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HLA Fusion™ Software, Version 3.4 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, 3.2 Hot Fix 1 and 3.3 software. Please review the New Features 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, v3.4 service pack is located on the One Lambda Download site:http://download.onelambda.com/pub/tray_info/Windows/HLA_Fusion_Catalogs/Document/

2. The service pack executable for upgrading HLA Fusion IVD v3.0, v3.2, v3.2 Hot Fix 1 and/or v3.3 to v3.4 is HLA Fusion 3.4.exe found in either of these files:

HLA Fusion 3.4.zip
HLA Fusion 3.4.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 IVD v3.4 Install Guide_EN.pdf

NEW FEATURES

General Analysis – All Modules

• You can export assigned test lists from the “Add More Test to Test List” function as
Luminex test lists.

Analysis - Molecular

• You can select one or more samples from LABType session summary screens and
then generate a print screen of the sample analysis for that sample.

• The Direct Request NMDP function activated by the +Rpt button in molecular analysis uses
your default web browser.

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Analysis - LABType

• The Local QC graph includes the option of seeing at a glance whether a bar on the
graph for a particular probe was labeled positive or negative.

• Right click in the upper left quadrant of the Local QC graph to access a drop-down
menu from which you can group by: (1) test date, (2) session ID, (3) technician, and
(4) serial # of the Luminex machine.

• You can resolve allelic ambiguities for P and G group alleles as a whole.

• The exon displays in the Bead Info tab of LABType analysis.

• The Other Assignment box has the same double click and expand functionality as
the User Comments box.

Analysis- MicroSSP

• In the SSP module, you’ll get a warning message if the reaction pattern consists of
positive probes with “limited sequence information."

• The SSP analysis defaults to a reaction value of zero for all wells when performing
an ambistrip analysis (SSPT1).

• You can resolve allelic ambiguities for P and G group alleles as a whole.

Analysis - Antibody

• You can select one or more samples from LABScreen session summary screens and
then generate a print screen of the sample analysis for that sample.

• You can make final assignments by selecting the specificities displayed underneath
the histogram in the Test Panel.

• In the Antibody Analysis Configuration, you have the option of excluding Patient
Typing (Self Antigen) by global default during sample analysis. System comments
will include a notation when this option has been selected.

Analysis – LABScreen

• During import, you can include sample treatment information for tests similar to the
dilution factor and secondary antibody. For example, you can specify whether a sample for a LABScreen test has been treated with EDTA, DTT, Adsorb Out, etc.

• The LABScreen Check controls graph on the Session Import Screen has been
enhanced.

• There is now auto-scaling of the LABScreen Mixed and LABScreen Multi samples.

• The name of the Quantiplex data used is in LABScreen analysis and reports when
Quantiplex data is applied to a LABScreen session.
• You can overlay samples tested with a different secondary antibody in LABScreen Mixed
Analysis screen.

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Analysis - LCT
• The system can automatically import LCT data exported from the Lambda Scan 5.9
software, eliminating the need for manual entry of the reaction pattern prior to analysis.

Information Management – Patient
• Birthdate is one of the search criteria in the Manage Patient module.
• The format and content of the file generated by "Export to UNet" in the Patient
Management Module is as follows:
o Field #1: SSN
o Field #2: Last Name
o Field #3: First Name
o Field #4: Transplant Center Code
o Field #5: Transplant Center Type; either (1) TX1= Transplant Center, or (2)
VA1= Veteran Hospital (This can be linked to the information in the Lab
Profile using the lab code description or by adding an extra "Transplant
Center Type" field)
o Field #6: Organ (refer to UNet for Organ code)
o Field #7: HLA Antibody Tested. If field #6 has KI, PA, or KP, this field must
have the HLA Antibody Tested code as follows: YA=Yes, Antibody Detected; YN=Yes, no antibody detected; NN=No, Not tested
o Field #8: Locus/Unacceptable Antigen
• You can use the UNOS cPRA calculator and their database of antigen frequencies.
The results shall be displayed in the patient management module, the antibody analysis, and the reports for a single antigen and also for a combined Class I and Class II cPRA from assays that were done separately.
• The Patient Management Module on the HLA Test Tab includes an Associate
Sample IDs search function. You can search for Sample IDs with wildcard searches to associate a Sample ID to a patient.
• The Sero Typing field in the antibody tracking module lists the patient and donor
information in HLA order.

Information Management - Sample
• In the "Add More Test to Test List" function under the "More Test" option by default
only the active test lists shall display, and you have the option to archive test lists.
• The test list in Sample Management must always have a sample.
• You can input xPONENT 4.2.1509 valid .csv files.

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Report – All Reports

• The system displays the Luminex serial number in HLA Fusion reports.

Report - Molecular

• You can include Ethnicity, DOB, and Gender information without SSN information in
the Molecular Custom report. There is a separate checkbox for SSN information in
the Custom Report profile.

• The Combined Sample Report displays the corrected alleles and corrected typings in
HLA order (e.g., A, B, C, DR, DQ, DP).

• The report title in the Combined Sample - LABType report displays the report name
that is saved with the report setup.

• The Combined Sample Report includes the Micro SSP tray reaction layout.

Report - Antibody

• You can view both the acceptable and unacceptable antigens on the Antibody
Custom Report. The Patient section of the report setup menu includes a checkbox
that allows you to indicate whether or not to include one of the fields, both fields, or
neither of the fields in the report.

• The assigned Epitopes on the Ab Custom Report show the associated specificity for each
amino acid position.

Report – Statistical

• You can generate a LABType Control Value report that includes, for example, a
listing of all control values for a particular lot, average number of samples, and
minimum and maximum values.

• You can track the tests they are running and how often you use them. You can access a
report summarizing the following:
1. Total number of tests across all products.
2. Total number of tests for each product group.
3. Within each product group, the number of tests for each individual product.
a. LABType: number of tests for each different product, (e.g. A, B, DRB, HD-A,
HD-B, HD-DRB).
b. LABScreen: number of tests for each different product, (e.g. Class I PRA,
Class II PRA, Class I SA, Class II SA, Mix).
c. SSP: number of tests for each locus type, (e.g. A; B; DRB; A,B,DR
d. LAT and Flow) similar to LABScreen.
e. LCT: number of tests for each different product, (e.g. Class I, Class II).
• You can exclude samples that do not meet the minimum PC value from the LABType
Control Value report and thus will not be included in the statistical calculations (Average, Maximum, Minimum, etc.).

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Report – Tools

• Donor Specific Antibodies (DSAs) are included as an option in the Data Export
function. You can export the antigens for the donors associated to a specific patient.

Report - Specialty

• In the LC Report, allele 1 shall be in positions 25-44 and allele 2 shall be in positions
45-64 to accommodate the increase in the size of allele names.

• A Navy specialty report shall be added.

Utilities - Installation

• Official documentation is provided verifying that the HLA Fusion 3.4 database is
compatible with a server running Microsoft SQL 2014.

• HLA Fusion automatically creates a default demographic filter using the frequency in
serological equivalent file. The filter is overridden and HLA Fusion software creates a new serological file whenever you import a serological equivalent file with new IMGT version. These filters are designated as system filters and cannot be deleted or modified.

• The NMDP Crosscode condensing rules have been enhanced.

Plate Designer

• You can export the plate design to Luminex IS 2.3, xPONENT 3.1, xPONENT 4.0,
and xPONENT 4.2.1509 software, retrieve the plate layout without redesigning it, and then run the appropriate software.

BUG FIXES

General Analysis – All Modules

• Corrected a problem with the comments box on the LABScreen Mixed Analysis
screen being obscured when the user open LABScreen.

Analysis - Molecular

• Corrected a problem where only some close bead reactions would display by default
initially or after hitting the enter key when the screen refreshes in LABType analysis.

• Corrected a problem with the ‘w’ in the results of homozygous DNA typing displaying
incorrectly.

• Corrected a problem with checkbox appearing when the exclude exon option is not
applicable for a locus.

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• Corrected a problem with the “close reactions” feature where reaction values close to
the positive cutoff are identified.

• Corrected a problem with the user getting an error message when trying to confirm
SSP analysis if they check “Patient Assign” first and then click on Save or Confirm.
• Corrected a problem with incorrect results when applying P grouping for DPB1.

• Corrected a problem with the Patient/Sample Results tab not showing the analyzed data for
the sample.

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Analysis - MicroSSP

• Corrected a problem with error message “Invalid data in column catalogIDCol”
displaying when the user selects an existing session from the “Existing Batches”
dropdown menu and then clicks on “New Batch,” during Micro SSP Batch Entry.

• Corrected a problem with the SA button not always being always being present in
MicroSSP analysis.

• Corrected a problem with the Epitope Analysis results not including Cw or DP locus
antigens when all beads in a LABScreen analysis are positive.
• Corrected a problem that user comments could not be saved.

Analysis - All Antibody Detection

• Corrected a problem with software freezing when the user sorts the Raw Data table
column in LABScreen analysis.

Analysis – LABScreen

• Corrected a problem with the MFI values displaying incorrectly in the epitope.

• Corrected a problem with the adjust-cutoff function in LABScreen analysis for a test
result that has one or more thresholds with a cutoff of 0. The cutoff values for the thresholds with an initial value of 0 become the same value as the adjusted cutoff.
• Corrected a problem with the user getting an error message ,
"System.Data.SqlClient.SqlException: Subquery returned more than 1 value", when
they attempt to import a LABScreen Singles session.

• Corrected a problem with the HLA Fusion minimizing when the user answers a system-
generated question (i.e., NC beads are low. Replace with another bead).

Analysis - LAT

• Corrected a problem with the Elisa button not appearing when creating one or more
trays using batch entry.

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Import - Luminex

• Corrected a problem with the user receiving an error message color coding the low
positive samples when importing .csv file for non-English Windows systems.

• Corrected a problem with a decrease in bead count after reanalysis of an existing HD
session.

Report – Molecular

• Corrected a problem with the data for Corrected Typing and Corrected Allele not
populating when the user uses the Export Report button.

• Corrected a problem with samples that had DRB1 assigned allele pairs not appearing in the
"Corrected Alleles" section of the LABType combined sample report.

Report - Antibody

• Corrected a problem with the CRAbCustomReport.rpt only displaying donor data and
donor serological typing when the match/mismatch option is selected. Also corrected match/mismatch function to display the acceptable and unacceptable antigens.

• Corrected a problem with the LAT-Mixed Raw data column not appearing when the user
prints results in the A4 format.

Report – Tools

• Corrected a problem in HLA Fusion 3.2 with the data export displaying both Class I
and Class II alleles in the column for Antibody_FinalAssignment_Class_II and the
Donor PRA for Class I and Class II alleles both displaying in the column for Antibody_DonorPRA_Class_II.

Report - Data Lookup

• Corrected a problem with the user not being able to filter results by session and then
select only loci from the selected plate.

Information Management - Record

• Corrected a problem with the user receiving the error message
“System.Data.ConstraintException: Failed to enable constraints. One or more rows
contain values violating non-null, unique, or foreign-key constraints.”

• Corrected a problem with the error message “Error - 2147217871 Msg: IDispatch error#3121
Desc: Query Timeout expired" displaying when the user moves sessions from one database to another using the Move Sessions button in the data menu.

Information Management – Patient

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• Corrected a problem with the Bw4/Bw6 tracking check boxes not appearing if a
donor is selected before a patient is selected in antibody tracking.

• Corrected a problem with Ab tracking only displaying the last typing entered and not
including molecular and serological typing information.

• Corrected a problem with the crossmatch results displaying incorrectly in the Crossmatch
Result tab in the Patient/Donor information window.
• Corrected a problem in the AB tracking module where a sample shows plots for the DQA
antibody at zero, even though the antibody had high MFI.

Information Management - Sample

• Corrected a problem with the error message “System.Data.SqlClient.SqlException:
Error converting data type varchar to uniqueidentifier.” appearing when saving if the
user chooses an existing patient using the browse button in Manage Sample.

Utilities - Database

• Corrected a problem with the system creating unpopulated tables when the user
upgrades to Fusion 3.0 and then to 3.2 HF1.

• Corrected a problem with performance after user upgrades from HLA Fusion 2.0 SP4
to HLA Fusion 3.2.

• Corrected a problem with the user not being able to merge an HLA Fusion 2.0 SP4
database to Fusion 3.0.

• Corrected a problem with CR users receiving an error message when trying to
upgrade their database from 2.0 to 3.0.

Utilities - Printer Setup/ UI – Home Page

• Corrected a problem with the user not being able to set up a new printer on the HLA
Fusion home page after upgrading to Windows 7.

Plate Designer

• Corrected a problem with a discrepancy between values for exon 2 probes for
RSSOH1C runs created using Plate Designer and those of runs created using the xPONENT software.

NOTES

• The batch print function on LABType and LABScreen summary screen in some cases may
error out due to insufficient memory. We recommended that you select no more than 25 samples at a time for batch printing. If you encounter an error while batch printing, please exit the software and try again with fewer samples.

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• 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.

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 2005 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

OTHER COMPONENTS (RECOMMENDED)
• Microsoft Windows supported graphics accelerator card
• Microsoft Windows supported printer
• Microsoft Excel 2000, 2003 or 2010
• Microsoft Word 2000, 2003, 2010 or other text editing or word processing program
• WinZip

®

Software 9.0 or higher
• Adobe

®

Reader

LIMITATIONS AND RISK MITIGATION

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

If the user imports a LABScreen session and moves X8 onto X2, placing 8, 6, 4, and 2 on the same line, the number next to X on a vertical line becomes unclear.
Risk: None
Mitigation: None.

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If the user assigns Bw4 and Bw6 from a test panel while using any non-English version of HLA Fusion, and then clicks on “T,” the R value for Bw4 will appear in Non-English. In English, this value appears as “NaN.”
Risk: None
Mitigation: None

If an imported serological file in Version 3.2HF1 or earlier is upgraded to 3.4.18, the file will be active in the database, but there is no system-created group in the demographic frequency window.
Risk: None
Mitigation: Re-import the serological file.

Saving layout while on Rec Site or Bead Info tab in LABType sample analysis screen may cause an exception if the user later navigates to a different LABType session.

Risk – None
Mitigation – If this happens, save the layout again from any tab other than Rec Site and Bead
Info tab.

REVISION HISTORY

Date Revision Revision Description
01/2015 0 Original release