

Evaluation of a New Konelab Assay for Creatinine in Urine Using Enzymatic Method

Väisänen SB¹, Dunder U¹, Kurki M², Harmoinen A³, Romppanen J¹

¹Kuopio University Hospital, Department of Clinical Chemistry, Laboratory Centre, Finland

²Thermo Electron Corporation, Vantaa, Finland

³Savonlinna Central Hospital, Finland

XXX Nordic Congress in Clinical Chemistry (NFKK 2006), Copenhagen, Denmark, 14 - 17 June

Aim

We evaluated a new enzymatic method for creatinine assays in urine samples. The method was compared with a modified Jaffé and another enzymatic method.

Materials and Methods

Instruments

The Konelab 60i (Thermo Electron Co, Finland) and Cobas Integra 700 (F. Hoffmann-La Roche Ltd, Basel, Switzerland) analyzers were used for creatinine measurements.

Reagents and Calibrators

An enzymatic method (Konelab CREATININE (Enzymatic), code 981845, Thermo Electron Co) was evaluated and compared with the modified 2-reagent Jaffé method (Konelab CREATININE (Jaffé), code 981810 or 981811, Thermo Electron Co) and with another enzymatic method (COBAS INTEGRA[®] Creatinine plus ver.2, Cat. No. 03263991, Roche Diagnostics). The calibrator for the Konelab methods was sCal (code 981831, Thermo Electron Co) The calibrator C f.a.s. (Cat. No. 10759350, Roche Diagnostics) was used in the enzymatic Roche method. Reagents for the evaluated method were ready-to-use with on-board stability up to 4 weeks.

Samples and Control Samples

Urine samples without any additives were used in correlation tests. Control samples were uTrol (code 981821) and uTrol High (code 981822) controls, Thermo Electron Co; Lyphochek[®] Quantitative Urine Control Normal (code 376) and Abnormal (code 377) controls, Bio-Rad.

Statistical Analyses

In order to calculate the within-run, between-day and total imprecision (coefficient of variation, CV), four control samples were analyzed twice a day with 2 replicates during 20-21 days. Analyse-it software (Analyse-it for Microsoft Excel, version 1.7, Analyse-It[®] Software Ltd, UK.) was used for the statistical analyses.

Results

Simple precision of the evaluated method for determination the proper function of the analyzer and reagents was done by analyzing six samples in 24 replicates for within-run CVs (Table 1). Four control samples were used for analyzing CVs for total, within-run, between-run and between-day variations (Table 2).

Table 1. Simple precision of the evaluated method in urine samples (n=24)

	Lypocheck Normal	Lypocheck Abnormal	uTrol	uTrol High	Patient 1	Patient 2
Mean creatinine (mmol/l)	7.9	21.8	6.7	14.8	8.6	36.4
CV %	1.0	0.7	0.8	1.0	0.8	1.0

Table 2. Imprecisions in the evaluated method. The results are based on the analyses of each sample twice a day with two replicates during 20-21 days.

	Lypocheck Normal	Lypocheck Abnormal	uTrol	uTrol High
Days	20	20	21	21
Mean creatinine (mmol/l)	7.9	22.2	6.7	14.8
CV %				
Total	3.1	3.5	3.5	3.4
Within-run	0.8	0.9	1.0	0.9
Between-run	0.5	0.9	0.8	1.2
Between-day	2.9	3.2	3.3	3.1

The method was linear up to 72 mmol/l without an additional predilution of the sample. The regression analysis of the method comparison between the evaluated and the Jaffé methods, and the difference between the methods are shown in Figure 1A-B. The comparisons between the enzymatic methods are shown in Figure 2A-B. Vitamin C up to 1 g/l did not interfere with the measurement.

Figure 1. The regression analysis (n = 120) between the evaluated Konelab enzymatic and the Jaffé methods (A), and the difference between the methods (B).

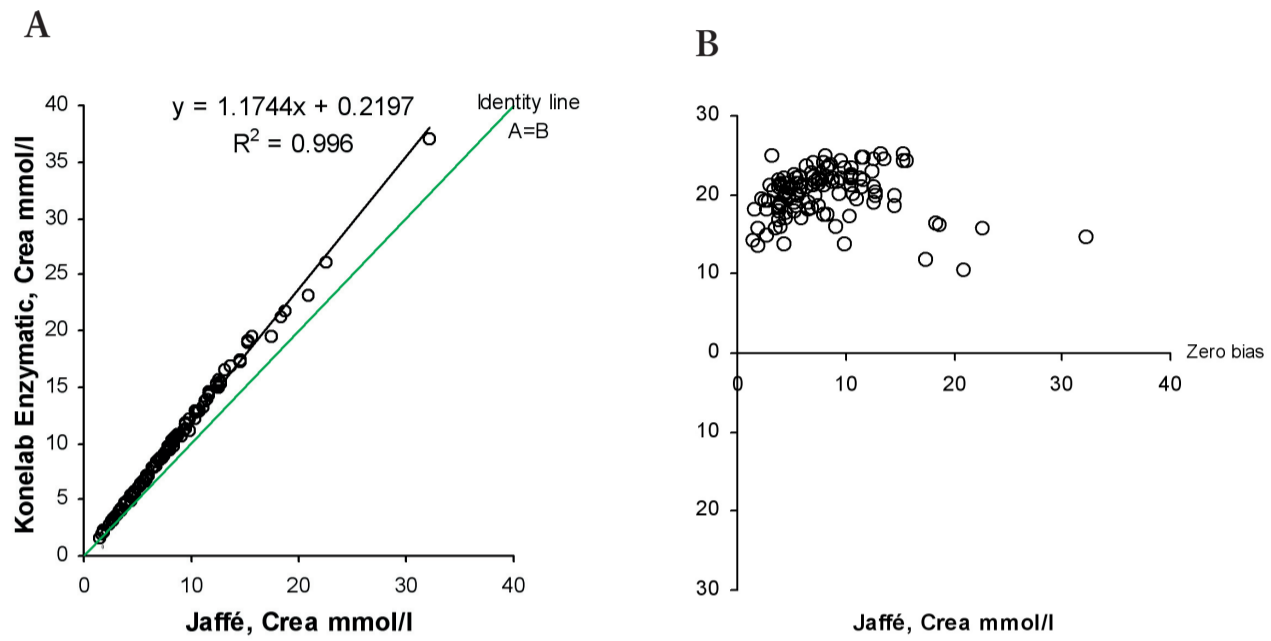
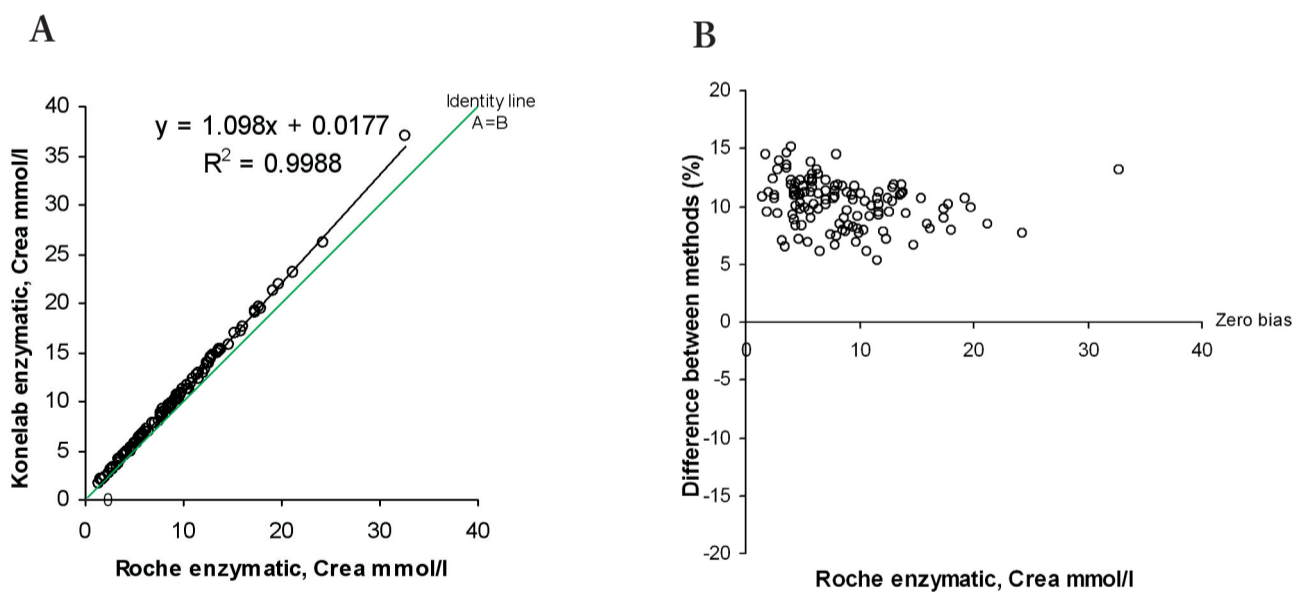


Figure 2. The regression analysis (n = 119) between the evaluated Konelab and Roche enzymatic methods (A), and the difference between the enzymatic methods (B).



Conclusions

The precision of the evaluated enzymatic creatinine method was excellent. Vitamin C did not interfere with the measurements. The comparison of the evaluated method with the Jaffé method and the Roche enzymatic method showed good correlation with both methods.

However, the difference in creatinine concentration between the evaluated and the Jaffé method was 20%, which is clinically significant. The main reason for the difference is that the same calibrator with different creatinine values was used in Konelab Jaffé (0.225 mmol/l) and enzymatic (0.255 mmol/l) methods. Moreover, plasma as a calibrator material is not ideal for urine analyses. In plasma samples, the evaluated enzymatic method showed excellent traceability with the reference material (IRMM-CRM-574). The difference between the Jaffé and enzymatic methods has to be noticed and informed to the customers before changing the method in a routine laboratory.