

Evaluation of a clinical chemistry analyser

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The clinical requirements of laboratory medicine are constantly changing. Due to the number of available hospital beds being ever reduced, more and more patients using primary healthcare services are diagnosed and treated on an outpatient basis. Consequently, the logistics of total patient care has become a talking point for politicians and patient organisations alike. Clinicians are asking for shorter turnaround times in laboratory results, for both patient and physician convenience. While immediate results available for direct discussion after the primary consultation would be of obvious interest to the patient, it would also result in reduced administration for the physicians.

These structural changes currently taking place in health care, together with the latest technological developments, are enabling point-of-care testing (POCT) of most basic analytes (and an increasing number of esoteric analytes). Although the introduction of conventional instruments focusing on chemistry analytes has so far been rather scarce, an increasing number of new instruments are now being introduced to the commercial market. The aim of this study was to test the Konelab 20i Clinical Chemical Analyser (Thermo Clinical Labsystems, Espoo, Finland) for analytical characteristics as well as practicability in a POC set up.

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System Description

The Konelab 20i is a fully automated, open, random access clinical chemistry analyser for routine chemistries as well as specific applications such as therapeutic drug monitoring and toxicological testing. The theoretical maximum

capacity is up to 200 tests/hr increasing to 380 tests/hr with an ISE included. The ISE module allows a direct determination of K⁺, Na⁺ and Cl⁻, with Li⁺ as an optional extra. For simultaneous determination of K⁺, Na⁺ and Cl⁻, 50 µL of undiluted serum plasma or urine is required. Samples are placed on 14-position sample segments in 0.5- or 2-mL sample cups or 5-, 7- or 10-mL primary tubes. Up to four reagent additions per test are possible and the required reagent volumes are typically as low as 150 µL/test. The photometric measurement takes place in a disposable multicell cuvette, with 12-reaction positions per cuvette. Automatic, pre-, post- and secondary dilutions in the range 1+1 to 1+120, as well as the ability to enter manually pre-diluted samples and obtain re-calculation of the result, are standard features.

Materials & Methods

Evaluation of the analyser was performed at the Primary Health Care Centre Laboratory in Mjölby, Sweden, following guidelines provided by the European Committee for Clinical Laboratory Standards¹ (ECCLS) and modified by Labquality (Finland), to meet with national requirements. Seven tests representing four different methods were selected for the study: ISE (K and Na), end-point measurement (triglycerides and calcium), kinetic measurement (aspartate aminotransferase [AST] and γ -glutamyl transferase [γ -GT]) and turbidimetric measurement (C-reactive protein [CRP]). The methods employed in the evaluation are listed in *Table 1*. Another leading analyser (Analyser A) was selected for comparison purposes. Calibrations and daily routines were performed according to manufacturer recommendations and reagents were stored on-board throughout the study. Patient samples used for precision tests were pooled and frozen in aliquots. Between-day precision was measured over a 14-day period, using duplicate measurements. Correlation studies with Analyser A were performed using 60 patient samples (fresh). The calibrator and quality control materials used were 980501 Calibrator I, 980502 Calibrator II, 980997 Specical, 981674 CRP Calibration set, 981043 Nortrol, 981044 Abtrol, 981251 CRP Control, 981679 CRP Control High (Thermo Clinical Labsystems) and Pathonorm H and L (Nycomed, Oslo, Norway).

Table 1 Test selection and methods used on the Konelab 20i and Analyser A.

Test	<ul style="list-style-type: none"> • Konelab 20i method employed • Product code • Analytical range with automatic dilution 	<ul style="list-style-type: none"> • Analyser A method employed • Product code • Analytical range without dilution
Aspartate amino-transferase	<ul style="list-style-type: none"> • IFCC/ECCLS • 81363 • 0–1800 U/L 	<ul style="list-style-type: none"> • IFCC • BM, 1876848 • 0–380 U/L
Gamma-glutamyl transferase	<ul style="list-style-type: none"> • IFCC/ECCLS • 981377 • 0–6000 U/L 	<ul style="list-style-type: none"> • IFCC • BM, 1730053 • 0–1200 U/L
Calcium	<ul style="list-style-type: none"> • Arsenazo III • 981367 • 0–13.50 mmol/L 	<ul style="list-style-type: none"> • Cresolphthalein • BM 1730240 • 0–6.0 mmol/L
Triglycerides	<ul style="list-style-type: none"> • GPO, Trinder • 981301 • 0–55 mmol/L 	<ul style="list-style-type: none"> • GPO-PAP • BM, 1730711 • 0–11.4 mmol/L
Potassium	<ul style="list-style-type: none"> • Direct potentiometry • 2–10 mmol/L 	<ul style="list-style-type: none"> • Indirect potentiometry • 0.5–100 mmol/L
Sodium	<ul style="list-style-type: none"> • Direct potentiometry • 100–200 mmol/L 	<ul style="list-style-type: none"> • Indirect potentiometry • 5–500 mmol/L
C-reactive protein	<ul style="list-style-type: none"> • Immunoturbidimetry • 981666 • 10–669 mg/L 	<ul style="list-style-type: none"> • Immunoturbidimetry • BM 1730371 • 0–205 mg/L

Abbreviations: IFCC: International Federation of Clinical Chemistry; BM: Boehringer Mannheim; GPO: glycerol-3-phosphateoxidase; PAP: peroxidase.

Results

Within-run precision

Within-run precision was studied using two commercial control sera — Pathonorm H and Pathonorm L — and one serum pool. Mean values and CV% were calculated from 24 measurements (*Table 2*).

Table 2 Within-run precision.

Sample	N= 24	K ⁺ mmol/L	Na ⁺ mmol/L	Trigl mmol/L	AST μkat/L	Ca mmol/L	GGT μkat/L
Pathonorm H	Mean	6.54	164	2.93	3.21	2.68	1.92
Pathonorm L		2.31	123	1.07	1.17	1.55	0.49
Pooled serum		4.55	150	1.59	0.55	2.28	1.82
Pathonorm H	SD	0.058	1.141	0.032	0.059	0.019	0.018
Pathonorm L		0.028	0.751	0.016	0.024	0.017	0.08
Pooled serum		0.059	1.329	0.034	0.017	0.035	0.026
Pathonorm H	CV%	0.89	0.70	1.10	1.84	0.70	0.92
Pathonorm L		1.22	0.61	1.54	2.08	1.10	1.54
Pooled serum		1.29	0.89	2.11	3.13	1.55	1.40

Abbreviations: K⁺: potassium; Na⁺: sodium; Trigl: triglycerides; AST: aspartate aminotransferase; Ca: calcium; GGT: gamma-glutamyl transferase; SD: standard deviation.

Table 3 Between-day precision.

Sample	N= 14 days	K ⁺ mmol/L	Na ⁺ mmol/L	Trigl mmol/L	AST µkat/L	Ca mmol/L	GGT µkat/L
Pathonorm H	Mean	6.3	160.9	2.8	3.1	2.6	1.9
Pathonorm L		2.2	123.1	1.1	1.2	1.5	0.5
Pooled serum		4.5	148.1	1.6	0.6	2.2	1.8
Pathonorm H	SD	0.094	1.657	0.093	0.065	0.046	0.032
Pathonorm L		0.050	2.349	0.051	0.037	0.047	0.010
Pooled serum		0.051	0.730	0.025	0.105	0.033	0.058
Pathonorm H	CV%	1.48	1.03	3.27	2.14	1.74	1.74
Pathonorm L		2.22	1.91	4.68	3.14	3.05	2.00
Pooled serum		1.15	0.49	1.58	3.47	1.49	3.25

Abbreviations: K⁺: potassium; Na⁺: sodium; Trigl: triglycerides; AST: aspartate aminotransferase; Ca: calcium, GGT: gamma-glutamyl transferase; SD: standard deviation.

Between-Day Precision

Between-day precision was studied using duplicate measurements, of which the second results were used for the calculations. The measurements were repeated over 14 days and the samples measured were Pathonorm H, Pathonorm L and a serum pool (Table 3).

Correlation Study

The correlation study was performed using 60 fresh patient samples, analysed first on the Konelab 20i and then immediately after on Analyser A. The results are shown in Figures 1–7.

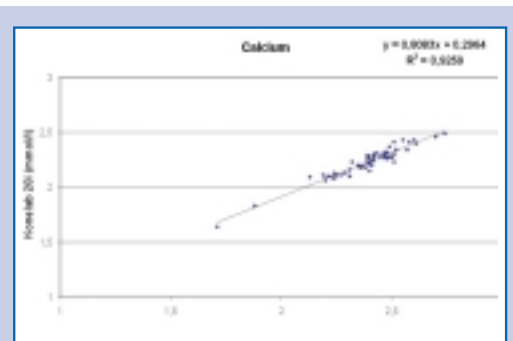


Figure 3 Correlation study of calcium.

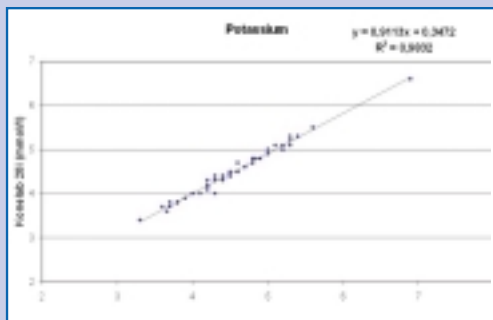


Figure 1 Correlation study of potassium.

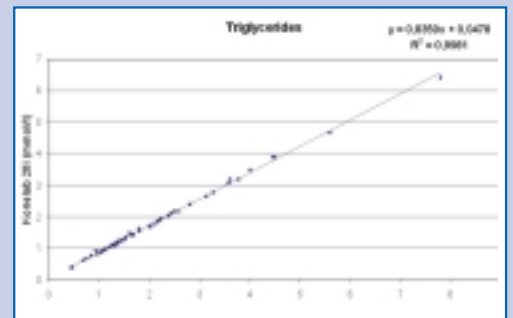


Figure 4 Correlation study of triglycerides.

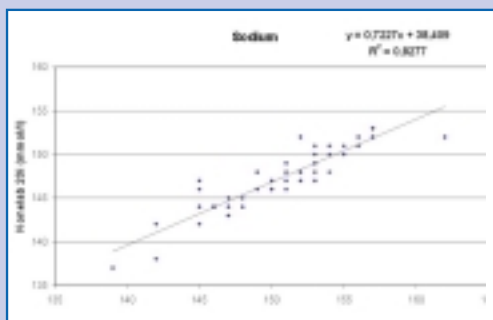


Figure 2 Correlation study of sodium.

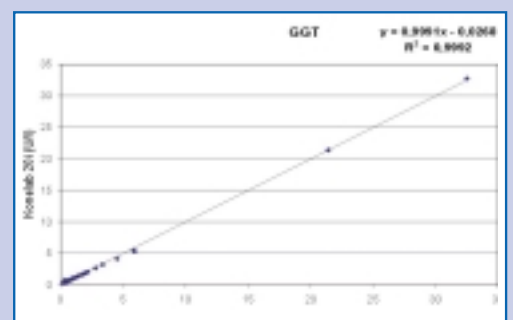


Figure 5 Correlation study of γ -glutamyltransferase.

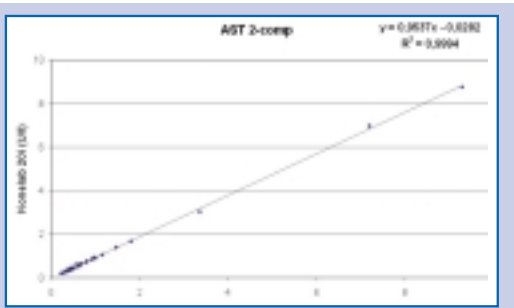


Figure 6 Correlation study of aspartate aminotransferase.

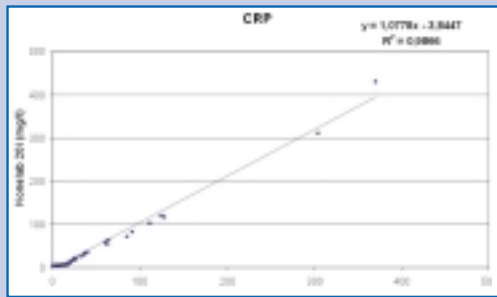


Figure 7 The correlation study of C-reactive protein

Discussion

For the within-run precision tests, coefficients of variation <0.89% were observed for Na and <1.29% for K. CV% <1.5 were observed for calcium and -GT, whereas triglycerides gave CV% <2.11% and AST <3.13%. For the between-day precision tests measured over a 14-day period, using duplicate measurements, a CV <2.2% was observed for the electrolytes, whereas CV% <3.5% was observed for the rest of the tests, except for low levels of triglycerides that showed a value of 4.7%. The correlation studies with Analyser A produced excellent correlation for all tests (coefficient of determination $r^2 > 0.98$) except for calcium ($r^2 = 0.836$).

Conclusion

The Konelab 20i is easy to handle and straightforward to use, a familiarisation period of one week is sufficient for the teaching of routine use. Sample, reagent and cuvette handling is convenient because of the continuous loading capability, while the analyser's own calibration log informs the user when recalibration is recommended. The calibration procedure of the instrument is easy to manage, although a little

time consuming. As part of the daily routine, QC's monitor the result level after start up while the result archiving on a CD-ROM using the R/W CD-ROM drive is another interesting feature.

Clinical requirements for analytical precision, both within-run and between-day, were met.

The analyser performed well and was reliable throughout the evaluation period. Clinical requirements for analytical precision, both within-run and between-day, were met. Correlation to Analyser A was found to be good except for sodium, for which a correlation coefficient of less than 0.9 was obtained. The difference however,

can be explained by the differences in the methodology used: Konelab 20i employs direct potentiometry, whereas Analyser A uses an indirect technique. If needed, this difference can be corrected. The instrument was found to have a good practicability and analytical turnaround time (<20 min) for all analytes, so could be an alternative for clinical chemistry testing in primary health care centres with laboratories serving less than four physicians.

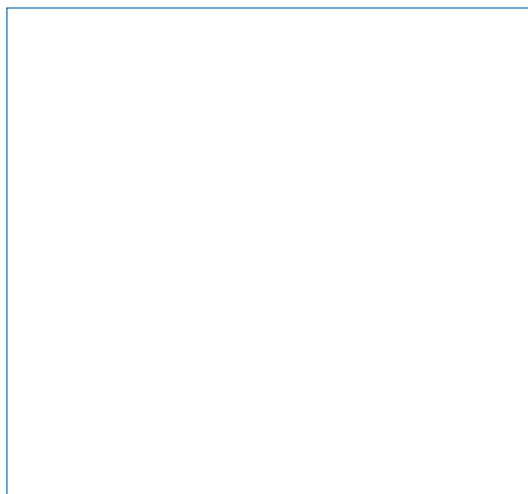
Reference

1. ECCLS (June 1986). *Guidelines for the evaluation of analysers in clinical chemistry*. ECCLS Document, 3(2).

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