

EVALUATION OF A RANDOM ACCESS ANALYSER KONELAB 30i

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Abstract

Konelab 30i was evaluated according to the guidelines of ECCLS. Eight methods (K, Na, AST, γ -GT, Glucose, Ca, Creatinine and CRP) were tested and results compared with a centrifugal analyser Cobas Fara tested results.

Within-run imprecision (CV%) was below 1% for ISE-assays and below 3% for other analytes. All tests, except Sodium, Calcium and Creatinine with slightly higher CV%, fulfilled the requirements of proposed between day imprecision based on intra individual variation.

Calibration intervals of one month are recommended for all but Creatinine assays. During one week, no significant long-term drift was found for Creatinine and during one month for the other analytes.

The reliability of the analyser was evaluated using an Accuracy Solution kit for clinical chemistry analysers (Konelab Corp.). The accuracy and precision of dispensing as well as the accuracy of wavelength and linearity of absorbances at 340 and 405 nm were excellent.

Instrument

Konelab 30i (Konelab Corp., Espoo, Finland) is a new, selective clinical chemistry analyser for colorimetric clinical chemistries, specific proteins, and drug tests. Furthermore, electrolytes are using ISE technology. Theoretical throughput of the analyser is 300 photometric and 180 ISE tests/hour. The operating principle is random access and the number of programmable tests is 500. The number of on-board sample positions is 84 plus 6 for stats. In addition, 39 cooled positions for calibrators and controls are available. Sample tubes with the volumes of 5 and 7 ml can be used, as well as 0.5 and 2 ml analyser cups. Sample volume is from 1 to 120 μ l, typically 2-15 μ l for photometric tests and 50 μ l for Na⁺, K⁺ and Cl⁻. The refrigerated reagent disk has positions for 45 vessels which total volumes can be 10, 20 or 60 ml. The automated reagent identification is based on the integrated barcode reader. The real time reagent status can be seen on the workstation window. The reagents' dispensing volumes are 2-250 μ l, up to four reagent additions per test is possible. The reaction cuvette for photometric tests is a discrete disposable multicell cuvette with 12 square reaction cells in a row. Automatic sample pre- and redilutions

between 1:1 and 1:120 is available. The use of stock calibrator with the same dilutions is possible. Linear, non-linear and bias calibrations as well as several blank possibilities can be used. Real time QC function is available including multiple and variable (Westgard) rules and chart printouts both daily and cumulative basis. The photometer is a single channel system with beam splitting reference and interference filters between 340 and 700 nm.

Materials and methods

A centrifugal analyser Cobas FARA (Roche Diagnostics, Basel, Switzerland) was used for comparison with the Konelab 30i.

The methods and reagents used in this study are summarized in Table 1.

Reagents used in Konelab 30i were prepared according to the instructions of the manufacturer. They were stored in the analyser's refrigerated reagent compartment. New reagent aliquots were taken every day for Cobas FARA and stored in the analyser at room temperature.

Calibrators and recommended calibration intervals are given in Table 2.

For imprecision study a serum pool and two control sera Pathnorm Low and High from Nycomed Pharma AS, Oslo, Norway were used. For the entire evaluation all control samples were dissolved at the same time and stored in 1.0 ml aliquots at -70°C.

Patient samples, minimum 75 for each analyte representing low, medium and high levels of measuring range were collected and stored at -70°C until used. They were analysed as duplicates in Konelab 30i. At the same time a single determination was performed in Cobas FARA. Double determinations in Konelab 30i were used to calculate the within-run imprecision. In the comparative study with Cobas FARA the first of the duplicate values was used in regression analysis.

An Accuracy Solution kit for clinical chemistry analysers, Konelab Corporation, product code 981577 and a standardised measurement protocol was used to test the reliability of instrument functions (1).

Table 1. Tests, methods and reagents used in evaluation.

Konelab 30i			Cobas FARA	
Test	Method	Wavelength (nm) Main/side	Method	Wavelength (nm) Main/side
Sodium and Potassium	ISE Direct measurement		ISE Direct measurement	
Total Calcium	Arsenazo III complexone End point, reagent blank Konelab 981367	660/700	O-cresolphthalein complexone End point, sample blank Boehringer-Mannheim 1553593, Germany	546
Glucose	Hexokinase End point, reagent blank Konelab 981304	340/380	Glucose dehydrogenase End point, water blank Merck 12193, Darmstadt, Germany	340
Creatinine	Modified Jaffé reaction Kinetic, one reagent Konelab 981374	510	Jaffé reaction, Kinetic, two reagents Boehringer-Mannheim 1489291, Germany	520
AST	IFCC/ECCLS Kinetic Konelab 981363	340/380	IFCC/ECCLS Kinetic Medix Biochemica 0557, Kauniainen, Finland	340
γ-GT	IFCC/ECCLS Kinetic Konelab 981377	405	IFCC/ECCLS Kinetic Medix Biochemica 0080, Kauniainen, Finland	405
CRP	Immunoturbidimetry End point, sample blank Konelab 981666	340	Immunoturbidimetry End point, sample blank Orion Diagnostica 67393, 68499, Espoo, Finland	340

Table 2. Calibrators and recommended calibration intervals of the analytes.

Analyte	Konelab 30i		Cobas Fara	
	Calibrator	Calibration interval	Calibrator	Calibration interval
Sodium and Potassium	ISE Cal 2 and 3 Konelab no 984035 ISE Cal 1 Konelab no 984031	One month Every assay	ISE standards 1 and 2 Roche no 07-2568-4 and 07-2569-2	Every assay
Total Calcium	Cal 1 Konelab no 980501 Cal 2 Konelab no 980502	One month	Roche human calibrator no 07 37186	Every assay
Glucose	Cal 1 Konelab no 980501	One month	Glucose calibrator no 120124 Reagenta Ltd, Kuopio, Finland	Every assay
Creatinine	Cal 1 Konelab no 980501	One week	Roche human calibrator no 07 37186	Every assay
AST	Factor (molar absorptivity)		Factor (molar absorptivity)	
γ-GT	Factor (molar absorptivity)		Factor (molar absorptivity)	
CRP	Calibration set Konelab no 981674	One month	Calibrator set no 67780 Orion Diagnostica, Espoo, Finland	One month

Results

Imprecision

The within-run imprecision was better than 1% in ISE measurements and better than 3% in all, except low levels of AST, γ-GT and Creatinine. The between-run imprecision was equal or better than 3% in all but low levels of analytes. The proposed requirements for imprecision (2) was fulfilled in normal and high levels of measurement, except Sodium, total Calcium and Creatinine assays. The results are presented in Tables 3 and 4.

On-board stability

The drift was tested over the calibration intervals used in this study. The calibration intervals were one week for Creatinine, three weeks for Calcium and one month for the rest of the tests. During the whole study the same batches of reagents were used and the bottles stored in the reagent department of the equipment. Once per day two control samples were analysed as triplicates and the mean values of each day were compared with the results obtained on the day of calibration. No significant drift was found during the calibration intervals.

Correlation

Patient samples of analytes with normal and pathological concentrations were assayed simultaneously in Konelab 30i and Cobas FARA. The regression analysis of the results are presented in Figure 1. The correlations were excellent, r^2 ranging from 0.926 to 0.999 in tested analytes. A significant bias of 8 to 15 per cent was found in the results of Creatinine assays depending on the measured concentration level of Creatinine.

Analyser reliability

The imprecision (CV%) of dispensing was 1.2, 1.0 and 0.4% for volumes of 2, 4 and 8 μl, respectively. The accuracy of dispensing was 0, +0.7 and -2.5% for the corresponding volumes. The accuracy and linearity of absorbance measurements at 340 and 405 nm were excellent. The accuracy of the wavelength did not show any bias. The temperature of the liquid in the cuvette was 36.4°C.

Table 3. Within-run imprecision of the methods used in KONELAB 30i.
The imprecision was calculated from duplicate determinations of patient samples on three different test levels.

Analyte (unit)	Mean	SD	CV%	n
K (mmol/l)	3.26	0.01	0.4	25
	4.15	0.03	0.8	25
	4.84	0.00	0.0	25
Na (mmol/l)	132.2	0.80	0.6	25
	140.5	0.28	0.2	25
	144.8	0.32	0.2	25
Ca (mmol/l)	2.01	0.03	1.3	25
	2.25	0.02	0.8	25
	2.41	0.03	1.2	27
Glucose (mmol/l)	2.17	0.05	2.1	27
	5.54	0.05	0.9	25
	11.1	0.15	1.3	25
Creatinine (µmol/l)	63	3.0	4.7	25
	119	4.2	3.5	27
	309	2.7	0.9	22
AST (U/l)	14.3	0.7	5.2	30
	24.2	1.7	7.0	30
	96.5	2.2	2.3	25
γ-GT (U/l)	17.8	0.8	4.3	30
	42.4	1.3	3.2	30
	299.6	4.5	1.5	25
CRP (mg/l)	31.1	0.4	1.3	25
	63.2	1.2	1.9	25
	128.4	2.9	2.3	25

Table 4. Between run imprecision of the methods used in Konelab 30i.
Proposed imprecisions based on intra individual variation are also given.

Test (unit)	Mean	SD	CV%	n	Proposed between-run imprecision CV%
K (mmol/l)	1.97	0.03	1.4 a	15	2.4
	4.28	0.04	1.0 b	15	
	6.32	0.04	0.7 c	15	
Na (mmol/l)	114.6	1.1	1.0 a	15	0.3 (0.6)
	141.4	0.7	0.5 b	15	
	156.3	1.4	0.9 c	15	
Ca (mmol/l)	1.52	0.05	3.0 a	15	0.9 (1.5)
	2.34	0.05	2.2 b	15	
	3.28	0.06	1.9 c	15	
Glucose (mmol/l)	2.33	0.06	2.7 a	15	2.2
	5.82	0.11	1.9 b	15	
	12.14	0.32	2.7 c	15	
Creatinine (µmol/l)	105.6	5.7	5.4 a	15	2.2
	120.3	3.6	3.0 b	15	
	633.7	14.7	2.3 c	15	
AST (U/l)	30.3	1.7	5.5 b	15	7.2
	47.0	1.7	3.5 a	15	
	194.5	5.8	3.0 c	15	
γ-GT (U/l)	29.0	1.3	4.5 a	15	7.4
	54.5	0.7	1.4 b	15	
	121.0	1.9	1.6 c	15	
CRP (mg/l)	15.4	0.7	4.6 d	15	-
	30.9	0.6	1.9 e	15	
	92.	2.0	2.2 f	15	

Where: a = Pathonorm Low, lot 408084, b = serum pool, c = Pathonorm High, lot 603086, d = serum pool with low CRP values, e = CRP control, lot 1539 f = serum pool, high CRP values. Within-run imprecision was calculated from duplicate patient samples divided in three groups: low, normal and high analyte levels, n = 25 in each group.

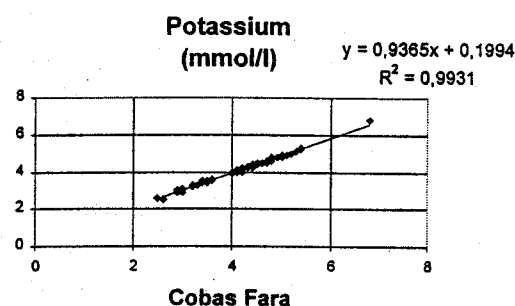
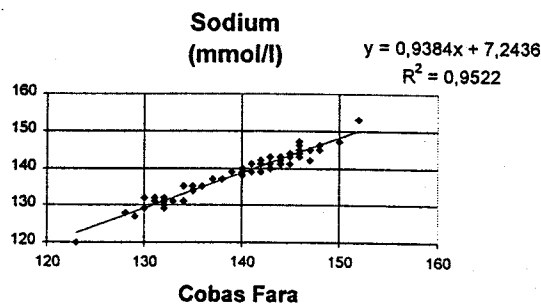
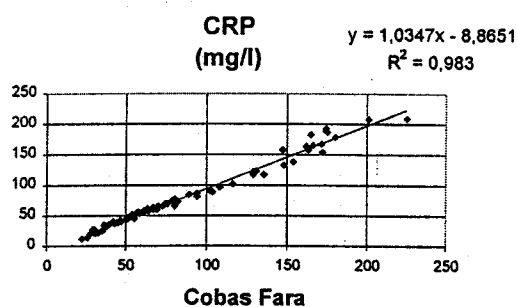
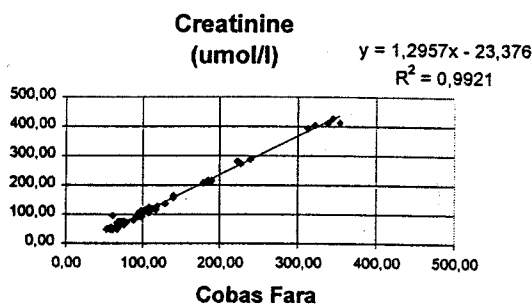
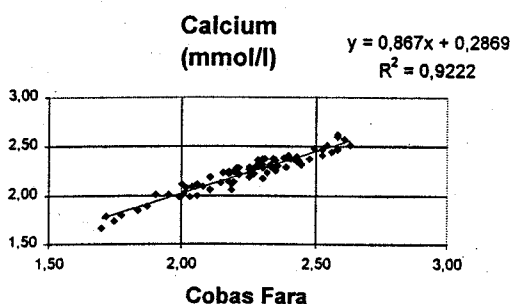
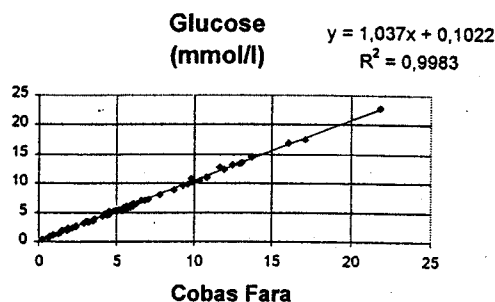
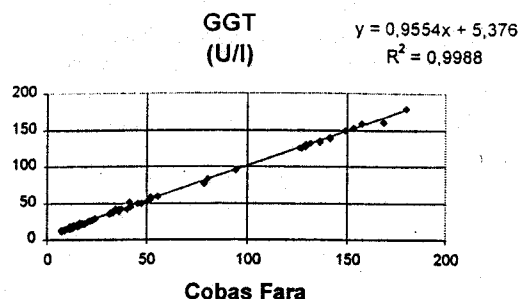
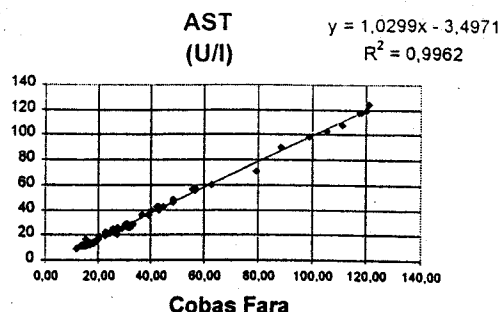


Figure 1. Correlations of the results measured by Konelab 30i (y-axis) and with the routine methods in Cobas Fara (x-axis). Regression lines and equations are presented in the figures.

Conclusions

The analytical performance of Konelab 30i was very good. The proposed requirements for imprecision were fulfilled in most of the assays. The correlations to the routine methods in the laboratory were excellent and the agreement of the results was good. The reagents were stable for one month for most of the tests, when stored in the instrument. Creatinine required a shorter calibration interval of one week.

The Konelab 30i is suitable for medium size and small laboratories. It has versatile features but is still user-friendly with self-guiding programme. The main routines, loading of samples, reagents and reaction cuvettes can be performed without any workload interruptions. The equipment demands very few daily maintenance operations. Konelab has a comprehensive range of system reagents for routine chemistries, specific proteins and drug tests as well as system specified calibrators and controls. Most of these diagnostics products are ready-to-use stable liquids. With Konelab system reagents it turned to be cost-efficient when compared with other analysers of equal quality.

References

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