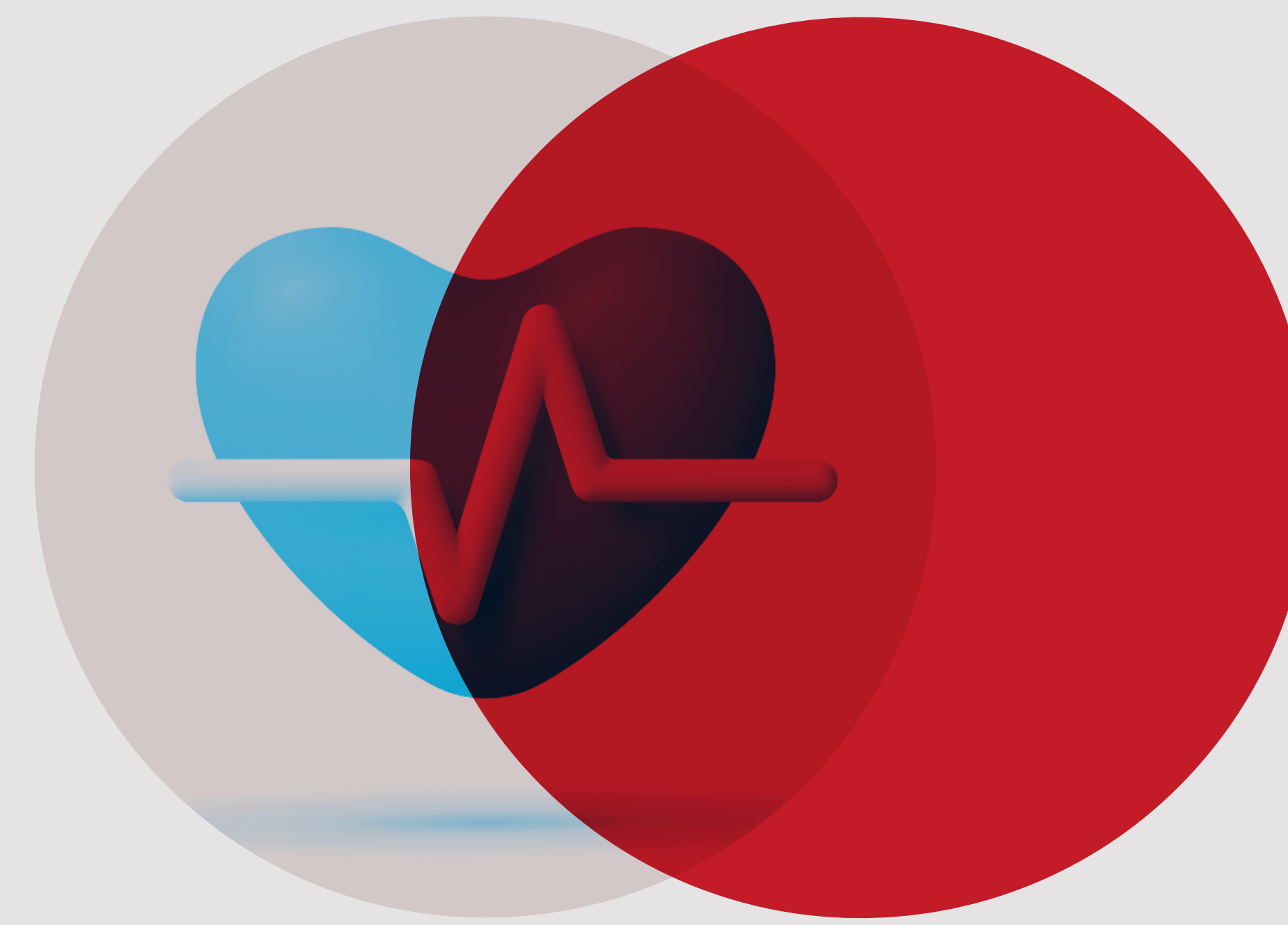


Comparison of low Troponin results in a commutable EQA program

Peter Graham, Natasha Robbins, Tony Badrick

Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP), St Leonards, Sydney, Australia



Introduction

Clinical decision levels for Troponin I and T have been progressively lowered with the introduction of high sensitivity assays. Studies using risk stratification of patients presenting to ED with a Troponin I ≥ 5 ng/L without diagnostic ECG changes have shown good outcomes¹.

Sourcing suitable (low-level Troponin) commutable material for External Quality Assurance Programs is challenging.

The RCPAQAP provides a Liquid Serum Chemistry Program sourced from consenting haemochromatosis patients, presenting for therapeutic venesection. Where possible, serum from individual patients is pooled over successive collections to ensure commutable samples. The option to report Troponin I and T was introduced in the 2022 program. Here we report on the performance of two low Troponin samples across 15 instruments from 5 vendors.

Method

Results for Samples 22-03 and 22-04 in the November 2022 Liquid Serum Chemistry survey were reviewed 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 3.0 ng/L (n=49) and for Sample 22-04 was 4.0 ng/L (n=49) (Table 1).

Apart from the Siemens Dimension EXL, the instrument medians were no more than 4 ng/L different from each other for both samples (Table 1). The EXL medians were 3 and 7 ng/L higher compared to the all result median for Samples 22-03 and 22-04 respectively.

The all-result CV's for samples 22-03 and 22-04 were 45.1% and 56.5%, respectively. The within instrument CV's varied from 0.0 to 20.6% across both samples (Table 1, Figure 1).

All submitted results were within the RCPAQAP Analytical Performance Specifications for a low level (± 2 ng/L) apart from the Siemens Dimension EXL group (high) and Abbott I-Stat 300 series devices (n=7, CV 137%), which were both below and above the APS, possibly due to the reporting limits for these devices (not shown in Table 1 or Figure 1).

Troponin T medians (6.0 ng/L for both samples, n=39), were consistent (within ± 1 ng/L) across the 4 Roche platforms (e 411, 601, 602 and 801). The "All result" CV's were 18.8% (Sample 3) and 19.0% (Sample 4). CV's between instruments ranged from 6.9 (e 801) to 26.2% (e 602).

A sampling of reference intervals provided on the example patient reports is shown in Table 2.

Discussion and Conclusion

This survey showed acceptable CV's for the 11 platforms shown in Table 1. There is also evidence of overall harmonisation of results. Laboratories associated with an ED, should assess their method to determine its suitability to assist with ED risk stratification. The variation between reported reference intervals warrants further investigation.

Table 1. Comparison of performance at low Troponin I levels across instruments where a minimum of 3 results were submitted

	n	Troponin I			
		Sample 22-03		Sample 22-04	
		Median ug/L	CV%	Median ug/L	CV%
All-Results	151	3.0	45.1	4.0	56.5
Abbott Alinity i	19	3.0	14.6	3.0	20.0
Abbott Architect i1000SR	10	4.0	18.2	3.0	10.9
Abbott Architect i2000SR	11	4.0	16.7	3.0	13.2
Beckman Coulter Access	7	3.0	0.0	4.0	0.0
Beckman Coulter Access 2	42	3.0	12.4	4.0	9.6
Beckman Coulter UniCel Dxl 600	12	4.0	21.8	6.0	14.3
Beckman Coulter UniCel Dxl 800	9	4.0	10.4	6.0	16.8
Ortho Clinical VITROS XT 7600	9	2.0	0.0	2.0	0.0
Ortho Clinical VITROS XT 5600(i)	7	2.0	0.0	2.0	0.0
Siemens Atellica IM	6	3.0	26.6	5.0	17.9
Siemens Dimension EXL	7	6.0	12.0	11.0	14.8

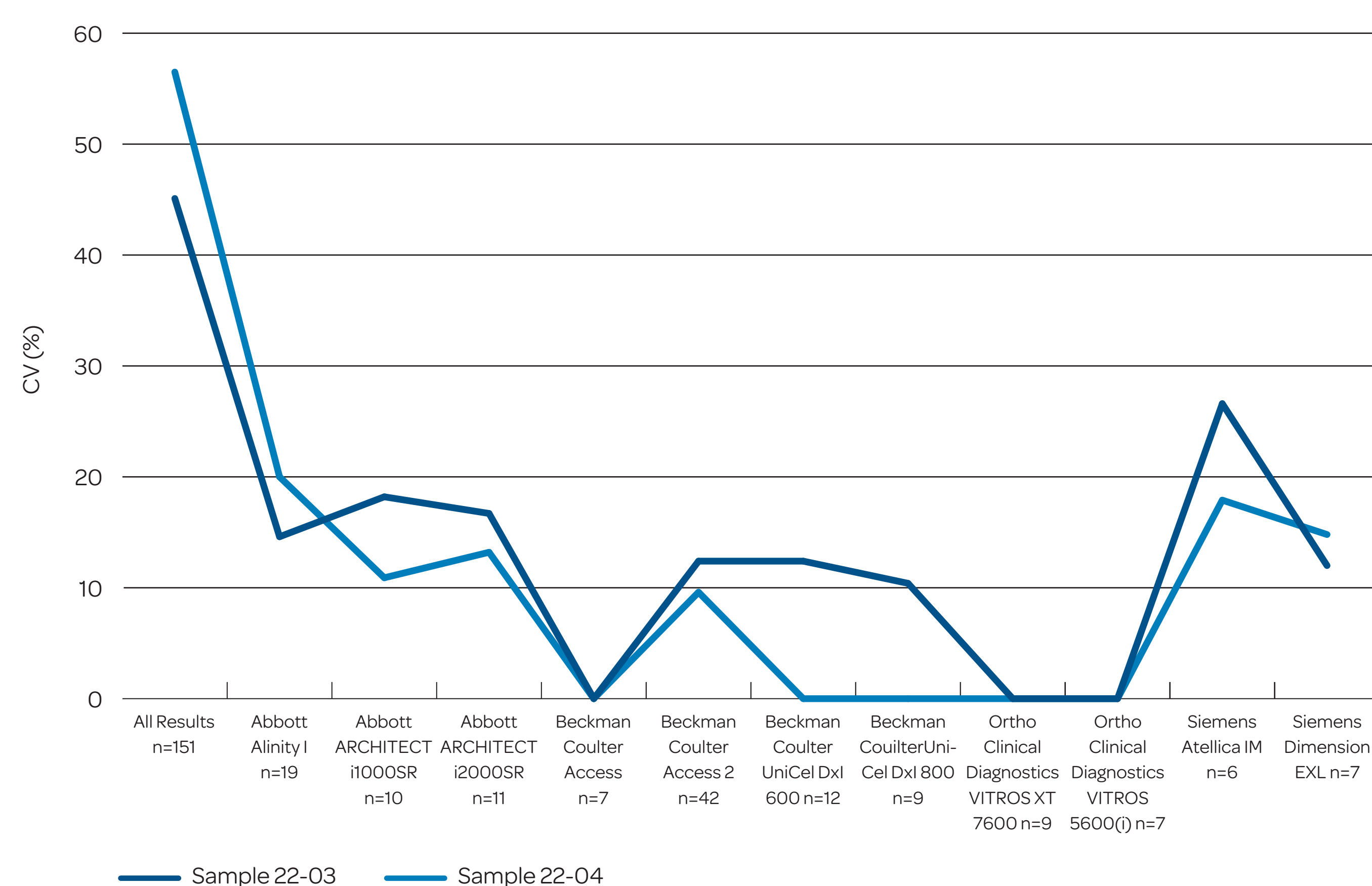


Figure 1. Coefficient of Variation for total Troponin I between different instruments

Table 2. Comparison of quoted Reference Intervals for Troponin I and T

Troponin I	Reference Interval (ng/L)
Abbott Architect i2000SR	<26
Abbott Alinity i	<26
Beckman Coulter Access 2	<40
Beckman Coulter UniCel Dxl 800	0–20
Ortho-Clinical Diagnostics VITROS 5600(i)	<26
Siemens Atellica IM	<50
Siemens Dimension EXL	<72
Troponin T	Reference Interval (ng/L)
Roche Diagnostics Cobas e 602	<15
Roche Diagnostics Cobas e 801	<15

References:

1. Arndt A, Lee KK, Chapman A et al. High-Sensitivity Cardiac Troponin on Presentation to Rule Out Myocardial Infarction: A Stepped-Wedge Cluster Randomized Controlled Trial. *Circulation* 2021;143:2214-2224.

