

EFFECT OF MANUAL SAMPLE DILUTION IN THE DETERMINATION OF URINARY ELECTROLYTES. SOURCES OF ERROR AND A NOVEL METHOD FOR UNDILUTED MEASUREMENT.

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BACKGROUND/AIM

Urinary electrolytes are used to aid the diagnosis hypovolemia, kidney damage, acid-base, and electrolyte disorders. Quantification of urinary sodium (Na), chloride (Cl), and potassium (K) by ion-sensitive electrodes (ISE) is a widely used for the management of critically ill patients. [1], [2]

Established methods require pre-analytical dilution steps, which entail metrological disadvantages. The aim of the study is to quantify the pre-analytical error caused by the dilution and to compare a novel undiluted urine method EXIAS e|1 Analyzer (e|1) with diluted Roche 9180 Electrolyte Analyzer (9180).

METHODS

A method comparison study (CLSI EP9A3, [3]) using random and first morning mid-stream urine samples from 145 male and female donors between the ages of 20 and 60 and different dietary habits (vegetarian, vegan, omnivore) and a precision study (CLSI EP5A3, [4]) with 3 dedicated donor pools were performed.

The statistical analysis for the comparison of both methods was performed using Deming regression. Repeatability (SD1) and Reproducibility (SD2) were estimated based on ANOVA. The samples on 9180 were diluted according to the instructions for use, with 2 dilutions being prepared and compared per aliquot (as factor in SD2), additional dilution with a.dest. for K \geq 60mmol/L.

RESULTS

The regression analysis of the comparison study demonstrated a slope from 0.99 (Na) to 1.02 (Cl). The results correlated well ($R^2>0.98$) and showed that e|1 and 9180 have no significant bias. It can thus be shown that the elimination of the dilution of the urine sample has no negative impact on the quantification of the analytes on the e|1. The deviations in the lower range of Na and Cl can be attributed to the uncertainty of the 9180 (x) resulting from the dilution.

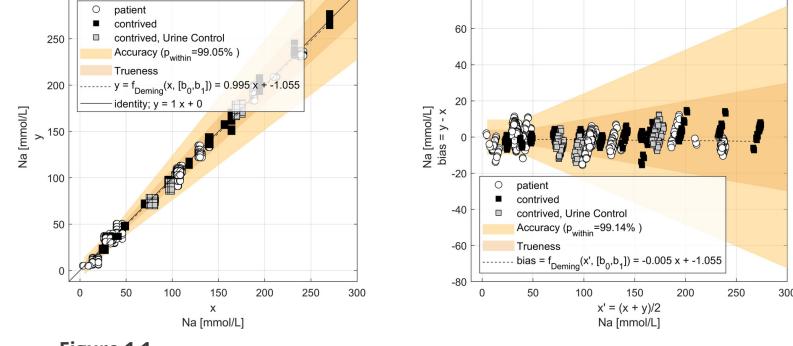


Figure 1.1

Method Comparison for Sodium according CLSI EP9A3 comparing 8 x e|1 (y, undiluted) vs. 2 x 9180 (x, diluted)

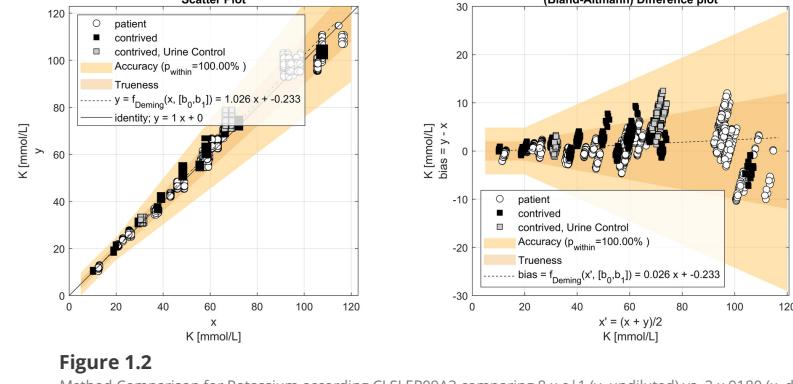


Figure 1.2

Method Comparison for Potassium according CLSI EP9A3 comparing 8 x e|1 (y, undiluted) vs. 2 x 9180 (x, diluted)

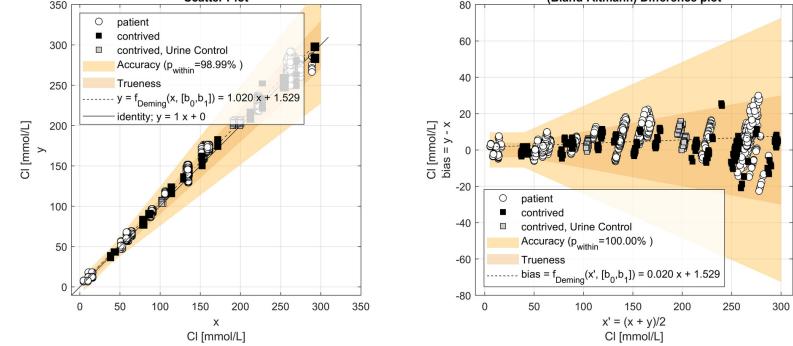


Figure 1.3

Method Comparison for Chloride according CLSI EP9A3 comparing 8 x e|1 (y, undiluted) vs. 2 x 9180 (x, diluted)

The precision study shows clear differences in the SD2 between e|1 and 9180, with the difference between the concentration of the patient sample and the diluent modulating the uncertainty on the 9180; e.g., Na at 44mmol/L; e|1: SD1=0.49, SD2=1.59; 9180: SD1=1.29, SD2=4.81. The significant difference between SD1 and SD2 shows that dilution is a non-negligible source of error. 25% of the samples required an additional dilution step with a.dest. due to altered K.

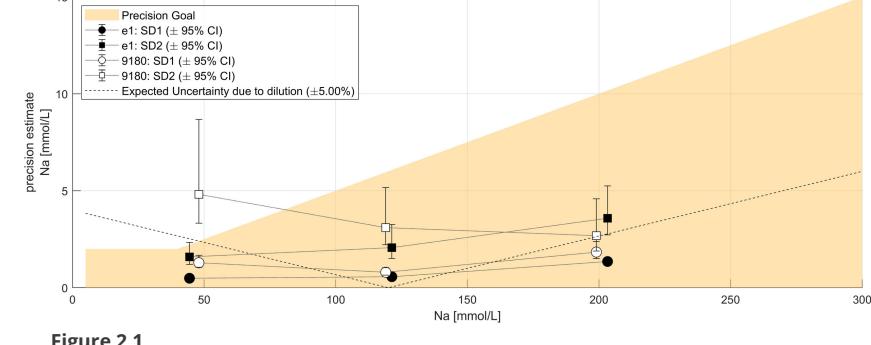


Figure 2.1

Precision profile for Sodium according CLSI EP05A3 for Repeatability SD1 and Reproducibility SD2 considering 8 x e|1 (undiluted), respectively 2 x 9180 (diluted) as factors for SD2; expected effect of dilution error shown dashed as additional factor in SD2 to 9180

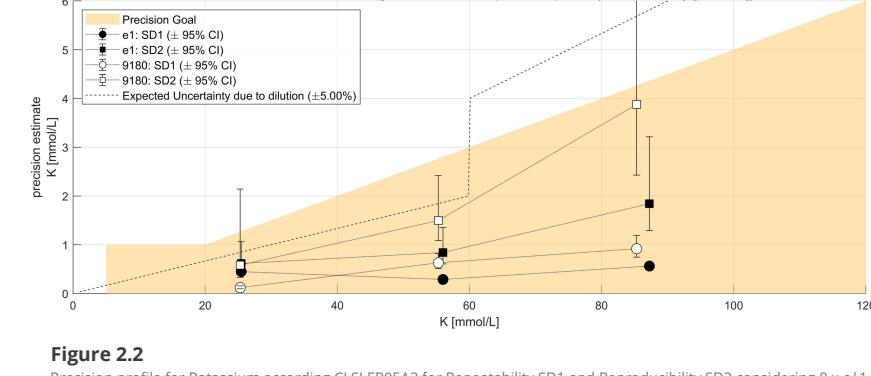


Figure 2.2

Precision profile for Potassium according CLSI EP05A3 for Repeatability SD1 and Reproducibility SD2 considering 8 x e|1 (undiluted), respectively 2 x 9180 (diluted) as factors for SD2; expected effect of dilution error shown dashed as additional factor in SD2 to 9180

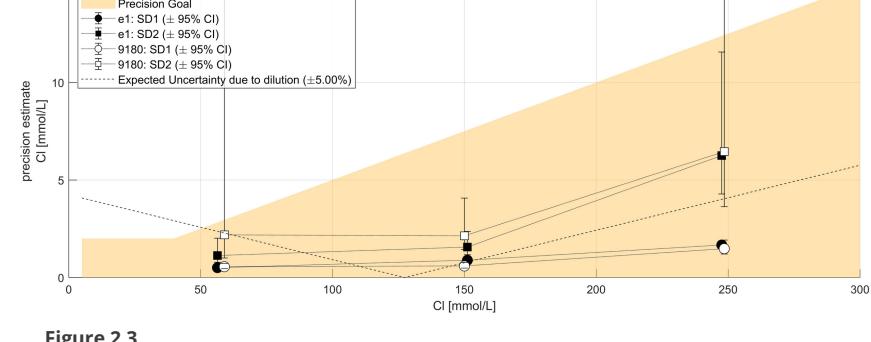


Figure 2.3

Precision profile for Chloride according CLSI EP05A3 for Repeatability SD1 and Reproducibility SD2 considering 8 x e|1 (undiluted), respectively 2 x 9180 (diluted)

CONCLUSION

By using an undiluted ISE method for quantification of urinary electrolytes, the preanalytical error can be significantly reduced compared to diluted methods with the same diagnostic quality of the quantification. In addition, the effort in the laboratory can be reduced to an absolute minimum.



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Ref. e|1 e2

[1] Uhlendorf et al. "Urinary electrolytes in the intensive care unit: From pathophysiology to clinical practice." Anesthesia & Analgesia 131.5 (2020): 1456-1470.

[2] Seifert et al. "Disorders of acid-base balance: new perspectives." Kidney Diseases 2.4 (2016): 170-186.

[3] Evaluation of Precision of Quantitative Measurement Procedure: Approved Guideline - Third Edition. CLSI document EP05-A3: 2014.

[4] Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition- CLSI document EP09-A3: 2013