1. From the Main Menu, select **Patient Info > Manage Patient**.
2. Select a patient/donor record.
3. Click the **Test Info** tab.
4. Click the Associate Donor IDs button.
5. In the **Patient/Donor Sample Association** window, highlight a Donor ID and click**>**to add it to the **Patient/Donor Sample List**. (Click **<** to remove a highlighted Donor ID from the list.)
6. Click **Save** to save data.
7. Click **OK** to return to patient record.
8. Click **Close** to return to the Main Menu.

Associating a Donor with Donor PRA Results

A Donor ID can be included in the calculation for Donor PRA percentage for the antigen products.

1. From the Main Menu, select **Patient Info > Manage Patient**.
2. Select a donor, or create a new one.
3. Make sure the Patient/Donor filed is set to **Donor**.

4. Select the **Include in Donor PRA** check box:



Printing Patient/Donor Records

HLA Fusion prints both Record Management tabs regardless of which tab is currently being viewed.

1. From the Main Menu, select **Patient Info > Manage Patient**.
2. Select a patient/donor record.
3. Click **Print** to print.
4. Click **Close** to return to the Main Menu.

Exporting Patient/Donor Records

Patient/donor records can be exported individually to a CSV file. The file has the same format as a Patient List.

1. From the Main Menu, select **Patient Info > Manage Patient**.

2. Select a patient/donor record.
3. Click **Export** to export.
4. Select a location to save the CSV file to and enter a file name.
5. Click **Save**.
6. Click **Close** to return to the Main Menu.

Archiving Patient/Donor Records

Archived patient/donor records are not available for reporting or associating. You can still view archived records and reactivate them by clearing the archive check box.

1. From the Main Menu, select Patient Info**> Manage Patient.**
2. Click the **General Info** tab.
3. Select a patient/donor record.
4. From the **Patient/Donor List** window, select **Archive** from the drop-down **Active/Archive** list.
5. Click **Save** to save.
6. Click **Close to** return to the Main Menu.

Deleting Patient/Donor Records

Patient/donor records can be deleted through the Manage Patient menu option.

1. From the Main Menu, select **Patient Info > Manage Patient**.
2. Click the **General Info** tab.
3. Select a patient/donor record.
4. Click **Delete** to delete the patient/donor record from the Fusion database.
5. Click **Save**.

Creating Patient/Donor Lists

The following is an example of a patient list that can be created and the guidelines for doing so. The patient list must be formatted for import via a program like Excel or Notepad and saved as a Windows compatible CSV file.

The first field/section must contain the names of the patient list fields, each separated by commas.

Note: Creating a new patient list can be made easier by first exporting an existing list into CSV format, and using the fields in that to build your new list.

Patient List Field Names and Format

```
PatientIDName,CategoryGrp,FamilyID,FirstName,MiddleName,LastName,Ssn,Dob,Gen
city,Address,City,State,Region,Country,ZipCode,Email,Phone,WkPhone,Cellular,
yer,SpouseName,SpouseBloodType,EmergencyContact,EmrgncyTel,DCN,HospitalName,
BloodType,Disease,RhBloodType,PatientDonorFlg,Associated SampleIDs,Associated
DonorIDs,HLA1_A,HLA2_A,HLA1_B,HLA2_B,HLA1_BW,HLA2_BW,HLA1_C,HLA2_C,HLA1_DRB1
1,HLA1_DRB3,HLA2_DRB3,HLA1_DRB4,HLA2_DRB4,HLA1_DRB5,HLA2_DRB5,HLA1_DQB1,HLA2
1_DQA1,HLA2_DQA1,HLA1_DPB1,HLA2_DPB1,HLA3,HLA1_DRB4,HLA2_DRB4,HLA1_DRB5,HLA2
1_DQB1,HLA2_DQB1,HLA1_DQA1,HLA2_DQA1,HLA1_DPB1,HLA2_DPB1,HLA1_DPA1,HLA2_DPA1
A,HLA2_MICA,HLA1_MICB,HLA2_MICB,HLA_KIR,ClassI_AbSpec,ClassII_AbSpec,MIC_AbS
eptableAntigens,AcceptableAntigens,Notes,SHLA1_A,SHLA2_A,SHLA1_B,SHLA2_B,SHL
A2_Cw,SHLA1_DR,SHLA2_DR,SHLA1_DR345,SHLA2_DR345,SHLA1_DQ,SHLA2_DQ,SHLA1_DP,S
onorType,IncludeInDonorPRA
```

Subsequent lines must list the actual patient information, alphanumerically, (can be letters and/or numbers) separated by commas. If there is no information for the patient in a particular field, that field still requires a comma as a placeholder.

Note: For *all* manual serology entries, the locus must precede the value. For example, for an A locus of value 23, you must enter **A23**.

Example Patient/Donor List

```
PatientID,CategoryGrp,FamilyID,FirstName,MiddleName,LastName,Ssn,Dob,Gender,Ethnicity,Address,City,State,Region,Coun
try,ZipCode,Email,Phone,WkPhone,Cellular,Fax,Employer,SpouseName,SpouseBloodType,EmergencyContact,EmergencyTel,DCN,H
ospitalName,Division,BloodType,Disease,RhBloodType,PatientDonorFLg,Associated SampleIDs,Associated DonorIDs,HLA1
_A,HLA2_A,HLA1_B,HLA2_B,HLA1_Bw,HLA2_Bw,HLA1_C,HLA2_C,HLA1_DRB1,HLA2_DRB1,HLA1_DRB3,HLA2_DRB3,HLA1_DRB4,HLA2
_DRB4,HLA1_DRB5,HLA2_DRB5,HLA1_DQB1,HLA2_DQB1,HLA1_DQA1,HLA2_DQA1,HLA1_DPB1,HLA2_DPB1,HLA1_DPA1,HLA2_DPA1,HLA1
_MICA,HLA2_MICA,HLA1_MICB,HLA2
_MICB,HLA_KIR,ClassI_AbSpec,ClassII_AbSpec,MIC_AbSpec,UnacceptableAntigens,AcceptableAntigens,Notes,SHLA1_A,SHLA2
_A,SHLA1_B,SHLA2_B,SHLA1_Cw,SHLA2_Cw,SHLA1_DR,SHLA2_DR,SHLA1_DR345,SHLA2_DR345,SHLA1_DQ,SHLA2_DQ,SHLA1_DP,SHLA2
_DP,DonorType,IncludeInDonorPRA
38450,Human,Neely,Jason,,Neely,021-09-2987,2/17/2001,M,caucasoid,560 Waiting
Street,,CA,NWW,USA,91022,jneely@yahoo.com,(213) 567-0987,(213) 567-0987,(213) 567-0987,(213) 567-0987,MIT
Research,Evvonne,AB,Evvonne,(213) 509-0198,101,St Judes's Hospital,MARROW Transplant,O,bONE
MARROW+,,Patient,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,A2,-,B78,B56,,,,,,,DQ-,DQ-,DP14,DP9,,
27614,Human,Martinez,Daniel,DM,Martinez,032-11-1934,9/12/1998,M,hispanic,40 Driveland Road,East
LA,CA,NWW,USA,90222,mdaniel@aol.net,(324) 489-1430,(324) 489-1430,(324) 489-1430,(324) 489-1430,Joba
Juice,Maria,B,Maria,(324) 489-1430,103,East LA Hospital,MARROW
Transplant,O,Marrow,-,Patient,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,A2,-,-,B6,,,,,,,DQ8,DQ2,DP19,-,,
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Road,Valencia,CA,NWW,USA,91355,kd@lions.net,(662) 234-1098,(662) 234-1098,(662) 234-1098,(662) 234-1098,Traveller's
Insurance,Kenneth,A,Kenneth,(662) 234-1098,221,Henry Mayo Hospital,,AB,Tissue,
+,Patient,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,-,A2,,,Cw8,Cw8,,,,,,,DP4,,,
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Road,Irvine,CA,NWW,USA,91120,pkatie@msn.com,(714) 760-1987,(714) 760-1987,(714) 760-1987,(714) 760-1987,General
Moters,Jerry,AB,Jerry,(714) 760-1987,103,Irvine General,BONE MARROW
Transplant,B,Marrow,-,Donor,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,-,B7,,,DR10,DR10,,,DQ2,DQ-,,,,
35720,Human,Quinn,Gayle,QG,Quinn,111-12-1212,5/25/1987,F,black,120 Papa
Road,Anaheim,CA,nnw,USA,92017,gquinn@msn.com,(714) 367-1022,(714) 367-1022,(714) 367-1022,(714) 367-1022,TY
Mortgage,Franklin,O,Franklin,(714) 367-1022,501,Anaheim Memorial Hospital,BONE MARROW Transplant,AB,BONE
MARROW,-,Patient,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,Cw,-,,,-,DR53,,,,,,
29817,Human,Leopoldo,Ramos,LEO,Leopoldo,102-00-1322,11/29/1949,M,hispanic,78 Joshua
Street,Fullerton,CA,NNW,USA,92357,lr@aol.com,(714) 298-1045,(714) 298-1045,(714) 298-1045,(714) 298-1045,KB
Homes,Louisa,O,Louisa,(714) 298-1045,203,Fullerton Special,Tissue,O,Tissue,
+,Patient,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,A1,A-,B18,B76,-,Cw,DR9,-,DR53,DR52,,,-,DP17,,
38533,Human,Rivas,Jose,JV,Rivas,331-00-1908,3/29/2000,M,hispanic,3202 Bio Court,Orange,FL,SSW,USA,32133,rm@jpl.com,
(312) 230-1098,(312) 230-1098,(312) 230-1098,(312) 230-1098,KB Homes,Terriana,O,Toula,(312) 230-1098,607,Miami
Hospital,BONE MARROW Transplant,AB,Marrow,
+,Donor,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,-,A80,-,B37,,,DR15,-,DR52,-,,,DP5,DP5,,
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Road,Bellflower,CA,NNW,USA,91314,jh@msn.com,(323) 981-0916,(323) 345-1234,(323) 506-7771,(714) 556-1289,Verizon
Corporation,Juanna,O,Juanna,(323) 345-1098,103,St Michael Hospital,MARROW Transplant,O,Tissue,
+,Patient,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,B10,-,,,DR-,DR8,,,,,,,,
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Road,Canyonville,OR,NNW,USA,97417,sc@msn.com,(541) 839-4467,(541) 839-6509,(541) 299-1098,(541) 760-1986,Juniper
Creek,Elizabeth,O,Elizabeth,(323) 345-1098,103,St Michael Hospital,MARROW Transplant,O,Tissue,
+,Donor,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,A2,-,,,,,,,DR53,-,,,,,,
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Court,Canyonville,OR,NNW,USA,97417,sc@msn.com,(541) 839-4467,(541) 839-6509,(541) 299-1098,(541) 760-1986,Juniper
Creek,Elizabeth,O,Elizabeth,(323) 345-1098,103,St Michael Hospital,MARROW Transplant,O,Tissue,
+,Donor,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,-,A2,,,Cw4,Cw1,DR-,DR-,DR51,DR52,DQ7,DQ6,,,,
28198,Human,Sharpitis,Thomas,T,Sharpitis,023-18-0002,1/1/1950,F,caucasoid,9701 Bicycle Lane,Cystal
Village,CA,SWW,USA,91002,shar60@yahoo.com,(714) 978-1098,(714) 978-1098,(714) 978-1098,(714) 209-7812,Joseph
```
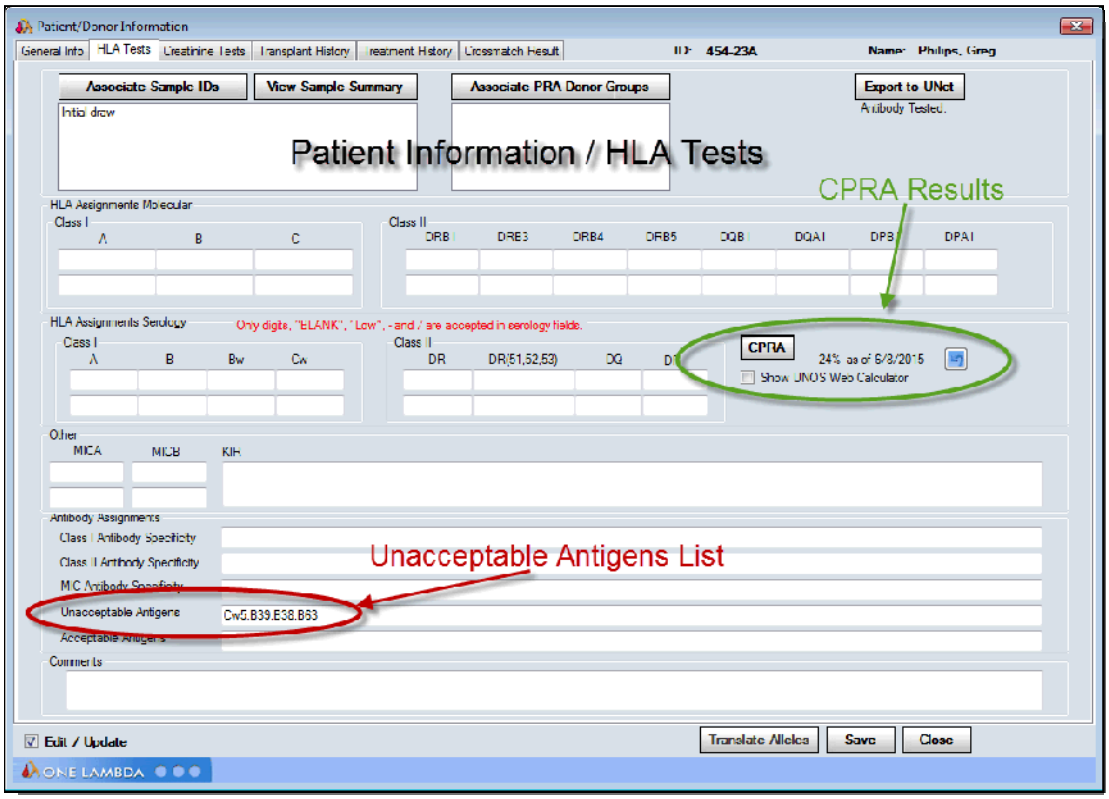
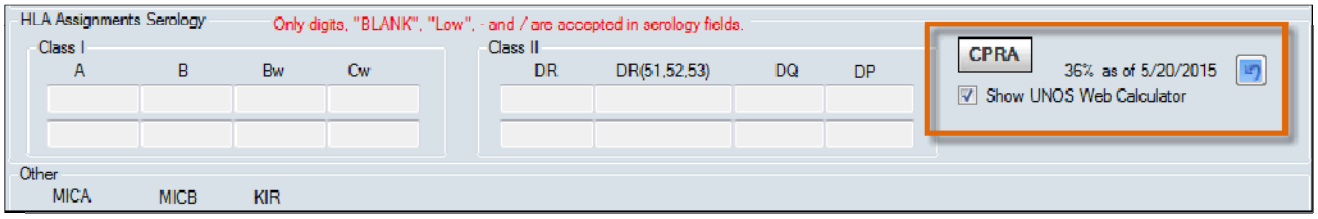

Calculated PRA

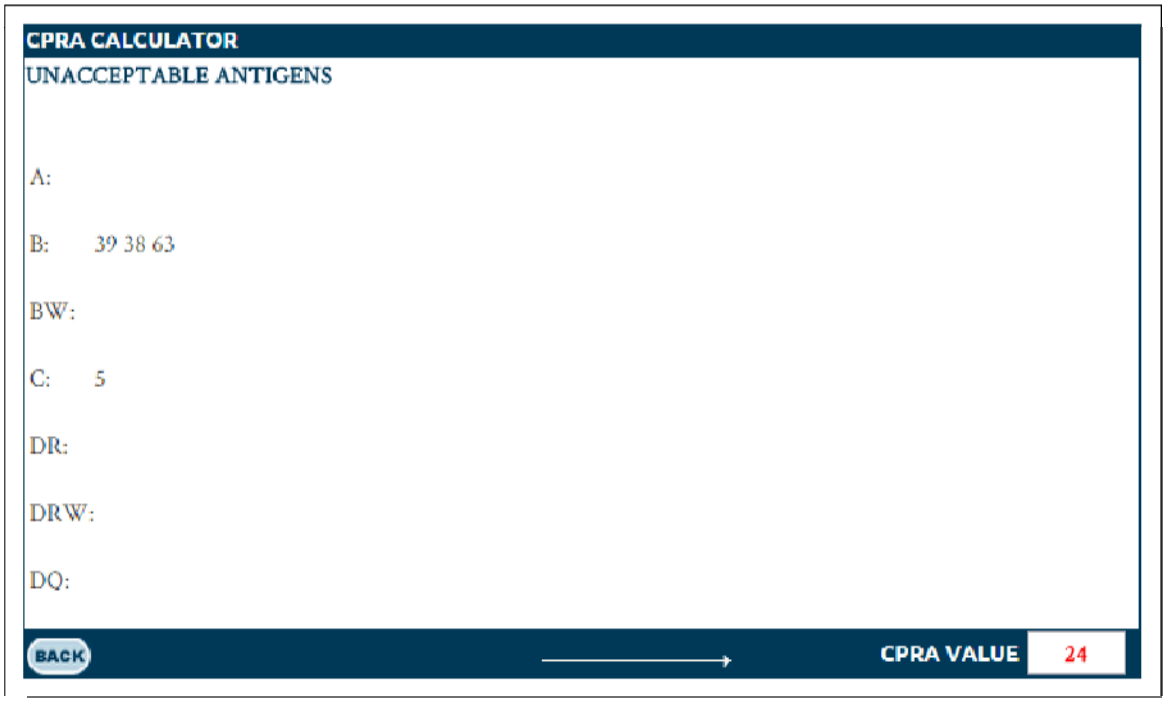
You can calculate the PRA (using the UNOS calculator method) within the **Patient Information** screen.

1. From the Main Menu, select **Patient Info > Manage Patient**.
2. Click the **General Info** tab. The patient/donor information screen appears.
3. Select a patient/donor record, then click the **HLA Tests** tab.
4. Observe the previously assigned Unacceptable Antigens list near the bottom left of the screen. If you have not already conducted analysis previously and assigned Unacceptable Antigens to this patient, you will have to enter values manually here.
5. Click the CPRA button near the middle right hand side of the screen. The Unacceptable Antigens list is now used to calculate CPRA percentage score, which is displayed next to the CPRA button:





If the "Show UNOS Web Calculator" checkbox is marked, the CPRA Web Calculator result window appears, hosted by an external website:



The blue refresh button updates the score to account for recent changes without requiring re-entry of data into the calculator.

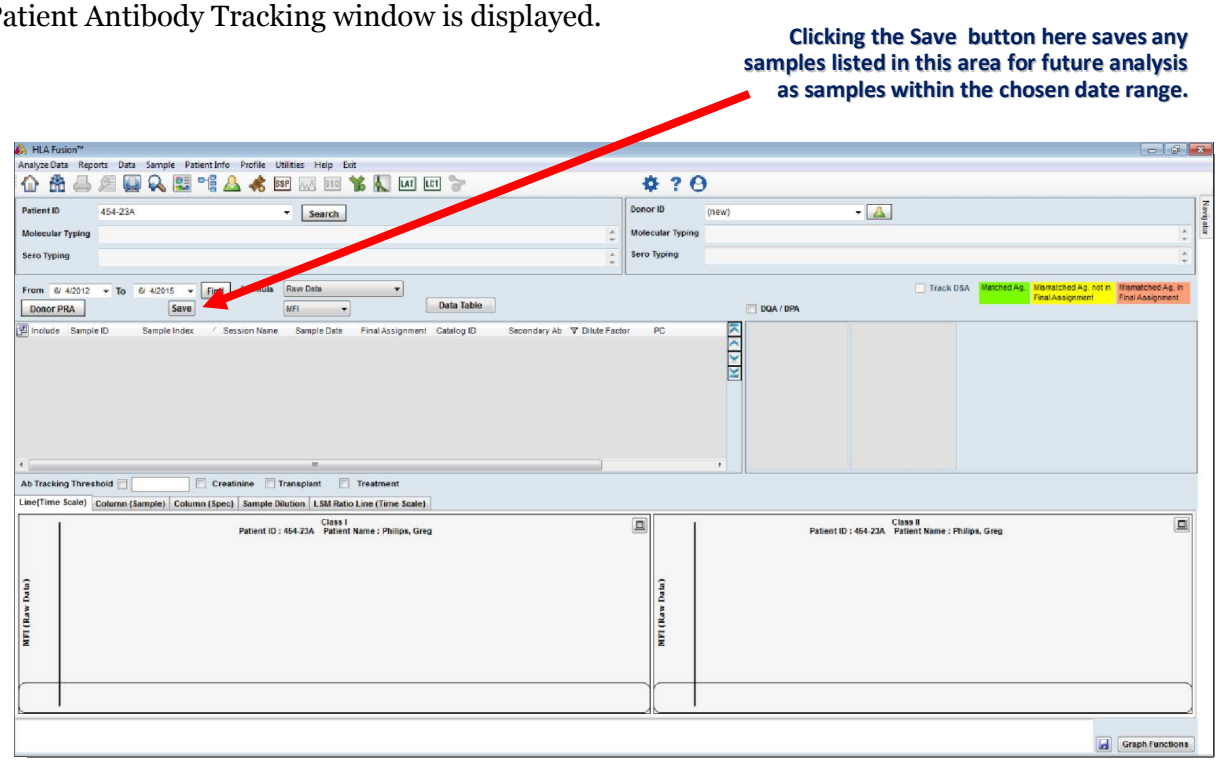
Patient Antibody Tracking

You can track antibody strength for each patient over a period of time. The information tracked is taken from the typing data stored in their Patient/Donor Info card and the antibody data in their analysis samples (LABScreen Single Antigen and LABScreen Singles) for the specified date range. Take the following steps to display graphs and data that track a patient's antibody data.

Make sure you have patient and donor information entered into HLA Fusion. If not, you can import it from a patient list and/or manually enter the data on the **Test Info** tab of the Patient/Donor Info card. Patient and donor records must be associated.

11. Select **Patient Info >Ab Tracking**.

The Patient Antibody Tracking window is displayed.



Patient Antibody Tracking window

2. Click the drop down arrow next to the **Patient ID** field to select from a list of patients stored in your Fusion database. Or click **Search** and search by Patient ID, First or Last name, etc.

3. The Molecular and Serological Typing fields are automatically filled with available data for the specified patient.

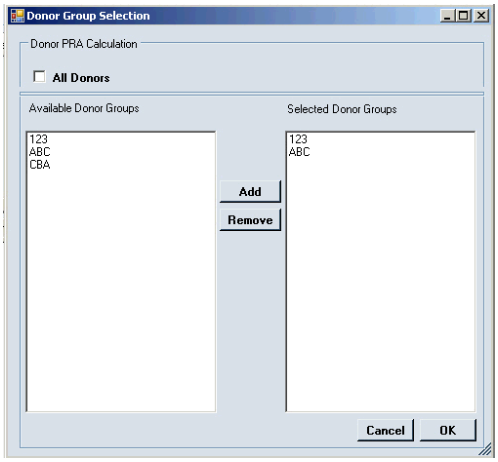
4. Select the start and end date range from which you want to view sample antigen data for this patient (click the drop down arrows in the date fields to display a calendar).

5. You can select Secondary Ab or enter one of your own. This is a way to filter samples and it means that samples you want to bring up must have this secondary Ab. Otherwise, they will not be available when **Find** is clicked.

   - (Optional) You can display the percentage of PRA from available donors in the system or from selected donor groups who match the computer-assigned antibodies for the current sample.

6. Click the **Donor PRA** button to bring up the following dialog box from which you can select donor groups or All Donors.

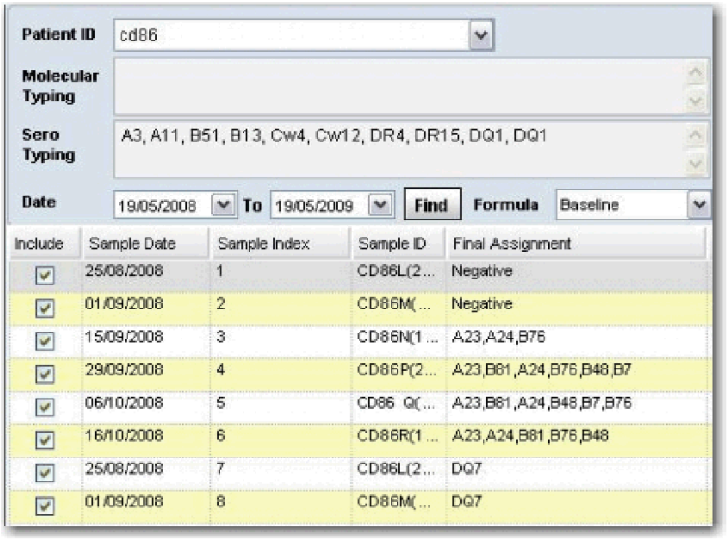
The Donor PRA calculation is displayed next to the **Donor PRA** button.



Donor Group Selection

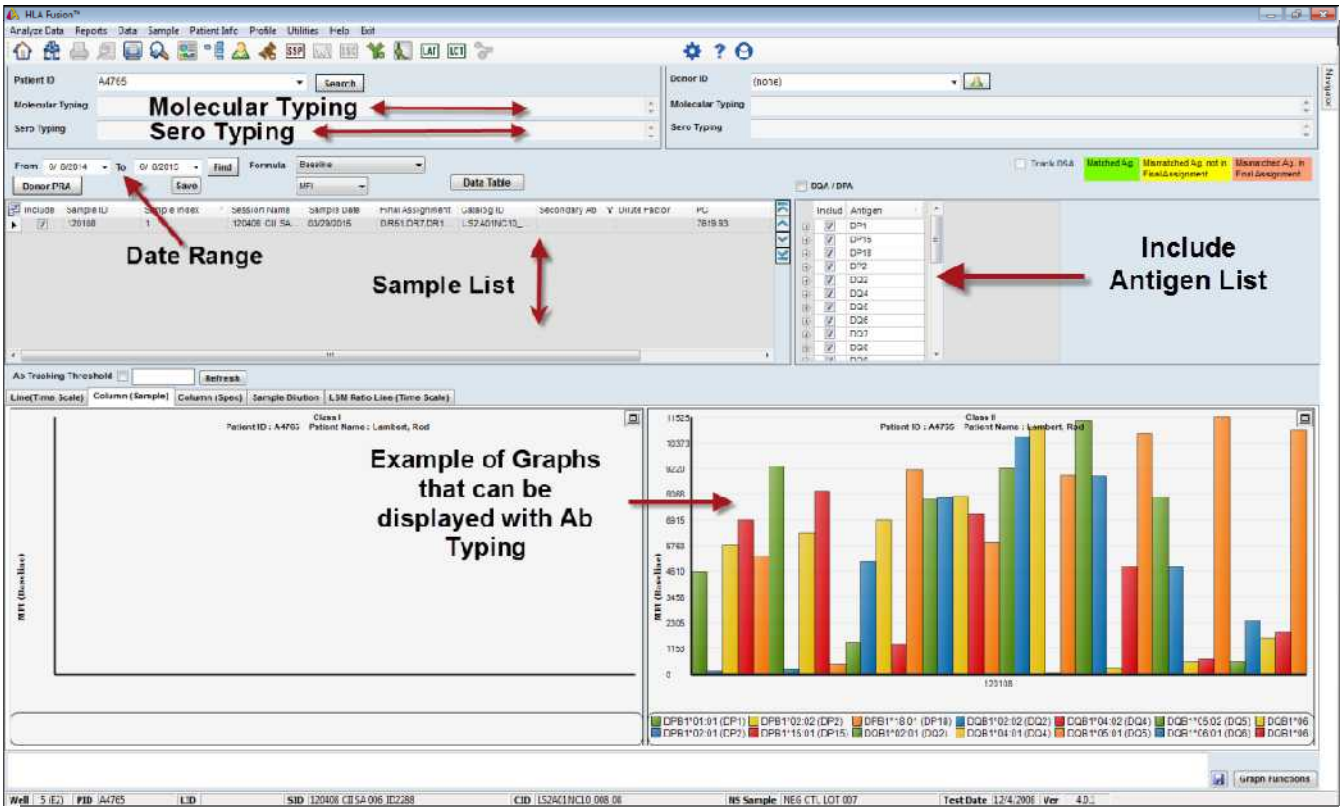
7. Click the **Find** button to display a list of samples for this patient that are within the specified date range.

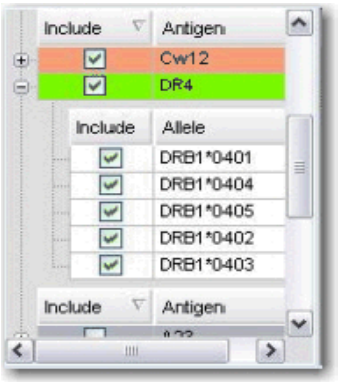
Find Patient List



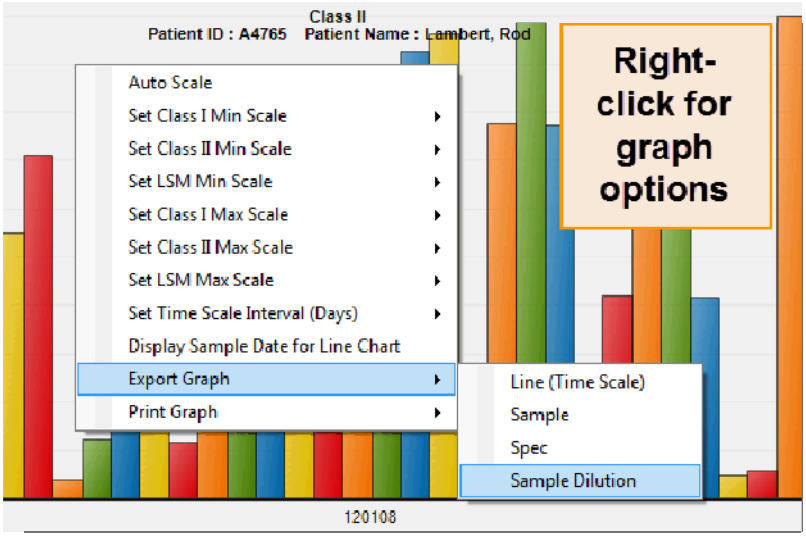
Note: To add final assignments to a sample, double-click in the **Final Assignment** column for the sample to display the analysis window and add the assignment. Also, only samples with a date can be included in this tracking. If the Sample Date column is empty for a sample, click on the empty Sample Date cell and use the pull-down date-finder to add a date.

8. Select the check box in the **Include** column for the sample(s) you want to include in the Ab tracking graphs and data. The graphs are displayed. (To display a specific type of graph, click on the associated tab). Select the check box for the antigen(s) you want to include in the tracking.





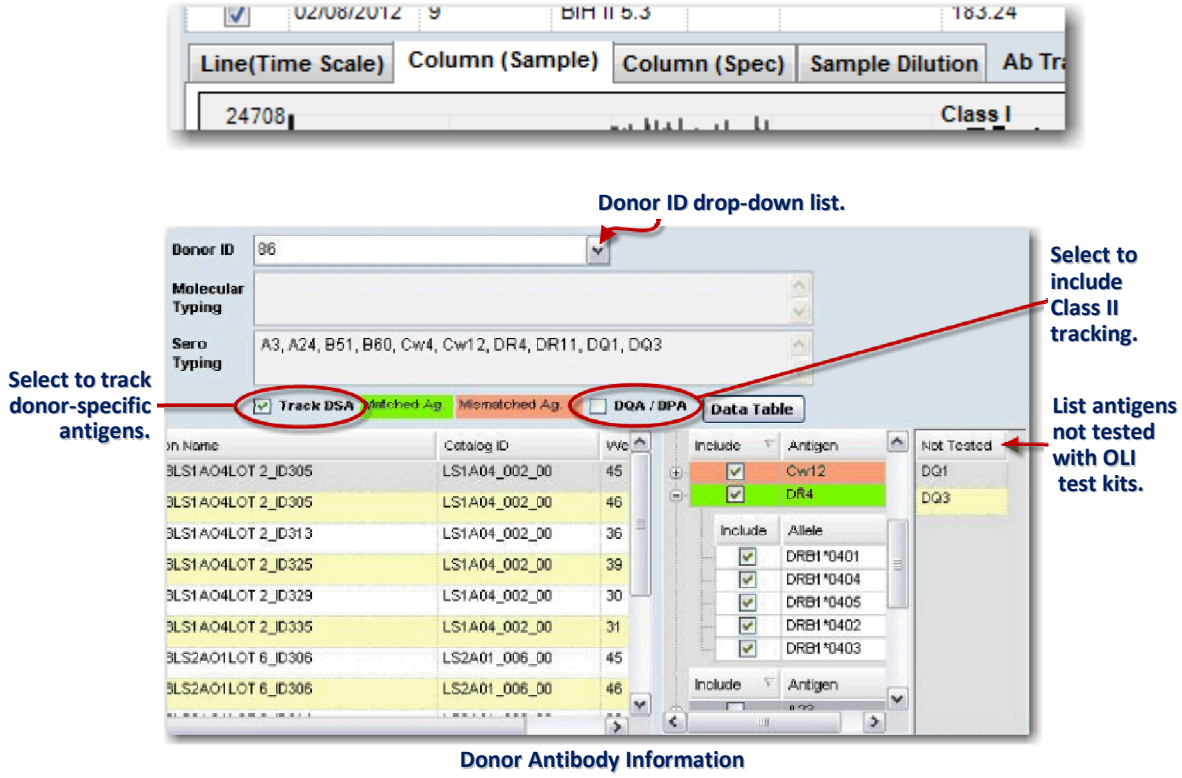
Include Antigen List



9. Select the formula to use for the graphs by clicking the drop down arrow in the **Formula** field, (Default versus Raw). The formula can also be changed after the graphs are displayed if you want to compare the tracking with different formulas.

You can double-click on a graph to expand it, and there are **right-click options available from each graph** (see graphic above). You can also use the expand/contract buttons in the upper right corners to expand the graphs.

- (*Optional*) You can add donor data, if desired, by using the drop-down arrow next to the Donor ID field to select from a list of donors associated with the selected patient. You can also create a new donor on the fly by typing a unique name into the Donor ID field and filling in the molecular and sero typing.
- (*Optional*) Enter a numeric value in the **User-defined cutoff** field. If you want to track the antibody signal strength with or without the cutoff applied, select or deselect the check box next to **User-defined cutoff**.
- (*Optional*) Select the check box next to **Track DSA** to track donor specific antigens. If this is selected and there are donor specific antigens that are not tested with OLI product kits, these are listed.



- (*Optional*) Select the DQA/DPA check box to include these in Class II tracking.
- (*Optional*) Manually enter the donor typing in the **Sero Typing** field.

10. Click the **Data Table** button to display a raw data table CSV file with the patient antigen signal over a period of time. The table can be printed or exported.

Profile Management

HLA Fusion™ tracks all changes to analysis data made by users and allows added data security with a two level analysis result confirmation (Save and Confirm). HLA Fusion also stores general laboratory information to be used on reports including multiple contract lab codes.

User Management

From the Profile main menu you can:

- Add new users
- Edit existing user profiles
- Change passwords
- Reset passwords
- Archive users

HLA Fusion uses two user levels for added security and control of typing and screening results.

Supervisor can...	Lab Technician can...
Modify all product configuration settings	Modify all product configuration settings—except to enable **Auto Accept All** and **Computer Generated Serology** for LABType and Micro SSP products
Save and Confirm analysis results	Analyze data and save analysis results
Update reference files, such as catalogs and NMDP codes	*(Only if authorized by the supervisor*) - Update reference files, such as catalogs and NMDP codes
Archive catalogs	Archive catalogs
Modify and delete session and sample data	(*Only if authorized by the supervisor*) - Modify and delete session and sample data

Modify own & other user accounts	Modify own account only
Change the Lab Profile	Manage sample and patient information

Viewing the User List

The List User option displays a list of all users currently in the database, both active and retired. You can look up and select user profiles.

1. From the Main Menu, select **Profile > List User**.
2. Type in a name and click **Search** to search for current users.
3. Double-click to the left of a user entry to view the profile.
4. Click **Close** to return to the main menu.

Adding New Users

Supervisors can add new supervisor or technician level users. Technicians cannot add new users. Fields marked with an (***)** are required.

1. From the Main Menu, select **Profile > List User**.
2. Click **Add User** to add a new user.
3. Enter new user information.
4. Select the **Active** check box under the Role field to activate the user account.

Note: If this is a lab tech profile and you want to allow reference file update and/or data management privileges for this user, select the appropriate check boxes.

5. Click **Save** to save the new user information and return to the main menu, or click **Close** to discard changes and return to the main menu without saving.

Editing User Profiles

Supervisors can edit the user profile of any user. Technicians can only edit their own profiles. Fields marked with an asterisk (*) are required.

1. To edit your own profile, select **Profile > My Profile**.

2. To select from a list of users to edit, select **Profile > List User** and double-click to the left of a user to select that profile.

3. Edit user information.

   Click **Save** to save user information and return to the Main Menu.

4. Click **Close** to discard changes and return to the Main Menu without saving.

Changing Passwords

Supervisors can change passwords for any user, but they must have the user's old password. Technicians can change only their own passwords.

1. From the Main Menu, select **Profile > My Profile**.

2. In the user profile, click the **Change Password** button.

3. Enter the current and new passwords.

4. Click the **Save Password** button to change the password. Or, click **Close** to close and return to the main menu without changing the password.

Resetting Passwords

If a user loses or forgets their password, HLA Fusion can reset the password. The new password is the same as the user's user name. Only Supervisors can reset a user's password.

1. From the Main Menu, select **Profile> List User** and select a user.

2. In the user profile, click the **Reset Password** button.

3. Click **Close** to return to the main menu.

Changing User Privileges

Only Supervisors can modify a user's privilege level.

1. From the main menu, select **Profile> List User**

2. Double-click to the left of a user to open their profile.

3. In the user profile, select the check box next to either **Manage Data** or **Update Reference Files,** or both, to give the selected user privileges for those activities within the Fusion application.

4. Click **Close** to return to the Main Menu.

Inactivating Users

Supervisors can inactivate users who are no longer using HLA Fusion. User information is still stored in the database, but the user is not able to log into the program.

1. From the Main Menu, select **Profiles > List User** and select a user to edit.
2. Clear the **Active** check box to deactivate the user.
3. Click **Save** to save user information and return to the main menu, or click **Close** to discard changes and return to the Main Menu without saving.

Note: If a User ID is still associated with analysis records, the User ID cannot be deleted.

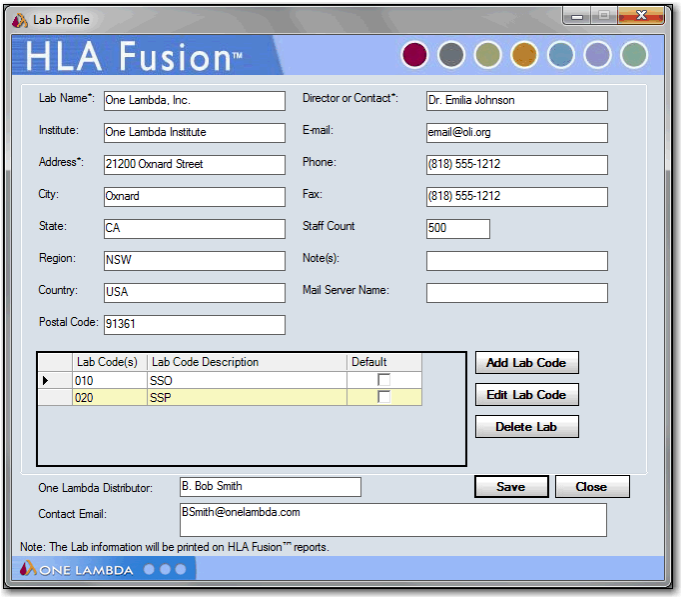
Lab Profile

The Lab Profile menu displays the contact information for your lab, network information used by HLA Fusion, and NMDP contract lab codes. Most of this information is entered during installation, but can be updated at any time. Only supervisors can change the Lab Profile.

From the Lab Profile menu you can:

- Edit the Lab Profile
- Add, edit and remove Lab Codes
- Change the Network Path
- Change the Email Server Name

Lab Profile Information Screen



Editing the Lab Profile

Laboratory information displays on most reports, and includes contact information for your lab. This information is initially entered during installation, and can be edited any time from the Lab Profile menu. Fields marked with an asterisk (*****) are required.

1. From the main menu, select **Profile > Lab Profile**.
2. Edit lab profile information.
3. Click **Save** to save changes and return to the main menu, or click **Cancel** to return to the main menu without saving any changes.

Managing Lab Codes

Lab codes are used on NMDP reports to identify contract labs. Multiple lab codes may be entered and stored in HLA Fusion. You can select the lab code you wish to use when creating an NMDP report. Only the first three digits of a lab Code are used on NMDP reports; lab code descriptions are not included on reports.

1. From the main menu, select **Profile > Lab Profile**.

Add, edit or delete Lab codes:

- Click **Add Lab Code** to add a new lab code. Enter information into the new row.
- Highlight a lab code to be edited. Click **Edit Lab Code** to edit the lab code.

2. Edit lab code information.
3. Highlight a lab code to be deleted.
4. Click **Delete Lab Code** to delete the lab code.
5. Click **Save** to save changes and return to the main menu, or click **Cancel** to discard changes and return to the main menu without saving.

Utilities

HLA Fusion™ uses a variety of reference files for data analysis that need to be updated for new products, lots and revisions. You can also change many global product settings to customize analysis for your lab, and you can modify default system settings to reflect your personal or network file system.

Warning: Always use the latest reference files for analysis. Otherwise, analysis results may not be accurate.

Managing Catalog Reference Files

Catalog reference files contain all of the reaction-specific information needed for analysis, including the following:

- Bead and well specificities
- QC information
- Cut-off values
- Bead and primer information

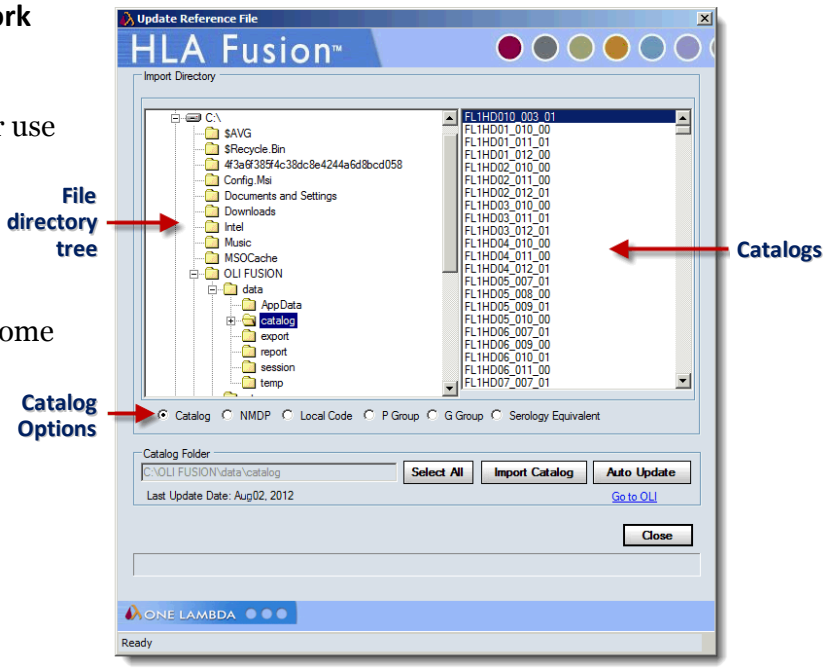
Each new lot or revision of a product needs its own catalog file for analysis results to be accurate.

Updating Catalog Files from a Local or Network Drive

Lab supervisors can input new catalog files for use in analysis when new products, lots, or updates become available. Catalog files are also available on the One Lambda download site.

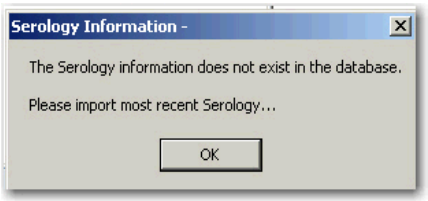
1. From the main or any of the product home pages, click the **[Download]** link, or from the main menu, select **Utilities > Update Reference > Update Reference File**.

   The Update Reference File dialog box displays.



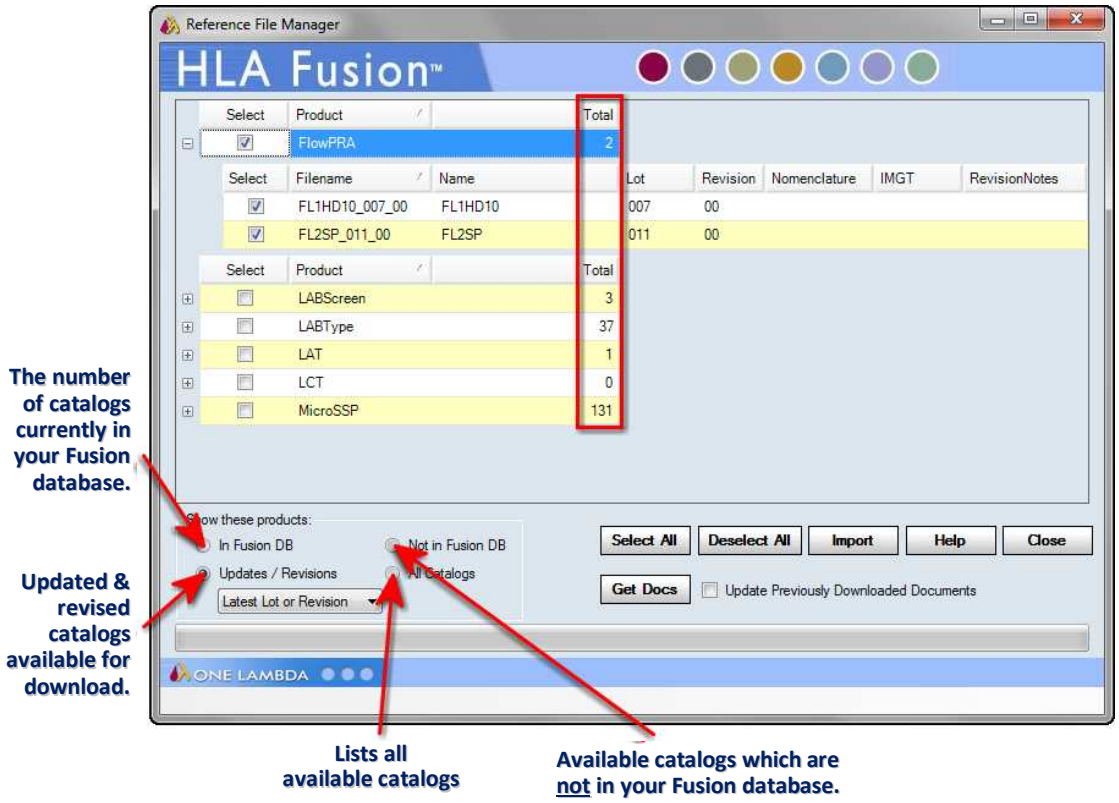
If your serology information is outdated, or you have not imported it yet, a message like the one shown below is displayed. If you do not see this type of message, go to the next step. If you see the message, click **OK** to open the Serology Import dialog box.

Serology equivalent file notice



Make sure the **Catalog** option is selected.

2. Using the file directory tree on the left, locate catalog files to be imported.



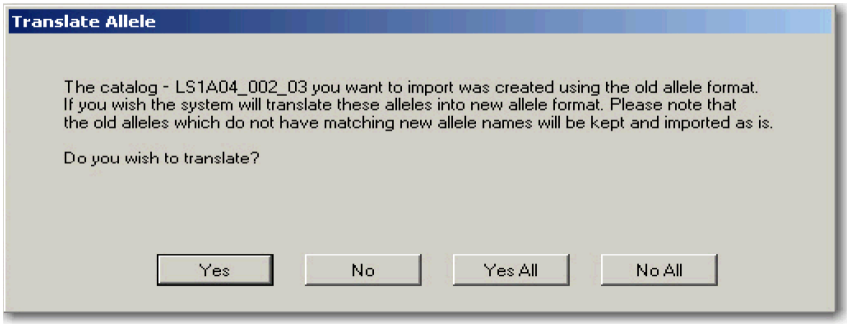
Note: To determine which catalog is the most recent available, HLA Fusion looks first at the lot number and then the revision number. An updated lot number gets flagged as the most recent version of a catalog, even if there is also an update to the revision number of the previous lot since you last downloaded catalogs.

3. Highlight the files you want to import, or click **Select All** Select All to select all files listed.

If you select a catalog to import that is in the old allele format, you are notified with a message. If you do not see this message, proceed to the next step. If you do see the message, select the translate option you want to use before going to the next step.

Note: If you select Yes or Yes All, the software will translate the old allele format into the latest format. For the Molecular products (LABType or Micro SSP), the software will drop the old format allele completely if it does not find a matching allele in the new format list. For Antibody products, if the software does not find a matching allele in the new format, it keeps the old format allele, but adds a colon.

Translate alleles Option



5. Click **Yes**, or **Yes All** to import the selected catalog files.

Note: Catalog import takes longer when you choose to translate alleles.

6. A confirmation dialog box displays import results, click **Close**.

7. Click **Close** to return to the Update Reference menu.

Imported catalog files can be used without restarting Fusion.

Updating Catalog Files from the One Lambda Download Site

- Product catalog files are available on the One Lambda download site (http://download.onelambda.com).

1. From the main or any of the product home pages, click the **Download** link, or from the main menu, select **Utilities > Update Reference > Update Reference File**. The Update Reference File dialog box displays.

2. Click **Auto Update** Auto Update to open the One Lambda **Catalog Updates Selection** window.

3. Select the check box next to the files you want to import. Click the plus or minus signs on the file directory tree, to locate the catalog files for each product. You can also click **Select All** or **Deselect All** to select or clear all the check boxes at once.

4. Click **Import**  to import the selected catalog files.
5. When the confirmation dialog box displays import results, click **OK**.
6. Click **Close**  and then **Yes** to return to the Update Reference menu.

Imported catalog files can be used without restarting Fusion.

Note: You can also click **Go to OLI**, click the links for the products and catalog files you want to import, and follow the download instructions.

If Auto Update does not respond, verify your network connectivity and that the URL you set for One Lambda in **Utilities > URLs & Paths** is correct.

Updating Molecular Typing Reference Files

Reference files contain allele code and serology equivalent information used in analysis. It is important to update them regularly for accurate allele code and serology assignments.

From the Update Reference menu you can download the necessary files:

- NMDP codes
- Local codes
- Serology Equivalent files

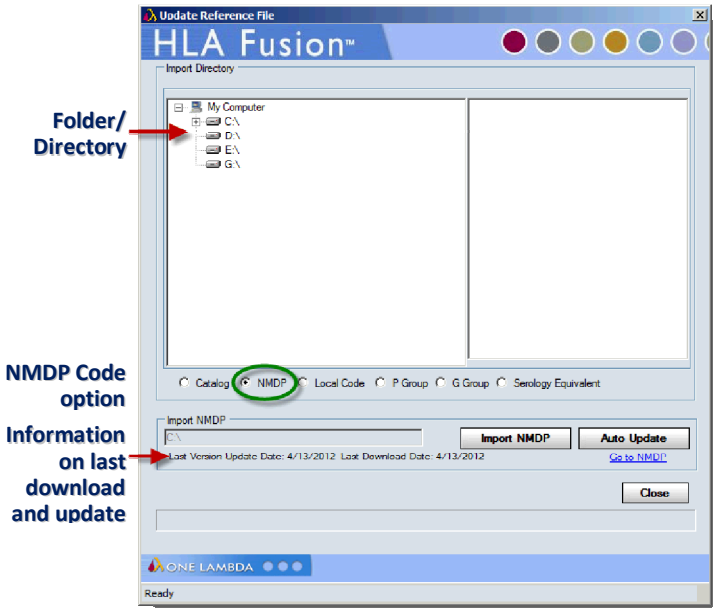
Updating NMDP Codes from a Local or Network Drive

The National Marrow Donor Program (NMDP) provides a list of allele codes that can be used in molecular typing analysis. If you have a current list stored on your local or network drive, use this procedure to import it so HLA Fusion can access it. The most current NMDP code file is available on the NMDP download site.

1. From the main or any of the product home pages, click the **Download** link, or from the main menu, select **Utilities > Update Reference > Update Reference File**.

The Update Reference File dialog box displays.

12. Select the **NMDP** option.



Updating NMDP Code

13. Navigate to the NMDP file on a local or network drive, using the **Import Directory** tree.
4. Click **Import NMDP** to import the selected file.
5. Click **Close** to return to the Update Reference menu.

Updating NMDP Files from the NMDP Website

Follow this procedure to import the NMDP list from the NMDP website.

1. From the main or any of the product home pages, click the **Download** link, or from the main menu, select **Utilities > Update Reference > Update Reference File**.
2. The Update Reference File dialog box displays.
3. Select the **NMDP** option.
4. Click **Auto Update,** which automatically imports the current NMDP file for use with HLA Fusion. Or, click **Go to NMDP** and follow the instructions for downloading an NMDP file from the website.

Note: If Auto Update does not respond, verify your network connectivity and that the URL you set for NMDP in **Utilities > URLs & Paths** is correct.

Creating a Local Code File

Local code files are created by individual labs; local codes are created to make ambiguous typing assignments easier to store and read. For example, ambiguities, such as B*1501/1501N/1502, can be condensed with a code to B*15AB for simpler record keeping.

1. Copy the local code template from the HLA Fusion CD to a local drive.
2. Use a text editor to edit the template and add code definitions.
3. Follow the example format, using a **Tab** to separate each field, and a slash to separate multiple values within a field:

- letter code <tab> numeric allele extension to which the code applies

4. Save the file as `local_code.txt`

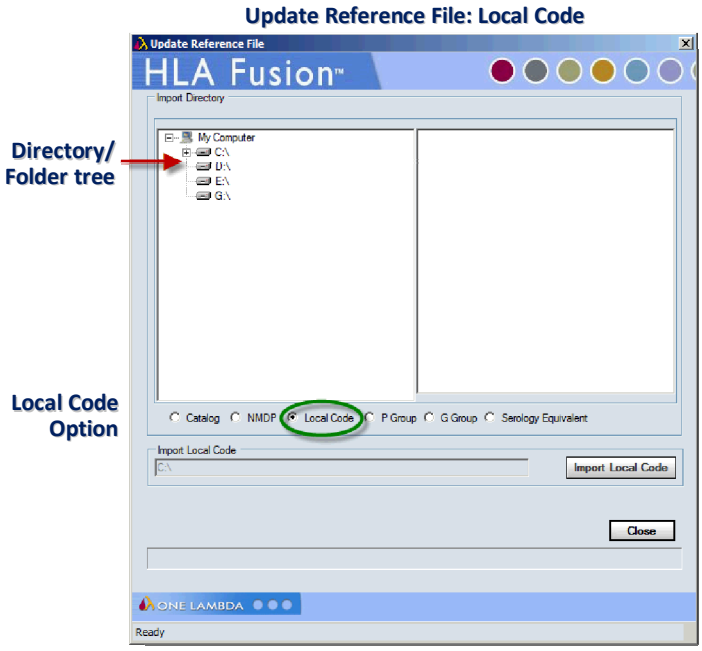
See the next section, *Updating the Local Code File*, to import the file.

Updating the Local Code File

After a Local Code file has been created, it must to be updated in HLA Fusion.

1. From the main or any of the product home pages, click the **Download** link, or from the main menu, select **Utilities > Update Reference > Update Reference File**.

The Update Reference File dialog box displays.



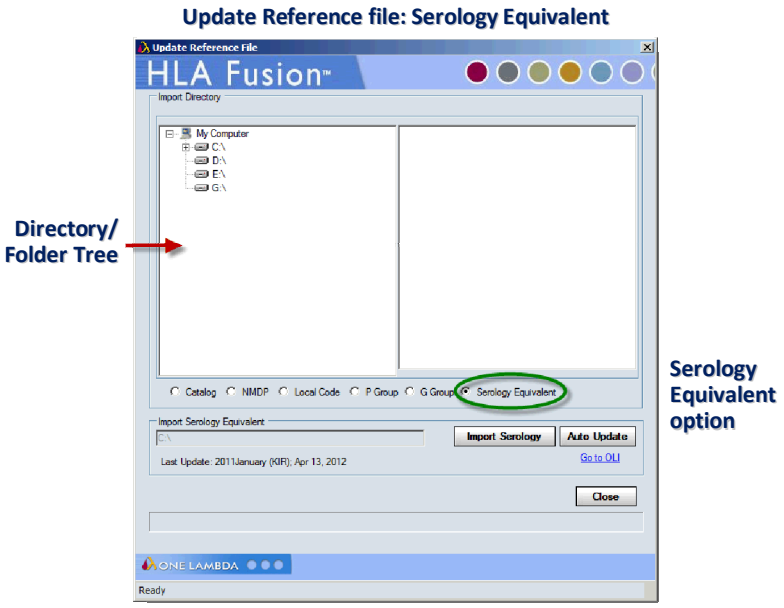
2. Select the **Local Code** option.
3. Use the **Import Directory** tree to locate and select the Local code file to be imported.
4. Click **Import Local Code** to import the selected file(s).
5. Click **Close** to return to the **Update Reference** menu.

Updating Serology Equivalent File from One Lambda Website

The Serology Equivalent file can be auto updated from the One Lambda download site (http://download.onelambda.com).

1. From the main or any of the product home pages, click the **Download** link, or from the main menu, select **Utilities > Update Reference > Update Reference File**.

The Update Reference File dialog box displays.



2. Select the **Serology Equivalent** option.
3. Click **Auto Update** [Auto Update] to open the One Lambda **Catalog Updates Selection** window.
4. Select the check box next to all files you want to import.
5. Click **Import Serology** to import the selected files. Catalog files are ready for use without restarting HLA Fusion.
6. A confirmation dialog box displays import results, click **OK**.
7. Click **Close** [Close] and then **Yes** to return to the Update Reference menu.

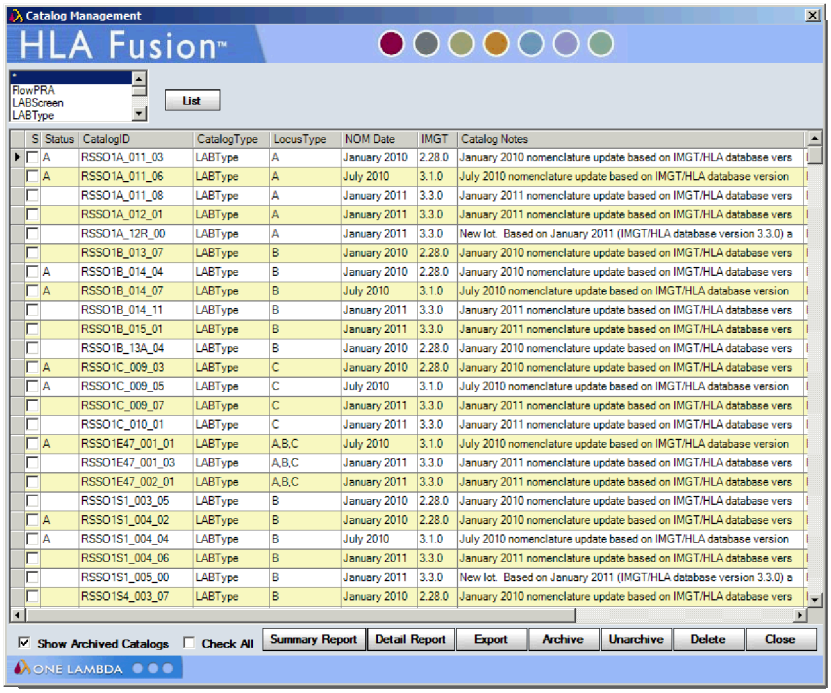
- If Auto Update does not respond, verify your network connectivity and that the URL you set for Serological in **Utilities > URLs & Paths** is correct.

Catalog Management and Information

Archive Catalogs

You can archive catalog files that are no longer used. The catalog information still exists in the database, but is not included in the list of available catalog files for analysis. Catalog files can also be restored for use in analysis.

1. From the Main Menu, select **Utilities > Update Reference > Catalog Information/Management**.



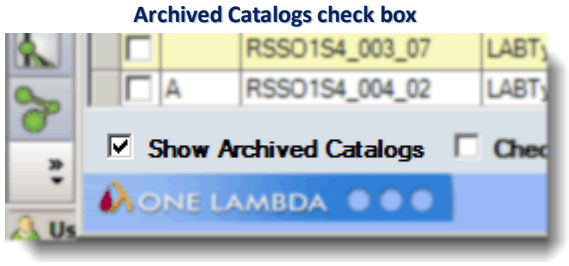
Archive Catalog

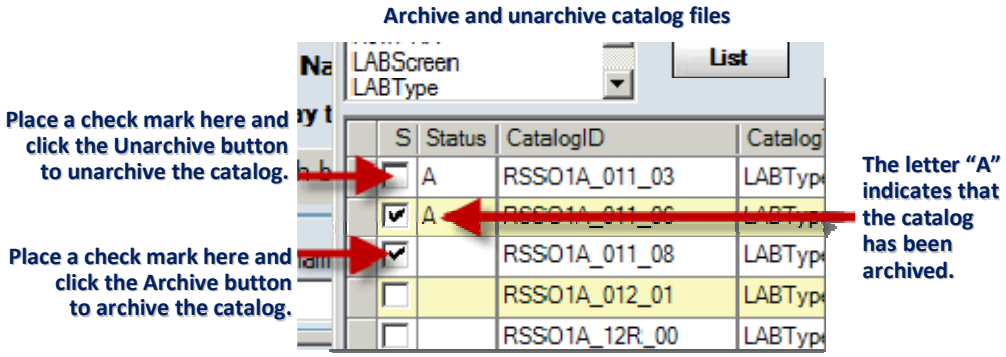
2. Select the **S (select)** check box for the catalog files you want to archive, and click **Archive** Archive.
3. When a pop-up message displays **Data Saved**, click **OK**.
4. Click **Close** to return to the **main menu**.

Note: When you import a new version of a catalog file, the system auto-archives the previous version.

Un-Archive Files

Archived catalog files display an **A** in the **Status** column when you view the catalog list and the check box for **Show Archived Catalogs** is selected.





- From the **Archive Catalog** window, select the check boxes next to the catalogs you want to unarchive, and click **Unarchive**.

Viewing Catalog File Information

You can view information about a catalog file and generate a report from the **Catalog Information** menu. Catalog files displayed with an **A** in their Status column have been archived.

1. From the Main Menu, select **Utilities > Update Reference >**Catalog Management.
2. Click a column header if you want to sort the catalog file list.
3. Click **Report** to display a printable, exportable report of the currently displayed catalog information.

Deleting Catalog File Information

You can delete a catalog file from the **Catalog Management** menu. Catalog files displayed with an **A** in their Status column have been archived.

1. From the Main Menu, select **Utilities > Update Reference >**Catalog Information/Management.
2. Select the check box next to any catalog you want to delete.
3. Click Delete to remove the catalog information.

Reporting Catalog File Information

You can view and report information about a catalog file and generate a report from the **Catalog Information** menu.

1. From the Main Menu, select **Utilities > Update Reference >Catalog Management**.
2. Click a **column header** if you want to sort the catalog file list.
   - (*Optional*) If you want a report in the old format, select the check box next to Old Format report.
3. Click **Report** to display a printable, exportable report of the currently displayed catalog information.

Associating Product Catalog Files and Luminex Templates

You can associate a catalog file with the Luminex template name used for a specific product. HLA Fusion automatically associates catalog ID and template names the first time you run the analysis for the product. After an association has been made, HLA Fusion automatically selects the catalog file associated with the template used in the CSV file when you start analysis. You can also manually add, remove, or change associations.

1. From the Main Menu, select **Utilities > Catalog Template Association**.

Add, remove or modify an association:

2. Add a New Association.
3. Select a catalog file.
4. Type in a new template name, or click **Browse** to select a Luminex template file (.lxt format) to associate with the filename.
5. Remove an Association.
6. Select a catalog file.
7. Select a template name and click **Remove**.

Modify an Association:

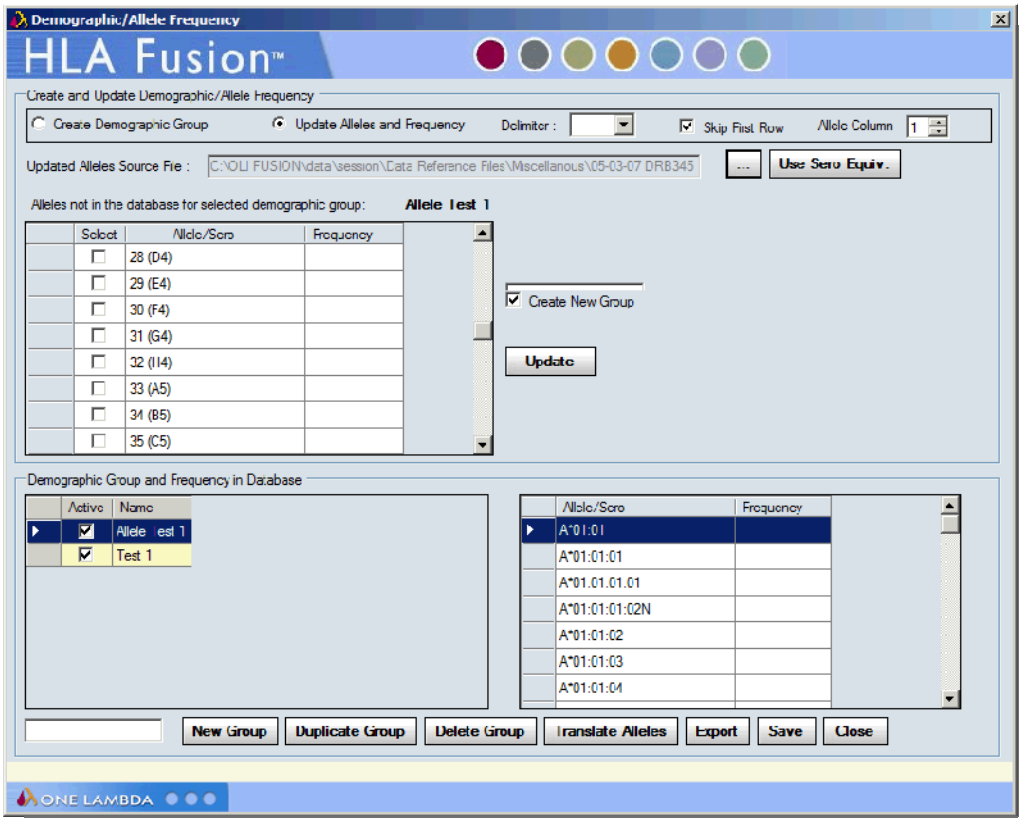
1. Select a catalog file.
2. Edit existing template name(s).
3. Click **Save** to save changes.
4. Click **Close** to return to the Main Menu

Importing Allele Frequency Files (Demographic Frequency)

You can import allele frequency files to use in analysis based on demographics.

1. From the Main Menu, select **Utilities > Update Reference** Allele Frequency.
2. Select the **Create Demographic Group** option.

Allele frequency import



3. Click the **browse** ... button and locate Allele Frequency files.
4. Click **Import**.

When an Allele Frequency file is successfully imported, the groups it contains are listed in **Demographic Group and Frequency in Database**.

5. Click **Save**.

If the header for the column of any allele frequency file you import is empty, the entire column is not imported into Fusion, regardless of any other data it contains. If columns are duplicated, Fusion gives you an error message and does not import the allele frequency file.

The data contained in the Allele Frequency file may look similar to this graphic.

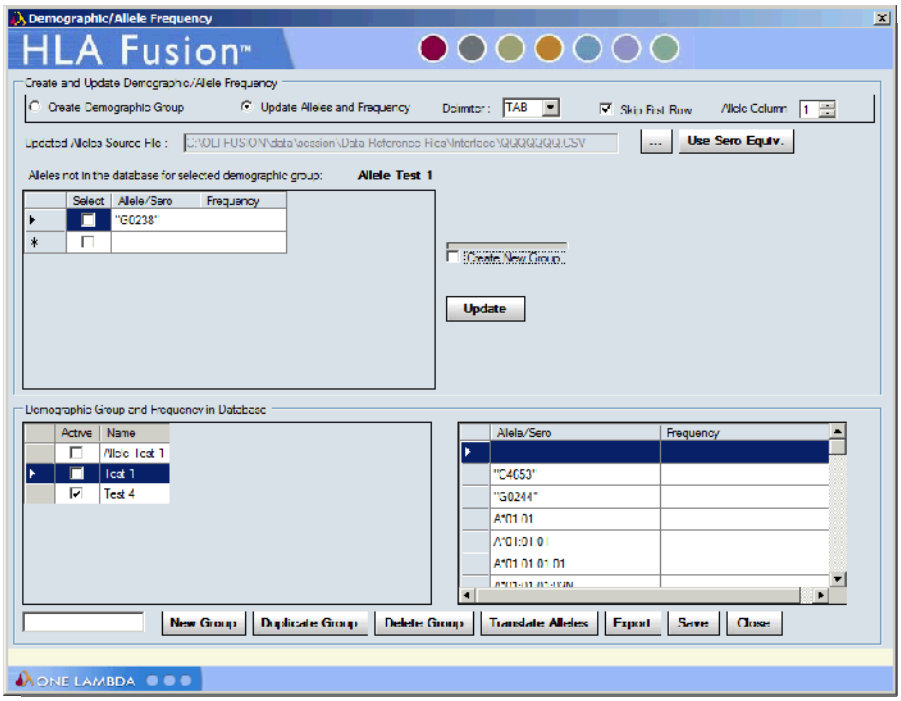
	A	B	C	D
1	Official Name	Japan	Caucasian	oli2
2	A*0101	0.2	0.1	0.2
3	A*010101	0.2	0.02	0.2
4	A*01010101	0.2	0.003	0.2
5	A*0201	10.9	2	
6	A*02010101	10.9	56	
7	A*020106	0.01	3	
8	A*020107	0.01	4	
9	A*020110	0.01	4	
10	A*020301	0.02	0.02	
11	A*020302	0.01	0.01	
12	A*020601	10.4	10.4	
13	A*020602	0.01		
14	A*0207	3.4	3.4	
15	A*0210	0.1	0.1	
16	A*0215N	0.01		
17	A*0218	0.02	0.02	
18	A*0228	0.02	0.02	
19	A*0242	0.01		
20	A*0251	0.01	0.01	
21	A*0253N	0.01	0.01	
22	A*0259	0.01		
23	A*0270	0.01	0.01	
24	A*0271	0.01	0.01	
25	A*0272	0.01		
26	A*0301	0.8	0.8	
27	A*03010101	0.8	0.8	
28	A*0302	0.02	0.02	
29	A*1101	8.1	8.1	
30	A*110101	8.1		
31	A*1102	0.1		
32	A*110201	0.1	0.1	0.1
33	A*24020101	35.6	35.6	35.6
34	A*24021	35.6	35.6	35.6
35	A*2404	0.02	0.02	0.02
36	A*2408	0.02	0.02	0.02
37	A*2420	0.02	0.02	0.02
38	A*2425	0.01	0.01	0.01
39	A*2443	0.01	0.01	
40	A*2601	9.8	9.8	
41	A*260101	9.8	9.8	
42	A*2602	2.2	2.2	
43	A*2603	2.1	2.1	
44	A*2604	0.01		
45	A*2605	0.02		
46	A*2606	0.02		
47	A*2611N	0.01		

Updating Allele Frequency Files (Demographic Frequency)

You can modify allele frequency files before using them in analysis based on demographics.

1. From the Main Menu, select **Utilities > Update Reference >Allele Frequency**.

Allele frequency import



2. Select the **Update Alleles and Frequencies** option.
3. Click the **browse** ... button and locate the Allele Frequency file you want to update.
4. Double-click on the file, or click **Open** in the browser window.
5. Do any or all of the following to modify the file:
   - Add/delete alleles
   - Delete existing demographics
   - Change the allele frequencies
   - Convert allele format
6. Click **Translate Alleles**
7. Click **Update**.
8. Click **Close**.

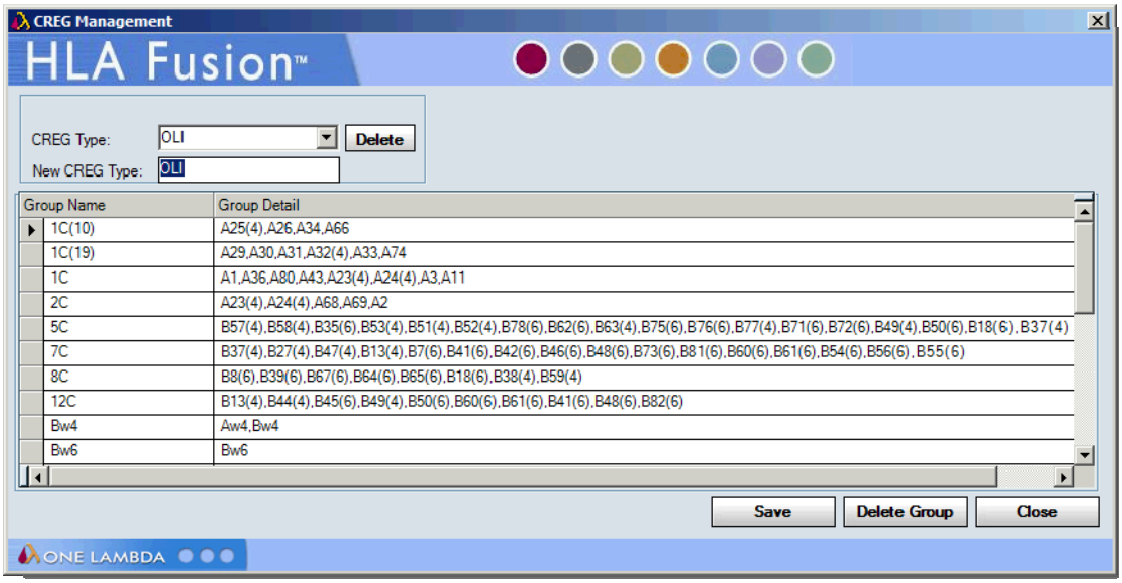
Managing CREG List Information

You can modify existing CREG lists or create new ones for use in PRA and Single Antigen LABScreen, FlowPRA, LAT, or LCT analysis. Take the following steps to create or modify a CREG list:

1. Select **Utilities > Update Reference > CREG Information Management**.

The CREG Management window displays.

CREG Management screen



2. Select an existing CREG group from the **CREG Type** drop-down list, or Enter a name for a new group in the **New CREG Type** field.

Do one of the following:

- Enter new or modify existing information in the **Group Name** and/or **Group Detail** fields and click **Save**.
- Highlight a row of existing group information, and click **Delete Group**.

3. When you have completed CREG group creation or modification, click **Close**.

Note: Please verify your data before saving, and please do not mix alleles with the older nomenclature format with alleles in the newer format within the same CREG table.

Changing Product Configuration Settings

Changes to product analysis settings apply only to samples not previously analyzed. Previously analyzed samples must be re-analyzed for the changes to be applied.

From the Product Configuration menu you can

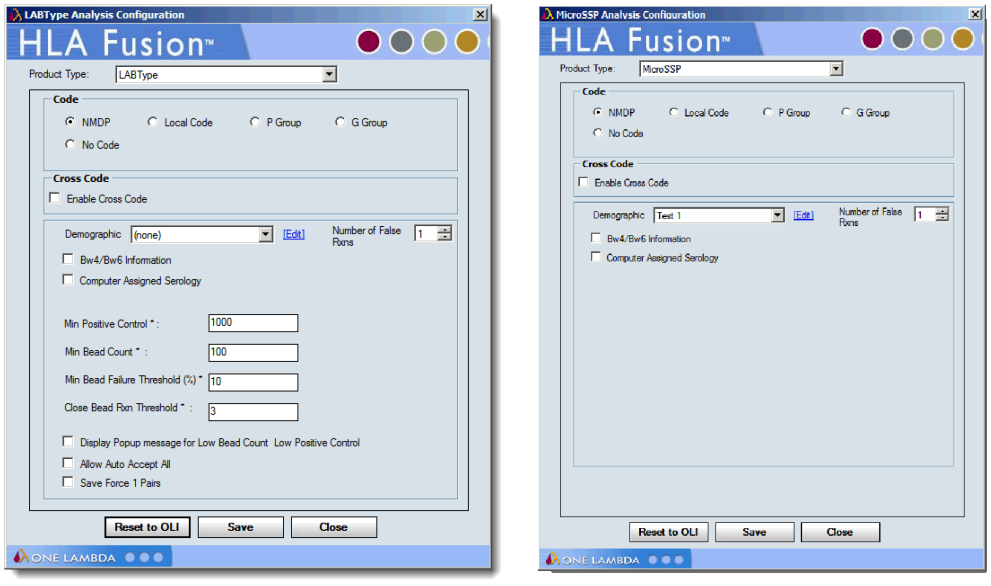
- Change Micro SSP product configuration
- Change LABType product configuration
- Change product settings for LABScreen Mixed analysis
- Change antibody screening analysis settings
- Change default negative serum values for LABScreen analysis

Changing Molecular Product Configuration

Changes to LABType and Micro SSP analysis settings apply only to samples that have not yet been saved or confirmed. To change analysis settings for previously saved or confirmed samples, you must change the settings from the product analysis window and re-analyze the sample.

1. From the LABType or Micro SSP home page click **Edit**, or select **Utilities > Molecular Product Configuration >Molecular Analysis Configuration** from the HLA Fusion main menu.

2. Select either **LABType** or **Micro SSP** from the Product Type drop-down menu.



LABType and Micro SSP Configuration settings

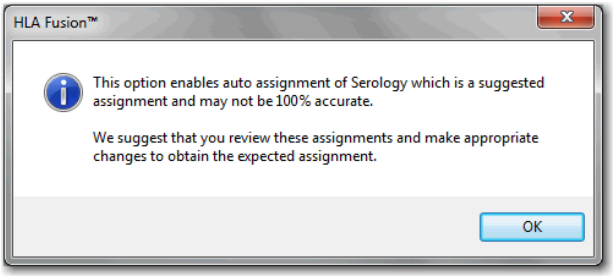
3. Change configuration values as needed.

   - **Save Force 1 Pairs** stores force 1 pairs in the database during analysis. The force 1 pairs are also displayed in reports that contain this information.

   - **Allow Auto-Accept All** *can only be selected by someone with Supervisor user privileges*, and allows you to select a button on LABType session summary to accept the batch analysis results for all samples.

   - **Computer Assigned Serology** *can only be selected by someone with Supervisor user privileges*, and automatically populates LABType and Micro SSP analysis serology assignment fields, as well as stores results in the database. If this is selected, a warning message displays as a reminder that the assignments are estimates, and should not be accepted without verification.

Serology auto-assignment warning



4. Click **Save** Save to save changes.

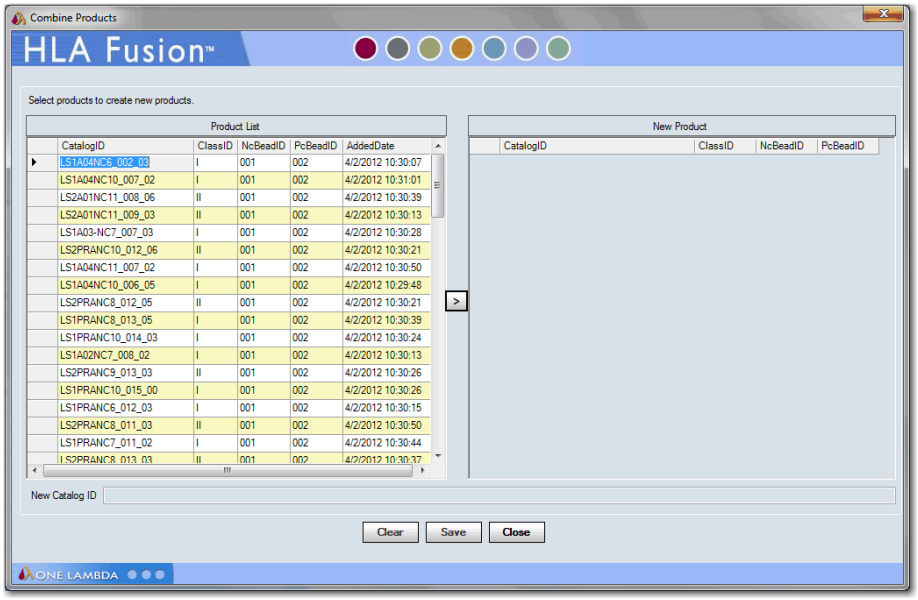
5. Click **Close** Close to return to the Update Reference menu.

Creating a Combined LABScreen Session Catalog

To run a Class I and Class II combined LABScreen analysis session, create a combined catalog to use for your session. You must use a Class I catalog file and a Class II catalog file that have the same positive and negative control beads, but do not have any other beads in common.

1. Select **Utilities > Antibody Product Configuration** from the HLA Fusion main menu.
2. Click **Create Combined Products** to open the Combined Products menu.

Combine LABScreen catalog files



3. Select the first product catalog to be combined and click >
4. Select the second product catalog to combine and click >.

   The new catalog file name appears at the bottom of the selection menu.

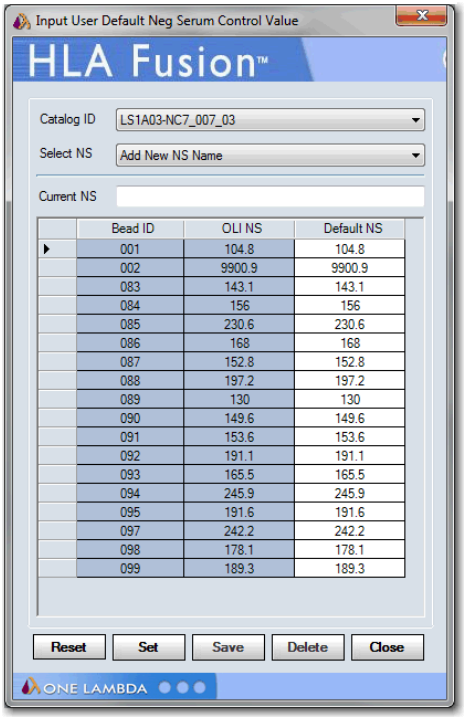
5. Click **Save** Save to save the new combined catalog file for use in LABScreen analysis.
   - **Optional:** Click **Clear** to reset the selections and start over.
6. Click **Close** Close.

Changing LABScreen Default Negative Serum

Negative control sera can be adjusted or added for each product or lot. You can change the trimmed mean fluorescence value for each bead individually.

1. Select **Utilities > Antibody Product Configuration** from the HLA Fusion main menu.
2. Click **Set Default Negative Serum Value** to open the Default Negative Serum Value screen.

Setting default negative serum value



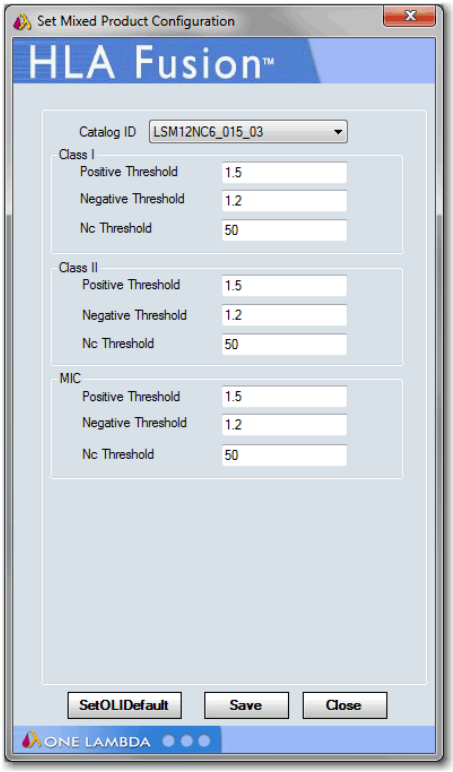
3. Select a catalog file.
4. Select an existing negative serum, or
5. Select **Add New NS Name** from the pull-down menu to create a new negative serum.
6. Type a name for the new negative serum into the Current NS field.
7. Edit Default NS values for the desired beads.
8. Click **Save** to save the changes.
9. Click **Close**.

Changing LABScreen Mixed Product Configuration

You can change LABScreen Mixed analysis positive and negative threshold settings for each product or lot. The new cutoff threshold values are used in every analysis session for that product or lot.

1. From the LABScreen home page click **Edit**, or select **Utilities > Antibody Product Configuration** from the HLA Fusion main menu.
2. Click **Set Mixed Product Configuration** to open the LABScreen Mixed Configuration menu.

LABScreen Mixed Product configuration



3. Select a product catalog from the **Catalog ID** drop-down list.
4. Edit threshold values. For LABScreen Mixed catalogs, the threshold values can be set at the bead level.
5. Click **Save**  to save values.
6. Click **Close**  .

Changing Antibody Screening Analysis Configuration

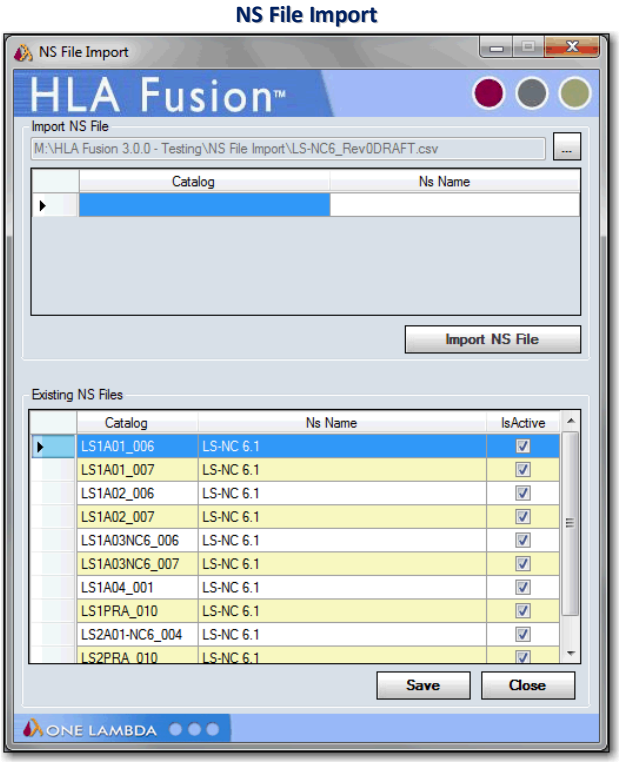
Changes in the antibody screening analysis configuration are made by product type and apply only to sessions analyzed after the changes were made.

1. From the LABScreen, FlowPRA, LAT or LCT home page click **[Edit]**, or select **Utilities > Antibody Product Configuration** from the HLA Fusion main menu.
2. Click Set Analysis Configuration to open the Analysis Configuration Settings menu.
3. Select a product type from the Product Type drop-down list.
4. Change values as needed.
5. Click Save to save values.
6. Click Close.

Importing NS Files

Negative Serum (NS) files can be imported to be referenced during analysis.

1. From the Main Menu, select **Utilities > Antibody Product Configuration**.
2. Click NS File Import to open the NS File Import menu.



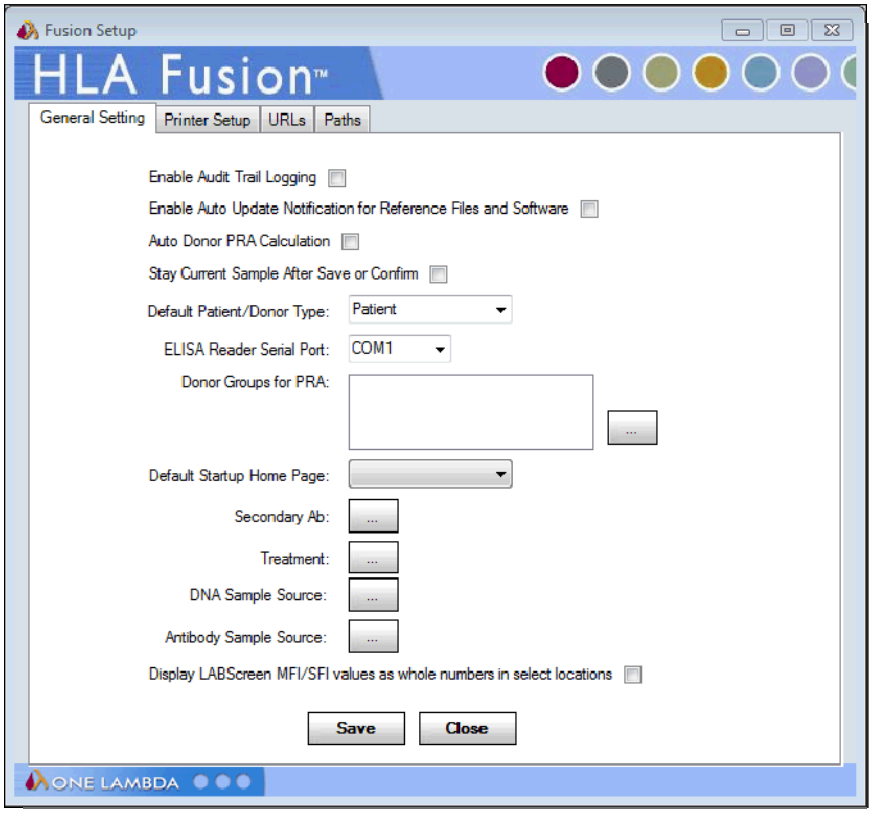
3. Click the **browse** button to locate and select NS files.
4. Click **Import NS File**.

   When an NS file is successfully imported, it is listed in **Existing NS Files**.
5. Click **Close** to return to the Update Reference menu.

Choosing General Settings

You can set a number of general system settings, including printer defaults and URLs and Paths.

1. Select **Utilities > General Settings** from the HLA Fusion main menu. The General Settings dialog box is displayed.



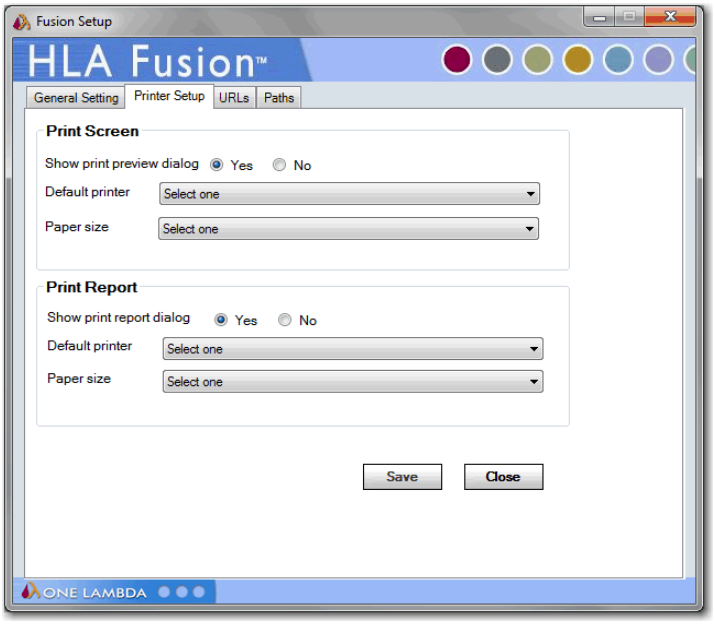
Fusion General Settings

2. Use the drop-down menus, or select check boxes to make your selections on this dialog box.
3. When you have made all of your selections, click **Save**.

Printer Defaults

From the Printer Setup tab on the General Settings dialog box, you can select settings such as default printer and paper size, which will be in place when you print reports or do a print screen.

1. Select **Utilities > General Settings**, and click the **Printer Setup** tab.



Printer Setup

2. Select from the following options for both the **Print Screen** and **Print Report** panels of the dialog box:

- If you want to see a print preview or print report dialog each time you print, make sure the **Yes** option is selected. Otherwise, select **No**.
- If you do not want to select a printer each time you print, select the default printer and paper size from the drop-down menus.

Note: This default printer configuration may be overwritten by the specific page properties of certain reports.

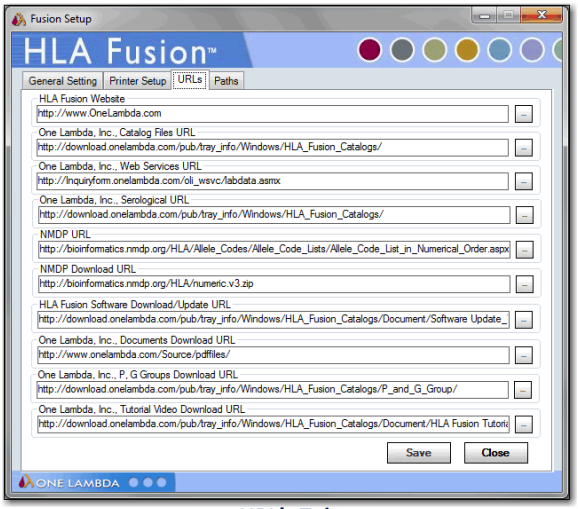
3. Click **Save** Save.

Setting HLA Fusion Default URLs and Directory Paths

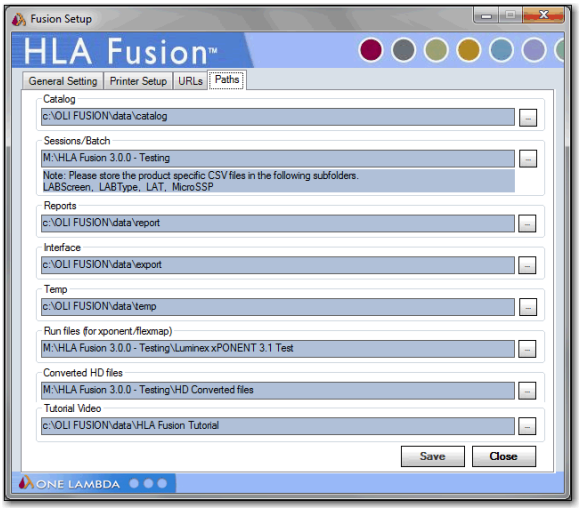
The **URLs & Paths** option under the General Settings menu allows you to set the default URLs for OLI and NMDP websites to download reference and catalog files, and product updates. This option also allows you to set the directory path where HLA Fusion, by default, stores catalogs, session/batch files, reports, etc. Modifying URLs or paths ahead of time allows you to avoid having to browse for files each time you need them.

1. Click [Edit]on the right side of the *General Configuration* panel of the HLA Fusion default home page, or select **Utilities > General Settings** from the HLA Fusion main menu.

Select the **URLs** tab or the **Paths** tab.



URL's Tab



Paths Tab

2. Enter a URL and verify it works by clicking [...].For paths, use the browse button [...] to locate the directory you want to use for the specified purpose (e.g., where you want to store reports when they are generated).

3. Click **Save** [Save].

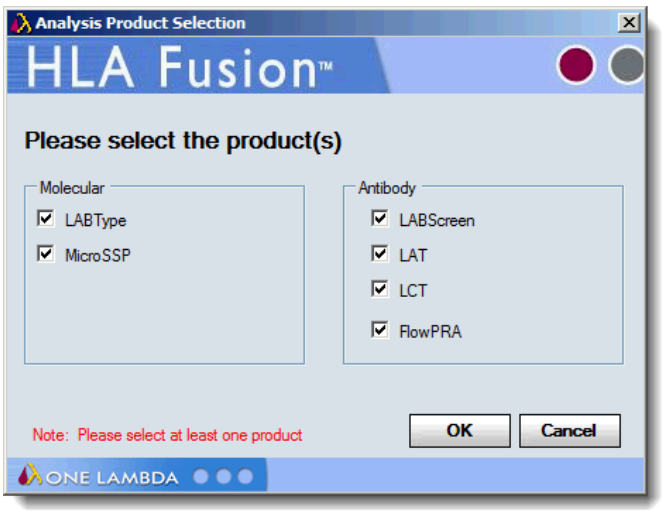
Activating Products

The Products Selection option on the Utilities menu allows you to activate or de-activate the various OLI analysis products that may be used with HLA Fusion.

1. From the Main Menu, select **Utilities > Products Selection**.

Select or **clear** the check box next to the product(s) you wish to activate or de-activate.

Click **OK** [OK].



Select/Activate products

Software Validation

The HLA Fusion software has functionality to help with the validation process required by Labs, Clinics, and hospitals seeking to comply with GCP, GLP and GMP. Validation of the HLA Fusion software for your lab environment for regulatory or performance reasons, can be automated by using the **IQ** (Installation Qualification**)** and **OQ** (Operational Qualification)options from the **Utilities > Validation** menu. Your lab may choose to run these as a standard regulatory validation process, to help troubleshoot issues, or to provide information to prepare for a software upgrade.

IQ (Installation Qualification)

The IQ process assists you with installation qualification of HLA Fusion software by providing a built-in function. Once the Installation qualification completes, a results report is generated, which you can save, print or export to Excel.

Note:	If your IQ results concern you, export them to an Excel file and e-mail the file to OLI customer support.

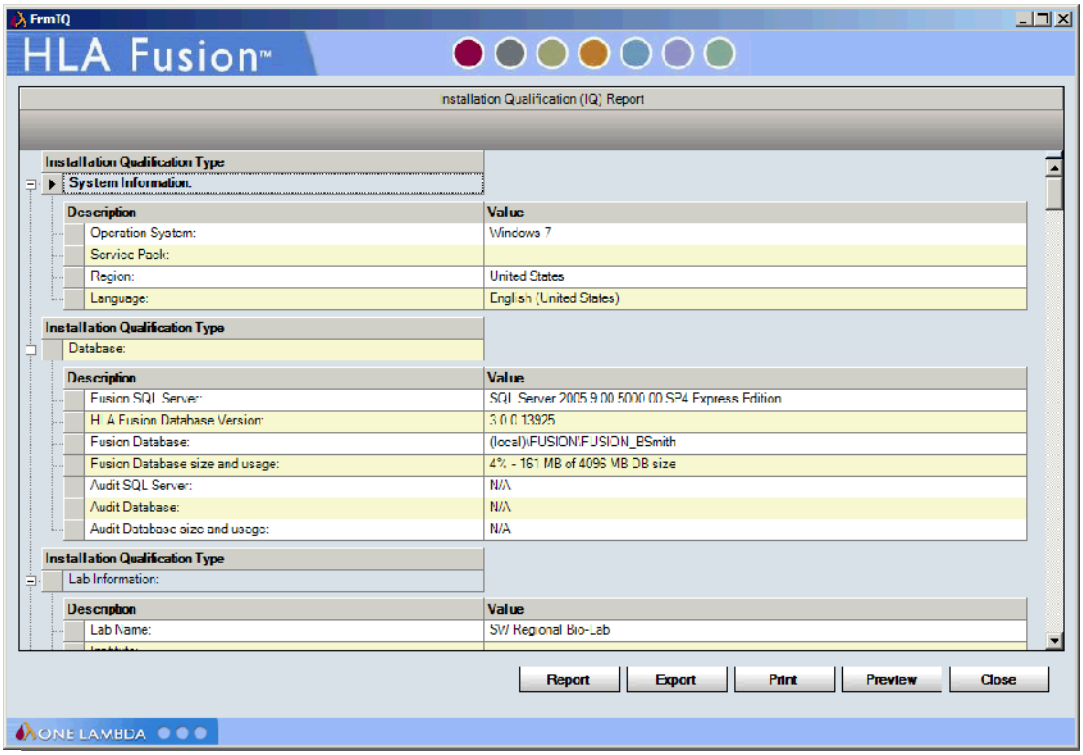
1. From the Main Menu, select **Utilities > Validation > IQ**.

The validation test runs. When it is complete, a report is displayed, with the following categories of data:

- Systems Information (e.g., operating system)
- Environment (e.g., directory path where the HLA Fusion program files are stored)
- URLs (e.g., the URL for the catalog download site)
- Database Information (e.g., name of the database)
- Number and types of files installed (e.g., dll)
- Lab Information (e.g., name and address of your lab)
- Analysis Configuration for each product (e.g., low bead count for LABType)

2. Choose to save the report, preview it, print it, or export it to Excel.

Example IQ Report



Typical IQ Report

IQ (Installation Qualification)

The IQ process assists you with the installation qualification by providing a built in functionality. This can be performed only if you have completed the IQ process as explained above. The installation qualification goes through a series of QA process to analyze pre-loaded batch and catalog, and compares them with pre-defined results.

Once the Installation validation completes, a results report is generated that you can choose to save, print or export to Excel. If the results concern you, export them to an Excel file and email this file to OLI Customer Support.

- From the Main Menu, select **Utilities > > Validation > Installation(IQ).**

The validation test runs. When it is complete, a report is displayed, with data regarding the operation of HLA Fusion in your computer environment.