7500 Upgrades – PAS software v1.6
Performance Check Write Up

Background

Idaho State Police's IT department has required all computers to have at least Windows 10 operating system, or higher. The currently utilized 7500 SDS version (v1.2.3) is not Windows 10 compatible, therefore an upgrade to v2.3 is required and will be performed during annual maintenance. The Plexor Analysis Software (PAS) v1.5.4 is currently used for quantification data analysis. This version does not have the ability to analyze the .xls export files from SDS v2.3, therefore an upgrade to the newest version, v1.6, is required as well.

Based on the release notes from the manufacturer, this upgrade will be classified as a major revision and include functional testing, reliability testing, and regression testing.

Objective

To perform functional, reliability, and regression testing of the PAS v1.6, confirming that the program performs tasks as expected.

Method

Functional testing:
At least one previously analyzed projected will be reanalyzed with the PAS v1.6 and compared to the previous results to ensure the software is functioning as expected.

Reliability testing:
At least two analysts will analyze data in the PAS v1.6 in order to demonstrate the reliability of the software with multiple users.

Regression testing:
During use of the new software, it will be noted if any functions are detrimentally affected. Comparison of the results prior to and post upgrade should demonstrate if any functions are affected.

Results

Functional testing:
The Plexor software concordance check was conducted by re-analyzing a previous casework quantitation plate, 070623KNB. The plate was analyzed by two different methods.

The first was to import the previously created .aan file for the plate and compare that data to the original results. No re-analysis of samples or standards was performed during this method. Once the plate was opened, the data was re-exported and compared to the original export. No changes to quantitation values or quality flags were observed. Some very minor rounding changes were noted in the Auto/Y ratio displays, in the hundredths or thousands positions. For all changes, the new software carried more significant digits than the original. For example, a sample with a previous ratio of 1, is now 0.9794.

The second was to reimport the melt and amp curves for this same data set, using the compatibility mode in the new software. This data was re-analyzed and new standard curves and sample values were generated. The standard curves created in the new software were identical to the original analysis. No changes to quantitation values or quality flags were observed. The same rounding changes were noted in this data set and are identical to those observed with the .aan re-export.

Reliability testing:
Four users utilized the PAS v1.6 during this process. No issues were reported with any user. The same data was analyzed twice with different users and no differences were noted between the two resulting projects.

User 1:

Well	Sample Name	Quantity ng/µl [Auto]	Quantity ng/µl [Y]	Auto/Y Ratio	IPC Status	ul Sample for Dilution	ul TE to be added	ng/ul Final	ul to be Amplified
H1	NTCA	N/A	N/A	N/A	OK	0	0.0	0	15.0
H2	NTCB	N/A	N/A	N/A	OK	0	0.0	0	15.0
A3	STD2372a	34.830	39.230	0.89	OK	5	1736.5	0.1	15.0
B3	STD2372a	40.440	37.830	1.07	OK	5	2017.0	0.1	15.0

User 2:

Well	Sample Name	Quantity ng/µl [Auto]	Quantity ng/µl [Y]	Auto/Y Ratio	IPC Status	ul Sample for Dilution	ul TE to be added	ng/ul Final	ul to be Amplified
H1	NTCA	N/A	N/A	N/A	OK	0	0.0	0	15.0
H2	NTCB	N/A	N/A	N/A	OK	0	0.0	0	15.0
A3	STD2372a	34.830	39.230	0.89	OK	5	1736.5	0.1	15.0
B3	STD2372a	40.440	37.830	1.07	OK	5	2017.0	0.1	15.0

Regression testing:
During the analysis performed, no functions were detrimentally affected. Comparison of the results prior to and post upgrade demonstrate that all functions are operating as expected.

Conclusion

Based on these results, the new version of Plexor Analysis software is performing as expected and is fit-for-purpose. The only notable change is the presence of additional significant figures in the Autosomal/Y ratio. This change does not affect data interpretation in any meaningful way, as ratios are only evaluated as whole numbers in practice.

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