

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.

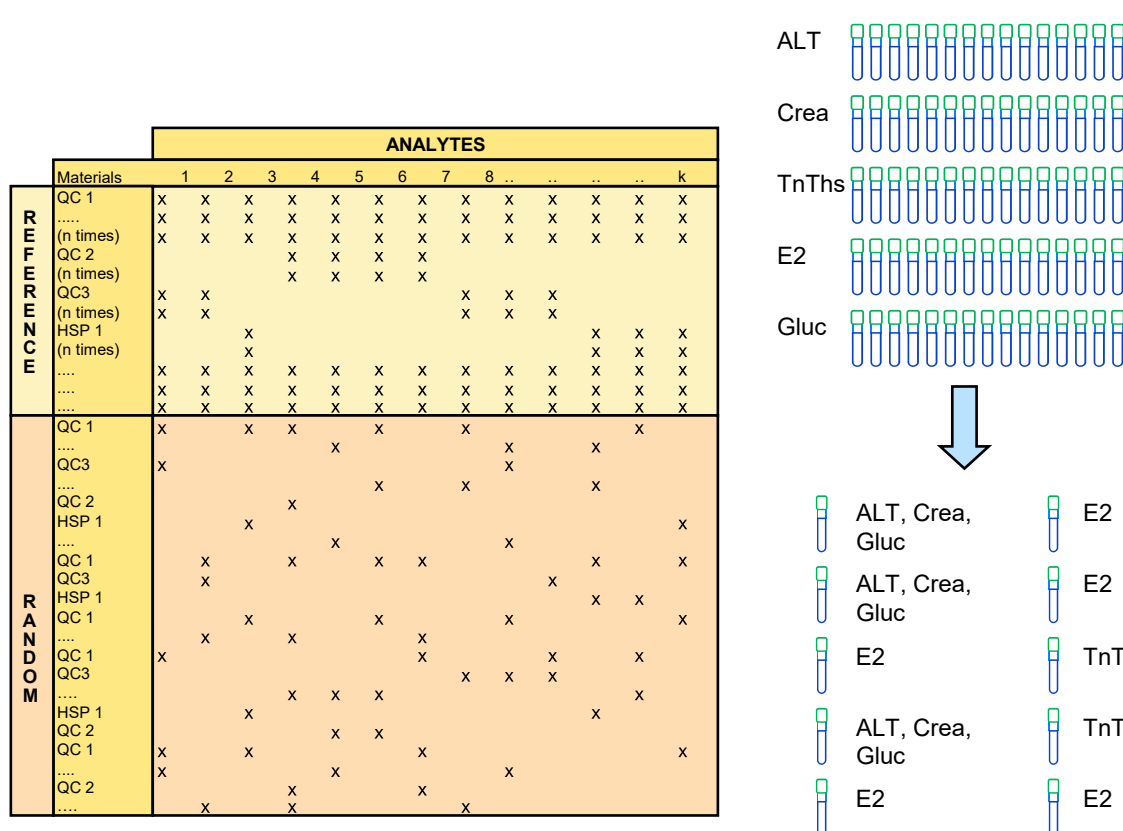
Objective

- 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

- 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**).
 - 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 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 random-access 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.

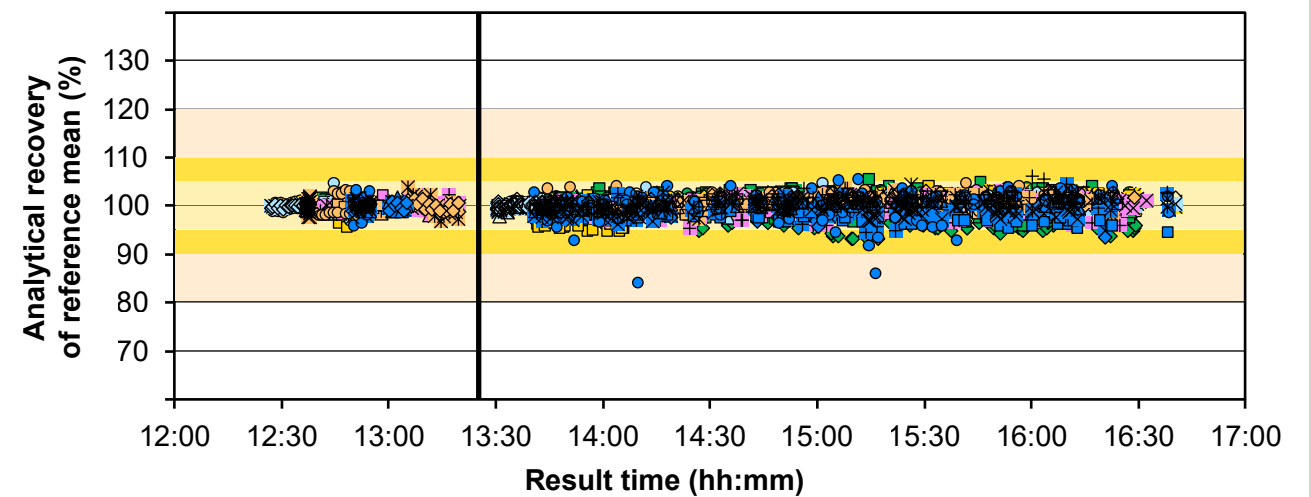
Figure 1. Request pattern for the reference and random-access part of the RSI experiment.



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 immunochemistry applications.



- ALP_2 20110 CSP CC/IA
- CK 20420 CSP CC/IA
- ALB_2 20090 CSP CC/IA
- GLUC_3 20630 CSP CC/IA
- TRIG 21130 CSP CC/IA
- CI 29250 CSP CC/IA
- PHOS_2 20990 CSP CC/IA
- TNT hs STAT 10240 CSP IA
- FT4_4 10195 CSP IA
- E2_3 10100 CSP IA
- CARB_4 20350 CSP TDM
- HIVDUOHIVAGsub 99981 CSP HIV
- UREA 21190 HUP/CUP
- MG_2 20891 HUP/CUP
- Reference | Random
- ALT_2 20140 CSP CC/IA
- GGT_2 20600 CSP CC/IA
- BIL-T_3 20310 CSP CC/IA
- HDL_4 20710 CSP CC/IA
- UA_2 21170 CSP CC/IA
- K 29240 CSP CC/IA
- APO A1 20190 CSP CC/IA
- CEA 10003 CSP CC/IA
- TSH 10172 CSP CC/IA
- BHCG 10072 CSP CC/IA
- CRP4 20500 CSP CC/IA
- CREA_2 20471 HUP/CUP
- Ca_2 20341 HUP/CUP
- Na 29231 HUP/CUP
- AST_2 20230 CSP CC/IA
- LDH_2 20810 CSP CC/IA
- LDL_3 20820 CSP CC/IA
- UREA 21191 CSP CC/IA
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