Method comparison of a new QuikRead go® HbA1c test to three commercial POC HbA1c tests and to IFCC calibrated reference method

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Introduction

Quantitative measurement of glycated hemoglobin (HbA1c) concentration is an established method for monitoring long-term blood glucose control in individuals with diabetes mellitus[1-3]. HbA1c measurement at the point of care (POC) offers an opportunity to improve the diabetes care[4,5]. The HbA1c results are ready to be discussed during the patient consultation and immediate modifications or intensification of treatment can be done. In addition, HbA1c concentration can be used as an aid in diagnosis of diabetes mellitus and as an aid in identifying individuals who may be at risk of developing diabetes[6]. QuikRead go HbA1c is an easy to use immunological in vitro diagnostic test for quantitative measurement of HbA1c from finger prick capillary blood or anticoagulated venous whole blood samples. The test is carried out using the portable POC device QuikRead go.

The objective of the study was to compare the QuikRead go HbA1c test to IFCC calibrated secondary reference measurement procedure (SRMP) method and to three commercial POC HbA1c tests already available on the market.

Methods

Method comparison was done between IFCC calibrated HbA1c Tosoh G8 (Tosoh Bioscience, Belgium) secondary reference method and three POC methods: A (Afinion™, Abbott Park, IL, USA), B (DCA Vantage™, Siemens Healthcare Diagnostics Inc., Germany) and C (Cobas b 101, Roche Diagnostics, Germany). Testing was done according to CLSI EP09C-3rd edition. Data set was gathered from total of 78 venous whole blood samples, which were obtained from ERL with respective reference values (European Reference Laboratory for Glycohemoglobin, Location Isala, Zwolle, The Netherlands). The results were obtained by measuring each sample once using all analyzed methods according to their instructions for use.

The data was analyzed visually using a difference plot (Bland-Altman plot) to verify that samples were equally distributed along the measuring range and to detect the nature of difference in analyzed POC methods. Constant coefficient of variance or changing difference between constant standard deviation to constant coefficient of variance was estimated for all methods. Based on this observation weighted Deming regression was chosen for linear regression analysis for method comparison.

The calculations were performed using Microsoft Excel spreadsheet and Analyse-it version 4.65.3 (Analyse-it, Ltd, Leeds, UK). The variance ratio between methods (λ) was estimated as 1. Moreover, largest allowed bias between POC methods and reference method was set to 10 %, which was seen as the largest allowable total error for the test system[7,8].

Results

The results showed all methods having excellent correlation r=0.99 with IFCC calibrated Tosoh G8 HPLC reference method. Weighted Deming regression parameters between POC methods and reference are shown in Table 1 and regression lines in Figure 1. Closest to reference method in this data set was POC method A followed by POC method C. QuikRead go was third closest to the reference method and method B was fourth. The result of two samples exceeded allowed bias of 10 %. One at low HbA1c level and the second on high level. QuikRead go exceeded allowed 10 % bias for three samples spread two at medium level and one at high level. POC method A exceeded allowed 10 % bias for five samples. Four of the samples were at low level and one at high level. POC method B exceeded allowed 10 % bias for 11 samples due to negative bias at low level samples. Regression parameters comparing QuikRead go HbA1c to POC methods A, B and C are shown in Table 2 and regression lines in Figures 2, 3 and 4.

Table 1. Weighted Deming regression line parameters when comparing POC methods to IFCC calibrated Tosoh G8 HPLC reference method.

Method	Slope	Intercept	Correlation
QuikRead go HbA1c	1.03	-0.9	0.99
POC A, Afinion HbA1c	1.01	-0.8	0.99
POC B, DCA Vantage	1.04	-4.2	0.99
POC C, Cobas b 101	0.98	-0.3	0.99

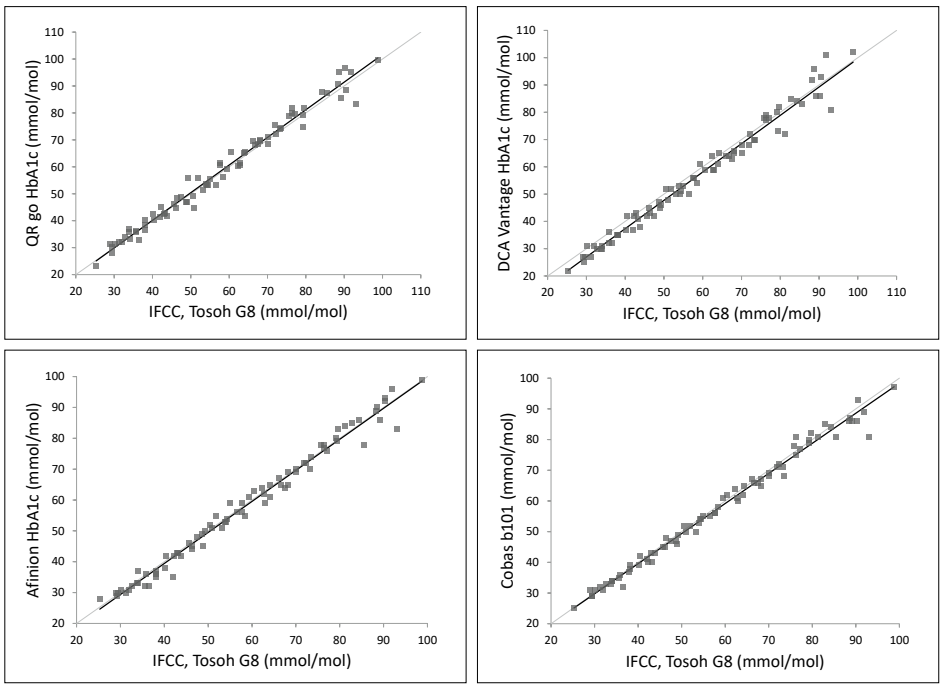

Figure 1. Weighted Deming regression comparing POC methods to IFCC calibrated Tosoh G8 reference method.

Table 2. Weighted Deming regression line parameters when comparing QuikRead go to POC methods A, B and C.

Method	Slope	Intercept	Correlation
POC A, Afinion HbA1c	1.02	-0.2	0.99
POC B, DCA Vantage	0.98	3.4	0.99
POC C, Cobas b 101	1.05	-1.3	0.99

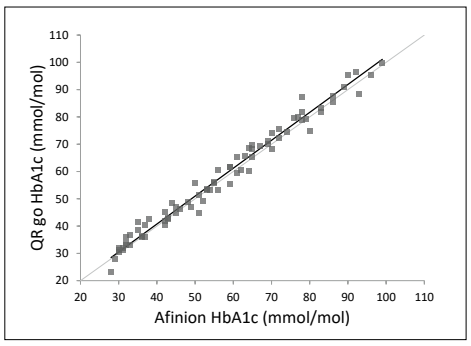

Figure 2. Weighted Deming regression line comparing QuikRead go HbA1c to Afinion HbA1c test.

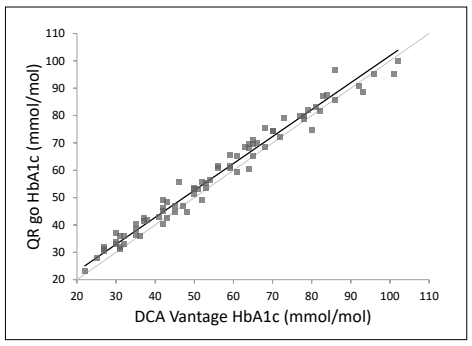

Figure 3. Weighted Deming regression line comparing QuikRead go HbA1c to DCA Vantage test.

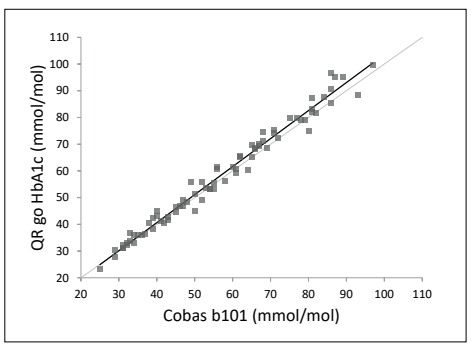

Figure 4. Weighted Deming regression line comparing QuikRead go HbA1c to Cobas b 101 test.

Conclusions

The obtained results indicate that QuikRead go HbA1c is very well in line with the HbA1c reference method and with tested POC methods. QuikRead go HbA1c has proven to be a reliable and effective method for the quantitative determination of HbA1c.

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