

EVALUATION OF THE KONELAB 20XTi CLINICAL CHEMISTRY ANALYZER – CHOLESTROL, CREATINE KINASE, GLUCOSE AND IMMUNOGLOBULIN A

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INTRODUCTION

Konelab 20XTi is a new clinical chemistry analyzer designed to meet the needs of small and medium routine and special clinical chemistry laboratories. We evaluated cholesterol (CHOL), creatine kinase (CK), glucose (GLUC) and immunoglobulin A (IgA) methods in plasma and serum samples.

The Konelab 20XTi was evaluated according to the guidelines of NCCLS (documents EP5-A and EP9-A) modified by Thermo Electron Corporation (Finland). The daily routines were done according to recommendations of the manufacturer except the calibrations, which were performed before every assay.

MATERIALS AND METHODS

Instruments

The Konelab 20XTi (Thermo Electron Co, Finland) is a random access, fully automated, selective clinical chemistry analyzer. Colorimetric, turbidimetric and ISE methods are applicable, and the analyzer is capable of handling routine and stat requests. Samples, reagents and cuvettes can be loaded at any time to the analyzer without interrupting the analysis in progress. Routine samples are inserted into segments, which the user may load immediately into the analyzer.

The methods of the Konelab 20XTi analyzer (the analyzer, system reagents and calibrators from Thermo Electron Co) were compared with those used by the Konelab 60i analyzer (CHOL, CK, GLUC) and IgA by the Immage Immunochemistry System (Beckman Coulter, USA).

Reagents

CHOL, CK and GLUC were analyzed using an enzymatic colorimetric, a kinetic IFCC and an end-point hexokinase method, respectively. IgA was analyzed immunoturbidimetrically (Konelab 20XTi) and immunonephelometrically (Immage). The reagents, calibrators and controls used in the study are summarized in Table 1. Heparin plasma samples (LH PST II, BD Vacutainer Systems, UK) were used in CHOL and CK analyses. Fluoride citrate plasma (FC Mixture, VF-053SFC, Terumo Europe n.v., Belgium) and serum (SST II, BD Vacutainer Systems, UK) were used in glucose and IgA analyses, respectively.

The reagents were prepared and stored according to the instructions of the manufacturers. Controls given in Table 1 were used as material for imprecision.

Statistical Analyses

In order to calculate the within-run, between-day and total imprecision (coefficient of variation, CV%), three control samples were analyzed twice a day with two replicates during 12 to 16 days.

The patient samples for the method comparisons were first analyzed as a single determination by the Konelab 60i or Immage analyzer. The samples were measured as duplicates in Konelab 20XTi thus having less than 1 hour between the first and second run. The IgA samples were frozen until analyses.

Analyse -it software (Analyse -it for Microsoft Excel, version 1.65, Analyse-It® Software Ltd, UK) was used for the statistical analyses.

Table 1. Reagents, calibrators and controls used in the evaluation.

Analyte	Reagents	Calibrator	Controls (20XTi)
Cholesterol	Konelab CHOLESTEROL, code 980813 (20XTi) code 981368 (60i)	Konelab Calibrator II, code 980502	Nortrol (981043) Abtrol (981044) Serum pool
Creatine kinase	Konelab CK, code 981372	Calculation factor	Nortrol (981043) Abtrol (981044) Serum pool
Glucose	Konelab GLUCOSE, code 981779 (20XTi) code 981304 (60i)	Konelab Calibrator I, code 980501	Nortrol (981043) Abtrol (981044) Serum pool
Immunoglobulin A	Konelab IMMUNOGLOBULIN A (IgA), code 981668 (20XTi) Immage Immunochemistry Systems Immunoglobulin A (IGA), code 446460 (Immage)	Konelab SpeciCal, code 980997 (20XTi) Calibrator I, code 449560 (Immage)	SpeciTrol (981250) SpeciTrol High (981799) Serum pool

20XTi = Konelab 20XTi

60i = Konelab 60i

Immage = Immage Immunochemistry System

RESULTS

Results from within- and between-run as well as total imprecisions are given in Table 2.

Table 2. Imprecisions in evaluated methods.

Analyte (unit)	Mean	Within-run		Between-run		Total	
		CV%	n	CV%	n	CV%	n
CHOL (mmol/l)	4,3	1,0	16	1,5	16	2,3	16
	4,8	1,1	16	0,9	16	2,1	16
	7,5	1,1	16	1,5	16	2,4	16
CK (U/l)	146	2,2	16	1,7	16	2,7	16
	328	1,9	15	1,4	15	2,3	15
	445	1,2	16	3,2	16	3,4	16
GLUC (mmol/l)	4,2	1,5	12	1,2	12	1,9	12
	5,7	1,2	12	1,0	12	1,7	12
	15,0	1,0	12	1,4	12	1,7	12
IgA (g/l)	1,68	1,6	12	1,3	12	2,8	12
	4,92	1,0	12	1,1	12	2,1	12
	5,26	1,4	12	1,3	12	3,0	12

Regression analyses of the method comparisons are presented in Figures 1-4.

Figure 1. Method comparison (n=134) of cholesterol between the Konelab 20XTi and 60i analyzers

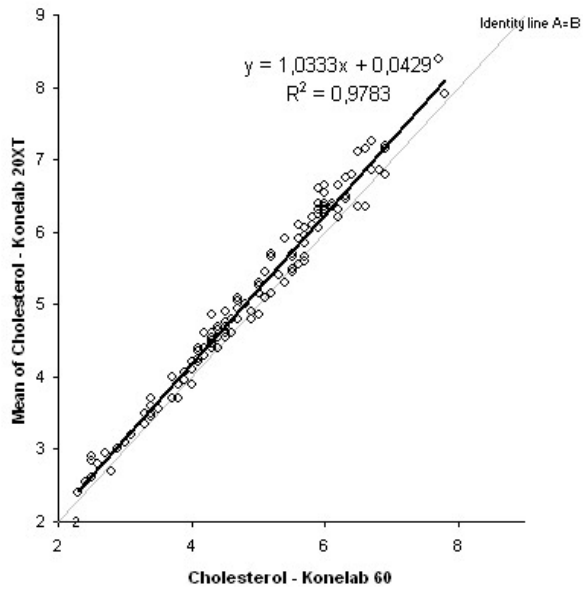


Figure 2. Method comparison (n=89) of creatine kinase between the Konelab 20XTi and 60i analyzers

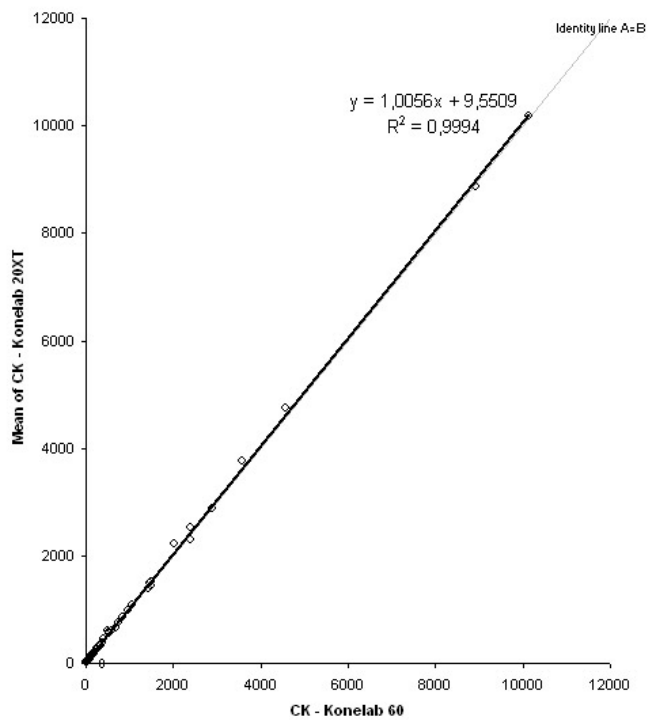


Figure 3. Method comparison (n=99) of glucose between the Konelab 20XTi and 60i analyzers

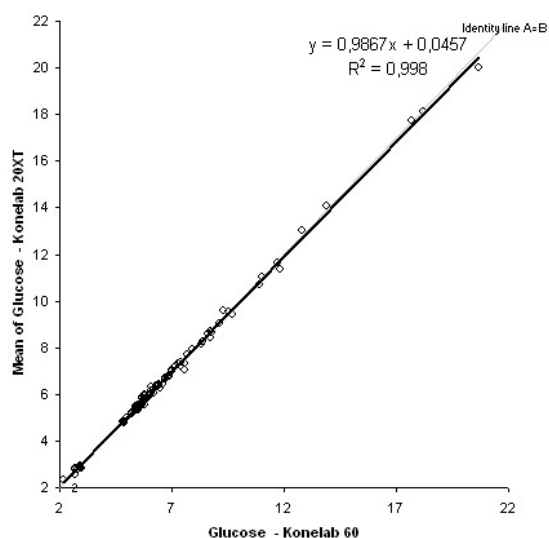
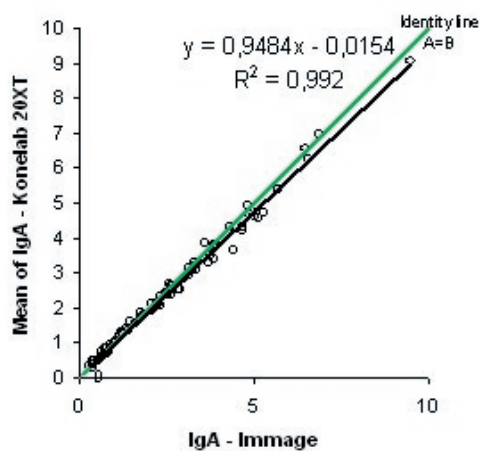


Figure 4. Method comparison (n=83) of Immunoglobulin A between the Konelab 20XTi analyzer and Immage Immunochemistry System



CONCLUSION

Comparisons between the evaluated and routine methods showed excellent correlation for all analytes. In addition, within-run, between-run and total variations were low, and the results together demonstrate that the Konelab 20XTi is a precise and reliable analyzer for these methods.