

TruSight[®] HLA Assign[™] 2.1 RUO Software

Customer Release Notes

For Research Use Only. Not for use in diagnostic procedures.

Introduction

These Release Notes detail the key changes to software components for the TruSight HLA Assign software since the package containing Assign 2.0.

For more information about operating the Assign 2.1 Software, see the [TruSight HLA Assign 2.1 RUO Software Guide \(document # 100000010450\)](#).

For frequently asked questions, see the [TruSight HLA v2 Sequencing Panel Support Page](#).

The software package includes:

- Assign TruSight HLA v2.1.0.943RUO.msi

NEW FEATURES (FROM v2.0):

- Updates to displaying and reporting ambiguities, G groups, P Groups, and NMDP codes:
 - Previous G and P Group functionality: in Assign 2.0, G Groups and P Groups could only be reported in the Full Report.
 - Previous ambiguity display functionality on Summary screen: in Assign 2.0, if no perfect and unambiguous match to an IMGT database was available, the result was displayed on the Summary screen with dashes (--:--:--). The Summary Table Report only exported the dashes and no information about the alleles. The ambiguity strings were only reported in the Full Report.
 - Previous ambiguity display functionality on Coverage screen: in Assign 2.0, alleles were listed in the Results panel in sequential order from lowest to highest. For example, when a DPB1*04:01 was paired with a DPB1*04:02, they were always ambiguous with a DPB1*105:01 and DPB1*126:01, listed in that order. This appeared to create an ambiguity between DPB1*04:01/105:01 (both presented as Allele 1) and DPB1*04:02/126:01 (both presented as Allele 2). However, DPB1*126:01 is actually part of the DPB1*04:01:01 G group and DPB1*105:01 is part of the DPB1*04:02:01 G group.
 - Previous NMDP ambiguity code generation: in Assign 2.0, the ordering of the alleles created ambiguity pairs based on allele nomenclature rather than on allele sequence.
 - New functionality: in TruSight HLA Assign 2.1, when two or more perfect matches are available creating an ambiguous result, the software will first check if the alleles share a G group and sort them by G group. If no G group relationship exists, then the software will sort by P group. If no P group relationships exist, then the software will sort sequentially from lowest to highest.

When G groups are present (or P groups if G groups are not present), these will be displayed on the Summary screen and in the Summary Report. In addition, the ambiguity strings are then reported on a new "Ambiguities" tab on the Summary Report. Using the previous example, the Summary screen and Summary Report will display Allele 1 as 04:01:01G and Allele 2 as

04:02:01G. The Ambiguities tab will display 04:01:01 + 04:02:01/126:01 + 105:01 /.

- CWD status has been added to the Summary Report XML report.
- Suppression of HLA-C typing results when unsure of primer source has been repaired. The TruSight HLA-B primers amplify HLA-C and can generate a typing result even if the amplification with HLA-C-specific primers fails. In Assign 2.0, the software suppressed results if it suspected the HLA-C result was generated from HLA-B primers only. The thresholds were set too stringently and HLA-C results generated from HLA-C-specific primers were still suppressed. In TruSight HLA Assign 2.1, the thresholds have been modified to ensure that proper HLA-C amplification is recognized. Rather than suppress the results, the software now flags HLA-C results that may be a product of HLA-B-only amplification.
- Summary Report XML report was missing closure of one tag. This tag has been closed and repaired.
- Reopening of .cgp project file is identically formatted to loading directly from fastq.gz.
- Selecting "Duplicate Homozygote Calls" and then clicking "Update" now persists as the default setting.
- When a DRB4*01:03N allele is present, it will be displayed and reported properly. In Assign 2.0, DRB4*01:03N was displayed on the Summary screen as an ambiguity even when the actual result was unambiguous. This has been repaired in TruSight HLA Assign 2.1.
- Fragment Analysis—Reports for the distribution of DNA fragments clustered and read by the sequencer and imported into Assign. The Fragment Analysis is an Excel report that provides details of the distribution of fragment sizes imported into Assign for each sample and each locus.
- In addition to the three summary screens, the Table report includes a worksheet to display the allele balance for each locus in which the frequency of the second allele is displayed. The Table report also includes a worksheet to display the frequency of reads that were determined to be the result of a PCR crossover event and have been removed from the analysis.

KNOWN ISSUES:

- Importing additional FASTQs into an open project is not permitted. Attempting to do so causes an "Out of Memory" error and will close the software.
- Assign 2.1 does not allow the user to create an individual report for a sample named "Sample1".
- When 2 or more projects are open in the same instance of TruSight HLA Assign 2.1, the field's combo box will not update the projects when switching between them. You will need to update each project separately. The Results display is not affected.
- Box A in the sample panel does not always turn green after a sample is verified at all positions indicated in the Navigator.

- The text option for a report is not always be available when reopening a saved project. To generate a text report, close and reopen the report dialog.
- FASTA report settings are not saved as default after clicking Update in report dialog.
- Clicking on the assign Software while the program is trying to load/import the FASTQ files causes the application to freeze with the "Software is not responding" message.