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Tel: +44 (0) 2920 314750
E-mail: contact@weqas.com
Web: www.weqas.com

Weqas
Unit 6, Parc Tŷ Glas
Llanishen, Cardiff, UK
CF14 5DU

Trueness of Calcium Measurements in the UK: Comparison to a Reference Measurement Method

DH Ducroq, MA Thomas

Introduction

Metrological traceability of laboratory results to the SI unit is essential for correct patient diagnosis, risk assessment and ongoing monitoring of patients. Changes in the metrological traceability of methods may influence clinical decision limits and reference intervals. The use of trueness EQA programmes is therefore an essential pillar underpinning the ongoing traceability of measurands[1], ensuring the transfer of accuracy from definitive methods to routine methods. Traceability of measurements is also a requirement of ISO 15189.

Methods

Eight samples encompassing the measurement range for calcium were distributed over a 12 month period with additional samples for serum indices (icterus, haemolysis and lipaemia). The base material was human serum, tested negative for HIV and Hepatitis B and C at donor level. The pools were filtered aseptically and gentamicin added to maintain sterility prior to spiking.

All serum chemistry samples were distributed to EQA participants on more than one occasion. Each sample was measured by a validated, accredited reference measurement method for calcium by a JCTLM listed flame atomic absorption spectrometry (FAAS) reference method[2]. The acceptance criteria as defined by Stockl et al[3] were within specification for calcium reference measurement procedures. As an observation of potential change in metrological traceability, data was observed from two time periods (September / October 2020 and February / March 2021) during the distribution period of the samples. Deviations from the 'true' result (the reference measurement procedure) for main analyser groups were plotted in the form of bias plots (Bland–Altman plots).

The traceability of the reference measurement procedure is given in table 1.

Table 1 Metrological Traceability of the Calcium Reference Measurement Method

Measurand	Certified Reference Standard	Purity	Reference Material
Calcium	Supelco Certipur® (Calcium carbonate)	99.97%	NIST 956d

Results

Figures 1-7 show the bias plots for all method groups currently participating within the Weqas Serum Chemistry calcium programme.

Figure 1 Abbott Alinity Arsenazo: Ca Bias plot relative to FAAS Method

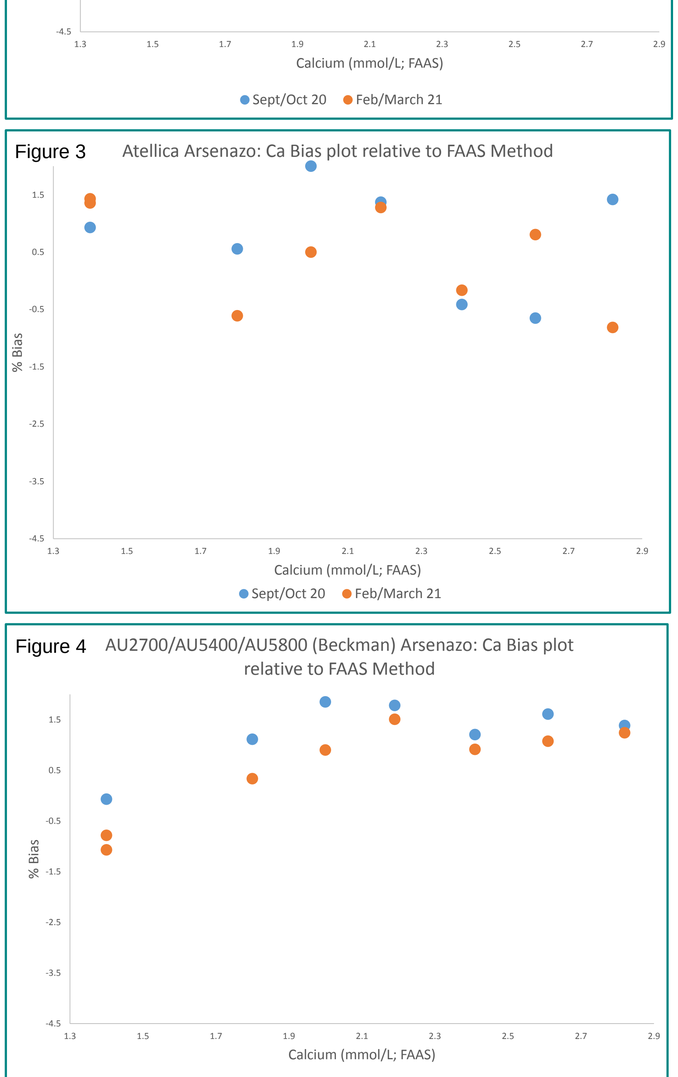


Figure 2 Advia Arsenazo: Ca Bias plot relative to FAAS Method

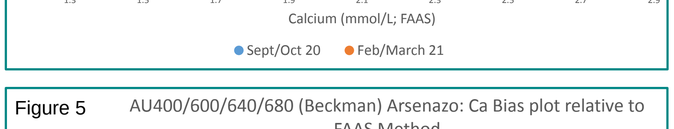


Figure 3 Atellica Arsenazo: Ca Bias plot relative to FAAS Method

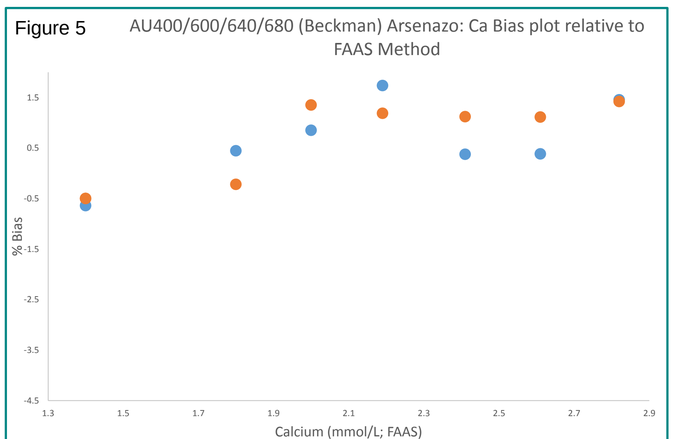


Figure 4 AU2700/AU5400/AU5800 (Beckman) Arsenazo: Ca Bias plot relative to FAAS Method

Figure 5 AU400/600/640/680 (Beckman) Arsenazo: Ca Bias plot relative to FAAS Method

Figure 6 NM-BAPTA Cobas C: Ca Bias plot relative to FAAS Method

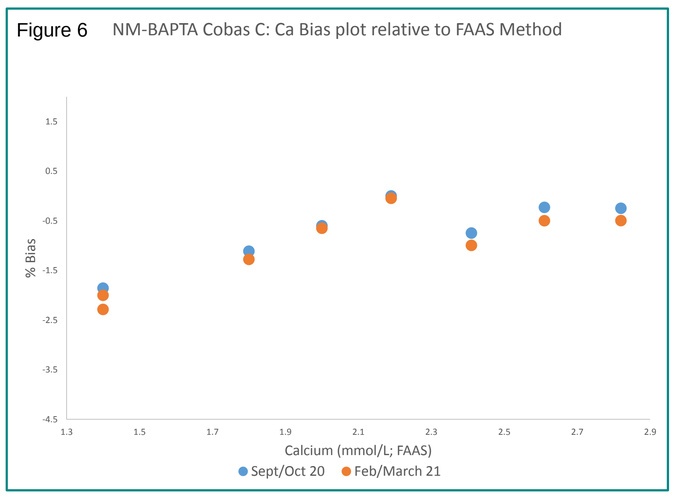
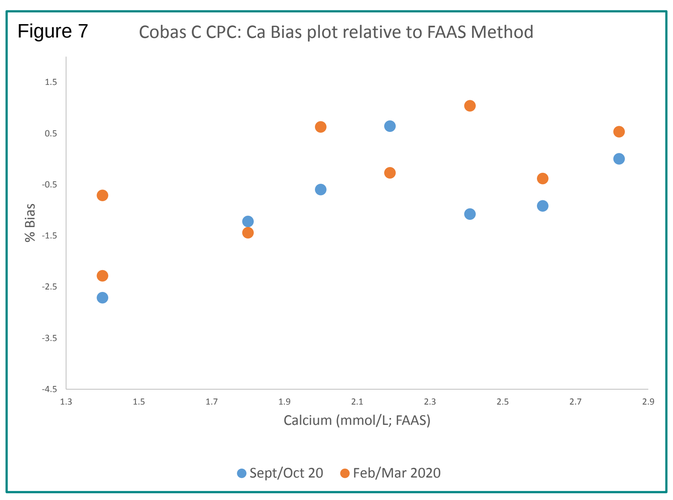


Figure 7 Cobas C CPC: Ca Bias plot relative to FAAS Method



Discussions

Figure 1 data for the Abbott Alinity arsenazo group shows reasonable agreement with the reference measurement value (RMV) at concentrations above 2.5 mmol/L in September / October 2020. The trend is towards a negative bias below this 2.5 mmol/L value. A shift in calibration in the order of -1 to -1.5% appears evident for the February / March 2021 data.

Both the Advia and Atellica arsenazo methods (figures 2 & 3) showed reasonable agreement across the measurement range observed. There does appear to be a positive calibration shift in the order of 0.5 – 1% for the more recent Advia calcium data. The Beckman AU analysers (figures 4 & 5) showed a slight positive bias above 2 mmol/L, trending towards a -0.5% bias below this value.

The NM-BAPTA and CPC methods from Roche (figures 6 & 7) showed very similar pattern, although there was greater scatter for the CPC method. The latter CPC method has fewer users, in the order of 5 - 6 which is probably contributing to the observed scatter. Both methods showed good agreement for values above 2 mmol/L and trending to negative values below this concentration in a similar manner to the Beckman groups.

The change in bias for some methods relative to the RMV could indicate inappropriate calibration value assignment or a change in reagents. In order to maintain the traceability chain and hence maintain accurate patient values, monitoring with a higher order reference method will highlight any changes in methods, in particular when samples are distributed on multiple occasions.

Conclusions

The study highlights the importance of using reference measurement methods and values (RMV) to assign target values in EQA programmes, rather than consensus mean and presents strong evidence on the variability in calibration of the methods for the calcium. Peer review of performance against method mean and overall mean data cannot identify true errors in accuracy. This can only be achieved by comparison with traceable reference measurement methods.

References

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2. Thomas, MA *et al* Performance of electrolyte assays in the United Kingdom - reference target values. Accred Qual Assur (2004) 9:159-163
3. Stöckl D *et al* Analytical specifications of reference methods compilations and critical discussion. Eur J Clin Chem Biochem 1996;34: 319-337