Roche

Comparability of selected assays on the new Cobas Pro integrated solutions Cobas ISE neo and Cobas c 703 analytical units under routine-like conditions

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Introduction

- The new, high throughput Cobas® ISE neo and Cobas c 703 analytical units are additions to the serum work area laboratory analyzer, the Cobas Pro integrated solutions (all Roche Diagnostics International Ltd, Rotkreuz, Switzerland).
- The ISE neo and c 703 analytical units have theoretical throughput of 1,800 and 200 results per hour, respectively.
- This multicenter study was conducted to assess analytical performance, functionality, reliability, comparability, practicability, and usability under routine-like conditions.

Objective

- To assess comparability of results between the ISE neo/c 703 analytical units and the Cobas 8000 modular analyzer series (Roche Diagnostics International Ltd, Rotkreuz, Switzerland) for a panel of ISE and clinical chemistry assays.

Methods

- Results generated at two study sites (Belgium and Germany; July–October 2023) during routine testing of residual samples on multiple 8000 modular analyzer series were compared with those derived from retesting on the new Pro integrated solutions ISE neo and c 703 analytical units.
- In total, 23 selected assays were assessed using preliminary application settings on the ISE neo (electrolytes) and c 703 (clinical chemistry analytes) analytical units.
- Method comparison analyses were performed to assess functionality using Passing-Bablok regression; slopes, intercepts, and correlations were calculated and compared with pre-defined acceptance criteria.

Results

- More than 48,000 result pairs were included in the analysis.
- For ISE assays, the bias at the MDP between Pro integrated solutions and the 8000 modular analyzer series varied from 1% (Cl) to 3% (K and Na) deviation.
- For clinical chemistry assays, bias at the MDP varied from 0% (CK and Gluc) to 13% (CRP) deviation.
- All 23 assays showed good comparability between Pro integrated solutions and the 8000 modular analyzer series (**Table 1**).

Table 1. Clinical chemistry Passing-Bablok regression of all assay applications.

Application	Unit	Site	N	Slope	Intercept	Pearson r
Cl	mmol/L	1	173	1.00	0.9	0.952
		2	504	1.11	-9.8	0.926*
K	mmol/L	1	2482	1.00	0.0	0.995
		2	677	1.02	0.0	0.994*
Na	mmol/L	1	2,340	1.05	-6.2	0.908*
		2	659	1.13	-13.3	0.809
ALB	g/L	1	N/A	N/A	N/A	N/A
		2	107	1.02	2.5	0.978*
ALT	U/L	1	2,572	0.98	1.0	0.996*
		2	701	1.08	0.5	0.995
AST	U/L	1	2,009	1.00	0.9	0.990*
		2	673	1.13	4.1	0.993
Ca	mmol/L	1	2,444	1.00	0.0	0.968*
		2	344	1.00	0.1	0.888
CHOL	mmol/L	1	1,696	1.02	-0.1	0.997
		2	462	1.03	-0.1	0.997*
CK	U/L	1	520	1.00	-0.4	1.000
		2	191	1.01	-0.9	1.000*
CREA	µmol/L	1	3,901	1.02	-0.8	0.999*
		2	802	1.03	3.1	0.999
CRP4	mg/L	1	1,864	1.07	-0.1	0.998
		2	503	1.18	-0.2	0.999
GGT	U/L	1	2,910	1.02	0.1	1.000*
		2	626	1.31	-6.9	0.999
GLUC	mmol/L	1	1424	1.00	0.0	0.999*
		2	647	1.03	0.0	0.998
HDL	mmol/L	1	1,303	0.96	0.0	0.998
		2	449	0.94	0.0	0.999*
LDH	U/L	1	961	0.97	-0.5	0.997*
		2	448	0.99	-2.1	0.998
LDL	mmol/L	1	1,553	0.99	0.0	0.998*
		2	N/A	N/A	N/A	N/A
LIP	U/L	1	447	0.99	-0.7	0.998
		2	281	1.01	-0.6	0.999*
MG	mmol/L	1	141	0.99	0.0	0.979
		2	258	0.99	0.0	0.971*
PHOS	mmol/L	1	1,450	1.00	0.0	0.997*
		2	N/A	N/A	N/A	N/A
TP	g/L	1	928	1.01	-1.6	0.974
		2	329	1.03	-1.1	0.974*
TRIG	mmol/L	1	1,527	1.01	0.0	0.999
		2	446	1.07	0.0	0.999
UA	µmol/L	1	2,251	1.01	0.9	0.998*
		2	N/A	N/A	N/A	N/A
UREA	mmol/L	1	2,129	0.98	0.2	0.999
		2	525	1.04	0.1	0.999*

Results within technical limits were included into the regression analysis. Site 1: Limbach in Heidelberg, Germany; Site 2: ASZ in Aalst, Belgium. *Comparisons that are shown as figures.

Results (cont.)

- Test results and sampling patterns from the 8000 modular analyzer series were electronically captured using web-based computer-aided evaluation (**Figure 1**).
- The same run was then repeated on the Pro integrated solutions and the results from the methods were compared using Passing-Bablok regression analysis (**Figure 2**).

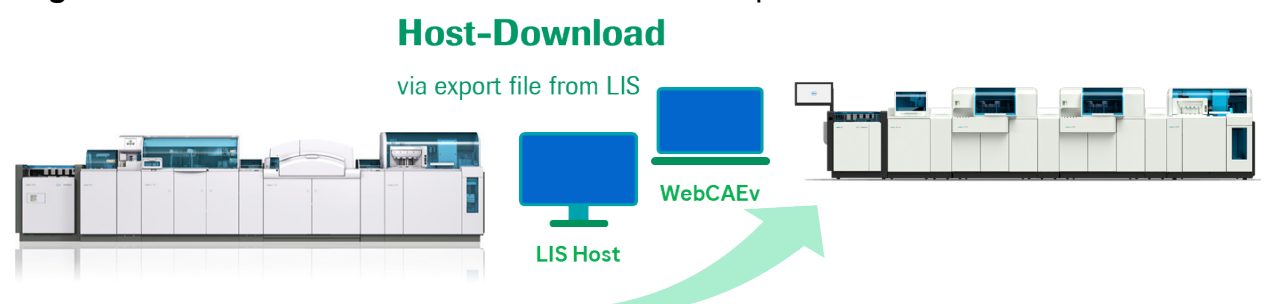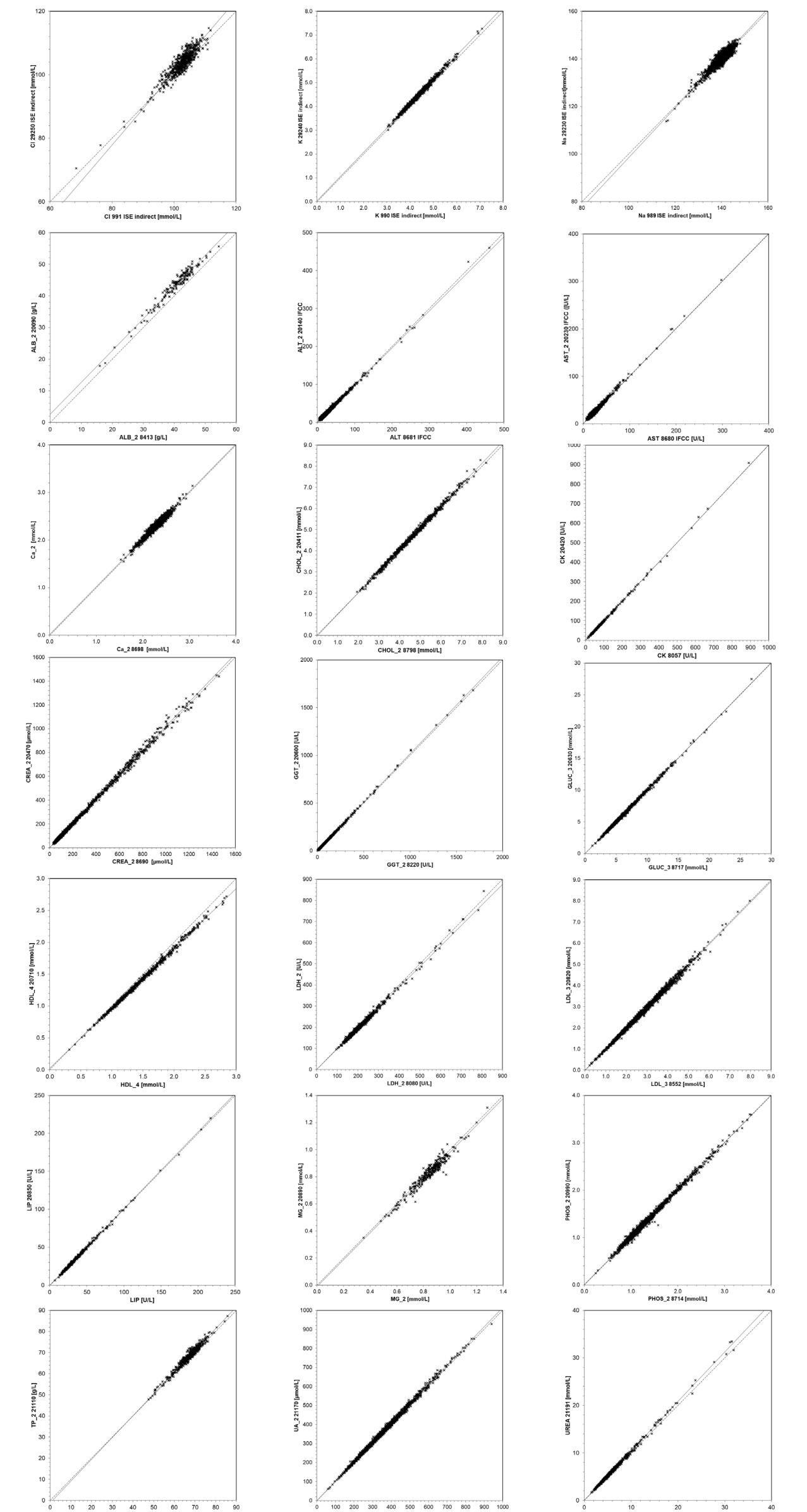**Figure 1.** Routine-simulation download method comparison.

Figure 2. Comparison of results from the Pro integrated solutions and 8000 modular analyzer series using Passing-Bablok regression analysis assay applications.

Conclusions

- The new, high throughput ISE neo and c 703 analytical units complement the Pro integrated solutions and provided comparable results to the 8000 modular analyzer series for a panel of ISE and clinical chemistry assays.

Abbreviations

ALB, albumin; ALT, alanine aminotransferase; AST, aspartate aminotransferase; Ca, calcium; CHOL, cholesterol; CK, creatinine kinase; Cl, chloride; CREA, creatinine; CRP, C-reactive protein; GGT, gamma-glutamyl-transferase; GLUC, glucose; HDL, high density lipoprotein; ISE, ion selective electrodes; K, potassium; LDH, lactate dehydrogenase; LDL, low density lipoprotein; LIP, lipase; MDP, medical decision point; MG, magnesium; N/A, not applicable; Na, sodium; PHOS, phosphate; TP, total protein; TRIG, triglyceride; UA, uric acid.

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