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Analytical precision performance evaluation of selected immunoassays on the immunochemistry analytical unit of cobas pure integrated solutions

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Introduction

- cobas® pure integrated solutions (Roche Diagnostics International Ltd, Rotkreuz, Switzerland) is a serum work area laboratory analyser consolidating clinical chemistry/ion selective electrolyte (cobas c 303) and immunochemistry (cobas e 402) testing in plasma, serum and urine on a single platform.
- cobas pure integrated solutions was developed as a successor to cobas 6000 (cobas c 501 and e 601); however, the system is more compact with footprint of two square metres.
- The immunochemistry unit of cobas pure integrated solutions (cobas e 402) is an alternative to the cobas e 602 and e 801 analysers.

Objectives

- **We conducted a multicentre study to evaluate the precision performance of selected immunoassays on cobas pure integrated solutions versus cobas legacy systems.**

Methods

- Precision experiments based on the Clinical and Laboratory Standards Institute EP05-A3 protocol were conducted at three external sites (Ludwigsburg/Heidelberg, Germany; Wroclaw, Poland) and one internal site (Penzberg, Germany) during May–June 2021.
- There were two runs per day for ≥5 days per instrument; for each sample and run, a single determination of three separate aliquots per sample was performed.

Methods (continued)

- Samples included Roche-produced Elecsys® quality control (QC) materials (low and high analyte concentration) and anonymised human serum sample pools covering the respective assay measuring ranges (negative and positive).
  - Identical samples (N=79) and reagents were used at each site.
- Comparator legacy systems included in the study were cobas e 601, e 602 and e 801; nine routine immunoassays were studied (**Table 1**).
- Coefficients of variation (CVs) for repeatability and intermediate precision (per site), and reproducibility (across all sites) were calculated and compared with pre-defined acceptance criteria.

Table 1. Comparator legacy systems and immunoassays studied

New system	Legacy systems	Immunoassay
cobas pure integrated solutions (cobas e 402)	cobas e 601	Anti-HBs II HBsAg II Anti-HCV II Anti-HBc IgM Anti-HBc II
	cobas e 602	Anti-HBe
	cobas e 801	free PSA total PSA HBeAg

Anti-HBc, antibody to hepatitis B core antigen; Anti-HBe, antibody to hepatitis B e antigen; Anti-HBs, antibody to hepatitis B surface antigen; Anti-HCV, antibody to hepatitis C virus; HBeAg, hepatitis B e antigen; HBsAg, hepatitis B surface antigen; IgM, immunoglobulin M; PSA, prostate-specific antigen.

Results

Distribution of precision

- Of the 79 samples tested, precision was calculated for 78 samples; one sample tested using the Anti-HBs II immunoassay demonstrated analyte recovery below the measuring range and was therefore excluded from the analysis.
- Of the 78 results, 30 samples recovered at a low analyte concentration level. The remaining 48 samples recovered at medium or high analyte concentration levels (**Table 2**).

Table 2. Distribution of repeatability, intermediate precision and reproducibility CVs

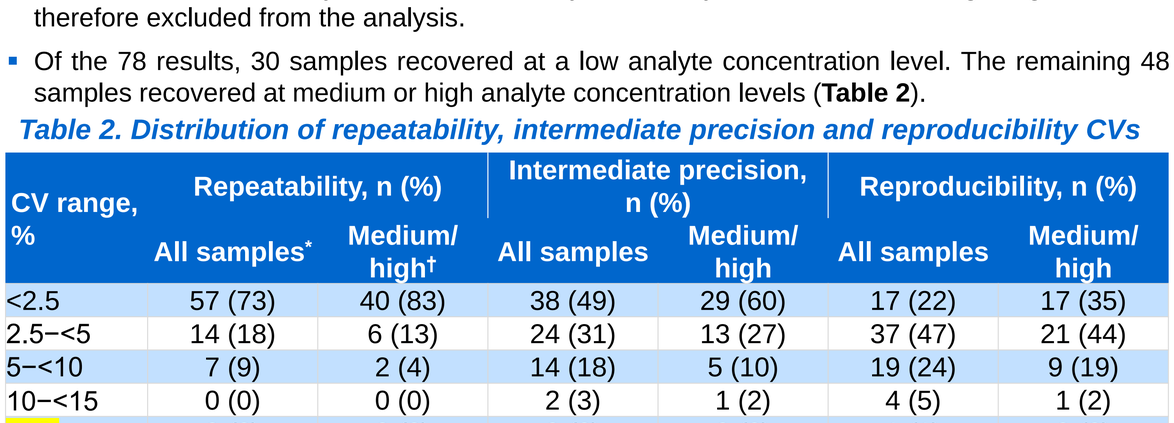
CV range, %	Repeatability, n (%)		Intermediate precision, n (%)		Reproducibility, n (%)	
	All samples*	Medium/ high†	All samples	Medium/ high	All samples	Medium/ high
<2.5	57 (73)	40 (83)	38 (49)	29 (60)	17 (22)	17 (35)
2.5–<5	14 (18)	6 (13)	24 (31)	13 (27)	37 (47)	21 (44)
5–<10	7 (9)	2 (4)	14 (18)	5 (10)	19 (24)	9 (19)
10–<15	0 (0)	0 (0)	2 (3)	1 (2)	4 (5)	1 (2)
≤16	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Total	78 (100)	48 (100)	78 (100)	48 (100)	78 (100)	48 (100)

*Of the 79 samples tested, precision was calculated for 78 samples. †Samples recovered at medium/high analyte concentration levels (n=48).

Samples close to the medical decision point (MDP)

- Precision performance in samples with analyte concentration close to the MDP on cobas pure integrated solutions was comparable to, or better than, the legacy systems (**Figure 1**).
- CVs for repeatability around the MDP or cut-off value for cobas pure integrated solutions ranged from 0.9% (HBeAg) to 4.7% (HBsAg II); those for intermediate precision ranged from 1.3% (anti-HBc II) to 6.5% (anti-HBs II), and for reproducibility they ranged from 2.3% (total PSA) to 8.9% (anti-HBc IgM).

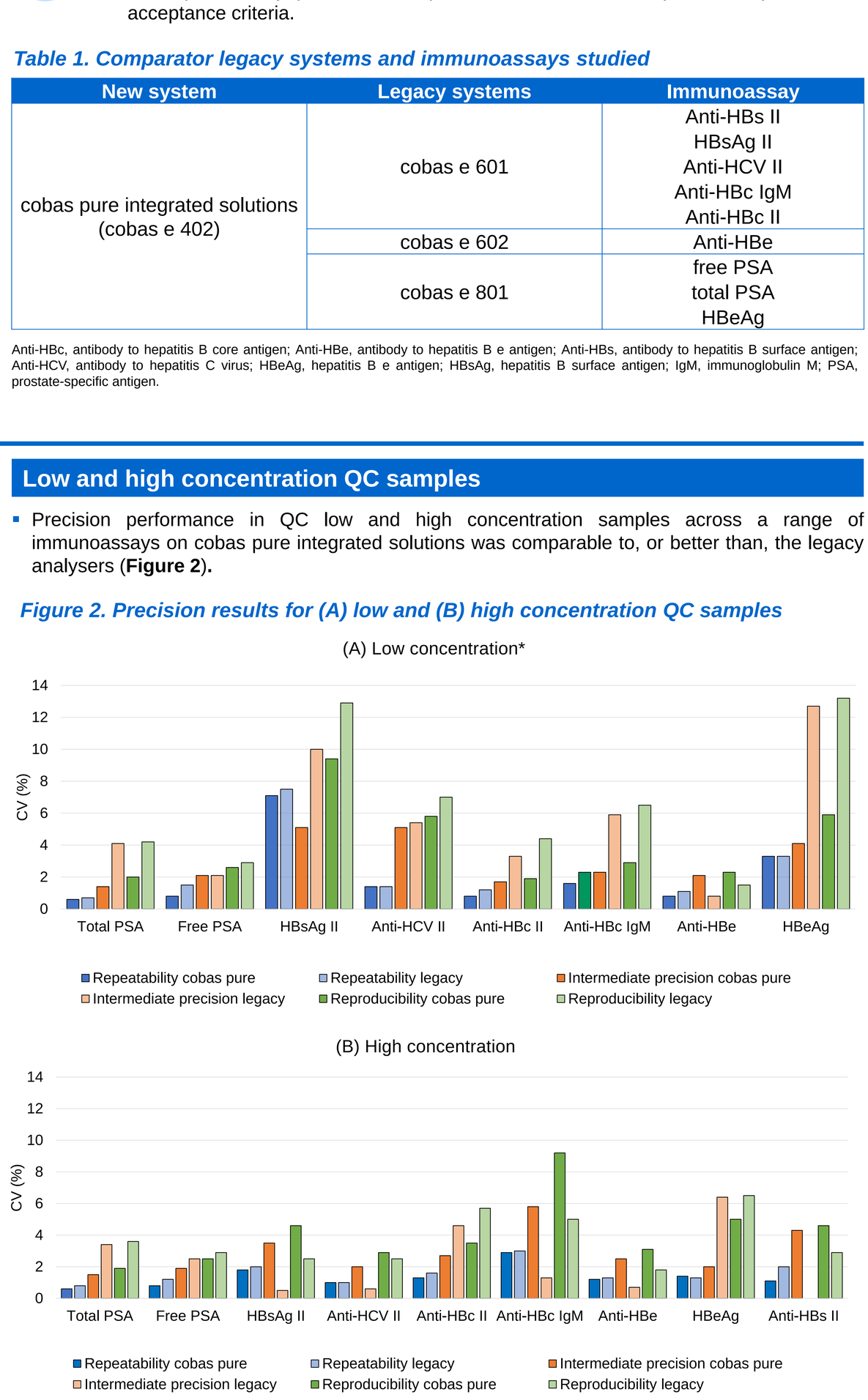
Figure 1. Precision results for samples close to the medical decision point



Low and high concentration QC samples

- Precision performance in QC low and high concentration samples across a range of immunoassays on cobas pure integrated solutions was comparable to, or better than, the legacy analysers (**Figure 2**).

Figure 2. Precision results for (A) low and (B) high concentration QC samples



*Anti-HBs II demonstrated analyte recovery below the measuring range and was therefore excluded from the analysis.

Conclusions

- **The analytical precision performance of cobas pure integrated solutions for a selected panel of immunoassays was comparable to, or better than, the precision performance of the Roche legacy analysers.**
- **These observations support the implementation of the immunochemistry analytical unit of cobas pure integrated solutions into routine clinical laboratory practice, and provide evidence to suggest that there should be a seamless transition from the legacy systems to the new system.**

Disclosures

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