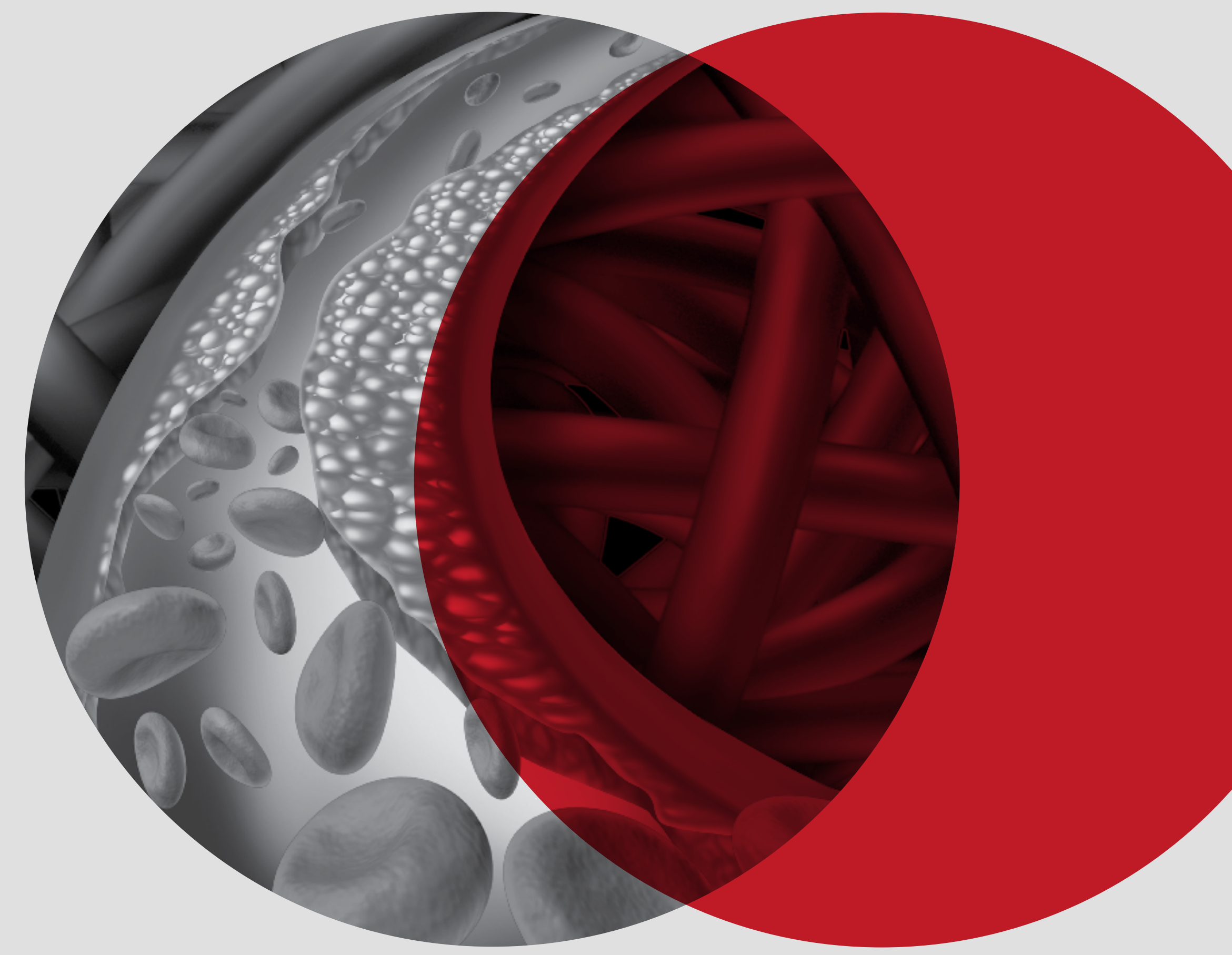


Cholesterol Measurement – Unexpected Results in a Commutable EQA Program

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Introduction

The Australian Heart Foundation publishes a recommended reference interval of <math><4.0\text{mmol/L}</math> for patients at high risk of cardiovascular disease. The RCPAQAP provides a Liquid Serum Chemistry Program sourced from consenting male and female haemochromatosis patients presenting for therapeutic venesection. Where possible, serum from individual male and female patients are pooled over successive collections. We report on some unexpected method differences in 2019, 2020 and 2021 Liquid Serum Chemistry Programs.

Method

The median results for different methods submitted by up to 210 participating laboratories for the three surveys were compared using RCPAQAP in-house software.

Results

While the majority of labs (>85 %) were within the Analytical Performance Specifications (+/- 0.30 up to 5.00; +/-6% >5.00 mmol/L) median differences of up to 0.91 mmol/L between the Siemens Dimension EXL and Beckman Coulter AU480 were noted (Table 1). An example of the relative scatter of results (samples 20-01 & 20-02) is shown in the Youden plot (Figure 1). The mean and CV's in this example were 5.80 mmol/L and 1.9% for Beckman and 4.90 mmol/L and 2.4% for Siemens. The histogram shown in Figure 2 of sample 2019-02 demonstrates a similar high/low bias. We also noted a similar pattern in the RCPAQAP General Serum Chemistry Program (not shown here). 99.8% of participating laboratories selected cholesterol oxidase/peroxidase as the reagent analytical principle along with "analyser specific" as their calibrator option. Of interest, in each of the surveys, the relative differences (at similar medians) were less pronounced for the female sample compared to the male (Table 1).

Discussion

While the number of Siemens EXL labs was small (n=8/9) the CV (2.4%) indicates acceptable agreement within the group. Given the Liquid Serum Chemistry, samples are commutable and laboratories use a common analytical principle as well as their manufacturer's calibrator, the difference in results may be due to the traceability of the calibrators. Further investigation of the secondary calibrators used by manufacturers may uncover some differences.

Conclusion

A change in a cholesterol result of 0.91 mmol/L in a patient being monitored for cardiovascular risk factors would likely prompt either a repeat measurement or management change. Patients moving between pathology providers may receive different lifestyle advice for cholesterol of 6.04 vs 5.13. Laboratories should consider patient sample exchanges to investigate these unexpected differences.

References:

1. https://www.heartfoundation.org.au/getmedia/39af72bc-770d-4bfd-a100-3e5b89f58b97/My-healthy-heart-plan_fillable.pdf

Table 1. Relative median differences between Beckman Coulter AU480 and Siemens Dimension EXL groups.

	2019 n Results	Sample 19-01 (F)	Sample 19-02 (M)	2020 n Results	Sample 20-01 (F)	Sample 20-02 (M)	2021 n Results	Sample 21-01 (F)	Sample 21-02 (M)
All Result Median mmol/L	184	6.23	4.62	192	4.83	5.59	210	4.80	4.98
Beckman Coulter AU480	25	6.55	4.80	24	5.06	5.79	24	5.04	5.25
Siemens Dimension EXL	8	6.20	4.26	9	4.76	4.88	9	4.62	4.77
Difference between AU480 and EXL group medians		0.35	0.54		0.30	0.91		0.42	0.48

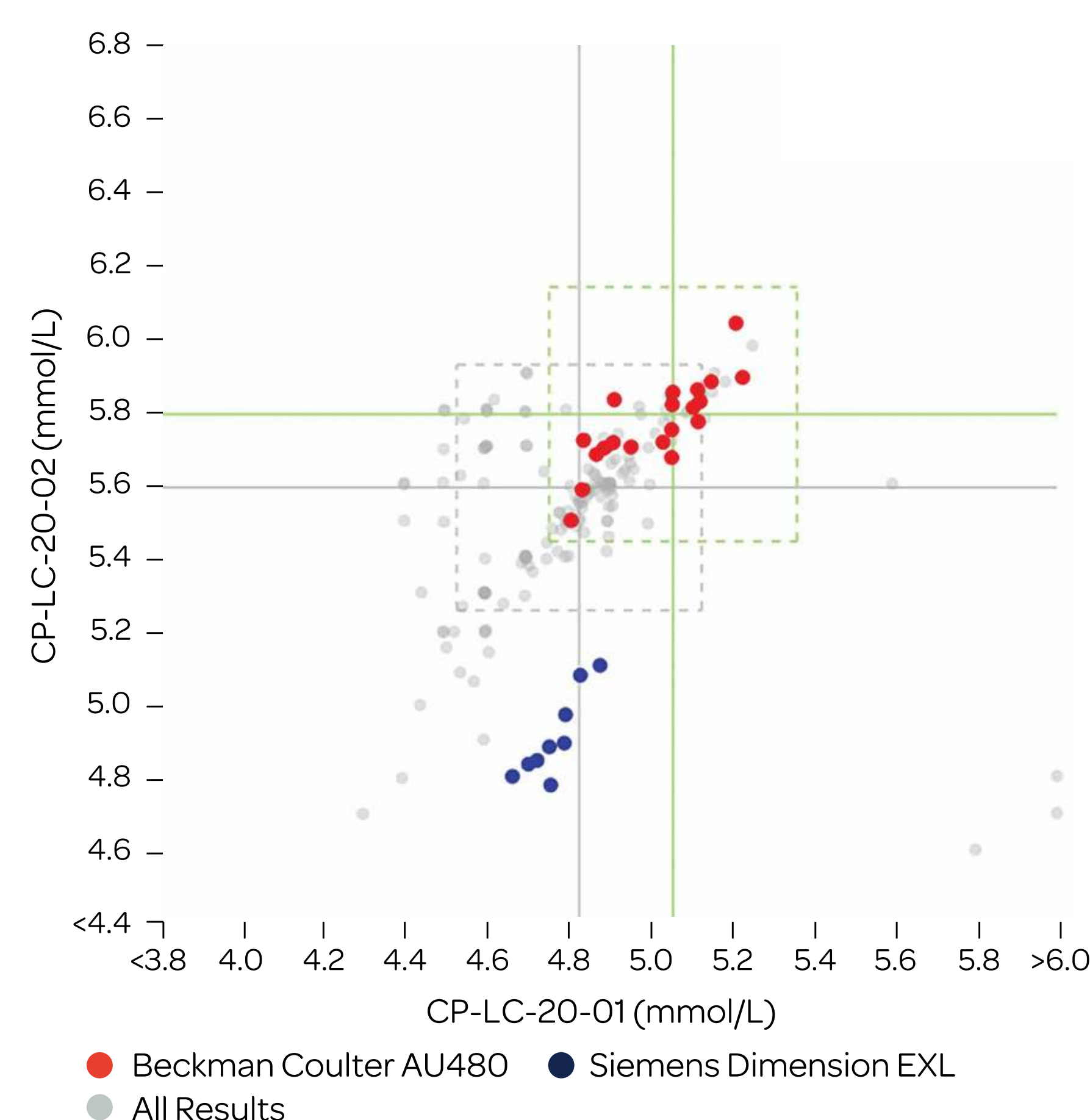


Figure 1. Youden Plot of 2020 Cholesterol results for samples 20-01 & 20-02. The green cross hairs and dotted lines indicate the median and APS limits for the Beckman group only. The grey cross hairs and dotted lines indicate the median and APS limits of all results.

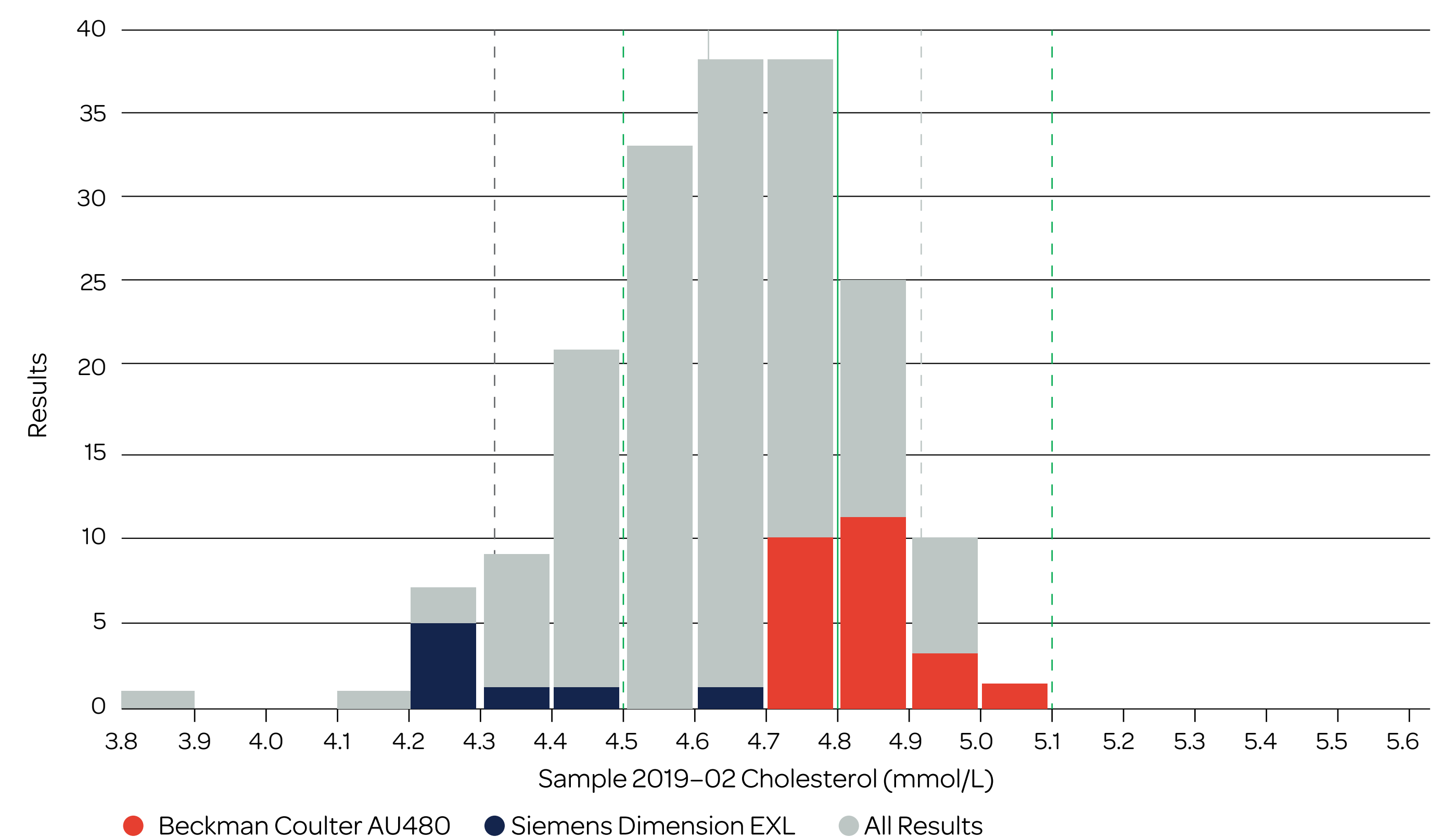


Figure 2. Histogram of 2019 Cholesterol results for samples 19-02. The green solid and dotted lines indicate the median and APS limits for the Beckman group only. The grey solid and dotted lines indicate the median and APS limits of all results.