

EVALUATION OF THE KONELAB PRIME 60i CLINICAL CHEMISTRY ANALYSER

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Introduction

Konelab PRIME 60i is the latest model in the Thermo Scientific Konelab range of clinical chemistry analyzers. The system includes instrument, reagents, applications as well as system specified calibrators and controls.

In this study we evaluated the performance of Alkaline Phosphatase, ALT/GPT, Creatinine, LDL-Cholesterol, Triglycerides and HbA1c assays using plasma or whole blood samples. The evaluation was done using NCCLS EP5-A document as a guideline.

The calibrations as well as other daily routines performed according to the recommendations of the manufacturer.

Materials and Methods

Instruments

Thermo Scientific Konelab PRIME 60i is a system for routine clinical chemistry tests, electrolytes and special chemistries including specific proteins, TDM and DoA tests. The new sample clot detection feature in PRIME 60i increases the operational efficiency and result integrity. The analyzer can be used as a stand alone model or it can be connected to the laboratory automation. Throughput of the system is maximum 600 tests/hour including electrolytes and it takes from 3 to 12 minutes to get results of tests. Continuous loading of samples, cuvettes and reagents facilitates laboratory workflow. Automated dilution features, pre- and postdilutions, make sample processing easier and when testing specific proteins, antigen excess detection feature is very useful. Versatile reagent handling, ability to add up to 4 reagents per test, and different blanking types, make the system very flexible for special tests, as well for the user specified applications.

ADVIA[®] 2400-analyzer (Siemens Medical Solutions Diagnostics, Tarrytown, NY, USA) was used as a comparison analyzer.

Samples

Heparin plasma samples (LH PST II, BD Vacutainer Systems, UK) were used in ALP, ALT, Creatinine, LDL-Cholesterol and Triglycerides analyses. Whole blood samples (K2E 5.4mg, BD Vacutainer Systems, UK) after hemolization were used in HbA1c test.

In the method comparison the patient results from Konelab PRIME 60i were compared to respective patient results measured by ADVIA[®] 2400 analyzer in routine use. The collection of patient samples and transportation from the laboratory running ADVIA[®] 2400 system to evaluation laboratory took no more than 3 hours. Samples were analysed as duplicates on Konelab PRIME 60i thus having less than 1 hour between the first and the second run.

The total time difference between measurement on ADVIA[®] 2400 and Konelab PRIME 60i was less than 6 hours, and samples were stored in coolbox until loaded to the analyzer.

Controls and Calibrators

All the controls and calibrators were dissolved and pooled in the beginning of evaluation, aliquoted to 0,5 ml and stored at -70° C. For every run a new deep-frozen aliquot were taken.

Reagents

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

Test	Konelab PRIME 60i		ADVIA [®] 2400	
	Method Ref# Measurement range (with automatic dilution)	Wave-length (nm) Main/Side	Method Ref# Measurement range (with automatic dilution)	Wave-length (nm) Main/Side
ALP	IFCC (kinetic) 981833 20-1000 (10000) U/L	405	Modified IFCC (kinetic) 06258679* 0-1100 U/L	410/478
ALT	IFCC (kinetic) 981769* 5-250 (1500) U/L	340/380	IFCC (kinetic) 02760612 0-1000 U/L	340/410
Crea	Enzymatic, colorimetric test (endpoint) 981845* 10-2500 (10000) µmol/L	540/700	Enzymatic, Creatinine deiminase/GLDH (endpoint) 07908766 0-2650 (22500) µmol/L	505/571
Trigly	GPO (endpoint) 981301* 0.05-11.0 (55.0) mmol/L	510/620	GPO, Trinder without serum blank (endpoint) 09580156 0-6.25 (25) mmol/L	505/694
LDL-Chol	Enzymatic, colorimetric test (endpoint) 981656* 0.09-11.0 (33.0) mmol/L	600/700	Elimination/catalase (endpoint) 09796248* 1-25.9 mmol/L	596/694
HbA1c	Hb, photometric (endpoint) HbA1c, turbidimetric inhibition immunoassay (endpoint) 981658* Hb: 60-250 g/L HbA1c: 3-23 g/L	600	Hb, photometric (endpoint) HbA1c, immuno-turbidimetric (endpoint) 00350395* Hb: 7-230 g/L HbA1c: 0.6-3.1 µmol/L	596
		340		694

*) Ready to use reagent

Table 2. Calibrators used in the evaluation

Konelab PRIME 60i Name Ref#	ADVIA® 2400 Name Ref#	Used in tests	Stated value	
			Konelab PRIME 60i	ADVIA® 2400
sCal 981831	Chemistry Calibrator 09784096	Crea (µmol/L) Trigly (mmol/L)	241 1.88	746 2.13
eCal 981830	Factor (Siemens)	ALP (U/L) ALT (U/L)	211 91	10729 4239
HDL/LDL Calibrator 981657	HDL/LDL Chol Cal 0030953	LDL-Chol (mmol/L)	3.50	3.32
HbA1c/Hb Calibrators 981658 0.9% NaCl (not included)	HbA1c Calibrator Set 06628018	0.9% NaCl/level1 (Hb / HbA1c) Hb (cal1/level2) HbA1c: cal1/level2 cal2/level3 cal3/level4 cal4/level5 level6	0 / 0 141 5.0 8.8 14.6 23.1 -	0 / 0 180 1.76 2.71 3.46 5.27 7.59
Hb: g/L HbA1c: g/L	Hb: g/L HbA1c: µmol/L			

Table 3. Controls used in the evaluation

Name of control, Ref#	Used in tests	Target value
NORTROL, 981043	ALP ALT Crea Trigly	89 U/L 33 U/L 52.0 µmol/L 2.25 mmol/L
ABTROL, 981044	ALP ALT Crea Trigly	389 U/L 83 U/L 504.0 µmol/L 1.03 mmol/L
LIPOTROL, 981653	LDL-Chol Trigly	2.90 mmol/L 1.51 mmol/L
HbA1c Control Normal, 981695	HbA1c Hb	4.8 g/L 142 g/L
HbA1c Control Abnormal, 981696	HbA1c Hb	13.6 g/L 150 g/L

Results

Table 4. Within-run imprecision of six analytes (n=24)

Analyte (unit)	Sample	Mean	CV%
ALP (U/L)	Control 1	90.2	1.3
	Control 2	395.6	0.8
	Patient 1	74.8	0.9
	Patient 2	352.7	0.6
ALT (U/L)	Control 1	33.9	1.8
	Control 2	85.0	1.0
	Patient 1	13.2	2.9
	Patient 2	137.2	0.6
Crea (µmol/L)	Control 1	50.5	1.3
	Control 2	508.2	0.4
	Patient 1	67.5	0.8
	Patient 2	188.0	0.2
LDL-Chol (mmol/L)	Control 3	2.7	0.8
	Patient 1	1.7	1.4
	Patient 2	4.3	0.6
Trigly (mmol/L)	Control 1	2.25	1.0
	Control 2	1.04	2.0
	Control 3	1.59	1.8
	Patient 1	5.94	1.0
HbA1c (%)	Control 4	6.6	1.9
	Control 5	11.1	1.3
	Patient 1	8.3	1.9

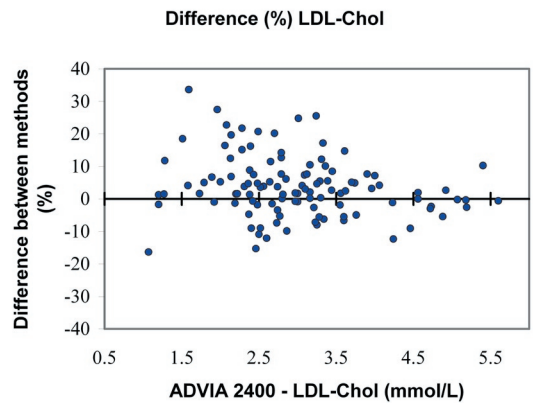
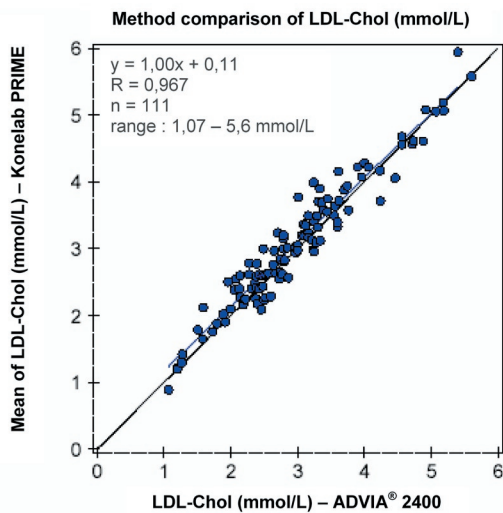
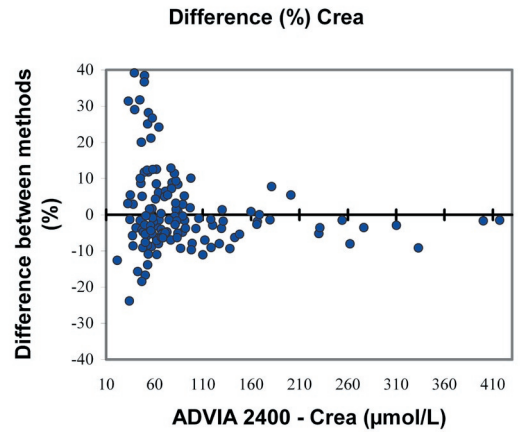
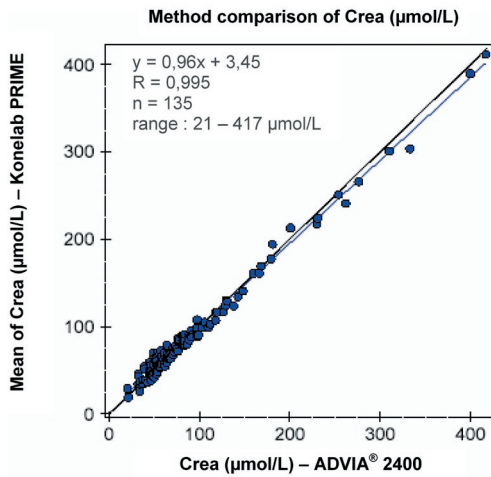
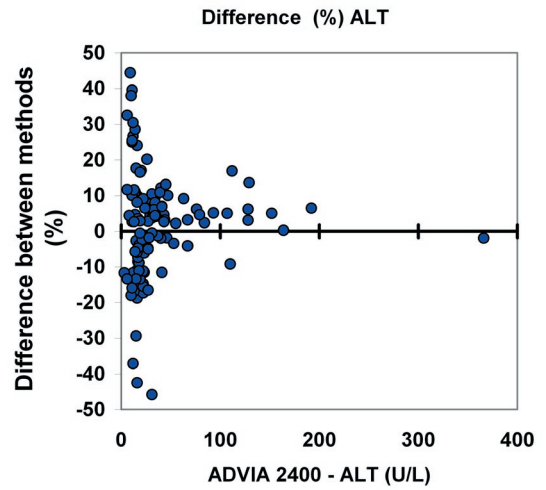
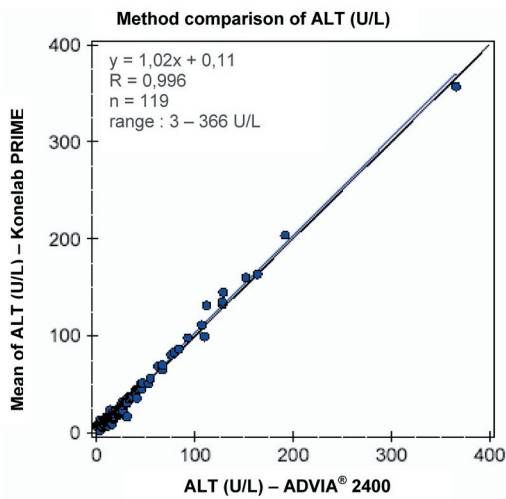
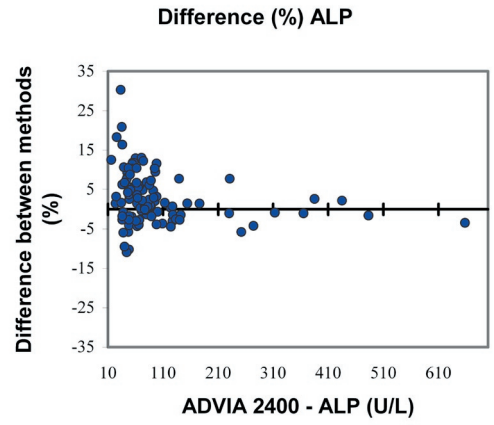
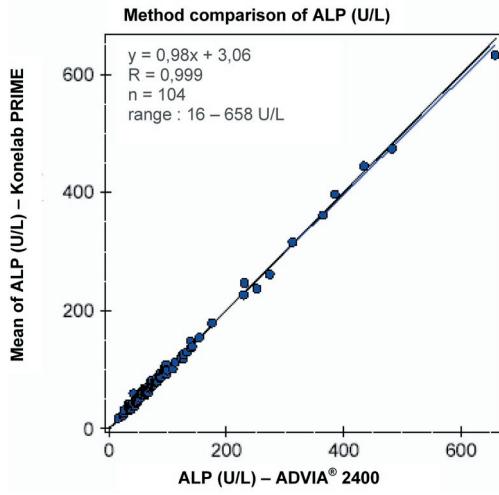
Table 5. Within-day and between-day imprecision of six analytes

Analyte (unit)	Sample	Mean	CV% (n=)		
			Within-day	Between-day	Total
ALP (U/L)	Control 1	84.4	1.7 (n=6)	3.0 (n=12)	3.4 (n=72)
	Control 2	390.3	1.3 (n=6)	2.6 (n=12)	2.9 (n=72)
	Patient 1	143.6	1.5 (n=5)	3.4 (n=8)	3.7 (n=40)
ALT (U/L)	Control 1	34.5	2.7 (n=6)	1.4 (n=13)	3.1 (n=78)
	Control 2	87.0	1.7 (n=6)	1.1 (n=13)	2.0 (n=78)
	Patient 1	44.5	0.8 (n=5)	0.7 (n=8)	1.0 (n=40)
Crea (µmol/L)	Control 1	51.7	1.5 (n=6)	1.7 (n=13)	2.2 (n=78)
	Control 2	517.5	1.1 (n=6)	1.3 (n=13)	1.7 (n=78)
	Patient 1	126.2	0.7 (n=5)	1.2 (n=8)	1.4 (n=40)
LDL-Chol (mmol/L)	Control 3	2.8	1.2 (n=6)	1.0 (n=12)	1.6 (n=72)
	Patient 2	1.8	1.0 (n=6)	0.7 (n=12)	1.2 (n=72)
	Patient 3	4.5	0.7 (n=6)	0.5 (n=10)	0.9 (n=60)
Trigly (mmol/L)	Control 1	2.31	3.9 (n=6)	0.7 (n=10)	3.9 (n=60)
	Control 2	1.06	1.8 (n=6)	1.3 (n=10)	2.2 (n=60)
	Control 3	1.52	1.6 (n=6)	0.6 (n=6)	1.7 (n=36)
	Patient 4	6.04	1.2 (n=6)	0.4 (n=9)	1.2 (n=54)
HbA1c (%)	Control 4	6.9	2.6 (n=6)	1.4 (n=9)	3.0 (n=54)
	Control 5	11.0	1.5 (n=6)	2.2 (n=10)	2.6 (n=60)
	Patient 5	8.5	1.5 (n=6)	0.8 (n=9)	1.7 (n=54)

Control sample 1 : NORTROL
 Control sample 2 : ABTROL
 Control sample 3 : LIPOTROL
 Control sample 4 : HbA1c Control Normal
 Control sample 5 : HbA1c Control Abnormal, Thermo Fisher Scientific, Finland
 Patient samples: plasma or hemolyzed whole blood (HbA1c)

Used controls were same as in Table 4.
 Patient sample 1, 2 and 4: pooled plasma samples
 Patient sample 3: pooled plasma sample, diluted 3:4 with 0.9% NaCl
 Patient sample 5: whole blood patient sample, which was hemolyzed as well as all patient samples in HbA1c-measurement

The results analysed with Konelab PRIME 60i were compared to ADVIA® 2400 tested results. These results are seen in the following figures.



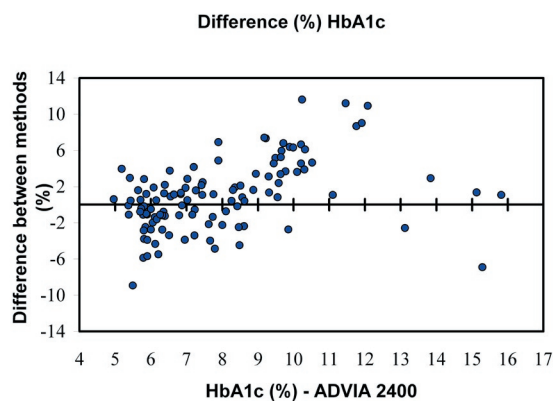
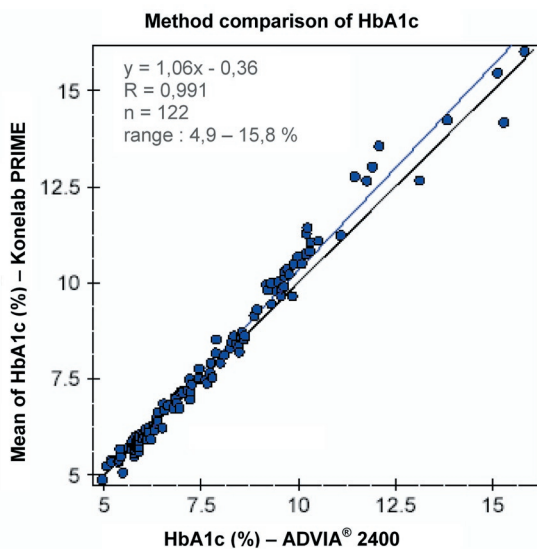
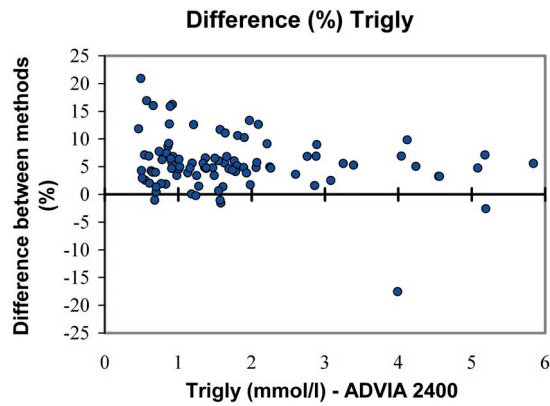
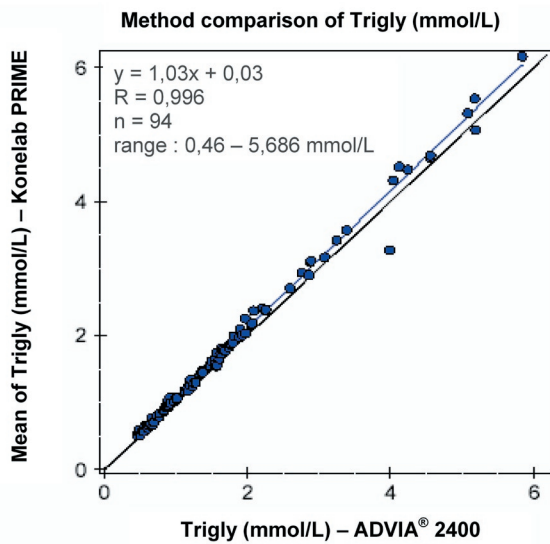


Figure 1 : Method comparisons and differences between Konelab PRIME 60i and ADVIA® 2400 analyzers for all six analytes.

Conclusion

Comparisons between the evaluated and routine methods showed excellent correlation for all tested analytes. The data shows that Thermo Scientific Konelab PRIME 60i is a precise and reliable analyzer for routine and special chemistries and can be highly recommended for medium size laboratories.

Acknowledgements

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