

Comparability of selected assays on cobas pure integrated solutions under routine-like conditions at four sites in Europe and Asia

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A-033

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Introduction

- The novel cobas pure integrated solutions (Roche Diagnostics International Ltd, Rotkreuz, Switzerland) is a serum work area laboratory analyzer developed to quantify ion selective electrolyte, immunochemistry, and clinical chemistry parameters in patient serum, plasma, cerebrospinal fluid, and urine samples.
- A multicenter study to evaluate cobas pure integrated solutions was conducted at five sites in Europe and Asia (Heidelberg & Ludwigsburg, Germany; Visp, Switzerland; Wrocław, Poland; Seoul, Republic of Korea).*

Objectives

- To evaluate the analytical performance, functionality, reliability, comparability, practicability, and usability of cobas pure integrated solutions under routine-like conditions.
- Here, we report the comparability of cobas pure integrated solutions versus respective routine analyzers at four sites.*

*Results for analytical performance and system validation are presented in posters A-034 and A-035, respectively, at this congress.

Results

- More than 35,000 result pairs were included in the analysis.
- For the 53 applications, 90% of the method comparisons with Roche methods met the Passing-Bablok slope and intercept acceptance criteria, as applied for standard method comparisons. We present 18 of the most common analytes in Figure 2.
- A total of 218 method comparisons generated a median Passing-Bablok regression slope of 1.00 (67% between 0.95 and 1.05), a median bias at the medical decision point of -0.1% (87% ≤ ±5%), and a median Pearson's r of 0.998 (Tables 1–3).

Table 1. cobas pure integrated solutions versus respective routine analyzers: ISE analytes

Analyte	Parameter	Site and analyzer			
		Visp: INTEGRA 400 plus	Ludwigsburg: cobas 8000	Seoul: BeCo	Heidelberg: cobas 8000
Cl	Slope	1.10	1.03	1.11	1.02
	Intercept	-13.4	-4.6	-12.0	-4.3
	Pearson's r	0.975	0.968	0.875	0.967
K	Slope	0.98	0.99	1.10	1.00
	Intercept	0.14	0.22	-0.21	0.06
	Pearson's r	0.996	0.982	0.980	0.988
Na	Slope	1.02	0.99	1.30	0.99
	Intercept	-1.9	2.1	-38.9	1.9
	Pearson's r	0.953	0.873	0.739	0.889

BeCo, Beckman Coulter AU5822 Clinical Chemistry Analyzer; Cl, chloride; ISE, ion selective electrolyte; K, potassium; Na, sodium.

Table 2. cobas pure integrated solutions versus respective routine analyzers: immunochemistry analytes

Analyte	Parameter	Site and analyzer			
		Visp: cobas e 411	Ludwigsburg: cobas 8000/ cobas pro	Seoul: Abbott Alinity II/ Siemens ADVIA Centaur	Heidelberg: cobas 8000
FT4	Slope	1.07	1.02*	-	1.00
	Intercept	-1.02	0.81	-	0.75
	Pearson's r	0.986	0.994	-	0.986
NT-proBNP	Slope	0.93	1.02*	-	1.06
	Intercept	4.68	-6.60	-	-5.03
	Pearson's r	1.000	1.000	-	0.999
TnT-hs	Slope	1.02	0.96*	-	1.05
	Intercept	-0.5	0.2	-	-0.56
	Pearson's r	0.999	0.999	-	1.000
TSH	Slope	1.00	1.03*	1.18†	0.99
	Intercept	-0.02	0.00	-0.02	-0.01
	Pearson's r	0.997	0.999	0.999	0.997
Vit B12	Slope	0.94	0.96†	0.87‡	0.94
	Intercept	-18.9	-14.4	-57.0	-0.49
	Pearson's r	0.979	0.997	0.932	0.995

*Measured on cobas 8000; †Measured on cobas pro; ‡Measured on Abbott Alinity II; §Measured on Siemens ADVIA Centaur.

FT4, free thyroid hormone thyroxine; NT-proBNP, N-terminal pro B-type natriuretic peptide; TnT-hs, troponin T-high sensitivity; TSH, thyroid stimulating hormone; Vit B12, vitamin B12.

Methods

- In total, 47 selected analytes with 53 applications were assessed; here, we present 18 of the most common analytes:
 - Electrolytes: chloride, potassium, and sodium.
 - Immunochemistry: free thyroid hormone thyroxine, N-terminal pro B-type natriuretic peptide, troponin T-high sensitivity, thyroid stimulating hormone, and vitamin B12.
 - Clinical chemistry: albumin, alanine aminotransferase, aspartate aminotransferase, calcium, cholesterol, creatinine, C-reactive protein, glucose, hemoglobin A1c, and phosphate.
- We conducted routine simulation method comparison experiments using routine leftover samples (pooled and stored at 2–8°C) to evaluate the comparability of cobas pure integrated solutions with the following routine analyzers at the following sites:
 - Visp, Switzerland: cobas INTEGRA 400 plus and cobas e 411.
 - Ludwigsburg, Germany: cobas pro and cobas 8000.
 - Seoul, Republic of Korea: Beckman Coulter AU5822 Clinical Chemistry Analyzer, Abbott Alinity II, Siemens ADVIA Centaur.
 - Heidelberg, Germany: cobas 8000.

- Available results from routine samples in the Laboratory Information Systems (LIS) Host were transferred to data capture software WinCAEV and then measurement requests were transferred by WinCAEV to cobas pure integrated solutions (Figure 1). Following sample measurement on cobas pure integrated solutions, Passing-Bablok regression analyses were performed; slopes, intercepts, and correlations were calculated and compared with pre-defined acceptance criteria.

Figure 1. Measurement of routine leftover samples



Figure 2. Method comparisons of cobas pure integrated solutions versus respective routine analyzers

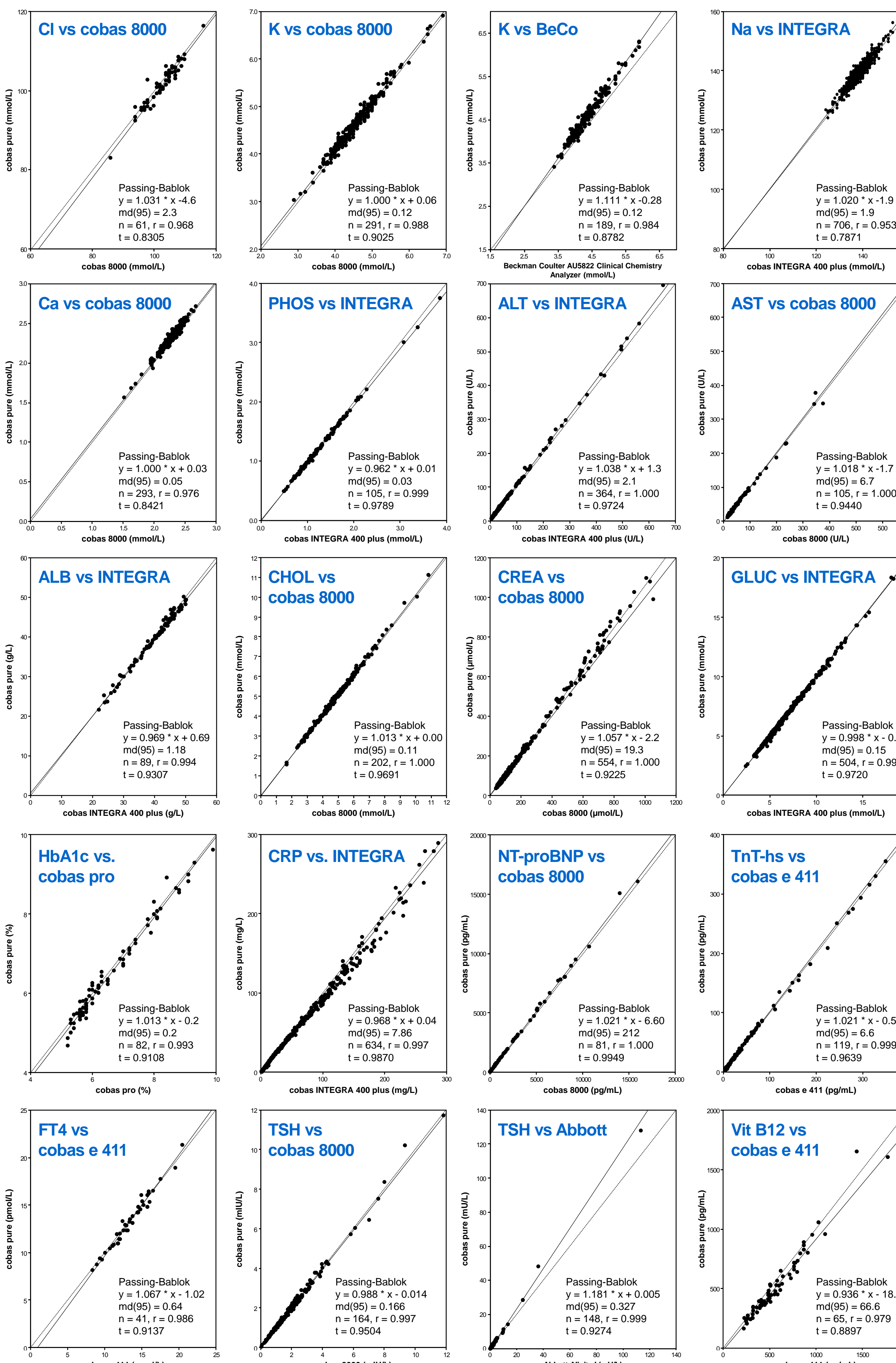


Table 3. cobas pure integrated solutions versus respective routine analyzers: clinical chemistry analytes

Analyte	Parameter	Site and analyzer			
		Visp: INTEGRA 400 plus	Ludwigsburg: cobas 8000/ cobas pro	Seoul: BeCo	Heidelberg: cobas 8000
ALB	Slope	0.97	1.07*	1.04	0.97
	Intercept	0.69	-3.92	3.69	1.16
	Pearson's r	0.994	0.977	0.961	0.983
ALT	Slope	1.04	1.03†	-	1.00
	Intercept	1.32	-0.05	-	0.10
	Pearson's r	1.000	1.000	-	0.999
AST	Slope	0.98	0.94†	-	0.99
	Intercept	1.39	0.29	-	0.83
	Pearson's r	0.999	1.000	-	0.992
Ca	Slope	0.98	1.04†	1.00	1.00
	Intercept	0.02	-0.03	0.01	0.03
	Pearson's r	0.983	0.968	0.847	0.976
CHOL	Slope	0.98	1.04*	0.96	1.01
	Intercept	0.05	-0.08	0.12	0.00
	Pearson's r	0.999	0.998	0.995	0.998
CREA	Slope	1.05	1.00*	1.08	1.06
	Intercept	0.32	-1.77	-7.10	-2.16
	Pearson's r	0.999	0.998	0.999	0.998
CRP	Slope	0.97	1.02†	0.83	1.07
	Intercept	0.04	-0.12	-0.07	-0.07
	Pearson's r	0.997	0.999	0.998	1.000
GLUC	Slope	1.00	0.98*	1.01	1.00
	Intercept	-0.03	0.05	-0.69	-0.08
	Pearson's r	0.999	0.997	0.987	0.996
HbA1c	Slope	0.92	1.01†	-	-
	Intercept	0.64	-0.20	-	-
	Pearson's r	0.983	0.993	-	-
PHOS	Slope	0.96	1.04*	0.97	1.00
	Intercept	0.01	-0.01	0.04	0.01
	Pearson's r	0.999	0.999	0.999	0.999

*Measured on cobas 8000; †Measured on cobas pro; ‡Measured on Abbott Alinity II; §Measured on Siemens ADVIA Centaur.

ALB, albumin; ALT, alanine aminotransferase; AST, aspartate aminotransferase; BeCo, Beckman Coulter AU5822 Clinical Chemistry Analyzer; Ca, calcium; CHOL, cholesterol; Cl, chloride; CREA, creatinine; CRP, C-reactive protein; GLUC, glucose; HbA1c, hemoglobin A1c; PHOS, phosphate.

Conclusions

- The results of this study demonstrate that cobas pure integrated solutions delivers comparable and accurate results versus commercially available analyzers at four different evaluation sites across a selection of 47 analytes under routine-like conditions.

Acknowledgments and Disclosures

The authors wish to thank their staff at the respective sites for the professional and dedicated support throughout the study. This study was funded by Roche Diagnostics International Ltd (Rotkreuz, Switzerland). Third-party medical writing support, under the direction of the authors, was provided by Sophie Lavelle, MSc, of Ashfield MedComms (Macclesfield, UK), an Ashfield Health company, and was funded by Roche Diagnostics International Ltd (Rotkreuz, Switzerland). COBAS, COBAS C, COBAS E, COBAS INTEGRA, and COBAS PRO are trademarks of Roche. All other trademarks are property of their respective owners. cobas pure integrated solutions is not registered for use in the US.