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Independent validation of salivary osmolarity measures made by the MX3 Hydration Testing System compared to a laboratory grade osmometer

This letter certifies that my research team has performed an independent validation of the MX3 Hydration Testing System. All measurements and analysis were conducted by Dr Jianxiong Chan on the 7th of March 2019. Overall we observed an excellent correlation between salivary osmolarity (SOSM) readings performed with the handheld MX3 Hydration Testing System and an FDA registered laboratory benchtop osmometer ($R^2 = 0.945$).

Experimental Design

Reference SOSM Values: 20 saliva samples were measured with a benchtop Micro-Osmometer (Advanced Instruments Model 3320, FDA Operator 1217058) as per the manufacturer's instructions, using a 20uL volume of unprocessed saliva. A single measurement was conducted for each sample.

MX3 SOSM Values: Triplicate measurements were conducted for each of the 20 saliva samples. 30uL of unprocessed saliva was pipetted into a sterile dish. The MX3 Hydration Testing System was then used to make 3 measurements from this sample as per instructions for use provided by MX3.

Results

A copy of the raw data may be found below **(Table 1)**.

An R^2 correlation coefficient of 0.945 was observed between SOSM measurements conducted by the MX3 Hydration Testing System and the Advanced Instruments Model 3320 Osmometer (**Figure 1**).

We observe the MX3 Hydration Testing System to be an accurate and precise tool for the measurement of salivary osmolarity.

Regards,

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Table 1. Osmolarity readings for 20 saliva samples from the Advanced Instruments Model 3320 Osmometer compared to the MX3 Hydration Testing System.

	Advanced Instruments Model 3320 [mOsm]	MX3 Hydration Testing System [mOsm]		
		Measurement 1	Measurement 2	Measurement 3
Sample 1	93	118	97	98
Sample 2	66	69	73	62
Sample 3	102	85	90	87
Sample 4	72	60	63	63
Sample 5	165	162	157	205
Sample 6	92	106	95	97
Sample 7	44	50	43	48
Sample 8	118	118	118	119
Sample 9	94	90	83	91
Sample 10	117	106	130	111
Sample 11	69	61	60	62
Sample 12	75	74	76	81
Sample 13	49	47	54	55
Sample 14	107	89	89	91
Sample 15	156	152	155	128
Sample 16	127	129	133	137
Sample 17	231	224	219	226
Sample 18	97	102	114	104
Sample 19	41	36	33	37
Sample 20	47	43	50	57

Figure 1. Correlation of SOSM readings for 20 saliva samples measured with the MX3 Hydration Testing System (average of triplicate measurement) and an Advanced Instruments Model 3320 laboratory osmometer (single measurement). Dotted lines represent 95% prediction bands.