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HLA Fusion™ Software, Version 3.3 Service Pack

Catalog # FUSPGR
For In Vitro Diagnostic Use

DESIGNATED USERS

This service pack is for the users of HLA Fusion IVD (FUSPGR) 3.0, 3.2, and 3.2 Hot Fix 1 software. Please review the New Features, Enhancements, and Bug Fixes as outlined below to verify the relevance of this software release to your environment.

RELEASE CONTENTS

1. The HLA Fusion Software release, v3.3 service pack is located on the One Lambda
Download
site:http://download.onelambda.com/pub/tray_info/Windows/HLA_Fusion_Catalogs/Docume nt/

2. The service pack executable for upgrading HLA Fusion IVD v3.0, v3.2, and v3.2 Hot Fix 1 to v3.3 is HLA Fusion 3.3.exe found in either of these files:

HLA Fusion 3.3.zip
HLA Fusion 3.3.rar

Download and save the appropriate file on your computer, depending on your system requirements.

3. The installation instructions for the service pack are found in the following document:

HLA Fusion v3.3 Install Guide_EN.pdf

NEW FEATURES

Antibody Detection

• % Donor PRA has been added to the Antibody Custom report for all applicable
antibody screening products.

• % Donor PRA will be calculated by user defined cutoffs for all Single Antigen
products (> LABScreen analysis screen). The information appears as a tooltip pop-up when you hover over the on-screen DPRA button, and will also be available on reports..

o DPRA X8 refers to the computed Donor PRA based on all antigens in
the 8 region
o DPRA X6 refers to the computed Donor PRA based on all antigens in
the 8, 6 regions
o DPRA X4 refers to the computed Donor PRA based on all antigens in
the 8, 6, 4 regions
o DPRA X2 refers to the computed Donor PRA based on all antigens in
the 8, 6, 4, and 2 regions

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1. Click the DPRA button to compute the results based on different regions

2. Click the Save button to save it in the database, where the donor PRA is calculated if Auto Donor PRA Calculation is checked in the configuration.

• Additionally, you are able to select a specific group or all donors for calculating the donor PRA, and even after antibodies are assigned donor typing will still be considered. Also, the Cw3 split antigen group is also accounted for in the Donor
PRA calculation.

Note: The % Donor PRA calculation does not refresh automatically when assignments are updated. You must click on DPRA or the Donor PRA button to recalculate the value.

• In Serology “view mode” when the Final Assignment column header is selected and allelic assignments are made, any corresponding serological bead specificities along with assigned serological specificities will be circled in blue in the Bead Specificity region.

In DNA “view mode,” when the Final Assignment column header is selected and serological specificities are assigned, all corresponding allelic specificities will be circled in the Bead Specificity region along with allelic assignments that have been made.

In addition, whether in Serology or DNA “view mode,” in the Bead Specificity region the system circles all of the antigens and corresponding alleles that match those entered in the Find Ag textbox (> LABScreen analysis screen)

This applies to the following session types:

o LABScreen Single Antigen (Class I and Class II)
o LABScreen PRA (Class I and Class II)
o LABScreen PRA Class I + Class II Combined (Class I + Class II)
o LABScreen Mixed (in this case the system circles the equivalent DNA)
o LABScreen MICA Single Antigen
o LABScreen Singles (Class I and Class II)

• An Overlay button, (> LABScreen analysis screen) has been added to compare single antigen beads that were tested using a secondary antibody, for example C1Q, IgG, or IgM, over a different set of single antigen beads tested using either the same or a different secondary antibody. The purpose is to compare different methodologies on the same sample draw date.

Click on the Overlay button. Click on Secondary Antibody in the dropdown box. In order to use this function, the two samples must have the same name, must have been tested using the same catalog, and must have been imported using the same test conditions. The system assumes the sample IDs are from the same draw. This feature applies to the following LABScreen products:

o Single Antigen Analysis
o PRA Analysis

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Abilityto reorder listingsin Final Assignmentgrid(> LABScreen analysis
screen)has been added. Clickon the specificity in the Final Assignment window,
hold, and then drag to reorder.
The antibody analysis Raw Data Tablereport will now include the PC and NC bead
values. This appliesto the following LABScreen products:
oLABScreen Single Antigen(Class I and Class II)
oLABScreenPRA(Class I and Class II)
oLABScreenMixed
oLABScreen PRA Class I and Class II Combined (Class I + Class II)
Blank specificity rows for A, B, Bw, Cw,DR,DQ, and DPhave been removed from
the analysis screen. This applies to:
oLABScreenClass I & Class IISingle Antigen Analysis
oLATClass IHDAnalysis
oFlowClass I & Class II HD Analysis
Note:Kits containing two cell lines for DQA1 will only include the first line.
TheWidth of the Panein the Tail Analysis, Epitope Analysis, and Final Assignment
result sectionsautomatically re-sizesaccording to the screen size or resolution so
the width of all three columns is the same. This applies to:
oLABScreen PRA and Single Antigen Analysis
oLAT Analysis
oLCT Analysis
oFlow PRA Analysis
TheWidth of the Specificity Columnin the Tail Analysis, Epitope Analysis, and
Final Assignment results sections automatically re-sizesbased on the longest
specificity entry and will not display a partial entry. This applies to:
oLABScreen PRA / Single Antigen/ Supplemental CombinedAnalysis/
Singles
oLAT PRA / HDAnalysis
oLCT Analysis
oFlowPRA and Single Antigen Analysis
Molecular (Typing Analysis)
The usercan now combineMicroSSP allele specific resultswith Exon 4-7and
LABType HDsessions that have already been combined.
1.Import, analyze, and save results of Exon 4-7 sessionby combining it
with a previously analyzed HD session; save in database.
2.Select aMicroSSP allelespecific tray toresolve ambiguities foundin
Exon 4-7 results;from the MicroSSP analysis screen, enter the reaction
scores for the wells; click on the Analyzebutton and view the suggested
results.
3.Click on theAnalyze combinedbutton; select the Exon 4-7 sessionfrom
Step 1 to see the combined results.

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You can combine SSP generic results with Exon 4-7 and LABType Generic or HD sessions by following the following steps:
A) If you analyze Exon 4-7 results before combining with MicroSSP generic
tray:
1. Import and analyze LABType Generic or HD session
2. Analyze Exon 4-7 results by combining it with the HD session.
3. Analyze and save the MicroSSP generic results.
4. Return to LABType Generic or HD session; combine with MicroSSP
generic; save.
5. Return to Exon 4-7; recombine with LABType HD.

B) If you analyze MicroSSP generic tray before analyzing Exon 4-7 results
1. Import and analyze LABType Generic or HD session.
2. Combine LABType Generic or HD session with MicroSSP generic tray;
save.

3. Combine results of Step 2 with Exon 4-7.

Note: The source samples must be SSP or LABType to combine with Exon 4-7.

• LABType and SSP session summary system comments will now flag samples
that have serological ambiguities within an allele string. Note that if a sample is serologically ambiguous there will be no auto sero assignment for that particular locus. Note that ambiguous means the sample is molecular or allelic ambiguous.

• The Sample-by-Sample analysis will now list the alleles on the Force Results tab in
the same order as the allele pairs display in the “Pairs” tab.

• Added the following new features to the LABType Analysis window:

o The related records window will now display matching samples in the
order of sample date by default. The system first sorts the sample date
in descending order, and then the sample ID in ascending order.

o Splitter and Save Layout buttons have been added to the lower right
quadrant. This allows you to adjust the window’s height so the assigned code textbox has space to display four lines, and then save the adjustment you made.

o A sort button, labeled AZ, and a zoom in / zoom out button, has been
added. The sort button allows you to reorganize the reactions by (1)
bead ID, (2) from low to high, or (3) from high to low. Clicking on the
button moves you through the three options. The zoom in / zoom out
button allows you to magnify the histogram bars for easier viewing. You
must Save Layout to keep the order selected as you navigate through
samples.

• User-assigned typing results will appear in the Tool Tip when you hover over a bar
in the Local QC Graph. Typing will only appear if a final assignment has been made. This does not apply to allele pairs or serological assignment (> LABType Analysis Screen). Only saved or confirmed samples will be included in the QC graph.

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• When you right-click on a bar in the Local QC graph (> LABType Analysis Screen
> Local QC Graph) the options have changed. You can remove samples from the graph as before, but now you can also restore samples to the graph. When you right
click on a bar, the pop up allows you to exclude that specific sample (click on
Exclude sample), or include again all samples that were excluded (click on Include
all samples). If samples have been removed, a note appears on the bottom of the graph, “Some samples were excluded.” You cannot exclude all samples; one sample must remain in the graph.

Reports / Exports

• User Reports Export and Import Template options have been added to allow
exporting and importing of report templates. The following is an example of the necessary steps to export a user report template: (Reports > Specialty > User Reports > Setup > Pick field > Save as Template > Export). This new feature creates two files using the same name that is in the setup, which can then be imported using the Import button. You have the option of changing the name and
the location of the exported templates, but neither the content nor the format of the exported files can be edited or updated manually. The person receiving an e-mailed template clicks on Import and selects that template.

• An Export and Import Data Template option has been added to allow exporting
and importing of data templates. The following is an example of the necessary steps to export an export data template: (Reports > Specialty> Export Data > Pick field
> Save as Template > Export). This new feature creates a text file that can then be imported into the Export Data module You have the option of changing the name
and the location of the exported template, but neither the content nor the format of
the exported files can be edited or updated manually. The person receiving the e-mailed template clicks on Import and selects that template.

• A Secondary Ab field has been added. This serves as a selection criteria to filter
data and allows you to create a report based on the secondary Ab or the other types of methodologies that were performed on a given sample.

• When you use the Setup button to create export templates a Default File Name
now appears on the Export Data report. The system will format the file name as follows with the hour in military time: exportTemplateName_DateTimeStamp (Year_Month_Day_hour_min)

o Example: antibody_2013_7_24_14_7.csv

• We have added a BML – ABCDR Allele Pair report that allows the following data to
be exported in .csv format:

1. Sample ID
2. For A, B, C, DRB1 locus: (1) Assigned Allele Pair and (2) Assigned
Serology

o The format is:
tanaka0803,A*24:02,A24,A*33:01,A33,B*52:01,B*52,B*15:18,B*71,C*01: 02,Cw1,C*03:03,Cw9,DRB1*09:01,DR9,DRB1*04:05,DR4

• Additional Export format options are now available for the following BmT reports:
LABType, MicroSSP, LABScreen, and ABDR; these reports all support the following format options: .txt, .csv, and .xml.

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• The UMC-Utrecht report now includes the letter at the end of allele codes that end
with L/N/S/Q in the Al_1_Result and Al_2_Result columns. For example, "A*30:14L" is exported as "*30:14L".The Al_1_Result/Al_2_Result column is thus
a string that consists of the 4-digit result and the L/N/S/Q suffix.

• The length of the NMDP code will be separated into two lines in the UMC-
Utrecht export report when it is too long, allowing you to import this file into your system.

• In the Cutoff Adjustment Summary report you will now see (1) the total number of
samples tested for a specific product, (2) the number of cutoff adjustments made, (3) and the percentage of the total. For example, a bead adjusted in 8 out of 100
samples displays at 8%. Only the most recent cutoff adjustment is stored and
reported. The cutoff adjustment, just like the bead exclusion report, uses global cutoff for adjustments made after the local cutoff.

• A Sample Date column has been added to the Antibody tab in the Antibody
Sample Summary screen so that the report now includes a test date and a sample date column.

• The Antibody Custom and the Antibody Screening/ID reports now include the
same information for both the manual tail and tail analysis sections - Avg Score, % Inclusion, and Str index (Reports > Generic Antibody > Antibody Custom) and (Reports > Generic Antibody > Antibody Screening/ID).

• The Antibody Custom report setup screen now includes an Add MFI Baseline
checkbox. This allows the system to print the baseline MFI for each antigen or allele
in the Match/Mismatch section of the report (Reports > Generic Antibody > Antibody Custom > Setup).

• A Default File Name now appears for a Print Screen report if you use the Export to
PDF function on the Sample Analysis screen. The format for the file name is as follows: SampleID_HLA Class 1 (or 2)_PatientFirst Name_Last Name. The file name cannot contain any of the following special characters: 8 \ /: *? < > |. See the Microsoft website for an up-do-date list of special characters as they may change.

• Both global and sample level bead exclusions will be included in the LABType
QC Overview report. The bead exclusion report applies the selection criteria in the catalog dropdown field and ignores any selections made in the grid, and includes all the samples that have been analyzed using the selected catalog. If there is no catalog, the report applies the selection made in the grid.

• A checkbox, Well Number, has been added to the Custom Micro SSP Report
Setup screen (Reports > Micro SSP > Custom SSP Report). When checked, the SSP Well Number will display in the Positive Well Summary section and the Test Details section of the report.

Antibody Tracking

• A read-only column, Archived, has been added to the sample information data
grid (Patient Info > Ab Tracking). You can filter samples under the archived column, selecting (1) all (archived and not archived); (2) false (not archived); or (3) true (archived).

• The Legend icons and the Xs on the Line Graph (time scale) are now squares
(Patient Info > Ab Tracking).

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• A data type Dropdown box allowing you to select SFI as an option has been added
(Patient Info > Ab Tracking). This allows you to select either SFI or MFI samples.

o Selecting the MFI option, which represents the true MFI value
(baseline/raw), displays all samples in the grid – those with and without
Quantiplex applied.

o Selecting the SFI option, which represents the Quantiplex value applied
to the MFI value (SFI baseline/raw), displays only samples in the grid that
have Quantiplex applied.

Utilities

• A checkbox, Display LABScreen MFI/SFI values as whole numbers in select
locations, has been added to the Fusion Setup General Settings screen (Utilities
> General Settings). When selected, no digits after the decimal will display, either
on the screen or in the report. You will see raw and normalized data as a whole number. However, the reaction computations still take into account the decimal.

o This feature applies to epitope analysis, raw data table, Ab ID Report, and
Ab Custom Report.
o This feature does not apply to tail analysis or tool tips.

• An Import button has been added to the Epitope Information Management screen.
This allows you to import groups in a Microsoft Excel format that have been downloaded from the HLA Matchmaker website, www.hlamatchmaker.net. This will
be the import template for all epitope information. Excel is required to use this
function. A template has been provided in the HLA Fusion 3.0 installation folder.

• A template name can now be assigned to multiple catalogs. During session import
you can select a catalog from a list of active catalogs that are associated with the template name. If the template is associated with more than one catalog a dialog box appears and prompts you to select a specific catalog.

• A Cancel Import button has been added to the Catalog Template Association pop-
up. If you do not want to continue with the import, you can cancel it and return to the previous screen.

• A checkbox, Expand allele frequency using allele name, has been added to the
Create Demographic Group option on the Create and Update Demographic/Allele Frequency screen (Utilities > Update Reference > Demographic/Allele Frequency). When checked, the system will find all alleles in the Sero equivalent file in the database that match the short form. When not checked, the alleles are
imported as they are in the file. For example:

o A*02 will find -> A*02:01, A*02:01:01,etc; A*02:05:01, A*02:05:02,
A*02:05:03, A*02:05:04, etc.
o A*02:05 will find -> A*02:05, A*02:05:01, A*02:05:02, A*02:05:03,
A*02:05:04, etc.
o A*11:11 will not find-> A*11:111

• A configuration path option for the xPONENT and Flexmap Run Files has been added to
the Validation Menu. When selected, the Installation (IQ) report includes these paths in addition to the path for the converted HD files under “Environment.”

• A checkbox Global Bead Adjustment (Impact All Samples) has been added to the
Molecular Product Configuration (Utilities > Molecular Product Configuration

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>Molecular Analysis Configuration [Product Type: LABType]). When checked and you
hit the Save button, the cutoff will be adjusted and you will see the comments for every bead
or sample whether impacted or not. When not checked, only those beads or samples that
have a sample reaction change will have their cutoff adjusted

o The comment makes note of the adjustment made to the cutoff for that particular
bead. For example, Global Adjust #001:6(15) means that the cutoff was adjusted
for Bead #001 from 15 to 6.
o Global adjustments are recorded as system comments at both the session and
the sample/well level.

• A checkbox Exclude Exon 3 Probes for DQ/DP Analysis, has been added to the
Molecular Analysis Configuration Setup drop down list (Home > Utilities >
Molecular Product Configuration > Molecular Analysis Configuration [Product
Type: LABType]). When checked you can exclude probes at the sample level for
kits with limited sequence information and Exon 3 probes, for example RSSO2Q and RSSO2P.

Note: The DQA1 and DQB1 checkboxes will be shaded blue when there is a false reaction on Exon 3 probes.

• Additional tests have been added to the Plate Designer. This allows you to export
the tests directly to the Luminex software.

• You can apply the type of secondary Ab used per sample in the Plate Designer
when using the sample work list (Utilities > General Settings > Secondary Antibodies). The secondary Ab will be identified by a color indicator in the center of the well. The assigned secondary Ab will also be reflected in Plate Design and Plate Detail screens as an additional tab labeled Secondary Ab (Sample > Create Plate Design) once it has been setup. By default, the secondary antibody assigned is IgG. You can click on the well to change that default assignment.

• The dropdown box for the Search by sample or Search by test list tabs in the Plate
Designer screen (Home Screen > Sample > Create Plate Design) remains open now after you open it, create a sample worklist, and save a test for one or more samples.

ENHANCEMENTS

Reports / Exports

• The system now issues an alert when you attempt to generate a Custom SSP
Report, SSP Report, Molecular Custom, or a Custom Typing Result by Sample report if there are more than 10,000 allele pairs in the selected samples. This number is an internal benchmark to keep the report time under 60 seconds. A warning message appears advising you it may take a significant amount of time to generate the report. You have the option to not include the allele pairs, which will then speed up the time to generate the report. Note that time may vary based on your computer configuration.

o When the message appears, click Cancel, go to the Custom Report
Setup Screen, and deselect the “Possible Allele Pairs” field, which
allows the system to generate the report in a shorter amount of time.

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BUG FIXES

Antibody Detection

• Corrected a problem with the LABScreen PRA search function for molecular
specificities on DRB3, DRB4 or DRB5 loci. In some instances only the alleles on the
fourth row were circled.

• Corrected the following issues with Epitope Analysis:

o The results were suggesting Class I specificities for a Class II
analysis. When all the Class II wells for an LAT Class I and II test were
positive, and one or more Class I wells were positive, the Class I specificities were appearing in the Class II epitope analysis results. For example, if 5DEFGH, 6ABCDEFGH, and A34 were positive in a LAT1240_007_01 test, the Class I specificities, A74, B44 and B57, would be included in the Class II epitope analysis.

o For both PRA and Single Antigen (SA), when the Use Mean of Normal
feature was enabled, Cw, DQA1, DPA1, and DPB1 loci specificities still displayed as the Mean of Raw value instead of the Mean of Normal value.

• Corrected the following issues with LAT module:

o When analyzing a session, if you adjusted the threshold from X6 to X2
directly, as opposed to adjusting the threshold in steps from X6 to X4 and then from X4 to X2, you would get different results.

o On the CREG bar in the analysis screen, the Class II positive alleles were
not showing up in purple as were the Class I positive alleles.

o After using the batch entry and running the analysis, the tray data
returned from the ELISA reader had a value of “1” for every well on the
tray.

o When you clicked on Re-analyze, whether or not you modified the
reaction scores on the tray layout grid, the OD values obtained from the
ELISA reader would be replaced with the Rxn scores for the first tray.
Once OD Values were replaced by Rxn scores, there was no way to undo
the process.

Note: The reanalyze button is disabled after a read using ELISA. When
you add a new tray, the analyze button is then enabled.

• Corrected a problem with the LAT -M test screen. The value displayed in the lower
bar in the HLA Pos field was getting cutoff and did not match the value in the Raw Data Table.

• Corrected a problem with adjusting the HNA cutoff in LSMUTR analysis
configuration. The cutoff was blank and HNA could not be adjusted.

• Corrected a problem when using combined LABScreen Class I & Class II PRA.
Prior to importing a session, the check control overlaid graph was empty if one of the individual catalog files in the combined catalog had been updated with a new
revision. The software has been corrected to work as intended. When an individual catalog file is updated or revised, if that file has been used in a combined LABScreen

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Class I & II PRA catalog, the software automatically creates a new combined catalog
file with the newer revision, which then generates a new entry in the Default NS with
the combined catalog file.

Molecular (Typing Analysis)

• Corrected a problem with importing and analyzing the RSS02345 kit using the No
Code option in conjunction with the enable cross code feature. Under these
specific circumstances, for all LABType products, the possible allele code would not contain the same loci if allele 1 and 2 had two different loci. For example, DRB3
DRB4 displayed as DRB3 DRB3. Also, the suggested no code results displayed the complete allele in the string rather than a 4-digit format.

• Corrected a problem with LABType analysis in the Rec Site tab. When you right-
clicked on a probe recognition site and then closed the pop-up, the other tabs could no longer be selected and were disabled, and the program became unresponsive. This happened when the software found no matching high resolution sample in the database.

• Corrected a problem with the Enable Cross Code for DP setting in LABType
Analysis Configuration. When a database was upgraded to HLA Fusion 3.2, after an RSSO2P session was imported and the batch analysis performed, the software was not able to analyze a sample if it had no matching NMDP code

• Corrected a problem with the LABType SSO Session Screen. When you clicked on
the Patient/Sample Results tab and then moved to the next sample, the software automatically would switch the display to the Rec Site tab, causing the user to have
to click back to the Patient/Sample Results tab. Now, by default Quadrant 1 always shows the QC tab when there is no Saved layout. If you click on another tab, that tab will be the one displayed when you move to the next sample. Once you save the layout, the Save Layout tab will be the one displayed as you move to the next
sample.

• Corrected a problem with Micro SSP combined analysis function. During combined
analysis of SSO and SSP in the SSP analysis mode, an allele that the SSO reaction pattern excluded still remained visible as a possible selection.

• Corrected a problem with Sample Analysis that was previously analyzed with IMGT
v2 format. When attempting to reanalyze a session with such a format, the software generated an error message, “Error in analyzing the sample. Length cannot be less than zero.”

General

• Corrected a problem with exporting a batch or a multi-batch directly onto the
Luminex xPONENT3.1 software. Customers were receiving an error message from xPONENT 3.1 stating the XY heater was out of range even if the XY heater was disabled. Note that the XY heater turns itself off when running the analysis.

• Optimize was incorrectly spelled “Optmize” in the database utility.

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Reports / Exports

• Corrected the following issues with the Antibody Custom report:

o The colors of the bars in the bead specificity chart did not match the
colors for the corresponding sample in the LABScreen analysis
histogram.

o When you chose the 1 Sample per Report option and included the Bead
Specificity chart in the report, the page numbers displayed incorrectly in
the report preview. The last page number for the previous sample would
be the first page number for the next sample. In addition, user comments for a sample would appear on the report for the next sequential sample,
for example comments for sample 3 printed out as comments for sample
4.

o When you checked the Manual Tail Assignment in both LAT and
FlowPRA, the test results would be there. When you went to reconfirm an
assignment and re-generate the same report for the same test, the results
would no longer be listed.

o Sample IDs were not appearing on every page of the report.

• Corrected a problem with the Data Export module. When creating an antibody
report, if you checked the Overall Results option under Antibody Result, two
columns “Antibody_Overall_Class_II,” and “Antibody_Overall_MICA” had repeated information carried over from the last column.

• Corrected a problem with the Audit Log report actions. When using the Auto Update
button, the actions performed on the different reference file updates (i.e. NMDP, Serological, P group, and G group) were not recorded in the Audit Trail Log report except for the catalog type.

Note: The Audit Log reports actions performed in the following modules only: (1) All analysis modules, (2) Catalog, NMDP, Serological, P group, and G group modules.

• Corrected a problem with the LABType - Australia report. The following columns
were not formatted correctly and values were appearing in the wrong column: LastName, FirstName, SampleID, Specimen Number and LastName (after Specimen Number).

• Corrected a problem with the Bead Exclusion report. When only sample level bead
exclusions were made, the global exclusions showed two times the number of
sample level exclusions, when there should have been none. Now, when a sample level exclusion is made, and then later a global exclusion is made in that session, the bead only shows up under the global exclusions, not under the sample level exclusions. Global exclusions override sample level exclusions.

• Corrected the following issues with the Molecular Custom report:

o The bead count was not displaying for regular (non-HD) sessions.

o If you selected the specific report you wanted, and then searched for the
patient, the Custom Report menu would disappear.

Note: The criteria you select on the left side of a Molecular Custom report does not change regardless of what you select on right side of the report.

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You must reset the left side of the report if you want to make changes to
that side of the report.

Utilities

• Corrected a problem with the Import Sample List module. It was exporting only the
last set of consecutive samples to a Luminex patient list if there were gaps between samples.

• Corrected a problem with the Manage Test List module. After creating a test list, the
test list order had randomly changed when you returned at a later time and revisited that same test list. Samples are now ordered by the entry order.

• Corrected a problem upgrading Fusion 2.0 databases. You were not able to
upgrade from 2.0 to 3.0 if the database contained NS File data. You are now able to insert the value Null in the “UpdUserID” field in the PRODUCT_NSFILE database table, allowing you to upgrade.

• Corrected the problem that would not allow you to email reports with extensions
other than “.com,” for example an “.It extension.” A dialog box now appears that allows you to configure the system to email reports for all email providers. For some providers you must supply SMTP Server information; for others the system automatically fills in that information. You will have to include a password when you complete the setup, but choosing to Save that password is optional.

• Corrected a problem with the program terminating prematurely when you pressed
the OK button after e-mailing a report.

NOTES

• The software supports all sizes of gel images provided the image can be resized to
fit on the screen, and sized so that the report can print it out. The software will generate an error message if it cannot resize the gel image, and if necessary will temporarily resize the gel image for preview and reporting. The software may generate an exception if the user does not have the appropriate level of software rights or enough disk space for temporary storage.

• When creating reports and exports, if the DQA and DQB allele code assignments
were made and saved in no particular order they will appear in the same order in the
report as well, but navigating back to this sample the software will automatically sort
the assignments in ascending order. You must confirm the new sort order for this to
match with the report.

• Kits containing 2 cell lines for DQA1 will include only the first line in the specificity panel of
the LABScreen Single Antigen analysis. These are older kits that are no longer in production.

• The user is responsible for maintaining and keeping up-to-date all external references, for
example groups exported from matchmaker, and NMDP code.

• The overall positive/negative results columns will be empty during the batch analysis for
LABScreen sessions, and will not be computed until the final assignments are made and you select Auto Accept All. The overall pos/neg of a sample is based on the final assignment made. The overall assignment displays as positive when there is an antibody

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assigned in final assignment. The overall assignment displays as negative when the final
assignment is negative.
• When performing Sequence Based Typing, only one window remains open when you click
on the Rec Site tab. All the other tabs in the LABType analysis screen are disabled until you
close the high resolution typing analysis window.

• It is suggested you export or print a report to mitigate the truncation issues that may appear
in the report viewer.

• The plate designer layout view report generates a blank first page. This will be addressed in
the future release.

SYSTEM REQUIREMENTS

• One of the following operating systems:
 Microsoft Windows 7
 Microsoft Windows XP
• For Windows XP systems, Microsoft Windows Installer 3.1
• Microsoft SQL Server 2005 or SQL Server 2008 Express
• Microsoft .NET Framework Version 3.5
• Visual JSharp (version must match the .NET Framework version you are using)
• Pentium 3, Pentium 4, or Pentium 5 Processor
• 4 GB hard disk space
• 512 MB RAM (minimum)
• 8-bit graphics adapter and display (for 256 simultaneous colors)
• VGA display with 1280 x 960 resolution (minimum)
• Mouse, or another Windows compatible pointing device; mouse with wheel required for
certain products

Note: Regardless of where you install HLA Fusion, as much as 400MB of space on your local hard drive may be required for temporary installation files as well as any other programs you may be using.

OTHER COMPONENTS (RECOMMENDED)

• Microsoft Windows supported graphics accelerator card
• Microsoft Windows supported printed
• Microsoft Excel 2000 or 2003
• Microsoft Word 2000, 2003, or other text editing or word processing program
• WinZip Software 9.0 or higher
• Adobe Reader

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LIMITATIONS AND RISK MITIGATION

HLA Fusion software does not contain serological equivalence for DQA or DPA in the file, and hence will not allow multi sero-equivalent assignment within the same loci. The Assigned Sero field can only take one assignment and will not support assignment for both DQA and DQB, or for both DPA and DPB.
Risk: None; Mitigation: None – the information populated by the software is non-informational, and the ability to assign serology to two loci is not required.

The use of the SSP Multi Loci kit in combination with HLA Fusion Software may cause a mis-assignment, recognizing a rare allele and missing a primary allele. For example, when DRB4*01:03 and DRB5*01:01 are present, the software only lists DRB1*15:65 and does not include DRB1*15:01 as a possible allele code due to a limitation in the software with cross loci wells.
Risk: Low – reporting a rare allele will prompt a secondary check for confirmation of the allele; Mitigation: Use manual analysis in these cases.
• You will see a pop-up message and an alert in the systems comments warning you about
the possible cross loci wells.

The NMDP condensing rules in HLA Fusion software are based on NMDP requirements. These condensing rules may change periodically, and due to the nature of their timing HLA Fusion software may not be 100% in sync with the condensing rules. Hence, in some cases the codes may not match and NMDP may reject the coded results. The user should verify and make appropriate changes in the exported file prior to an NMDP submission. Risk: None; Mitigation: Perform a manual update to the exported file.

The Navigator right-click menu option Reanalyze with New Nomenclature is not supported for
Exon 4+. Risk: Low. Mitigation: Use supplemental analysis.

The Force tab in LABType analysis does not apply to Exon 4-7. Risk: None. Mitigation: None

The RA “Resolve Ambiguity” button is not applicable to MICA product. Risk: None: Mitigation: None.

When all beads in an Antibody analysis are positive, the Epitope Analysis results do not take into consideration all antigens. However, Tail Analysis does display All Positive and %PRA is 100%. Risk: None. Mitigation: Customer should use Tail Analysis Results and %PRA, or use manual assignment.

REVISION HISTORY

Date Revision Revision Description
03/27/2014 0 Original release