

Addendum to User Manual HLA Fusion™ Software, Version 3.X.X For In Vitro Diagnostic Use 2012/03

P. 103

Addition of clarifying text prior to Manual Allele Code Assignment section. Section now reads:

The NMDP condensing rules HLA Fusion software utilizes to present the allele pairs in the **Possible Allele Code** field when the NMDP Code option is enabled are based on NMDP requirements. The NMDP may change these condensing rules periodically, and due to the nature of their timing HLA Fusion software may not be synchronized 100% with the newer NMDP condensing rules. Hence, in some cases, the codes may not match and NMDP may reject the coded results. The **Possible Allele Code** displays suggested software analysis results and user should verify and make appropriate changes to the **Assigned Code** field prior to exporting the file for NMDP submission. Risk: None; Mitigation: Perform a manual update to the exported file.

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.

P. 162-163 & 167

Deletion of references to CREG bar in CREG Bar section on page 167 and Find Antigen section on pages 162-163. Find Antigen section now reads:

Find Antigen

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

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.





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 A24 will be circled.

P. 168

Deletion of reference to Reanalyze button in Saving Assignments section. Section now reads:

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 <u>prior</u> to confirmation if you need to make changes.

REVISION HISTORY		
Revision	Date	Revision Description
0	2014/02	Original release