

Result precision 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 precision of the new Cobas[®] Pro integrated solutions Cobas ISE neo, Cobas c 703 and the existing e 801 analytical units (Roche Diagnostics International Ltd, Rotkreuz, Switzerland) was measured under intended use conditions in a routine simulation setting.
- This multicenter study was conducted to assess analytical performance, functionality, reliability, comparability, practicability, and usability under routine-like conditions.
- One evaluation site (MVZ Labor Dr. Limbach, Heidelberg, Germany) during the pilot phase (July-October 2023) of the Pro integrated solutions design evaluation study was used for this analysis.

Objective

• To assess the precision of Pro integrated solutions in a routine-like environment with routine-based workloads over an extended period of time, to assess random and/or systematic errors originating from software, hardware, chemistry, or interaction thereof.

Methods



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- The interaction of hardware, software, assays, and samples was tested at a single site using a routine simulation precision experiment.
 - RSI consists of a reference part in which a defined number of aliquots (per application) is processed consecutively (within-run batch), and a random part, in which all applications and materials are requested in a randomized order (random-access mode; Figure 1).

Results

- Overall, 49 applications were measured during the reference and random-access parts of three RSI runs: six ISEs (three serum, three urine), 35 clinical chemistry (27 serum, eight urine), and eight immunochemistry (all serum).
 - A routine simulation precision run comprised 899 samples (797 serum/plasma, 102 urine) with 7,155 requests across the 49 applications.
- Three independent runs were performed.
- Run one was used as a reference run and Run two and three included provocations such as 'sample short with false bottom tube' and 'sample barcode read error' (Figure 2).
 - Provocations included: the use of AutoCal for ISE, forcible loading and unloading of racks, calibration and control measurement during run and loading of STAT samples.

Figure 2. RSI Run 3 including provocations across the ISE, clinical chemistry and immunohistochemistry applications.



- Recovery under various stressed routine-like conditions, including provocations, was tested.
- The interaction of new and existing analytical units was evaluated using the Pro integrated solutions configuration comprising one ISE neo, two c 703, and one e 801 (existing) analytical units.
 - The ISE neo and c 703 analytical units are not yet commercially available; the e 801 analytical unit is commercially available.
- The precision of batch type measurements was compared with the precision 000 under routine simulated, random-access conditions.
 - By using sample material suitable for clinical chemistry and immunochemistry applications, all samples were able to be tested on each analytical unit of the Pro integrated solutions during the randomaccess mode.
 - Random-access CVs that exceeded 1.5× reference batch CVs, or single measurements deviating by >10% from the batch mean, triggered in-depth analysis of the system components that contributed to the result.
 - Tests for potential systematic or random errors compared precision of the reference (batch) with random-access results.

Figure 1. Request pattern for the reference and random-access part of the RSI experiment.







CK 20420 CSP CC/IA	× GGT_2 20600 CSP CC/IA	O LDH_2 20810 CSP CC/IA	■ LIP 20850 CSP CC/IA
▲ ALB_2 20090 CSP CC/IA	♦ BIL-T_3 20310 CSP CC/IA	CHOL_2 20411 CSP CC/IA	CREA_2 20470 CSP CC/IA
■ GLUC_3 20630 CSP CC/IA	HDL_4 20710 CSP CC/IA	* LDL_3 20820 CSP CC/IA	▲ TP_2 21110 CSP CC/IA
♦ TRIG 21130 CSP CC/IA	UA_2 21170 CSP CC/IA	UREA 21191 CSP CC/IA	× Ca_2 20340 CSP CC/IA
OL 29250 CSP CC/IA	* K 29240 CSP CC/IA	△ MG_2 20890 CSP CC/IA	♦ Na 29230 CSP CC/IA
+ PHOS_2 20990 CSP CC/IA	APO AI 20190 CSP CC/IA	× Fe_2 20770 CSP CC/IA	o IgM_2 20750 CSP CC/IA
ж TNT hs STAT 10240 CSP IA	△ CEA 10003 CSP CC/IA	♦ CEA 10003 CSP IA	# FT4_4 10195 CSP CC/IA
FT4_4 10195 CSP IA	x TSH 10172 CSP CC/IA	TSH 10172 CSP IA	* E2_3 10100 CSP CC/IA
▲ E2_3 10100 CSP IA	♦ ßHCG 10072 CSP CC/IA	# I3HCG 10072 CSP IA	PTH 10061 CSP IA
× CARB_4 20350 CSP TDM	CRP4 20500 CSP CC/IA	K HIV DUO 12018 CSP HIV	▲ HIVDUOAHIVsub 99984 CSP HIV
HIVDUOHIVAGsub 99981 CSP HIV	CREA_2 20471 HUP/CUP	GLUC_3 20631 HUP/CUP	■ UA_2 21171 HUP/CUP
UREA 21190 HUP/CUP	* Ca_2 20341 HUP/CUP	△ CI 29251 HUP/CUP	♦ K 29241 HUP/CUP
+ MG_2 20891 HUP/CUP	Na 29231 HUP/CUP	× PHOS_2 20991 HUP/CUP	O ALBT2 20061 HUP/CUP

UREA + MG 2 20891 HUP/CUP □ Na 29231 HUP/CUP

- Reference | Random

* ALP 2 20110 CSP CC/IA

- Of the six ISE (serum and urine) applications, the mean reference and random-access CVs were both 0.8% (Figure 3 and Figure 4).
- Of 35 clinical chemistry applications, the mean reference CVs were 0.9% (serum), and 1.2% (urine), and the mean random-access CVs were 1.0% (serum), and 1.7% (urine).
- Of eight immunochemistry applications (serum only), the mean reference and random-access CVs were 1.0% and 1.2%, respectively.

Figure 3. Mean reference CVs across the ISE, clinical chemistry, and immunohistochemistry applications.







Conclusions

- This study demonstrated that the new Pro integrated solutions ISE neo and c 703 analytical units show consistent results over a prolonged time period under routine-like conditions, with most CVs <1.1%.
- These results also demonstrated the successful integration of the new ISE neo and c 703 analytical units into the Pro integrated solutions, with seamless interaction of existing and new analytical units under stressed conditions.

Disclosures

Abbreviations

ALB, albumin; ALBT2, tina-quant Albumin Gen. 2; ALP, alkaline phosphatase; ALT, alanine aminotransferase Access this



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APO AL Apolipor protein A-I: AST aspartate aminotransferase: BHCG human chori adotropin + 8-subuni BIL-T, total bilirubin; Ca, calcium; CARB, carbamazepine; CC, clinical chemistry; CC-U, clinical chemistry (urine); poster using the CEA, carcinoembryonic antigen; CHE, cholinesterase; CHOL, cholesterol; CK, creatinine kinase; CI, chloride; quick response Crea/CREA, creatinine; CRP, C-reactive protein; CSP, control serum pool; CUP, control urine pool; CV, co-efficient of variance; E2, Prostaglandin E2; Fe, iron; FT4, free thyroxine; GGT, gamma-glutamyl-transferase; (QR) code or by Bluc/GLUC, glucose; HDL, high density lipoprotein; HIV, human immunodeficiency vinus; HSP, human serum pool; HUP, human urine pool; IA, immunoassays; IC, immunochemistry; IgM, immunoglobulin M; ISE, ion selective visiting: electrode; ISE-U, ion selective electrode (urine); K, potassium; LDH, lactate dehydrogenase; LDL, low density lipoprotein; LIP, lipase; MG, magnesium; Na, sodium; PHOS, phosphate; PTH, parathyroid hormone; QC; quali control; RSI, routine simulation precision; STAT, short turnaround time; TDM, therapeutic drug monitoring; TnThs. Troponin T; TP, total protein; TRIG, Triglyceride; TSH, thyroid-stimulating hormone; UA, uric acid.