Evaluation of Concordance for VITROS® Chemistry Products A1c Slides* on the Ortho VITROS® 5600/XT 7600 Integrated and VITROS® 4600/XT 3400 Chemistry Systems

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Introduction

Globally, due to the rise of pre-diabetes and diabetes, expert groups recommend glycated hemoglobin A1c (A1c) for screening at-risk populations and managing diagnosed patients at regular intervals.

The high demand for A1c testing requires laboratories to deliver accurate A1c results with high volume operational efficiencies. VITROS® Chemistry Products A1c Slides* are being developed for the measurement of A1c on the automated VITROS® 5600/XT 7600 Integrated and VITROS® 4600/XT 3400 Chemistry Systems and are compatible for use with the VITROS® Automation Solution (VAS) configuration.

Compatibility with the VAS track enables customers to load and automate testing of suspended whole blood samples. The VAS modules will de-cap the primary test tube and automatically route to the VITROS® Systems for sample check, testing, error detection and analysis. There is no pre-treatment step as the red blood cells are lysed directly on the VITROS® A1c Slides. Ortho verification has demonstrated acceptable sample metering within a conservative 20-minute default time-out on VAS. User adjustment of the time-out on the VAS is possible, based on the customer's validation for red blood cell settling time with the customer's patient population

Methods

The results obtained with the VITROS® A1c Slides* measurement on VAS compared to the VITROS® 5600/XT 7600 Integrated Systems and VITROS® 4600/XT 3400 Chemistry Systems was evaluated for both result correlation and precision. Forty (40) unique whole blood patient samples were tested across the VITROS® Systems (10 samples per VITROS® System) at 10 replicates per fluid-system combination. Two (2) levels of quality control (QC) fluids were also tested across each VITROS® System at thirty (30) replicates per fluid-system combination.

Precision was analyzed by performing a statistical F-test across each System and quality control fluid combination and across each System and all patient sample replicates at a 95% confidence interval. VITROS® System result correlation to VAS was analyzed by performing a paired T-test and linear regression across each VITROS® System and patient sample means at a 95% confidence interval. Data was additionally summarized by computing the grand mean, SD (SD for patient samples pooled by patient), and %CV.

Results

The F-test conducted for precision assessment showed no statistical difference (p-values > 0.05) at a 95% confidence interval for both patient samples and quality control fluids for each system. The paired T-test conducted across the ten (10) patient sample means showed no statistical difference at a 95% confidence interval.

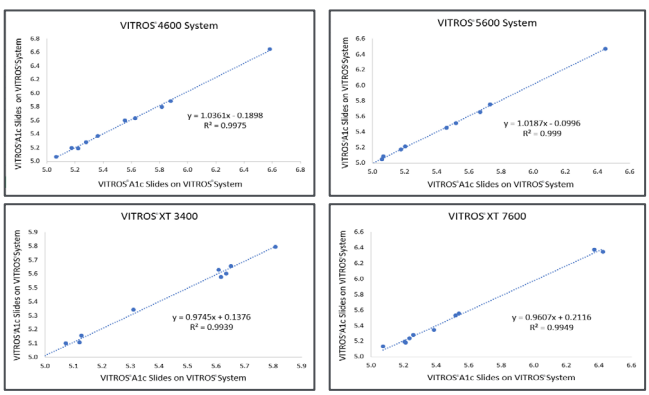
Summary Statistics, F-Test, and T-Test

System	Fluid	VITROS Summary Statistics			VAS Summary Statistics			F-Test Summary		T-Test Summary	
		Grand Mean (%A1c)	SD / Pooled SD (%A1c)	%CV	Grand Mean (%A1c)	SD / Pooled SD (%A1c)	%CV	F-Value	P-Value	T-Value	P-Value
VITROS 4600	QC Fluid Level 1	5.965	0.041	0.69%	5.965	0.030	0.50%	1.890	0.091		
	QC Fluid Level 2	10.466	0.079	0.76%	10.439	0.065	0.63%	1.480	0.300		
	Patient Samples	5.556	0.035	0.62%	5.567	0.031	0.55%	0.930	0.721	1.22	0.252
VITROS 5600	QC Fluid Level 1	5.842	0.050	0.85%	5.831	0.059	1.02%	0.690	0.330		
	QC Fluid Level 2	10.322	0.070	0.68%	10.288	0.060	0.58%	1.360	0.412		
	Patient Samples	5.432	0.030	0.54%	5.434	0.030	0.55%	0.960	0.851	0.340	0.741
VITROS XT 3400	QC Fluid Level 1	5.831	0.031	0.53%	5.846	0.037	0.63%	1.810	0.115		
	QC Fluid Level 2	10.470	0.058	0.56%	10.373	0.055	0.53%	0.690	0.322		
	Patient Samples	5.374	0.036	0.67%	5.375	0.034	0.63%	1.05	0.818	0.070	0.947
VITROS XT 7600	QC Fluid Level 1	5.858	0.053	0.90%	5.867	0.039	0.67%	0.700	0.342		
	QC Fluid Level 2	10.513	0.080	0.76%	10.451	0.096	0.92%	1.120	0.769		
	Patient Samples	5.522	0.036	0.65%	5.517	0.036	0.65%	1.05	0.807	-0.460	0.656

Linear regression analysis showed excellent correlation between System and VAS for the patient samples:

VAS = 1.036 * VITROS® 4600 A1c - 0.19; (r) = 0.998
VAS = 1.019 * VITROS® 5600 A1c - 0.10; (r) = 0.999
VAS = 0.975 * VITROS® XT 3400 A1c + 0.138; (r) = 0.994
VAS = 0.961 * VITROS® XT 7600 A1c + 0.212; (r) = 0.995

Linear Regression Plots



Conclusions

The data presented here demonstrates that VITROS® A1c Slides* show excellent result concordance between testing on the VITROS® Automation Solution and on the VITROS® Systems. VAS compatibility for VITROS® A1c Slides* could enable laboratories to deliver accurate A1c results with high volume operational efficiencies.

*Not regulatory approved/cleared product, not available for sale. *The performance characteristics of this product have not been established.*

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Appendix – SI Units (mmol/mol)

Evaluation of a New Metering Algorithm to Enable Whole Blood Sampling for VITROS® Chemistry Products A1c Slides* on the Ortho VITROS® 5600/XT 7600 Integrated and VITROS® 4600/XT 3400 Chemistry Systems

Summary Statistics, F-Test, and T-Test

System	Fluid	Front-Load Summary			Track-Load Summary			F-Test Summary		Paired T-Test Summary	
		Grand Mean (mmol/mol)	SD / Pooled SD (mmol/mol)	%CV	Grand Mean (mmol/mol)	SD / Pooled SD (mmol/mol)	%CV	F-Value	P-Value	T-Value	P-Value
VITROS 4600	QC Fluid Level 1	41.673	0.450	1.08%	41.681	0.327	0.78%	1.890	0.091		
	QC Fluid Level 2	90.868	0.868	0.96%	90.572	0.714	0.79%	1.480	0.300		
	Patient Samples	37.208	0.379	1.02%	37.329	0.335	0.90%	0.930	0.721	1.22	0.252
VITROS 5600	QC Fluid Level 1	40.338	0.541	1.34%	40.217	0.650	1.62%	0.690	0.330		
	QC Fluid Level 2	89.296	0.767	0.86%	88.922	0.657	0.74%	1.360	0.412		
	Patient Samples	35.855	0.323	0.90%	35.874	0.326	0.91%	0.960	0.851	0.340	0.741
VITROS XT 3400	QC Fluid Level 1	40.213	0.336	0.84%	40.381	0.402	0.99%	1.810	0.115		
	QC Fluid Level 2	90.916	0.637	0.70%	89.852	0.603	0.67%	0.690	0.322		
	Patient Samples	35.221	0.393	1.11%	35.228	0.371	1.05%	1.05	0.818	0.070	0.947
VITROS XT 7600	QC Fluid Level 1	40.508	0.575	1.42%	40.609	0.427	1.05%	0.700	0.342		
	QC Fluid Level 2	91.389	0.876	0.96%	90.713	1.055	1.16%	1.120	0.769		
	Patient Samples	36.839	0.394	1.07%	36.730	0.602	1.64%	1.05	0.807	-0.980	0.352

Linear regression analysis showed excellent correlation between System and VAS for the patient samples:

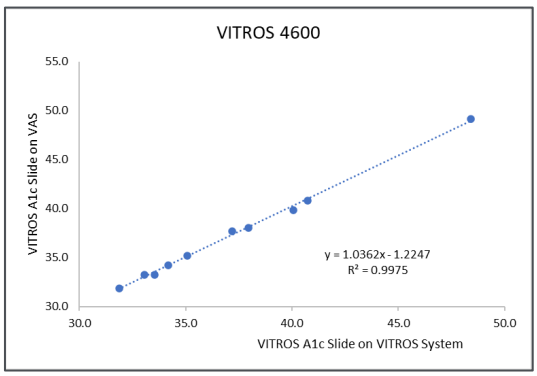
VAS = 1.036 * VITROS 4600 A1c - 1.225; (r) = 0.998

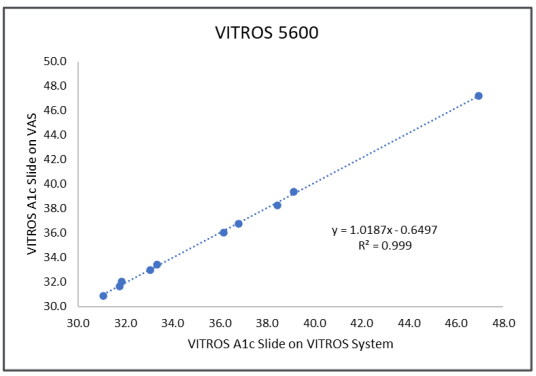
VAS = 1.019 * VITROS 5600 A1c – 0.650; (r) = 0.999

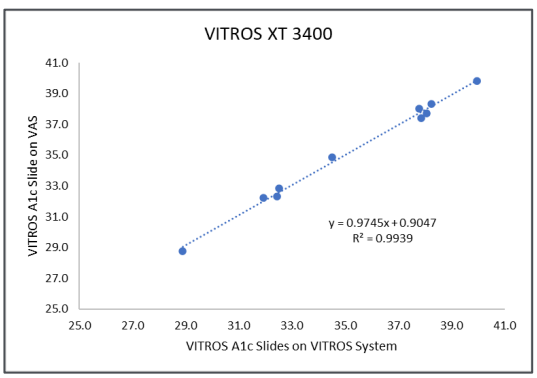
VAS = 0.975 * VITROS XT 3400 A1c + 0.905; (r) = 0.994

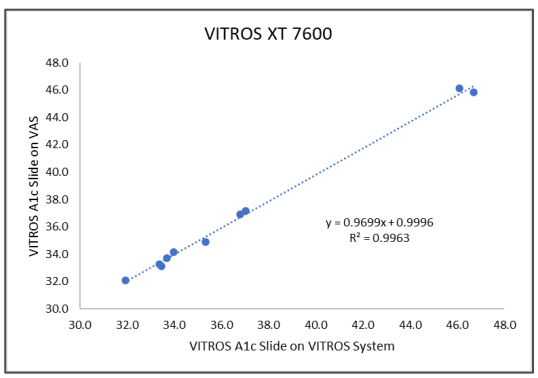
VAS = 0.961 * VITROS XT 7600 A1c + 0.999; (r) = 0.995

Linear Regression Plots









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