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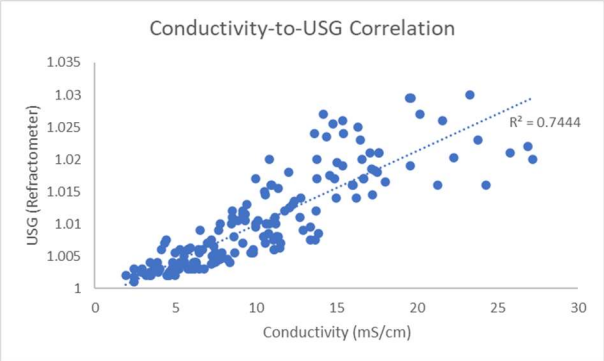
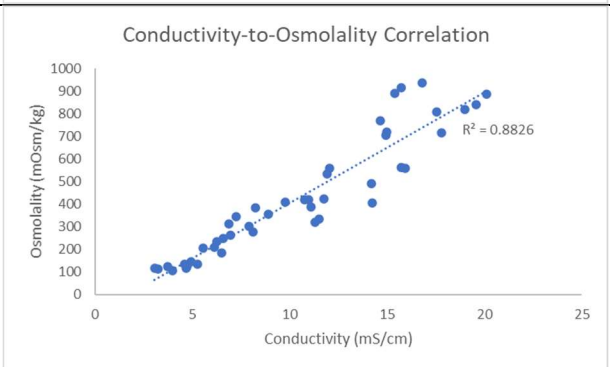
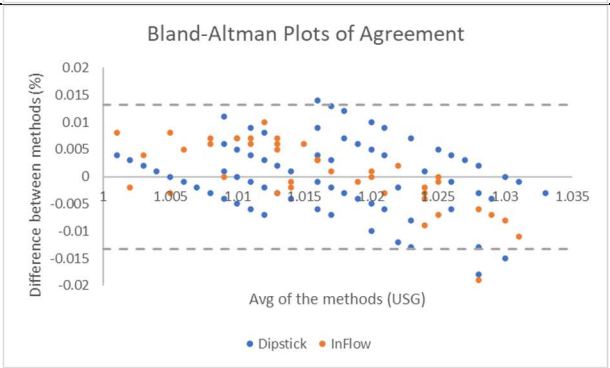
Test Development, Characterization, and Performance

Conductivity as a urine hydration marker (USG) Academic literature[1,2,3,4] and internal testing (n=177) have demonstrated a positive, significant correlation (R^2=0.74) between urine conductivity and urine specific gravity (USG), a well-used marker of hydration status.	
Conductivity as a urine hydration marker (Osmolality) Internal testing (n=65) also demonstrated a positive, significant correlation (R^2=0.88) between urine conductivity and urine osmolality, a well-used marker of hydration status and often used as a gold-standard for urine hydration assessment.	
Interchangeable Measurement Techniques A Bland-Altman Plot of Agreement demonstrates the agreement between InFlow and dipstick testing[5] against an optical refractometer's USG reporting. The two methods are largely interchangeable, with 97.6% (n=40) falling within the limits of agreement (μ±1.96*s*).	

[1] Fazil Marickar YM. Electrical conductivity and total dissolved solids in urine. Urol Res. 2010 Aug;38(4):233-5. doi: 10.1007/s00240-009- 0228-y. Epub 2009 Nov 17.
[2] Kavukcu S, et al. Could conductivity be used as a parameter in urinalysis? J Pak Med Assoc. 1998 Aug;48(8):238-40.
[3] Wang JM, et al. Evaluating the performance of urine conductivity as screening for early stage chronic kidney disease. Clin Lab. 2014;60(4):635-43. doi: 10.7754/clin.lab.2013.130628.
[4] Kutlu M, Guler G. Assessment of hydration status by urinary analysis of elite junior taekwon-do athletes in preparing for competition. J Sports Sci. 2006 Aug;24(8):869-73. doi: 10.1080/02640410500249357.
[5] de Buys Roessingh AS, Drukker A, Guignard JP. Dipstick measurements of urine specific gravity are unreliable. Arch Dis Child. 2001 Aug;85(2):155-7. doi: 10.1136/adc.85.2.155.

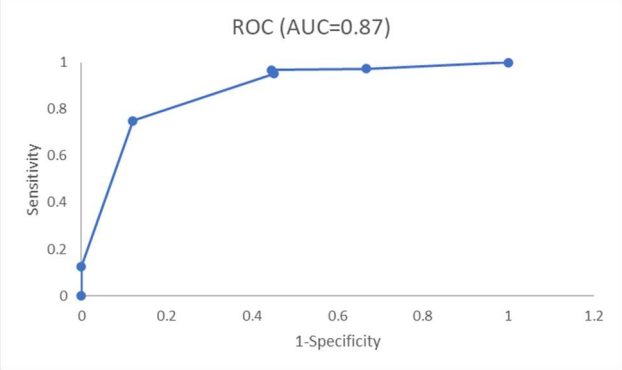
Test Performance at USG=1.020 Threshold

True condition is represented by dehydration (U_{sg} (Optical Refractometer) ≥ 1.020) and a negative condition is represented by hydration (U_{sg} (Optical Refractometer) < 1.020). A negative test is represented by U_{sg} (InFlow) < 1.020 and a positive test represented by U_{sg} (InFlow) ≥ 1.020. Professional athlete subjects (n=41) correctly classified by the test are represented by TP and TN cells.

		U_{sg} (Optical Refractometer)		
		≥ 1.020	< 1.020	Total
U_{sg} (InFlow)	≥ 1.020	TP 29.3% (n=12)	FP 9.8% (n=4)	16
	< 1.020	FN 7.3% (n=3)	TN 53.7% (n=22)	25
Total		15	26	41
		Sensitivity 75.0%	Specificity 88.0%	Accuracy 82.9%

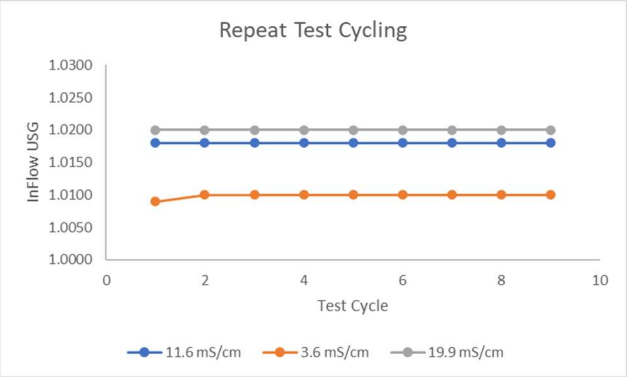
Receiver Operating Curve (ROC)

The test quality was assessed at varying thresholds to examine the relationship between sensitivity and specificity, produce an AUC of 0.87 and representing a generally acceptable threshold for a good quality test.



Repeat Analytical Test Error

Testing cycling through standard solutions of different conductivity at 1 to 30 minute intervals show minimal test to test variance. The coefficient of variation ($CV = {}^{\sigma}/_{\mu}$) was 3.55%, 1.09%, and 0.840%, at conductivities of 3.6, 11.6, and 19.9 mS/cm, respectively. Back-to-back cycling through urine solutions demonstrated a stabilized SD of ± 0.402 (CV=3.43%).



Interpretations & Conclusions

InFlow has demonstrated appropriate accuracy, sensitivity, and specificity for use in the quantification of urine specific gravity for the purposes of assessing hydration status. Given the combination of bias (systematic error), random error (test precision), and biological variability (inter- and intra-individual USG variability), the results demonstrate the test is fit for purpose and accuracy exceeds that of urine dipsticks tests.

Limitations & Future Development

Current testing is limited by a small amount of field trial data. Increasing the number of testing subjects, test samples, true positive prevalence, and diversity of subject demographics will lead to an improvement in the reliability of the test statistics. Repeat testing data is also limited by a lack of field trial data at lengths of time spanning months and beyond.