Traceability of Glucose Assays in the UK – Comparison with JCTLM listed Reference Method

Ducroq DH, Strevens C, Thomas MA

WEQAS
Unit 6, Parc Tŷ Glas,
Llanishen
Cardiff
CF14 5DU
Tel: +44 (0) 2920 314750
Fax: +44 (0) 2920 314760
Email: office@weqas.com

Introduction

Metrological traceability of methods is a requirement of ISO15189 accreditation and labs are now becoming aware of the need for traceability of their routine methods. To meet this need analysis of traceable material in the chosen method is required. The preferred method of comparison of returned EQA results is to the SI unit utilising reference target, ensuring the transfer of accuracy from definitive methods to routine methods. Defined MAPS (Minimum Analytical Performance Specification) criteria available for glucose measurements aims to improve the performance of routine methods, with comparison to the ID-GCMS reference method.

Method

Eight samples encompassing the analytical range for glucose (1.8 – 22mmol/L) were distributed over a ten month period. All samples were analysed by a validated, accredited reference method utilising a JCTLM listed, ID-GCMS (NIST traceable; table 1), reference method. Deviations from the 'true' result (the reference method) for main analyser groups were plotted in the form of bias plots (Bland–Altman plots). Additional samples used for serum indices (haemolysis, lipaemia and icterus) were also distributed over this period. For each of the indices samples, an additional unadulterated matched sample was also distributed.

Table 1 Traceability of Methods

Measurand	Certified Reference Standard	Purity (%)	Reference Material
Glucose	NIST917c	99.7	NIST965b

Results

All methods were within the acceptable MAPS bias criteria of +/- 10% at 2mmol/L apart from the Abaxis Piccolo which gave a positive bias in the order of 20 – 25% (data not shown; fig. 1). The overall mean was heavily influenced by the predominant hexokinase method, which showed a 2% positive bias between 2 to 10mmol/L, rising to 4% at values above 15mmol/L. Within the hexokinase methods, differences in calibration can be seen between instruments (fig. 2). The Siemens Advia hexokinase method had good agreement with the reference target value, whereas the Roche, Abbott and Beckman methods were positive (between 4-6%).

For the GOD-PAP method group a 3% constant positive bias was observed. The Oxygen/peroxide electrode method group showed a 2-3% negative bias below 10mmol/L rising to a 1% positive bias above this level. For the Vitros a proportional bias of approximately 3% was observed with a cross-over at approximately 12mmol/L.

Indices samples (figs 3-5)

Observation of the haemolysed samples showed good agreement with the matched sample apart from the Roche Modular group where

Results (cont)

a slight negative bias was observed. Within the distribution of samples that included a lipaemic sample, again most methods showed good agreement with the matched sample result. Both the Roche Modular and Abaxis Piccolo had a slight positive bias, with the GOD-PAP method group showing a marked positive bias. For the icteric distribution, both the Beckman and Oxygen Peroxide groups showed a slight negative bias compared to the matched sample. The GOD-PAP method group had a marked negative bias. All other methods showed good agreement.

Figure 1 Comparison with ID-GCMS Reference Method (All Methods)

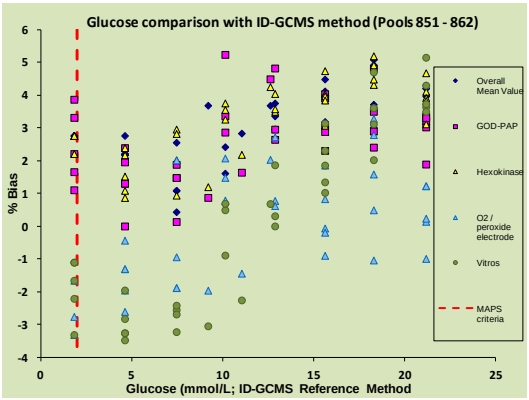


Figure 2 Comparison with ID-GCMS Reference Method (Hexokinase Manufacturer Methods)

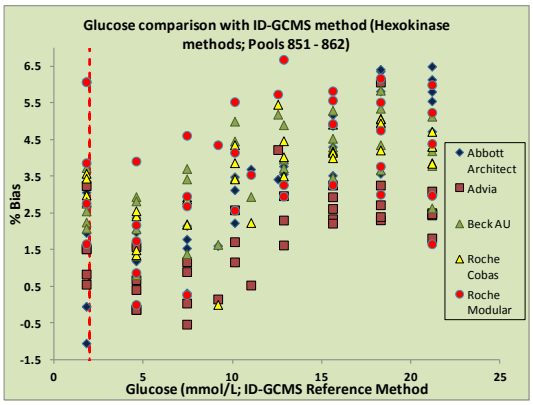


Figure 3 Indices: Haemolysed Pool

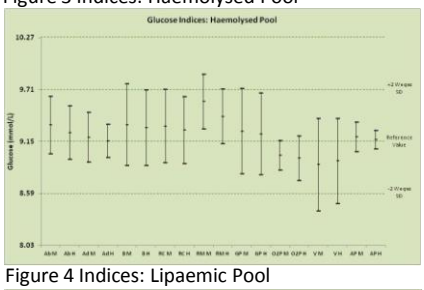


Figure 5 Indices: Icteric Pool

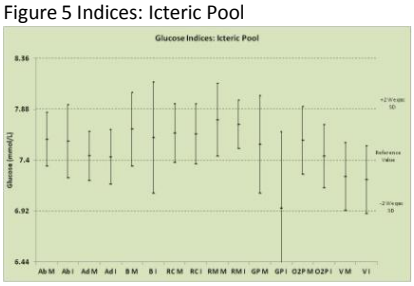
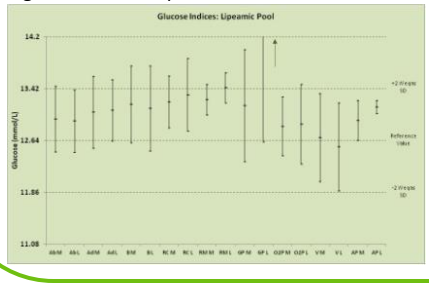


Figure 4 Indices: Lipaemic Pool



Key to Figs 3-5

Ab: Abbott Architect, Ad: Siemens Advia, B: Beckman AU, RC: Roche Cobas, RM: Roche Modular, GP: GOD-PAP, O2P: Oxygen Peroxide, V: Vitros, AP: Abaxis Piccolo

M: Matched paired sample, H: Haemolysed, L: Lipaemic, I: Icteric

Conclusions

All glucose methods currently conform to the MAPS criteria at the level of 2mmol/L apart from the Abaxis Piccolo. The use of reference target assigned values to EQA samples provides a far superior comparison where the 'true' value of the sample is used, as opposed to using trimmed method means. Within the hexokinase method groups, there still appears to be method to method variation which may be accounted for by issues relating to standardisation.

Distribution of the matched indices samples has highlighted some issues relating to haemolysis, lipaemia and icterus. These studies will be ongoing within the Clinical Chemistry EQA sheme.

Where available, Weqas is committed to the use of Reference Measurement target values for EQA schemes. Such data is useful to ensure metrological traceability and aid laboratories meet the requirement of ISO15189.