HLA Fusion™ Version 4.0
New Product Features

REF **Catalog # FUSPGR**

IVD For In Vitro Diagnostic Use (European Union only in the case of HLA Fusion™ Research).

DOCUMENT CONTENT

This document describes features for both the IVD and Research versions of HLA Fusion software on the pages listed as follows:

HLA Fusion™ Version 4.0

REF **Catalog # FUSPGR**

IVD For In Vitro Diagnostic Use.

DESIGNATED USERS

All users of HLA Fusion™ Software. This applies to LABScreen™, LAT™, LCT™, FlowPRA™, LABType™, and Micro SSP™.

RELEASE CONTENTS

The HLA Fusion™ 4.0 package includes the following items:

1. HLA Fusion™ 4.0 CD
2. HLA Fusion™ 4.0 User Manual
3. HLA Fusion™ 4.0 Installation Guide
4. HLA Fusion™ 4.0 Release Notes/Read Me
5. HLA Fusion™ 4.0 Database Utility User Manual

WHAT HAS CHANGED

Every effort has been made to insure that this document is accurate, complete, and up to date. All changes made since the previous version of the HLA Fusion™ software have been incorporated herein. It is inevitable that occasional omissions will occur

NEW FEATURES

General – All Modules

- Microsoft Windows XP and SQL Server 2005 are no longer supported. Microsoft SQL Server 2014 Express and Windows 8.1 are now supported. Microsoft SQL 2014 Express is included in the HLA Fusion installation.
- Please note that Microsoft SQL Server 2014 Express requires Windows 7 Service Pack 1 and .NET 3.5.1 on Windows 8.1. In some cases, if your SQL 2014 installer fails, you will need to manually download and install Microsoft .NET 3.5.1. Alternatively, you can also install and configure Microsoft SQL Server to use with HLA Fusion software.
- The Combined Products feature (CSVs) from the import modules in the LABScreen and LABType products has been removed.
- The graphical user interface of HLA Fusion 4.0 has been updated to make it easier to use. Graphics such as the home page, product page and analysis screens have been updated to facilitate easier navigation.
- When using the Patient or Donor ID to search for donor records with the Search Function (the binocular icon), the resulting records are now shown in the Navigator window sorted in descending order by Sample Date and then Sample ID.
- The Family ID has been added to the search criteria in the Data Management module.
- The Print Screen function now previews screen images in the PDF viewer, while automatically saving the print screen PDF file in a user-specified folder.

Analysis - Molecular

- All serological assignments in the SSP and LABType analysis screens are tagged with the corresponding locus. For Class II serological assignment, a popup window now appears to allow users to select the corresponding locus.

General Analysis – LABType

- LABScan3D-based XR and CWD products are now supported. The Plate Designer module also now supports XR and CWD products.

- A new color scheme of color codes has been assigned to the EXON 4+ Supplemental Analysis / Import screen. The five colors and their meanings are:
    - Light Gray: No related test is available to combine
    - Light Blue: Found more than one sample for a locus (Exon 4+ only)
    - Light Yellow: Nomenclature data is different
    - Pink: Mismatch or false reaction: For Exon 4+ the sample with false is disabled.
    - Orange: Sample is ambiguous. Locus may have no assignment.
- User and system comments from A, B, C LABType analyses now appear in the corresponding E4-7 analysis and in the reports of the E4-7 session. Comments are clearly labeled so that they can be traced to their corresponding test. When the sample is batch analyzed the comments from sample to which the E4-7 test is combined with is included in the comments (user and system comments) based on the following format and condition:
    - Format: [Combined with session: Session name (catalog ID): Comments from the session/test].
    - If there are no comments from the combining sample there are no comments added.
    - Every time a combined analysis is performed, sample comments are parsed and replaced with refreshed comments.
- Performance improvements have been made in 1. batch analysis, 2. batch load, 3. sample-to-sample navigation (in the Analysis Screens), and 4. loading a sample from within the Navigator. Users may continue to experience slower performance with sample analysis that exceeds n Number of allele pairs. Generally this will occur during the LABType Classic A Locus tests.
- Probe IDs are viewable from the following locations -- 1. Bead Info tab, 2. Rec Site tab from the LABType screen, and 3. Sample Profile (third quadrant) of the Analysis screen. The Probe ID appears in a pop-up window when viewing from the Rec. Site screen.
- The user can now click on the Save button multiple times before finalizing and confirming the results.

Analysis – MicroSSP

- A new "Show Me" feature allows SSP users to display the corresponding positive wells for genotypes in the kit.
- Additional gel system views are now available:
    - Centipede
    - ElectroFast 96
    - E-Gel
- MicroSSP and Molecular Custom reports now include an option to list all the potential genetic typing missed for a non-amp well.

Analysis – Antibody products

- A separate PRA donor value is available for each selected donor group. This information is available in the antibody custom reports.
- Antigen typing results for a patient now can be viewed by toggling between different associated donors. By default, the most recent donor associated to the patient is shown first. The antigen typing results are now circled.
- The values in the DSA column under the Match/Mismatch window are dependent upon the configured active formula.
- It is now possible to import a sample list for LAT, LCT, and FlowPRA products. This feature is similar to the "Import from file" function in SSP analysis where the file contains a catalog ID and sample ID.
- The overall assignment column in the session summary screen is now split into two columns. One column shows suggested positive or negative results while the other column shows positive or negative values based on final assignments. The suggested result is negative if either tail or Epitope analysis results are negative, otherwise it is positive.
- The UNOS CPRA calculator is now available from the Antibody analysis screens.

Information Management – Sample, Plate Designer

- The Plate Designer now uses a specific color to identify test list samples.
- The Tray Layout Report in the Plate Designer now allows association of Patient IDs with Sample IDs.
- The Plate Designer now allows importing of sample lists using various formats such as Swisslab. Additionally, the Plate Designer can now split the exported plate into two separate batches. The

separated output file names can automatically be named to reflect the catalog and bead reagent lot that was used.
- All file extensions (.txt, csv) are now visible in navigation/browse windows when importing external test files. The user can also filter potential input selections based on the desired file format.
- The External File import function now allows importing from a LIMS. Additionally, Swisslab samples can now be imported in .csv format. The plate is automatically loaded and tests are automatically assigned according to imported samples. Users are still able to rearrange samples in the plate after import.
- The Plate Designer module also now supports XR and CWD products.
- When exporting a plate design to Luminex software, the plate will be split into separate batches corresponding to the test assignment. The batch name will be automatically populated with user configured values, i.e. Session Name, Date Format, Separator, Locus, and Template.
- In Auto-batch naming configuration, if a template is included in batch naming format and the batch name is changed before selecting the template, the template name will not be included in the batch name.
- The Plate multi-batch name is editable before exporting data to Luminex software.
- Plate designs containing XR/CWD tests from LABType can only be exported to xPonent 4.0 or xPonent 4.2 (LABScan 3D related software).
- The user may now design the plate by assigning samples in both vertical and horizontal directions (column by column, row by row).
- Plate detail now changes to reflect changes in the plate direction (horizontal/vertical direction).
- Customers may now view and print the plate layout format and/ or list format report with patient identification information.
- Customers changing sample locations or creating duplicate samples must refresh the plate designer window to see correct patient identification information.
- When searching for individual samples or samples in the test lists, the samples which already exist in the current plate design are now differentiated for customer convenience.
- The samples that are present in the current plate design are indicated using a blue and bold color.
- Luminex plate reading direction is defined by the direction in which the plate design was last saved.
- The use of special characters in batch, plate, and sample names is not supported.

Information Management – Profile, Data, Utility
- uType reference files can be imported into the HLA Fusion IVD database using the Catalog Import function.
- The Serological file can be imported multiple times now

Information Management – Patient and Patient Ab Tracking
- Search results in the Antibody Tracking module now show additional sample information.
- The Sample Detail Table in the Ab Tracking module can now be rearranged by including, excluding or by dragging and dropping columns.
- Patient IDs can now be updated.
- The Antigen table now preserves the list of antigens even if DPA and DQA checkbox is toggled during Ab Tracking configuration.

Reporting Module – Reports
- A Control Value report is now available for the LABScreen product. This report shows the number of samples in the product, the number of times low bead counts occurred, NC was high or low, PC was low, and the PC/NC ratio was low. Additionally, the report also shows the maximum, minimum and average of positive and negative control values for a catalog.
- The Bead Specificity Chart within the Custom Antibody report can now be sorted in HLA order instead of MFI values. This option is only applicable to Single Antigen analysis.
- Manzen - LABScreen report now includes user comments instead of the system comments.
- All molecular reports that allow sorting by locus type may now be sorted in HLA order.
- The CREG table in the Custom Antibody report now shows improved colors, with non-DSA specificities circled in blue, DSA Negative specificities yellow, and DSA Positive red. Yellow-marked DSA Negative specificities not found in Epitope Analysis results are circled yellow.
- Either one of the MFI Baseline and/or Raw MFI data can now be shown in the Bead Specificity chart in the Antibody Custom report. MFI Baseline is the default sorting criteria.

- The UMC Utrecht Specialty report has been updated to include the nomenclature update date and IMGT version of the catalog being used for the analysis.
- User comments have been added to the BML report.
- User would like the option to include the Mean from the Epitope Analysis Results for the assigned specificities in data exported with the Export Data module similar to the Final Assignment with MFIs in the LABScreen - Australia MFI report.
- The Antibody Screening Results report now includes the Sample Date.

Information Management – Data Base Utility

- The database upgrade script can be viewed in the database utility.

ERRORS CORRECTED

General - All Modules

- Alleles in the reports now appear in HLA order for loci A, B, C, DR, and DQ.
- The inconsistencies in HLA Fusion 3.0 IVD user manual have been corrected. The references to CREG Bar and Reanalyze one the page 167 and 168 respectively have been removed.

General Analysis – LABType

- Corrected the problem where the minimum bead count column in the session summary table displays the original Luminex bead count from the converted file
- Sample status upon initial analysis was displaying stale or blank system comments. The system now correctly shows the status (i.e., “Possible Homozygous, or other label, as applicable) in the system comments bar
- Continuous clicking on the print screen button no longer displays an error message
- The data issue associated with DR52, - assignment now has been addressed. The users will be prompted to associate a locus while making sero assignment
- The RA function now displays a message “The sample is not ambiguous”
- By default the possible allele pairs are not loaded on the LABType session summary screen
- All serological assignments in the LABType analysis screen are tagged with the corresponding locus. For Class II serological assignment, a popup window now appears to allow users to select the corresponding locus

General Analysis – SSP

- All serological assignments in the SSP analysis screen are tagged with the corresponding locus. For Class II serological assignment, a popup window now appears to allow users to select the corresponding locus

General Analysis – LABScreen

- The refresh issue associated %PRA or %SA in the LABScreen analysis statistics box has now been addressed.
- The Side by Side Analysis screen now displays the bead graph properly.
- The LABScreen analysis histogram MFI scale no longer changes when antigens are sorted or when beads are overlaid. Scaling of MFI histogram has also been addressed.
- Samples with NC Raw and PC/NC values over 1,000 now appear correctly on analysis screens.
- The inconsistencies between the session summary Local ID column and the LID value on the status bar of the analysis screens has now been addressed.

Information Management – Profile, Data, Utility, Data Base Utility

- The user comments are now not automatically saved unless the Save or the Confirm button is clicked.
- The issue of keyword “log” present in the Audit Log database name which caused an error has now been addressed.
- The Switch database module now allows users to enter User ID and password in order to address the issue of assumed default password.
- The issue where two active serology references prevented catalog updates has now been addressed.
- The Database Utility module now displays an informative message if users who lack administrator privileges try to upgrade the database.

Reporting Module – Reports

- UMC Utrecht specialty reports now correctly export DQA1 and DQB1 typing and serology information. Users may continue to see sorting issues when exporting sessions that were analyzed with older catalogs.
- The data export tool now includes user comments in the output file.
- The "Blank" value under Q.A./Control Values and Pos/Neg ratio calculation issues in LAT custom report has been addressed.
- The SSP Custom Report now can be generated for samples analysed with SSPR1-42 lot 2 Rev 9 and Rev 10 catalogs. Similar issue with SSP reports caused by SQL execution plan has been addressed.
- The chopping of NMDP codes in combined panel summary report has now been addressed.
- The print icon is now functional in the Single Antigen Summary Report.
- The date format issue which caused search function to skip certain batches and not display in the reporter “Sessions” tab now has been addressed.
- The NIH report now includes the IMGT date instead of the nomenclature date.

Information Management – Patient and Patient Ab Tracking

- The antibody tracking module now removes DQA1* antibodies from the chart if deselected.
- The antigens used in the UNOS PRA calculator have been corrected by removing the inclusion of broad group antigens. Another related issue with the antigen name has been addressed.
- In antibody tracking data table the inclusion of Class I data with Class II data has now been addressed. This issue occurred when either Class I or Class II samples had allelic final assignments.

KNOWN LIMITATION

- When creating plate design with Testlist, samples do not immediately change their color if they assigned to plate. Instead they change color when they refreshed by search.
- The coloring of CWD-C in plate design may appear inconsistent based on the quality of graphics and display monitor.
- The uType file name now has the format “uTYPEDBmmddyyyy.Zip”.

KNOWN ANOMALIES

- Customers changing sample locations or creating duplicate samples must refresh the plate designer window to see correct patient identification information.

GENERAL NOTES

- Pink and the green bars in the bead analysis tab in the session summary is +/- 5 and independent of the close bead reaction threshold
- Copying a large set of patient data from one database to another may result in an error. We suggest to copy patient data in smaller sets.
- Hovering over the cutoff line in LABType may not display the middle point value depending upon where the mouse location on the line. However, this does not impact the analysis results.
- Track DSA and Ab Tracking Threshold still resets the Antigen table, causing all antigens to be selected.
- For “Negative” final assignment the %SA/%PRA is zero otherwise it is computed by the reaction of the beads for the sample.
- Only the whole number is taken from PC Raw and NAC Raw for LAT and LATM cutoff value calculation.
- Only V3 format is supported for AllSet Gold SSP kits.
- The scaling of the Y-axis on histogram has been changed to represent multiples of 10X depending on the highest Y value on LABScreen analysis screen for Single Antigen and PRA sessions.

- The scaling of the Y-axis on histogram has been changed to represent multiples of 10X depending on the highest Y value on LAT, LCT and Flow Specificity analysis screen.
- HLA Fusion 4.0 software is a full version release and the HLA Fusion 3.0 software users will not be flagged of this update through Auto Update feature.
- The FAQ file is a combined files for both IVD and Research version. The HLA Fusion IVD 4.0 and Research 4.0 will display one FAQs file.

Updating Databases from Prior Versions of HLA Fusion™

For users of previous versions of HLA Fusion after installing Fusion 4.0 for the first time:

1. After you have followed the HLA Fusion Installation Guide to install version 4.0 of HLA Fusion, open the HLA Fusion Database Utility by double-clicking the shortcut on your computer desktop.
2. Choose the function, Upgrade prior versions of **HLA Fusion database to 4.0** from the Fusion Database Utility Menu. Note that only the migration of databases created by HLA Fusion versions 2.0 or higher is supported.
3. Select the database you want to update, and specify a location in which you want to store a backup copy.
4. Click the '**Upgrade'** button.
5. Choose the **'Select Database'** function from the Fusion Database Utility.
6. Select the database you upgraded in step 3, and click the '**Set'** button.

EUROPEAN AUTHORIZED REPRESENTATIVE

EC REP MDSS GmbH, Schiffgraben 41, 30175, Hannover, Germany

CE

HLA Fusion™ Research Version 4.0

REF **Catalog # FUSREPGRX**

For Research Use Only. Not for use in diagnostic procedures(USA and Canada)

IVD For In Vitro Diagnostic Use. (European Union Only)

DESIGNATED USERS

All users of HLA Fusion™ Research Software. This software applies to ConsenSys/SeCore, Micro SSP™ for use with E-Gene, KIR Genotyping, and Quantiplex™

RELEASE CONTENTS

The HLA Fusion™ Research 4.0 package includes the following items:

1. HLA Fusion™ Research 4.0 CD
2. HLA Fusion™ Research 4.0 User Manual
3. HLA Fusion™ Research 4.0 Installation Guide
4. HLA Fusion™ Research 4.0 Release Notes/Read Me
5. HLA Fusion™ Research 4.0 Database Utility User Manual

WHAT HAS CHANGED

Every effort has been made to insure that this document is accurate, complete, and up to date. All changes made since the previous version of the HLA Fusion™ Research software have been incorporated herein. It is inevitable that occasional omissions will occur

NEW FEATURES

General – All Modules

- Microsoft Windows XP and SQL Server 2005 are no longer supported. Microsoft SQL Server 2014 Express and Windows 8.1 are now supported. Microsoft SQL 2014 Express is included in the HLA Fusion installation.
- Please note that Microsoft SQL Server 2014 Express requires Windows 7 Service Pack 1 and .NET 3.5.1 on Windows 8.1. In some cases, if your SQL 2014 installer fails, you will need to manually download and install Microsoft .NET 3.5.1. You can also install and configure Microsoft SQL Server on your own to use with HLA Fusion Research software.
- The Ab Tracking feature has been removed.
- The graphical user interface of HLA Fusion Research 4.0 has been updated to make it easier to use. Graphics such as the home page, product page and analysis screens have been updated to facilitate easier navigation.
- When using the Patient or Donor ID to search for donor records with the Search Function (the binocular icon), the resulting records are now shown in the Navigator window sorted in descending order by Sample Date and then Sample ID.
- The Family ID has been added to the search criteria in the Data Management module.
- Performance improvements were made to batch analysis, batch load, sample-to-sample navigation (in Analysis screens), and in the Navigator when loading samples.
- The user can now click on the Save button multiple times before finalizing and confirming the results.
- Sample and Test List search performance is now improved.
- The system allows the inclusion of sources of serum and DNA as listed under DNA Sample Source and Antibody Sample Source menus in the General Settings screen. This list is configurable and expendable. This information is also available on the Molecular Custom and Antibody Custom reports.
- The Print Screen function now previews screen images in the PDF viewer, while automatically saving the print screen PDF file in a user-specified folder.

Analysis – MicroSSP

- A new "Show Me" feature allows SSP users to display the corresponding positive wells for genotypes in the kit.
- Additional gel system views are now available:
  - Centipede
  - ElectroFast 96
  - E-Gel
- MicroSSP and Custom Molecular custom reports now include an option to list all the potential genetic typing missed for a non-amp well.

Analysis – SSO/KIR

- Probe IDs are now visible in additional locations such as the Bead Info tab in KIR Sample Analysis.
- KIR Analysis now also includes the same type of functionality present in the Close Bead Reaction found in LABType Analysis screens.
- The user can now click on the Save button multiple times before finalizing and confirming the results.
- The Delete button on the KIR import screen has been disabled to avoid unintentional issues arising from combining multiple .CSV files.

Analysis – ConsenSys and SeCore

- The uType SBT module has been integrated for new analysis/reporting. The Conexio SBT module allows viewing/reporting of samples analyzed using HLA Fusion 3.0 and prior versions.
- The Reference File and Analysis module has been updated to use uType's LGN reference file and discontinue the use of Conexio reference files for new samples.

Information Management – Sample & External Files, Plate Designer

- The Plate Designer now uses a specific color to identify test list samples.
- The Tray Layout Report in the Plate Designer now allows association of Patient IDs with Sample IDs.
- The Plate Designer now allows importing of sample lists using various formats such as Swisslab. Additionally, the Plate Designer can now split the exported plate into two separate batches. The separated output file names can automatically be named to reflect the catalog and bead reagent lot that was used.
- All file extensions (.txt, csv) are now visible in navigation/browse windows when importing external test files. The user can also filter potential input selections based on the desired file format.
- The External File import function now allows importing from a LIMS. Additionally, Swisslab samples can now be imported in .csv format. The plate is automatically loaded and tests are automatically assigned according to imported samples. Users are still able to rearrange samples in the plate after import.
- The Plate Designer module also now supports XR and CWD products.
- When exporting a plate design to Luminex software, the plate will be split into separate batches corresponding to the test assignment. The batch name will be automatically populated with user configured values, i.e. Session Name, Date Format, Separator, Locus, and Template.
- In Auto-batch naming configuration, if a template is included in batch naming format and the batch name is changed before selecting the template, the template name will not be included in the batch name.
- If the user makes changes in the Batch naming configuration tab in the Plate Design window, these changes will also apply to the automation settings in Settings window.
- The Plate multi-batch name is editable before exporting data to Luminex software.
- Plate designs containing XR/CWD tests from LABType can only be exported to xPonent 4.0 or xPonent 4.2 (LABScan 3D related software).
- The user may now design the plate by assigning samples in both vertical and horizontal directions (column by column, row by row).
- Plate detail now changes to reflect changes in the plate direction (horizontal/vertical direction).
- Customers may now view and print the plate layout format and/ or list format report with patient identification information.
- Customers changing sample locations or creating duplicate samples must refresh the plate designer window to see correct patient identification information.
- When searching for individual samples or samples in the test lists, the samples which already exist in the current plate design are now differentiated for customer convenience.
- The samples that are present in the current plate design are indicated using a blue and bold color.

- Luminex plate reading direction is defined by the direction in which the plate design was last saved.
- The use of special characters in batch, plate, and sample names is not supported.

LABXpress – Run Design

- The volume calculation for LABScreen run (and report) now includes an extra wash buffer volume calculation.
- LABType Run now includes XR/CWD in the plate search/run summary display grid.
- A plate direction column has been added in the Plate Search/Run summary display grid.
- The combination of horizontal and vertical direction runs is not supported.
- The plate design direction can be changed until a run is assigned.

LABXpress – Run Monitor

- The real time validation of bay loading is now improved to avoid rework.
- The Run Monitor now shows plate design direction, views, assigned tests, and well information in tool tips. The well information includes the sample and test name, well location, the patient ID, and the secondary antibody if LABScreen.
- The Run status bar now displays the plate direction and a newly added plate information button. The barcode status box has been removed.
- Horizontal direction plate runs are not supported if using in conjunction with Luminex IS 2.3 software.
- Error log handling: Users are now able to automatically collect the log between desired date ranges into a .zip file, easing communications and troubleshooting efficiency between the end user and product support.
- The Abort Run option is now available in the Batch Preview, Template Selection and Reagent Validation windows.

LABXpress – Settings

- The system now automatically suggests batch names using one or more of the following: Session Name, Date, Separator, Locus, or Template based on the selected configuration.
- Two new options, Additional Wash and Keep Beads Suspended are now supported for LABScreen products.
- A new option, Keep Beads Suspended is now supported for LABType products.
- Luminex software xPonent 4.2 on LABScan 3D is now supported.

Information Management – Patient and Patient Ab Tracking

- Search results in the Antibody Tracking module now show additional sample information.
- The Sample Detail Table in the Ab Tracking module can now be rearranged by including, excluding, or by dragging and dropping columns.
- Patient IDs can now be updated.
- The Antigen table now preserves the list of antigens even if DPA and DQA checkboxes are toggled during Ab Tracking configuration.

Information Management – Patient Identification – LABType XR/CWD Tests

- For LABType, XR-CWD tests are now available by using the following methods:
    - Search by sample (test name dropdown)
    - Search by test list (test name dropdown)
    - External file (select test list)
    - Double Click on well (test name dropdown)

Reporting Module – Reports

- Manzen - LABScreen report now includes user comments instead of the system comments.
- All molecular reports that allow sorting by locus may now be sorted in HLA order.
- When sorting molecular reports by locus, customers may now sort by HLA order, not just alphanumeric. This improvement was done for all reports which allow sorting by locus.
- The UMC Utrecht Specialty report has been updated to include the catalog nomenclature update date and IMGT version.
- The BML report now includes user comments.
- The NIH report now includes the IMGT date instead of the nomenclature date.

Information Management – Data Base Utility

- The database upgrade script can be viewed in the database utility.

Information Management - Utilities

- The serological file can be uploaded multiple times now.
- All serological assignments in the SSP analysis screen are tagged with the corresponding locus. For Class II serological assignment, a popup window now appears to allow users to select the corresponding locus.

ERRORS CORRECTED

- The Database Utility module now displays an informative message if users who lack administrator privileges try to upgrade the database.
- UMC Utrecht specialty reports now correctly export DQA1 and DQB1 typing and serology information. Users may continue to see sorting issues when exporting sessions that were analyzed with older catalogs.
- The data export tool now includes user comments in the output file.
- The mismatch bead column highlighted in pink is now displayed for mismatch assignments.
- The Plate Designer module has been corrected to allow for multiple samples with the same sample ID to coexist including the assigned tests.
- The Plate Designer module now proactively prohibits users from using special characters in the test names.

KNOWN LIMITATION

- Any data file import function in HLA Fusion Research Software uses a predefined data format and file structure. Any deviation will result in an error or an exception.
- When selecting templates during run processing, incorrect plate readings can result if customers assign a different template direction than the run direction.
- When creating plate design with Testlist, samples do not immediately change their color if they assigned to plate. Instead they change color when they refreshed by search.
- During run processing, incorrect Luminex output can result if customers change the batch naming convention.
- Luminex software should be closed before starting a LABXpress run.
- The uType reference file name must be in the following format: “uTYPEDBmmddyyyy.Zip”.
- The coloring of CWD-C in plate design may appear inconsistent based on the quality of graphics and display monitor.

KNOWN ANOMALIES

- Customers changing sample locations or creating duplicate samples must refresh the plate designer window to see correct patient identification information.

GENERAL NOTES

- Only V3 allele format is supported for AllSet Gold SSP Kits.
- HLA Fusion Research 4.0 software is a full version release and the HLA Fusion Research 3.0 software users will not be flagged of this update through Auto Update feature.
- The FAQ file is a combined files for both IVD and Research version. The HLA Fusion IVD 4.0 and Research 4.0 will display one FAQs file.

INSTRUCTIONS

Updating Databases from Prior Versions of HLA Fusion Research™

Upgrading a Prior Version of an HLA Fusion Research Database after a New Installation:

For users of previous versions of HLA Fusion Research:

7. After you have followed the HLA Fusion Research Installation Guide to install version 4.0 of HLA Fusion Research, open the Fusion Research Database Utility by double-clicking the shortcut on your computer desktop.
8. Click the option, "**Upgrade prior versions of HLA Fusion Research database to 4.0**" from the Fusion Research Database Utility Database Migration menu. Note that only the migration of databases created by HLA Fusion versions 2.0 or higher is supported.
9. Select the database you want to update, and specify a location in which you want to store a backup copy.
10. Click the **'Upgrade'** button.
11. Click the **'Select/Connect to Fusion Database'** option on the Fusion Research Database Utility Database Tasks menu.
12. Select the database you upgraded in step 3 in the drop-down list, and click the **'Set'** button.

EUROPEAN AUTHORIZED REPRESENTATIVE

EC REP MDSS GmbH, Schiffgraben 41, 30175, Hannover, Germany

REVISION HISTORY

Revision	Date	Revision Description
0	07/2015	Original Release