7500 Upgrades – SDS v2.3
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.

This software is used as a component of instrumentation. 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 SDS v2.3, confirming that the program performs tasks as expected.

Method

Functional testing:
A standard curve and SRM 2372a (Component A) will be quantified in duplicate on each 7500 (serial numbers 275003950, 275003223, and 275003947) prior to the upgrade. These will then requantified in duplicate after the upgrades and the results compared between the two runs to ensure the software is functioning as expected.

Reliability testing:
At least two analysts will set up a plate prior to and after the upgrades are performed to demonstrate the reliability of the software with multiple users in the laboratory environment.

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:
A standard curve and SRM 2372a (Component A) were quantified in duplicate on each 7500 prior to the upgrade. These were then requantified in duplicate after the upgrades. The results (shown below) demonstrate consistency between runs and that the new software is performing as expected. While differences in exact SRM values are seen, this is to be expected due to pipetting differences and the inherent variability of running multiple quantifications.

7500 A – Serial number 275003950

SDS v1.2.3:

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	45.300	38.700	1.20	OK	5	2260.0	0.1	15.0
B3	STD2372a	42.400	48.900	0.90	OK	5	2115.0	0.1	15.0

SDS v2.3:

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

7500 B – Serial number 275003223

SDS v1.2.3:

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	41.000	46.400	0.90	OK	5	2045.0	0.1	15.0
B3	STD2372a	33.600	47.700	0.70	OK	5	1675.0	0.1	15.0

SDS v2.3:

Well	Sample Name	Quantity ng/µl 2	Quantity ng/µl 2	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	33.810	44.900	0.75	OK	5	1685.5	0.1	15.0
B3	STD2372a	28.790	43.350	0.66	OK	5	1434.5	0.1	15.0

7500 C – Serial number 275003947

SDS v1.2.3:

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	43.400	54.100	0.80	OK	5	2165.0	0.1	15.0
B3	STD2372a	35.900	52.400	0.70	OK	5	1790.0	0.1	15.0

SDS v2.3:

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	52.250	59.590	0.88	OK	5	2607.5	0.1	15.0
B3	STD2372a	42.250	55.320	0.76	OK	5	2107.5	0.1	15.0

Reliability testing:
Three analysts used the new software during this performance check and no discrepancies between users were seen. This demonstrates the reliability of the software to function properly between users in our laboratory setting.

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 the 7500 software (SDS v2.3) is performing as expected and is fit-for-purpose.

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