Commutability of external quality material for blood glucose measuring systems.
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Introduction – Assessing the measurement accuracy of blood glucose measuring systems (BGMS) is a critical aspect of laboratory quality management. One of the commonly accepted measurement accuracy assessment methods is that of external quality assessment (EQA), but their limitations should be recognized. Especially for glucose, commutable EQA material has been a quest for years. CueSee® Glucose –PT (Eurotrol) material was launched a few years ago and shows resemblance to whole blood samples. In some aspects though, this material is different from human blood. It is prepared for instance from whole blood from cows and cells may have been in a starving state for quite a while. The Belgian WIV uses this material for their three-monthly obligatory EQA POCT glucose program. Repeatedly a bias around -15% was reported with our in-house Nova Statstrip BGMS (Nova Biomedical, Waltham, MA, USA). On the contrary the Accu-Chek BGMS (Roche Diagnostics, Mannheim, Germany) shows a very small bias (around 2%). Because of multiple studies and the experience we have with the Nova Statstrip BGMS these results are surprising and the hypothesis of non-commutability of this EQA material was made. To confirm this hypothesis a comparison of human with bovine blood on Nova StatStrip Connectivity BGMS, Accu-Chek Inform II BGMS and cobas 6000 c 501 analyzer (Roche Diagnostics, Mannheim, Germany) was done.

Methods – Heparinized venous blood was drawn from one healthy female adult volunteer and one cow. After glycolysis 20 aliquots of each sample were spiked with a saline solution (0.9%) containing a high concentration of glucose to create samples covering the entire BGMS measuring range. These spiked aliquots were analysed in duplo on the Nova Statstrip Connectivity BGMS and Accu-Chek Inform II BGMS. Within 5 minutes the whole blood samples were centrifuged and analyzed with the HK/G6PDH assay on Cobas 6000 c501 analyzer. The data are statistically analyzed by deming regression and Bland-Altman residual plots constructed with Excel 2010 (Microsoft, USA).

Results – The range of glucose values covered on Cobas was 2,5–19,61 mmol/L and 2,89-35,22 mmol/L for human and bovine blood respectively. Deming regression analysis demonstrated a slope of 1,07 versus 0.95 and an intercept of -0.52 mmol/L versus -0.69 mmol/L glucose for StatStrip versus Accu-Chek in human and bovine blood respectively. Statstrip and Accu-Chek measure almost identically (bias -0.13% and 95% confidence interval [-11.41% – 11.16%]) over the whole range in human blood. Also in the low range (<5.56 mmol/L) biases were small (<0.5 mmol/L). In bovine blood large differences between the measurement on Statstrip and Accu-Chek were found with an almost constant bias of -12.51% and 95% confidence interval [-0.97% – -24.05%] over the whole range.

Figure 1: Bland Altman plots of bias between Statstrip and Accu-Chek in human and bovine blood.

Conclusion – The results of this comparison study confirms our hypothesis of non-commutability of the CueSee® Glucose-PT (Eurotrol) material. Bovine blood reacts differently than human blood on Statstrip vs. Accu-Chek BGMS. Therefore this EQA cannot be used to compare accuracy between different types of BGMS. We therefore recommend to not calculate biases as it is useless and can be misleading and commercially misused. To our knowledge no commutable EQA material for POCT glucose BGMS exists.