ADVANCED INSTRUMENTS

SCIENTIFIC RESOURCE

CLINICAL VALIDATION COMPARISON: OSMO1® SINGLE-SAMPLE MICRO-OSMOMETER VERSUS MODEL 3250 SINGLE-SAMPLE OSMOMETER

BACKGROUND

The Osmo1® Single-Sample Micro-Osmometer is the replacement for the Model 3250 Single-Sample Osmometer which was discontinued in 2020. The Osmo1 provides additional benefits over the Model 3250 including but not limited to a touchscreen display for ease-of-use, integrated barcode scanning, a small 20 µL sample size and the elimination of heat transfer fluid. This paper summarizes a study comparing the performance of the Osmo1 and Model 3250 osmometers. In the study, the Osmo1 exhibited no significant performance difference compared to the Model 3250 and met all acceptance criteria for linearity, precision and accuracy.

INTRODUCTION

The Model 3250 Single-Sample Osmometer was discontinued on December 31, 2020. The Osmo1 Single-Sample Micro-Osmometer is the replacement for the Model 3250 in clinical laboratories and offers additional benefits to improve workflow efficiency as shown in the table below.

The purpose of this report is to present results comparing the performance of the Osmo1 to the Model 3250. The scope of testing involved three (3) Osmo1 and three (3) Model 3250 osmometers. **The following testing was performed for each Osmo1 instrument:**

- Linearity using the Advanced Instruments Linearity Set (5 levels), with 5 replicate tests per level.
- Precision & Accuracy using Clinitrol™ 290 Reference Solution, Protinol™ Protein-Based Controls & Renol™ Urine Osmolality Controls, with 5 replicate tests per sample.
- Accuracy correlation of Osmo1 to the Model 3250 (reference instrument) using 40 biological samples (20 urine and 20 serum/plasma), with a single replicate test per sample.

The testing for each individual sample was completed within one day on all six (6) instruments. The testing spanned multiple days. In addition to data analysis in Excel, the clinical laboratory data analysis software EP Evaluator was used.

Features	Model 3250	Osmo1®
LIS Connectivity (Ethernet)	—	✓
Touchscreen Display	—	✓
3-Point Calibration Capability	—	✓
On-board Levey-Jennings Charts	—	✓
User Traceability & Password Protection	—	✓
Integrated Barcode Scanner	—	✓
No Heat Transfer Fluid	—	✓
Sample Size	250 µL	20 µL
Testing Time (seconds)	120-180	90
Instrument Memory	30 results	1,000 results
	0 events	10,000 events

ACCEPTANCE CRITERIA

Osmo1 Linearity

- Allowable Total Error (TEa) based on 3SD = 6 mOsm & 3%, with 33% for Systematic Error (SEa)
- Mean results accurate within SEa (1.98 mOsm & 1%)
- Individual results accurate within TEa
- Linear within SEa of 1.98 mOsm or 1%
- Value of lowest (100 mOsm) & highest specimen (2000 mOsm) must be within following limits: 96 to 104 mOsm & 1980 to 2020 mOsm
- Lowest & highest specimens must meet accuracy specifications

Osmo1 Precision and Accuracy with Controls

- Clinitrol 290: SD ≤ 2 mOsm and individual values from 284 to 296 mOsm
- Protinol 240: SD ≤ 4.7 mOsm and individual values from 233 to 247 mOsm
- Protinol 280: SD ≤ 4.7 mOsm and individual values from 273 to 287 mOsm
- Protinol 320: SD ≤ 4.7 mOsm and individual values from 313 to 327 mOsm
- Renol 300: SD ≤ 6.7 mOsm and individual values from 290 to 310 mOsm
- Renol 800: SD ≤ 6.7 mOsm and individual values from 790 to 810 mOsm

ACCURACY CORRELATION OF OSMO1 TO MODEL 3250 (REFERENCE INSTRUMENT) WITH URINE AND SERUM/PLASMA SAMPLES

- Slope: 0.95 to 1.05 (Allowable proportional bias of ± 5%)
- Intercept: -6.0 to +6.0 (Allowable constant bias of ± 6 mOsm)

RESULTS

All osmometers met the linearity acceptance criteria. A summary of the linearity results is shown below in Table 1.

Table 1. Summary of Linearity Results

Instrument Model	Serial Number	Slope	Intercept [mOsm/kg]	Observed Error	Observed range [mOsm/kg]	Linear within allowable error?	Meet reportable range?
Osmo1	18020224A	1.000	1.0	0.6 mOsm/kg or 0.3%	100.4 to 2003.2	Yes	Yes
	18030359A	1.002	-1.4	0.7 mOsm/kg or 0.3%	98.2 to 1997.2	Yes	Yes
	19050672B	0.998	-0.6	0.8 mOsm/kg or 0.4%	98.4 to 2001.8	Yes	Yes

RESULTS (CONT.)

All osmometers met the precision and accuracy acceptance criteria with Advanced Instruments Controls. A summary of the precision and accuracy results with the Controls are shown below in Table 2.

Table 2. Summary of Precision and Accuracy Results with Controls (N=5 for each sample)

Instrument Model	Serial Number	Sample	Mean [mOsm/kg]	SD [mOsm/kg]	Meet Precision?	Allowable Range [mOsm/kg]	Meet Accuracy?
Osmo1	18020224A	Clinitrol 290	291.8	1.6	Yes	284 to 296	Yes
		Protinol 240	238.2	0.8	Yes	233 to 247	Yes
		Protinol 280	280.4	1.1	Yes	273 to 287	Yes
		Protinol 320	320.8	2.4	Yes	313 to 327	Yes
		Renol 300	301.4	1.1	Yes	290 to 310	Yes
		Renol 800	802.0	0.7	Yes	790 to 810	Yes
	18030359A	Clinitrol 290	290.0	0.7	Yes	284 to 296	Yes
		Protinol 240	237.2	0.8	Yes	233 to 247	Yes
		Protinol 280	278.2	0.8	Yes	273 to 287	Yes
		Protinol 320	317.8	1.5	Yes	313 to 327	Yes
		Renol 300	299.8	0.8	Yes	290 to 310	Yes
		Renol 800	801.6	2.4	Yes	790 to 810	Yes
	19050672B	Clinitrol 290	288.2	1.6	Yes	284 to 296	Yes
		Protinol 240	238.0	1.4	Yes	233 to 247	Yes
		Protinol 280	279.8	2.9	Yes	273 to 287	Yes
		Protinol 320	319.2	2.6	Yes	313 to 327	Yes
		Renol 300	298.8	1.3	Yes	290 to 310	Yes
		Renol 800	798.0	0.7	Yes	790 to 810	Yes

The correlation method comparison Passing-Bablok regression analysis of the average results of the clinical samples (serum, plasma, and urine) of the Osmo1 osmometers versus the average results of the Model 3250 osmometers passed acceptance criteria. In addition, the correlation method comparison of each of the three Osmo1 versus each of the three Model 3250 osmometers also met acceptance criteria. No statistically significant proportional or constant biases between the Osmo1 and Model 3250 osmometers, tested with clinical samples, were present in the regression analyses as the 95% confidence intervals for all the slopes encompassed 1.0 and encompasses 0.0 for the intercepts. The correlation results are summarized in Table 3.

Table 3. Summary of Passing-Bablok Regression Analyses with Clinical Samples (N=40)

Test Method Osmo 1 SN	Reference Method 3250 SN	Slope (95% CI)	Intercept (95% CI)	Meet Correlation?
Osmo1 Instruments Combined (Avg)	Model 3250 Instruments Combined (Avg)	1.000 (0.992 to 1.012)	1.2 (-2.55 to 3.80)	Yes
18020224A	15010117	1.010 (1.000 to 1.029)	0.0 (-1.0 to 3.5)	Yes
	15010117E	1.012 (1.000 to 1.029)	-1.0 (-6.7 to 3.0)	Yes
	16070752E	1.012 (1.000 to 1.031)	-1.3 (-8.3 to 3.0)	Yes
18030359A	15010117	1.006 (1.000 to 1.013)	0.0 (-2.7 to 2.5)	Yes
	15010117E	1.003 (0.995 to 1.012)	0.3 (-3.3 to 3.5)	Yes
	16070752E	1.005 (1.000 to 1.014)	-0.6 (-3.8 to 1.0)	Yes
19050672B	15010117	0.993 (0.980 to 1.004)	2.6 (-1.7 to 8.9)	Yes
	15010117E	0.991 (0.979 to 1.000)	2.2 (02.0 to 7.9)	Yes
	16070752E	0.991 (0.979 to 1.000)	2.0 (-1.5 to 7.1)	Yes

SUMMARY/CONCLUSION

The Osmo1 Single-Sample Micro-Osmometer is ideally suited to replace the Model 3250 Single-Sample Osmometer in clinical laboratories. The Osmo1 drives workflow efficiencies with a touchscreen display for ease-of-use, integrated barcode scanning, a small 20 µL sample size and the elimination of heat transfer fluid, all while maintaining the high level of performance laboratories have come to expect.

All three Osmo1 osmometers met acceptance criteria for linearity using the Advanced Instruments linearity kit.

All three Osmo1 osmometers met acceptance criteria for precision and accuracy using Advanced Instruments Clinitrol™ 290 Reference Solution, Protinol™ Protein Based Controls (three levels), and Renol™ Urine Osmolality Controls (two levels).

When compared to three Model 3250 osmometers, all three Osmo1 osmometers exhibited no statistically significant biases when tested with 40 clinical samples based on regression analyses.

The Osmo1 osmometers exhibited no significant performance difference with clinical samples as compared to the Model 3250 osmometers and met all acceptance criteria for linearity, precision and accuracy.

APPENDIX

MATERIALS/EQUIPMENT

Material/Equipment	Part Number	Serial #/Lot#
Osmo1® Single-Sample Micro-Osmometer	Osmo1	18020224A
Osmo1® Single-Sample Micro-Osmometer	Osmo1	18030359A
Osmo1® Single-Sample Micro-Osmometer	Osmo1	19050672B
Model 3250 Single-Sample Osmometer	3250	15010117E
Model 3250 Single-Sample Osmometer	3250	15010117
Model 3250 Single-Sample Osmometer	3250	16070752E
50 mOsm Calibration Standard	3MA005	191756152
100 mOsm Calibration Standard	3LA010	20172156767
500 mOsm Calibration Standard	3LA050	20E0656182
850 mOsm Calibration Standard	3MA085	20C0356134
900 mOsm Calibration Standard	3LA090	19F0456192
1500 mOsm Calibration Standard	3LA151	2030356192
2000 mOsm Calibration Standard	3LA201	19E0456490
Clinitrol 290 Reference Solution	3MA029	20C0956392
Renol Urine Osmolality Controls	3LA085	16327/16328
Protinol Protein-Based Controls	3MA028	16328/16328
20 Urine Samples	N/A	N/A
20 Serum/Plasma Samples	N/A	N/A
20 µL Sampler	3M0825	170954041048
20 µL Sampler	3M0825	131244937006
20 µL Sampler	3M0825	190158530076
Model 3250 Sample Tubes	3LA825	N/A
250 µL Pipette	N/A	928485
Pipette Tips for 250 µL Pipette	N/A	N/A
Micro-Sample Test Kit	133800	N/A
Heat Transfer Fluid (as needed)	3DA811	N/A
Printer Paper (as needed)	FLA835	N/A
PC/Laptops for data collection	N/A	N/A
Microsoft Excel version: 2013	N/A	N/A
EP Evaluator software	N/A	N/A