Comparison of low PSA results in a commutable EQA program

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Introduction

Prostate Specific Antigen (PSA) is an androgen-regulated serine protease produced by both prostate epithelial cells and prostate cancer and is the most commonly used serum marker for prostate cancer[1].
Post-prostatectomy patients are monitored for small changes in PSA as a potential indicator of recurrence and prognosis[2].

The RCPAQAP provides a Liquid Serum Chemistry Program sourced from consenting male and female haemochromatosis patients presenting for therapeutic venesection, which by definition is fully commutable. Where possible, serum from individual male and female patients is pooled over successive collections. The option to report Total PSA and Free PSA was introduced in the 2022 program. Here we report on the performance of two low Total PSA levels across 6 instruments from 4 vendors.

Method

The results for each platform submitted by 49 participating laboratories for Samples 22-03 and 22-04 in the November 2022 Liquid Serum Chemistry survey were assessed and compared between instruments using RCPAQAP in-house software. While instrument groups with <3 results were included in the overall (all-result) statistics, they were not assessed for within-instrument CV's. We also asked the laboratories to provide example patient reports to compare their quoted reference intervals.

Results

The all-result median for Sample 22-03 was 0.47ug/L (n=49) and for Sample 22-04 was 0.77ug/L (n=49) (Table 1).

Apart from the Siemens Atellica, the instrument medians were no more than 0.04 ug/L different from each other for both samples (Table 1). The Atellica medians were 0.11 ug/L lower compared to the all result median for both samples (Table 1).

The all-result CV's for samples 22-03 and 22-04 were 12.8% and 11.0%, respectively. The within instrument CV's varied from 3.8 to 11.6% for Sample 22-03 and 1.4 to 8.2% for sample 22-04 (Table 1, Figure 1).

All submitted results were within the RPCAQAP Analytical Performance specifications for a low level (+/- 0.40 ug/L).

A sampling of reference intervals (for a 50 yr old male) provided on the example patient reports is shown in Table 2.

Discussion and Conclusion

This survey showed acceptable CV's and overall harmonisation of results and reference intervals between the 4 vendors reviewed. However, there is still the potential for a clinician to suspect a significant change (>0.2 ug/L) when monitoring total PSA for their post-prostatectomy patients[2].

Table 1. Comparison of performance at low Total PSA levels across all instruments and those where a minimum of 3 results were submitted

	Total PSA				
		Sample 22-03		Sample 22-04	
	n	Median ug/L	CV%	Median ug/L	CV%
All-Result	49	0.47	12.8	0.77	11.0
Abbott Architect i2000SR	8	0.47	9.1	0.77	6.9
Abbott Alinity i	15	0.47	7.2	0.77	5.6
Beckman Coulter UniCel DxI 800	3	0.45	5.6	0.78	8.0
Roche Diagnostics Cobas e 602	5	0.49	3.8	0.81	1.4
Roche Diagnostics Cobas e 801	6	0.49	6.3	0.80	4.0
Siemens Atellica IM	7	0.36	11.6	0.69	8.2

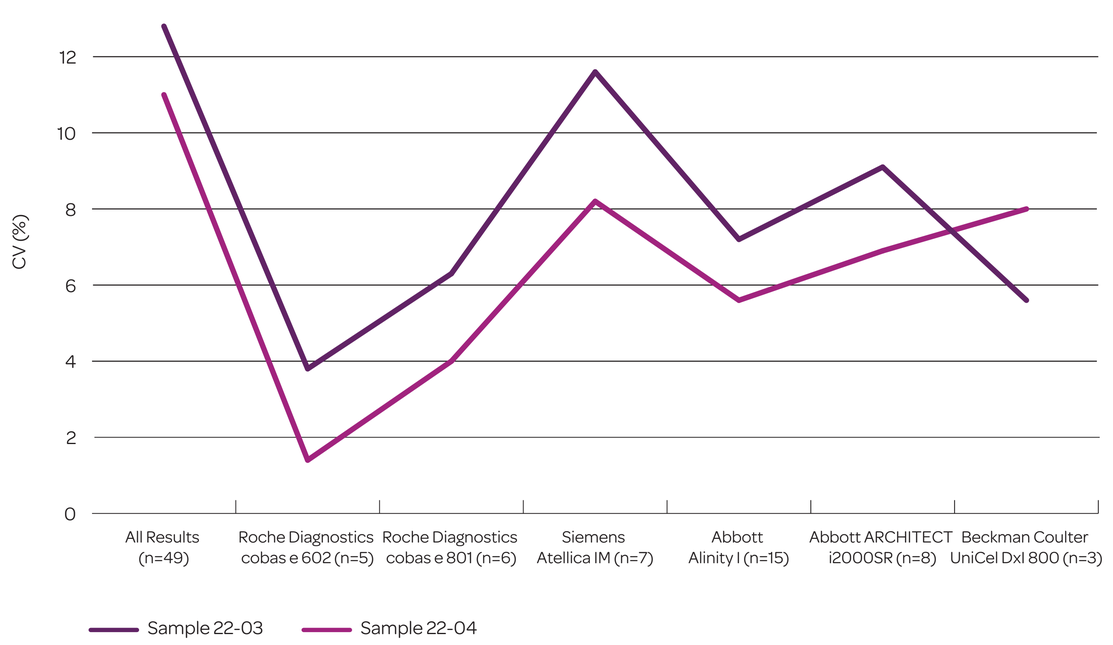

Figure 1. Coefficient of Variation for total PSA between different instruments

Table 2. Comparison of quoted Reference Intervals (for a 50yr old male)

Instrument	Reference Interval (ug/L)
Abbott Architect i2000SR	<3.50
Abbott Alinity i	<3.00
Beckman Coulter UniCel DxI 800	<3.00
Roche Diagnostics Cobas e 602	<3.00
Roche Diagnostics Cobas e 801	<3.00
Siemens Atellica IM	<3.50

References:

1. Balk SP, Ko YJ, Bubley GJ. Biology of prostate-specific antigen. J Clin Oncol. 2003 Jan 15;21(2):383-91. doi: 10.1200/JCO.2003.02.083. PMID: 12525533.
2. Zakaria AS, Schwartz RN, Hodhod A et al. Detectable Prostate-specific antigen value between 0.01 and 0.1 ng/mL following robotic-assisted radical prostatectomy (RARP); does it correlate with future biochemical recurrence? World J Urol. 2021 Jun; 39(6):1853-1860. PMID: 32696130.

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